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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TECHNICAL ELECTRONIC PRODUCT RADIATION
SAFETY STANDARDS COMMITTEE MEETING

THIRTIETH MEETING

Wednesday, October 1, 2003

8:30 a.m.

Food and Drug Administration
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MILLER REPORTING COMPANY, INC.
735 8th Street, S.E.
Washington, D.C. 20003-2802
(202) 546-6666

PARTICIPANTS

MEMBERS

General Public

Lawrence Rothenberg, Ph.D., Chairperson
Richard Kaczmarek, Executive Secretary
Jane Benson, M.D.
James W. Platner, Ph.D., CIH

Industry

David Lambeth, Ph.D.
Michael Caswell, Ph.D.
Kimberly Kantner, BSc
Wayne Myrick, MS

Government

Kiyohiko Mabuchi, M.D.
Jill Lipoti, Ph.D.
Michele Loscocco, MS
John Cardarelli, Ph.D.

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P R O C E E D I N G S

Greeting and Introduction

MR. KACZMAREK: Good morning. My name is Rick Kaczmarek. I am the executive secretary for this advisory committee.

I am going to begin by reading a few words, a few paragraphs which describe why we are here, the business of the committee, then, I am going to turn over the control of the business to Dr. Larry Rothenberg, who is the chairperson.

In accordance with the Radiation Control for Health and Safety Act of 1968, Public Law 9602, 21 USC Subsection 360kk, the Secretary of the Department of Health and Human Services has established the Technical Electronic Product Radiation Safety Standards Committee for consultation on matters relating to technical electronic product radiation safety.

As specified by Public Law 9602, the Committee consists of 15 members including the chairperson who are appointed by the Commissioner of Food and Drugs for overlapping terms of four years or less.

Five members are selected from government agencies, including State and Federal Governments,

1 five from affected industries, and five members
2 from the general public, of which at least one
3 shall be a representative of organized labor.

4 Members must be technically qualified by
5 the training and experience in one or more fields
6 of science of engineering applicable to electronic
7 product radiation and safety standards.

8 The primary function of TEPRSSC is to
9 provide advice and consultation to the Commissioner
10 of Food and Drugs on the technical feasibility and
11 reasonableness of performance standards for
12 electronic products to control the emission of
13 electronic product radiation from such products and
14 to review amendments to such standards before being
15 prescribed by the Commissioner.

16 The Committee is not requested to review
17 individual applications or particular products of
18 specific firms.

19 Public Law 9602 and its legislative
20 history clearly indicated that the TEPRSSC members
21 are expected to represent a wide range of interests
22 with at least one-third of the committee nominated
23 by the regulated industry itself and appointed on
24 the basis of their being able to represent
25 industrywide concerns.

1 Section 534 of the Federal Food, Drug, and
2 Cosmetic Act specifies that TEPRSSC members are not
3 to be considered officers or employees of the U.S.
4 for any purpose including conflict of interest
5 determinations, however, to be consistent with
6 FDA's general policies regarding advisory
7 committees, the agency believes that a public
8 disclosure memorandum should be made part of the
9 public record which identifies each member and
10 provides their employment affiliation.

11 So approved June 9, 2000, April 24, 2002,
12 and August 1, 2003, by delegated authority of the
13 Commissioner of Food and Drugs, the members of the
14 Technical Electronic Product Radiation Safety
15 Standards Committee are:

16 Dr. Jane Benson from Johns Hopkins
17 University School of Medicine; Dr. Francis Gasparro
18 from Cheshire High School in New England; Dr. James
19 Platner, Center to Protect Worker's Rights; The
20 Honorable Robert Pleasure from the Center for
21 Working Capital; Dr. Larry Rothenberg, Memorial
22 Sloan-Kettering Cancer Center.

23 The government persons are:

24 Dr. John Cardarelli from National
25 Institute for Occupational Safety and Health; Dr.

1 Jill Lipoti from the New Jersey Department of
2 Environmental Protection and Energy; Lieutenant
3 Commander Michele Loscocco from the U.S. Navy Joint
4 Readiness Clinical Advisory Board; Dr. Kiyohiko
5 Mabuchi from the National Cancer Institute; Dr.
6 Maureen Murdoch Nelson from the Minnepolis VA
7 Medical Center.

8 The industry members are:

9 Dr. Michael Caswell from C.B. Fleet
10 Company; Dr. George Kambic from Philips Medical
11 Systems; Kimberly Kantner from AT&T; Dr. David
12 Lambeth from Lambeth Systems; and Wayne Myrick from
13 Sharp Electronics Corporation.

14 Now I am going to turn over the conduct of
15 the meeting to Dr. Rothenberg, he will make some
16 remarks, and then we will get underway with our
17 first speaker.

18 **Chairperson's Opening Remarks**

19 DR. ROTHENBERG: Thank you, Rick.

20 I am Dr. Larry Rothenberg from Memorial
21 Sloan-Kettering Cancer Center. I am a medical
22 physicist working in the area of radiology and
23 radiation protection.

24 I would like to welcome you all here for
25 today's session. I would particularly like to

1 thank the members of the committee for taking time
2 out from their busy schedules to participate in
3 this important activity.

4 I think what I would like to do also just
5 to orient those in the audience is maybe, starting
6 on my left, just have each committee member very
7 briefly introduce yourself and say just a sentence
8 or two about your activities and specialties.

9 So, Dr. Lambeth, would you begin.

10 DR. LAMBETH: I am David Lambeth of
11 Lambeth Systems. I am Professor of Electrical and
12 Computer Engineering at Carnegie Mellon University.
13 My background is in physics and electrical
14 engineering and material science. I work a lot in
15 the field of magnetics and more recently in sensor
16 systems and chemicals.

17 DR. PLATNER: Good morning. My name is
18 Jim Platner. I am with the Center to Protect
19 Worker's Rights, which is the research institute
20 for the building trades unions in the AFL-CIO. My
21 background is in radiation biology and toxicology
22 at the University of Rochester, and I spent 10
23 years operating Health and safety extension
24 services at Cornell University prior to coming to
25 the building trades.

1 CDR LOSCOCCO: I am Commander Michele
2 Loscocco. I have had a slight change in rank and
3 duty station since the notes that Rick Kaczmarek
4 indicated.

5 MR. KACZMAREK: Congratulations.

6 CDR LOSCOCCO: Thank you. I am now at the
7 National Naval Medical Center. I am the head of
8 the Physics Division there. My background is
9 medical physics and I am boarded in diagnostic
10 radiological physics.

11 DR. CASWELL: I am Mike Caswell. I work
12 for C.B. Fleet Company in Lynchburg, Virginia. My
13 background is skin biochemistry.

14 DR. BENSON: I am Jane Benson. I am a
15 pediatric radiologist in practice for 17 years.
16 Thirteen of those years have been at Johns Hopkins
17 Hospital where I am an Assistant Professor of
18 Radiology and Pediatrics at the Johns Hopkins
19 School of Medicine.

20 DR. MABUCHI: I am Kiyo Mabuchi. I am
21 from Radiation and Epidemiology Branch at the
22 National Cancer Institute. I am involved in
23 epidemiological studies of radiation-exposed
24 populations including A-bomb survivors in Japan,
25 victims, and U.S. radiological technologies, and so

1 forth.

2 DR. LIPOTI: I am Jill Lipoti. I am the
3 Assistant Director. I am in charge of Radiation
4 Protection Programs for the State of New Jersey and
5 also release prevention, which involves the toxic
6 catastrophe prevention and discharge prevention
7 containment and countermeasures.

8 My experience with radiation involves the
9 regulation of X-ray machines, the licensure of
10 radiologic technologists, the certification of
11 radon testers and mitigators, the licensure of
12 naturally-occurring and accelerated produced
13 radioactive materials, non-ionizing radiation, and
14 with the Bureau of Nuclear Engineering that reports
15 to me, we respond to nuclear events and monitor
16 around nuclear power plants.

17 MS. KANTNER: My name is Kim Kantner. I
18 am with AT&T's Environment, Health, and Safety
19 Organization. I am currently the radiation safety
20 program officer for AT&T mostly related to
21 occupational and safety concerns related to both
22 non-ionizing and ionizing source. I am nationally
23 registered as a radiation protection technologist,
24 as well as a certified laser safety officer.

25 My background involves compliance

1 inspection of diagnostic machines, as well as
2 material licenses and familiarity with
3 manufacturing requirements for lasers, as well as
4 performance standards for diagnostic and
5 fluoroscopic units.

6 MR. MYRICK: Good morning. I am Wayne
7 Myrick. I am the national manager of product
8 safety for Sharp Electronics. We manufacture a
9 large variety of products including microwave
10 ovens, televisions, and a series of laser products.

11 My responsibility is making sure that all
12 our products comply with safety standards and all
13 the federal performance standards.

14 DR. CARDARELLI: Good morning. My name is
15 John Cardarelli. I am a commander in the U.S.
16 Public Health Service. I work at the National
17 Institute for Occupational Safety and Health. My
18 background is in nuclear engineering, health
19 physics, and industrial hygiene. For the past nine
20 years, I was conducting dose reconstructions in the
21 DOE complex for occupational epidemiologic studies.

22 Slightly after that, specifically, the
23 last three years, I have been doing health hazard
24 evaluations in both the ionizing and non-ionizing
25 radiation area, as well as primarily responsible

1 for the radiological emergency activities for my
2 agency.

3 DR. ROTHENBERG: Thank you all very much
4 again for taking time out from your other
5 activities to participate in today's session.

6 We will start the program now. Our first
7 speaker is Ms. Lillian Gill, who is the Senior
8 Associate Director at CDRH. She will give us an
9 update of informal issues and CDRH strategic plan.

10 **Update of Informal Issues and**
11 **CDRH Strategic Plan**

12 MS. GILL: Good morning. I want to
13 welcome on behalf of Dr. Feigal, our Center
14 Director, and the rest of the staff, I want to
15 welcome you to this TEPRSSC Advisory Committee
16 meeting. I want to especially send our welcome to
17 the five new committee members who are joining us
18 today.

19 We are pleased that you have made time in
20 your schedules to consult with us and to advise us
21 on our agenda items today - the performance
22 standards for sunlamps, our proposed amendments to
23 the X-ray standard, and an update on a report that
24 we commissioned from the National Council on
25 Radiation Protection and Measurements on the safety

1 of security screening systems.

2 Before we hear from our staff on those
3 issues, I want to bring you up to date on three
4 issues that we have presented to this committee in
5 the past - the wireless phones, our laser standard,
6 and computed tomography safety.

7 If you have specific questions about these
8 three areas, we have our technical experts in the
9 audience this morning that will be happy to provide
10 any answers for you.

11 The last item you see up here I have
12 included. My intent is to just give you some brief
13 insight into some of the issues that are currently
14 under discussion in the Center as we look at the
15 best ways to provide protection from the public in
16 this area, in a time when there are significant
17 challenges in the technology and our resources to
18 address these challenges are dwindling.

19 In order to ensure that needed research is
20 conducted to address the public health concerns
21 about the safety of wireless phones, CDRH signed a
22 CRADA, a Cooperative Research and Development
23 Agreement with CTIA, the Cellular
24 Telecommunications and Internet Association.

25 FDA, under this agreement, provides

1 research recommendations and oversight for those
2 studies funded by CTIA on the health effects of
3 radio frequency emissions from wireless phones. To
4 date, five studies have been funded. In 2001, CTIA
5 funded three studies on research needed to address
6 reported structural changes in genetic material of
7 blood cells after exposure to signals from wireless
8 phones. Those were the micronuclear studies.

9 Earlier this year, CTIA, under the CRADA,
10 funded two studies that are investigating the best
11 epidemiological tools for assessing exposure to
12 radio frequency from wireless phones.

13 Phase III of the CRADA, which comes into
14 effect in 2004, calls for the Center to convene a
15 scientific meeting to determine and define other
16 areas of research that are needed. We plan to do
17 that next year.

18 About three of four years ago, FDA
19 requested that NIEHS's National Toxicology Program
20 consider studying radio frequency radiation
21 emissions from wireless communication devices for
22 toxicology and carcinogenicity.

23 NTP evaluated all of the research efforts
24 underway and concluded that while these efforts
25 have an excellent probability of producing some

1 very high quality research results, that additional
2 studies were needed and are warranted to clearly
3 define any potential health hazards to the U.S.
4 population. They have agreed to conduct studies and
5 are proposing a very large animal study.

6 In addition, our own in-house staff, the
7 Radiation Biology Branch within CDRH, is also
8 conducting a number of replication studies of
9 positive findings reported in the literature.
10 These studies are looking at those enzymes linked
11 to cancer that are turned on by radio frequency.

12 We do have some results of those studies,
13 and those results have been accepted for
14 publication in scientific literature.

15 Lastly, FDA is collaborating with other
16 federal agencies and is a member of the Radio
17 Frequency Interagency Work Group. It is a group of
18 federal agencies that have regulatory
19 responsibility to control the risk from use of,
20 and/or exposure to, radio frequency, or have
21 responsibility for regulation and management of the
22 use of the RF radiation spectrum.

23 The group includes the Federal
24 Communication Commission, the National
25 Telecommunications and Information Administration,

1 the National Institute for Occupation, Safety, and
2 Health, the Occupational Safety and Health
3 Administration, and the Environmental Protection
4 Agency, and we, of course, we, FDA, are a member of
5 that group.

6 An issue that this group has recently
7 discussed--and, in fact, our staff is just back
8 from a three-day meeting--is the development of a
9 new exposure standard for cell phones, one that is
10 based on biology as opposed to dosimetry. Dr. Cyr,
11 who is in the audience, was part of those
12 discussions.

13 In the area of laser products, for the
14 past two sessions, I have reported on the status
15 of our proposed amendments to the laser standard.
16 We are amending the standard because of recent
17 scientific knowledge of laser bioeffects, at least
18 recent in 2000 and 2001, and our desire to
19 harmonize FDA requirements with those of IEC.

20 We have acknowledge the advantages of
21 having one set of criteria and requirements
22 worldwide. Certainly the regulated industry, the
23 manufacturers have asked the Center to provide a
24 least burdensome approach to their having to meet
25 two sets of requirements, the IEC and the FDA

1 requirements.

2 In our 2001 guidance document, we provided
3 conditions under which the laser product
4 manufacturers could introduce products into the
5 U.S. that complied with the IEC standards as they
6 were amended and also listed those FDA requirements
7 and standards that manufacturers needed to meet in
8 addition to IEC.

9 Since the last TEPRSSC meeting, we have
10 been in discussions with the IEC on the use of
11 their copyright-protected standards and with our
12 own internal staff particularly our Office of Chief
13 Counsel on how we can best use these standards to
14 accomplish our regulatory mission.

15 We are still in discussions with them and
16 for that reason our proposals for amendment are on
17 hold at the current time.

18 Given the past concerns about dosing from
19 CT, at the May 2002 TEPRSSC meeting, last year's
20 meeting, an FDA work group suggested three
21 technical features that could eventually reduce by
22 about 50 percent the radiation dose from CT scans.
23 These three included display and reporting of
24 standardized indices, the CT dose, an automatic
25 X-ray exposure control determined by individual

1 patient thickness, and a limitation of the X-ray
2 field size to reduce the amount of overbeaming in
3 multi-slide CT systems.

4 After that meeting, we discussed those
5 considerations with a number of stakeholders, and
6 you can see our schedule of meeting and talking
7 about these issues with them. We did that both to
8 alert them of our thinking and to get some feedback
9 on these ideas.

10 As we weigh the potential of implementing
11 these dose-saving features against our resource
12 constraints, as well as our likelihood of getting
13 new rules developed, our CT Work Group is
14 considering a number of other approaches to
15 expediting the adoption of up-to-date standards.

16 For example, we are considering a formal
17 recognition of the IEC CT safety standard, which is
18 certainly encouraged under the Food and Drug
19 Administration Modernization Act FDAMA. Under
20 those FDAMA provisions, voluntary declaration of
21 conformity of CT systems to recognize a standard,
22 in that case, manufacturers would not need to
23 submit additional information of safety aspects
24 that are covered under the IEC standard.

25 FDA could also require compliance with the

1 IEC CT standard as a special control, thereby
2 giving us more enforcement control. In this
3 manner, FDA could make use of a more dynamically
4 evolving standard with control exercised through
5 our medical device law.

6 Later this month, we are participating in
7 a joint meeting with an IEC Working Group to
8 further develop our plan and to work through these
9 other approaches.

10 In the last two areas that I have
11 mentioned, you have noted FDA giving greater
12 consideration to the role of IEC or the consensus
13 standards in our regulation of products. This is
14 certainly an indicator to us that the FDA role in
15 regulating radiation-emitting products is changing.

16 As you may know, we have a history of
17 leadership in developing performance standards,
18 however, because our expert force over the years
19 has dwindled from about 400 to 60 FTEs, and we no
20 longer have that resource capacity, we have
21 attempted, and we are attempting, to make
22 adjustments in the program to find alternative ways
23 to get standards of safety out to the manufacturing
24 and use community, to address our highest priority
25 areas, and to cover our responsibilities under

1 counterterrorism.

2 Last year, the Center staff worked with a
3 consulting group to focus on the direction of the
4 program, the content, and the resources needed to
5 support our rad health program.

6 We looked at our definition of roles and
7 responsibilities, our assessment of what the future
8 trends would be in the area, how we might best
9 address these, and whether or not we can use all or
10 parts of the consensus standards that are currently
11 being developed to satisfy requirements for some
12 very outdated mandatory standards on our book.

13 To complement and assess changes and
14 expectations from some of our stakeholder
15 interviews that were conducted during the
16 mid-nineties in the Center's reengineering project,
17 our consultants talked with a number of
18 representatives at the state level, some
19 professional associations, as well as some user
20 groups about their perspective of the Center's
21 future role in rad health.

22 Four major themes came from those
23 discussions. The Center should, according to our
24 stakeholders, either lead or participate actively
25 in four areas, not all areas across the products or

1 the issues involved, but certainly have some role
2 based on these four issues: our quality, the
3 assessing of quality of product, and quality
4 meaning our participation on implementing in the
5 application and the development and improvement of
6 standards, in our assessment of consensus versus
7 the mandatory standards, and in the quality of
8 manufacturing of product.

9 Our stakeholders also thought that we
10 should take a larger role in the knowledge,
11 management of data, that being the analysis and
12 sharing of data associated with product use.

13 We heard a lot particularly from the
14 states about the need for CDRH to step up our
15 involvement in the education and in informing of
16 the user community on key issues for training, as
17 well as consumer awareness on the safety of certain
18 products, and finally, they thought that the Center
19 ought to take a more active role in assessing the
20 emerging technology, that is, keeping track of the
21 impact of this technology, to address both the
22 positive and negative impact on the future public
23 health environment.

24 With the challenge from the Center
25 Director to look more closely at the issues in the

1 medical ionizing area, our small in-house group
2 sort or parsed the program into the four areas you
3 see here and identifying some of the products that
4 we currently are working on under those four areas.
5 These are just examples of some of the products.

6 But as you can see from these examples of
7 the types of products in those areas, there are
8 some very significant issues or concerns for the
9 Center under each, again, with our need to look at
10 those presenting to us the sort of highest priority
11 and the greatest public health issue.

12 While we did have concerns in all four
13 areas, and will look to carry out one of the four
14 roles for the high-priority issues under those
15 areas, there was one that stood out particularly
16 more than the others, and that is the medical
17 ionizing area.

18 For example, as the group talked about our
19 concerns in this area, there were a number of
20 things that we thought putting some focused
21 attention on would serve us and serve the public
22 well in the future, and I have listed a few of
23 those there.

24 Our assessment is we are not keeping up in
25 most of the areas with the technology, and there is

1 a need for us both to know what is going on in the
2 area, know the new design for some of these
3 technologies, and the use, as well as some of the
4 training on the use for some of this product.

5 So, therefore, we have as one of the
6 recommendations to our senior staff, and we have
7 scheduled for the end of the month, a report on our
8 efforts to date to look at all four areas and to
9 provide the Center Director with a blueprint or
10 some format for addressing the highest priority
11 areas.

12 We do intend to focus quite a bit of our
13 attention in the medical ionizing area,
14 particularly on the quality standards for
15 performance and use, understanding some of the
16 risks and benefits from this new equipment, and
17 partnering with manufacturers in educating users of
18 this dose-intensive equipment.

19 That is all that I am prepared to share
20 with you on our new focus. I certainly intend to
21 provide more at your next meeting as we put into
22 place some of the plans for handling some of the
23 new issues that will be facing us in this area.

24 Again, I welcome you to the meeting and
25 look forward to a very hearty discussion of our

1 issues today.

2 Thank you.

3 DR. ROTHENBERG: Thank you very much.

4 At this point, do any of the committee
5 members have questions for Ms. Gill? Yes.

6 DR. PLATNER: I just had one question.
7 When you say you are refocusing towards medical
8 imaging systems, it seems to me that it is the
9 non-medical systems that really lack the resources
10 on site, like health physicists and radiation and
11 safety officers that we see in medical and
12 university settings, laboratory settings.

13 It seems to me that non-medical area is
14 where people need the most guidance. I was just
15 curious if you could comment on that.

16 MS. GILL: In our discussions, some of
17 that certainly was talked about, those who are
18 currently working in those areas. We do not plan
19 to abandon the needs for those areas. Certainly
20 the medical ionizing has the largest stake we think
21 in the emerging technology area, and in the others
22 probably increasing our participation, our
23 leadership in the training, in the information and
24 sharing in the training areas would help in that
25 area, so that we are not abandoning it at all. We

1 will just have to focus what makes the best use of
2 our time to address those issues in that area.

3 DR. ROTHENBERG: Dr. Lipoti.

4 DR. LIPOTI: I have three questions for
5 you. The first one is with regard to the Radio
6 Frequency Interagency Work Group. I had been
7 familiar with the Interagency Steering Committee on
8 Radiation Safety Standards discourse, but this was
9 a group that I had not realized was formed. You
10 mentioned that they had a recent meeting and that
11 it is a forum for health and regulation issues.

12 Are there minutes that come out from this
13 group? Is there some way that we can become
14 involved with their meetings and their conclusions?

15 MS. GILL: I am going to let Dr. Cyr who
16 is just back, I think it was an IEEE meeting, for
17 which they floated the idea that this committee
18 will be working on, but I will let him handle
19 those.

20 DR. CYR: Yes, it was an IEEE meeting held
21 down in Rosslyn, Virginia. IEEE is the group that
22 is trying to revise the exposure standards for cell
23 phones for radio frequency, the safe levels. The
24 Interagency Group that was described met beforehand
25 because we had some issues with regards to this

1 particular standard, and we attended and
2 participated in that meeting, listened.

3 Why don't we meet afterwards, I will get
4 your name and address, e-mails and that. We have
5 some small minutes from our group, but mainly we
6 can put you on the IEEE mailing list, and you will
7 receive all of their e-mails, and it's a lot of
8 them.

9 DR. LIPOTI: Thanks. Question No. 2 has
10 to do with the CT and reduction of CT radiation
11 dose. I noted that the direction which had been
12 discussed with this group before listed display and
13 reporting of CT dose. Then, when you discussed
14 your alternative considerations based on the
15 resources that are available, I think that all of
16 the items there may have discussed display of CT
17 dose, but have left off the reporting.

18 I guess it would be important for us to
19 know what you are losing by not going forward with
20 the previous direction.

21 MS. GILL: I am going to let Dr. Shope
22 address why that one was dropped.

23 DR. SHOPE: I don't know that we reached
24 any firm conclusions on this, but I think the idea
25 is as the use of reference dose levels or reference

1 levels as are talked about in the radiological
2 community for providing tools to facilities to do
3 quality assurance kinds of activities, and if you
4 have equipment that is capable of indicating dose,
5 it is probably worth considering whether that
6 equipment ought to also assist the people
7 implementing quality assurance programs to be able
8 to record and maintain those kinds of records.

9 So, I think that is where the recording
10 has come from. Clearly, we haven't implemented
11 requirements for recording of dose on other
12 equipment, although we have had those discussions
13 here with this committee, so I think it is an early
14 development.

15 Currently, the IEC standards for CT do
16 have requirements for display, they don't have
17 requirements for recording although there are
18 discussions underway about the DICOM header that is
19 used to transmit medical images back and forth and
20 some adaptation of those headers to include places
21 to put dose information, so I think there is a
22 number of things working that we want to stay
23 plugged into and keep our finger on in terms of how
24 this ought to be happening either with CT or
25 potentially even with other modalities, but it is

1 very early on I think to see how that is going to
2 play out with the user community.

3 There are a lot of issues that come up
4 here when you start talking about recording and how
5 that information will later be used and where it
6 will be end up, so I think there are some issues
7 that we will have to work through.

8 MS. GILL: That was certainly a much
9 better answer than I could have provided you.

10 DR. LIPOTI: The third and last question.
11 You mentioned that you are focusing on medical
12 imaging and you gave some examples, but it seemed
13 to me that one of the future trends is with what I
14 would call fusion technology where you are using
15 not only CT, but CT PET or merging even
16 non-ionizing MRI modalities.

17 I was wondering if the Center considers
18 fusion technology as one of those areas where you
19 need to be further involved in the future.

20 MS. GILL: Yes, I do remember that in our
21 small group discussion of where the future trends
22 are going, and it is on the list of those things
23 that we really do need to track and get additional
24 training awareness of, so sure, it isn't excluded
25 from the list, as well.

1 Any other questions?

2 DR. ROTHENBERG: I just had one comment
3 with regard to the CT dose question and the
4 recording of it. I think certainly this is one
5 area that we should certainly stay strongly plugged
6 into because this is one of the modalities where,
7 as you mentioned with the Dicom Headers, and so on,
8 where it would be most possible to keep track of
9 this type of thing, whereas, with other areas,
10 some of the interventional units and so on, it
11 seems to be most of the systems are set up, so that
12 there is some kind of dose display and then it
13 disappears when the next patient comes in.

14 I know we will hear some more about things
15 related to the fluoroscopy standard later this
16 afternoon, so I don't want to pursue that now, but
17 just a comment.

18 Anyone else have questions? Yes, Dr.
19 Cardarelli.

20 DR. CARDARELLI: I just wanted to briefly
21 follow up on the comment that Dr. Platner had
22 earlier about the emphasis on medical versus
23 non-medical technology and whether research funds I
24 guess will be directed to.

25 One thing I would like to at least point

1 out is if a decision goes that way, if it could be
2 clearly publicized on the public health basis. A
3 number of people in the United States are affected
4 by that particular technology.

5 I would think that the general public, the
6 non-medical folks, the people who are not receiving
7 medical treatment, those numbers are huge out there
8 compared to those that are being exposed to the
9 medical technology, however, their doses are
10 probably very low, you know, relatively speaking.

11 I just wanted to put that point out there
12 to clearly communicate the basis from a public
13 health perspective of why our dollars are being
14 shifted or emphasized in one area.

15 MS. GILL: Thank you. We will certainly
16 do that.

17 DR. ROTHENBERG: Thank you very much, Ms.
18 Gill. I know you have other engagements this
19 morning.

20 MR. KACZMAREK: I think we can go ahead if
21 there is no other questions from the committee with
22 the first speaker.

23 DR. ROTHENBERG: Our next presentation
24 will be on Performance Standards for Sunlamp
25 Products. Dr. Howard Cyr and Sharon Miller have

1 prepared that.

2 **Performance Standards for Sunlamp Products**

3 DR. CYR: I am Howard Cyr. I am the
4 Acting Branch Chief of the Radiation Biology
5 Branch. I have been the person for the last few
6 years, I guess at least four years, who have come
7 before you and been the one to brief you on the
8 progress of our work toward amending the
9 performance standard for sunlamp products.

10 However, this year, Sharon Miller is going
11 to be the key person and she will present our
12 ongoing program of research that we hope leads to
13 some regulatory changes.

14 I am here to brief you on the work that I
15 have done in the last few years and to tell you a
16 little bit about the work that is still left for
17 Sharon to do.

18 Over the last four years, we have been
19 pursuing new amendments for at least three reasons,
20 one of which is that the science of photobiology is
21 telling us that some of our regulations are a bit
22 outdated particularly in terms of dosimetric
23 considerations and that we should be making some
24 changes and incorporating these changes into our
25 rules and regulations and recommendations.

1 There has also been a move toward
2 harmonization and it means that we in the United
3 States should be making changes to facilitate
4 international trade and some of the regulations
5 need changes to put them in sync with those of the
6 international community. Sharon will tell you
7 about these efforts particularly our work with the
8 International Electrical Technical Commission, the
9 international agency that writes these standards.

10 There has also been research done
11 suggesting connection between sunlamps and
12 melanoma, some very controversial research, and I
13 will describe that a little bit.

14 Each year we have met with you and you
15 have given us advice. Some of it was that we were
16 somewhat premature when we first gave our suggested
17 amendments particularly with regards to recommended
18 exposure sessions.

19 You told us that we probably should go
20 back and do some research on skin types and the
21 doses that were needed to produce tans, that we
22 weren't really ready at that time to come up with
23 the exact recommendations that we were proposing.

24 You have also told us that we should go
25 back and spend more time with the various parties,

1 the interested groups who have a stake in these
2 regulations, both the indoor tanning industry and
3 the dermatology community, and have done both of
4 those.

5 What we originally thought was going to be
6 a simple process of revision has actually turned
7 into a multi-year effort, and we are still ongoing.

8 Since we began four years ago, I would
9 like to go into some of the new scientific
10 happenings and projects that have taken place.

11 As I mentioned, we in the Center have
12 started research projects. One of those is on how
13 to measure changes in the skin and now Sharon
14 Miller has a second project on skin types and the
15 amount of dose that it takes to produce the tan and
16 to keep a tan, and she will describe those.

17 There have also been elsewhere efforts,
18 new risk assessment efforts particularly done by
19 the National Toxicology Program in North Carolina.
20 They put out reports on carcinogens, the Ninth
21 Report and the Tenth Report, in which they actually
22 named sunlamps as a known cause of cancer. This
23 finding and this conclusion is somewhat at odds
24 with the conclusions of some epidemiologists and
25 also the International Agency for Cancer Research

1 which doesn't go quite that strongly. They
2 conclude that sunlamps are a probably cause, not a
3 known cause, so there has been some controversy on
4 the melanoma/sunlamp association.

5 There has actually been new data in the
6 last few years, a couple years, on this connection.
7 A group in Sweden headed by Wester, et al., has
8 done another larger study, and they conclude that
9 the connection between sunlamps and melanoma is
10 even stronger than they had previously reported.

11 On the other hand, there is a group headed
12 by Ultiay [ph] who did a study previously and said
13 there was an association. He has now done a larger
14 study, and is only I believe in abstract form and
15 presented at a meeting, it is not in final
16 publication, but he now says that the association
17 is not there. So, melanoma/sunlamp connection is
18 truly complicated and still remains highly
19 controversial.

20 There has been a new initiative
21 particularly on the part of the indoor tanning
22 industry to emphasize the benefits of UV in
23 connection with production of vitamin D, and I
24 would like to point out to you that there is going
25 to be a major conference next week, Thursday and

1 Friday, at the National Institutes of Health on the
2 risk and benefits of UV exposure in connection
3 actually more on vitamin D, the UV association will
4 be part of that conference, and we plan on
5 attending and participating.

6 We have also had recent interactions with
7 the Academy of Dermatology and tried to bring to a
8 focus our various ways of protecting the public
9 from the risk of UV interactions, and we are
10 continuing those interactions. I believe a
11 representative from the Academy is here today and
12 probably will speak later on. I haven't seen her
13 yet, but I think she will show up.

14 I am saying all of these things to
15 highlight to you the complexities of the problem we
16 have here at FDA. We are quite literally caught
17 between two opposing viewpoints on UV risk.

18 On the one hand, we have got the
19 dermatology community which has been telling us
20 that any exposure is risky and could lead to
21 serious health effects. In fact, a few years ago,
22 they have asked us to ban sunlamps.

23 More recently, we actually within the last
24 month, we have received another letter from an
25 individual dermatologist, not from the Academy, but

1 an individual dermatologist who again in a letter
2 to the Commissioner has asked us to ban sunlamps.
3 We are still preparing a response to his request.

4 On the other hand, the indoor tanning
5 industry feels that moderate doses are, in fact,
6 safe and are even beneficial in the fact that they
7 can produce vitamin D, and there are epidemiology
8 studies to show that in areas where you have high
9 ultraviolet radiation, you, in fact, have lower
10 cancer risk for certain other kinds of cancers.

11 They are making the association that
12 vitamin D prevents cancers and that, in fact, there
13 are some beneficial effects from moderate UV
14 exposures, and they have had a somewhat of a small
15 lobbying effort to have us, in fact, allow them to
16 put claims for benefits on UV lamps.

17 So, there are complex scientific issues.
18 What we thought would at this time, we would hope a
19 finished product, we would have our recommendations
20 in to you and we would be done, has actually turned
21 out to be an intense debate. I think the level of
22 debate and the seriousness of the issues are
23 probably now at an all-time high.

24 But the main reason I am addressing you
25 today is to tell you that unfortunately, I am no

1 longer the lead person in this sunlamp issue. I am
2 still very much interested in the area, but I have
3 been assigned to new projects.

4 A key person in our branch left us more
5 than a year and a half ago, he was our branch
6 chief. I volunteered to be a temporary branch
7 chief until such time as we could find a new one.
8 I am now the branch chief for some 16 months, and I
9 don't see any sign that we are going to get a new
10 branch chief, so I have had that job and probably
11 will have it for at least a few more months here.

12 Also, this person was in charge of our
13 CRADA, the Cooperative Agreement that we had with
14 the telecommunications industry involving cell
15 phones, and I took over that project, too. So, as
16 much as I would like to stay involved in sunlamps,
17 I am staying involved, I just don't have the time
18 to be the lead person, and I asked Sharon Miller to
19 take over that job for me.

20 Sharon is extremely qualified to do this.
21 She is actively involved in the research project.
22 Like I said, she has a project starting on the
23 doses that are required to obtain and maintain a
24 tan in an effort to perhaps say that one could use
25 less dose than we are presently using to get a tan.

1 Sharon is an engineer, she understands the
2 dosimetry of these lamps and the classification
3 schemes that she is going to propose. She is a
4 member of this International Electrical Technical
5 Commission and she knows the national and
6 international standards and the recommendations
7 related to sunlamps.

8 So, as I say, as much as I would like to
9 stay in this area, I must give this responsibility
10 to Sharon, and she will now be the lead person. I
11 will be available for consults, but for now Sharon
12 will be your contact person and will be the one who
13 will present our program of research and the
14 interactions with the international agencies and
15 our continued effort toward modernizing our
16 regulations and recommendations.

17 At this time, I turn the proceedings over
18 to Sharon Miller. Thank you.

19 MS. MILLER: Thank you, Howard.

20 As Howard was saying, as he has moved on
21 to new challenges, I have inherited this job of
22 presenting our proposals to you. Today, I would
23 like to propose six amendments to our performance
24 standard for sunlamps.

25 Some of them you have seen before and a

1 few of those have been adjusted slightly in order
2 to either improve harmonization with international
3 standard or to take care of some minor technical
4 problems that we have discovered in the past year.

5 I will give you a brief history for the
6 benefit of the members who are new to the committee
7 and for some of the other people in the audience
8 who might not be quite up to speed with what has
9 happened since we first decided to make amendments
10 to our performance standard.

11 Back in 1998, we did publish an Advanced
12 Notice of Proposed Rulemaking, which I will refer
13 to as the ANPRM. As Howard mentioned, some of the
14 reasons we did this were because there were
15 concerns about melanoma being related to sunlamp
16 use, also, that there was a melanoma epidemic
17 occurring in this country and also other countries.

18 The AMA sent us a petition to ban sunlamps
19 and, in addition, we received a citizen's petition
20 to increase the enforcement of sunlamp products.
21 Also, as mentioned, we would like to harmonize as
22 much as possible with the international standard
23 for sunlamp products.

24 Lastly, the technology of the sunlamp
25 industry and our knowledge base have changed since

1 1985 when our last iteration of the standard was
2 published. I just noted that the original standard
3 was published in 1979.

4 Now, I am going to tell you what the
5 proposals were that we did publish in the ANPRM in
6 1998. The first was to update our recommended
7 exposure schedules. At that time, we were really
8 seeking input from the experts on how we could
9 improve the exposure schedules that we had provided
10 guidance to manufacturers in a policy letter that
11 was published in 1986.

12 At the TEPRSSC meeting, I think it was two
13 or three years ago, we talked about this, and the
14 committee actually advised us to do research and
15 develop scientifically-based exposure schedules, so
16 that is what this current research that Howard
17 mentioned that I am doing is addressing this.

18 We are doing a human study right now that
19 is about halfway finished. We are looking at
20 trying to come up with guidance for exposure
21 schedules that can produce tans, but significantly
22 lower the dose. So far the research is very
23 promising. It looks like we can reduce the
24 cumulative dose by about a factor of 4. If you
25 have any other questions on that, I can give you

1 more details later.

2 Another thing we wanted to do was, as I
3 mentioned, this guidance for the exposure schedules
4 was in a policy letter, it wasn't in the actual
5 standard in the 21 CFR document, so we wanted to
6 make the recommended exposure schedule part of the
7 standard to increase the enforceability of that.
8 That is something that we would like to do after we
9 finish fine-tuning these recommendations.

10 The third item was that we wanted to
11 clarify what the definition of "manufacturer" was.
12 By that, we mean that the manufacturer would
13 include things like making significant
14 modifications of a sunlamp product. That is
15 something that is also already in our laser
16 standard.

17 Next, we wanted to update the warning label
18 mainly to make it more succinct and easier to read,
19 and also to require that this warning label be
20 reproduced in catalogs and advertising literature,
21 so that people who, for instance, bought the
22 products for home use would see the warning label
23 and know what types of risks they were being
24 exposed to before they got the product home.

25 Lastly, we wanted to develop a uniform

1 rating scale for replacement lamps because as lamps
2 in these sunlamp products age and need to be
3 replaced, it has become very difficult for salon
4 owners to know which lamps are suitable, because we
5 want to have a biologically equivalent lamp put in
6 that product, so that the timer setting will not be
7 made, you know, you don't want to burn people.

8 So, it was to simplify the tasks of salon
9 owners and also inspectors, because when both FDA
10 inspectors and state inspectors go into salons, one
11 of the things they look for is whether or not the
12 right lamp is in the product. It is such a complex
13 system, it is almost like a telephone book or
14 similar to the catalogs you find at auto part
15 stores when you are looking at cross-referencing
16 your bed or the original lamp and what the new lamp
17 model number is. It is very confusing for people.

18 Also, we wanted to increase safety as I
19 mentioned. We want to avoid people getting burned
20 from the wrong lamp being put in the product.
21 Actually, we sponsored two meetings at FDA about
22 this issue since 1998, and we have made a lot of
23 progress, so that is one of the things we will be
24 talking about later.

25 More recently, last year at the TEPRSSC

1 meeting, we only presented four proposals that we
2 felt we were ready to go with at that time. It was
3 the simplified warning label, the requirement that
4 the label be reproduced in advertising literature,
5 redefining what a manufacturer is, and we also
6 wanted to revise the specifications for eyewear
7 because the current definitions are not
8 quantitative and we wanted to improve that.

9 At that meeting, you gave us a tentative
10 go-ahead on all but the third proposal, and the
11 third proposal was the one reference to what a
12 manufacturer is. I believe you thought that that
13 needed a little bit more work on making it clear
14 exactly what kind of modifications we were talking
15 about.

16 When you gave the go-ahead, you did
17 understand that there would be a 90- to 120-day
18 comment period after the official proposed rule is
19 published and that at that time, FDA is required to
20 address every comment. So, if there were some
21 major technological why our recommendations were
22 not prudent, we would have to address that at that
23 time.

24 I just also wanted to add that proposals
25 1, 3, and 4 have been fine-tuned or slightly

1 modified since the last meeting partly in order to
2 better harmonize with IEC.

3 Also, some of the things Howard mentioned,
4 there have been two meetings of the IEC Committee.
5 I attended and also Dr. Beer who is here today, who
6 is a biologist and an expert in this area. We have
7 been very active in introducing new changes to the
8 IEC standard. We feel we have come a long way
9 towards harmonizing our standard with their
10 standard. I will go over some of the highlights of
11 those meetings in the next slide.

12 Lastly, the end of June, we met with the
13 American Academy of Dermatology and also the
14 American Society for Photobiology to discuss some
15 of their concerns about our regulations and our
16 research.

17 Just to tell you a little bit about what
18 happened at the October IEC meeting, the things
19 that were discussed was, first of all, the
20 incorporation of a new action spectrum, which is
21 basically a function that you use to determine what
22 the relative effectiveness is of different
23 wavelengths of a sunlamp, at least in this case a
24 sunlamp.

25 They decided to go ahead and approve the

1 use of a new action spectrum, which is for
2 non-melanoma. This has just recently, or I would
3 say maybe a couple of years ago, been adopted by
4 the CIE organization.

5 The IEC has now decided to also use it in
6 their standard in addition to the erythema action
7 spectrum, which is for sunburn.

8 The other item we talked about was
9 changing the classification. There were previously
10 four types of products, and they are classified
11 according to the balance of UVB and UVA radiation
12 that they emit. An additional type was added in
13 order to include products that had previously been
14 excluded from this list.

15 An important item that was discussed was
16 an absolute cap on how much irradiance the sunlamp
17 product can emit. It was voted on and accepted
18 that this level of 1 W/cm² weighted with the
19 non-melanoma action spectrum would be the limit
20 that beds could emit. Just to give you an idea,
21 this limit is about 2 times the intensity of
22 tropical sun.

23 Lastly, we were still working on the
24 details of replacement lamps. What we decided to
25 do, in the International Committee, it is a little

1 bit more complicated because the committee that we
2 normally work with, the IEC TC 61, has
3 responsibility for the sunlamp product and the bed
4 or the booth.

5 Yet, there is another committee, that is,
6 TC 34, that has responsibility for the single
7 fluorescent lamps and how they are measured. So,
8 we had to work out a system where we could liaison
9 with this committee and try to get their help on
10 coming up with an acceptable measurement scheme and
11 coding scheme. At this meeting, we decided to
12 create a liaison with them.

13 Then, in June, one of the things we talked
14 about was modifying the instructions for use. One
15 of the things that was changed here was including
16 limiting the use of products by minors.

17 The thing that probably took the most time
18 was the replacement lamp issue. Members of this
19 other committee that I told you about actually
20 attended and they presented a scheme for
21 measurement and coding, and we reached a compromise
22 on how to do that. That is the scheme I will be
23 presenting today.

24 Just briefly, the meeting we had with the
25 American Academy of Dermatology, we told them about

1 our research and the regulations of sunlamps, and
2 they told us about their concerns, which were, one,
3 that they were seeing an increased use of sunlamp
4 products over the last few decades especially among
5 young women and even children, and they are also
6 seeing increased rates of skin cancer among
7 Americans, so they are very concerned that we
8 should try to strengthen our warnings and
9 regulations as much as possible.

10 At that meeting, they told us they had
11 plans to send petitions to the FDA Commissioner to
12 this effect.

13 Now I am going to go through the six
14 proposed amendments. As I said, some of them have
15 been presented before and I will just repeat them,
16 so that we can make sure that you understand what
17 we are presenting now.

18 The Proposed Amendment 1 is to change the
19 warning label. This is a reproduction of the
20 current label which you can see is very wordy and
21 it is not very ergonomic, so we wanted to improve
22 that.

23 This is the Proposed Revised Label. It is
24 basically what is in the international standard.
25 It just says, "Warning - Ultraviolet radiation may

1 cause injury to the eyes and skin, skin aging, and
2 skin cancer."

3 "Read instructions carefully. Wear
4 protective eyewear provided. Certain medicines and
5 cosmetics may increase sensitivity to ultraviolet
6 radiation."

7 This last part that is in pink is
8 something that some people at the Agency would like
9 to see added to the FDA label. This is currently
10 not in the IEC standard, but there are certain
11 deviations that we are allowed to make with that
12 label. We would probably like to get your opinion
13 on whether or not that is a good idea to add that
14 or not.

15 We also will have requirements on the size
16 of the lettering, so that it is clearly legible.

17 Proposed Amendment 2 is just including the
18 warning label on catalogs and, as I said, this is
19 consistent with requirements already in the laser
20 standard.

21 Proposed Amendment 3 is the definition of
22 "manufacturer." This also is consistent with
23 requirements we have in the laser standard.

24 This would be the language that would
25 appear in the standard, and it reads: "The

1 modification of a sunlamp product, previously
2 certified under Section 1010.2 by any person
3 engaged in the business of manufacturing,
4 assembling, or modifying sunlamp products shall be
5 construed as manufacturing under the act if the
6 modification affects any aspect of the product's
7 performance on intended function for which this
8 section has an applicable requirement. The person
9 who performs such modification shall recertify and
10 re-identify that product in accordance with the
11 provisions of Sections 1010.2 and 1010.3."

12 Just to clarify, things that we would
13 consider to be significant modification would be
14 the following: Replacing original lamps with lamps
15 that are incompatible. Increasing the maximum timer
16 setting beyond what it originally was set at, and
17 something like removing required labeling or
18 replacing original labeling with a labeling that
19 would render the product noncompliant.

20 Proposed Amendment 4 deals with eyewear.
21 The current language in the standard reads like
22 this: "The spectral transmittance shall not exceed
23 a value of 0.001 over basically the UVB range,
24 actually, a little bit lower than UVB, .200 to 320,
25 and a value of 0.01 over the UVA range of 320 to

1 400 nanometers, and shall be sufficient over the
2 wavelength range greater than 400 nanometers to
3 enable to user to see clearly enough to reset the
4 timer."

5 It is this part that we want to improve,
6 because it is not quantitative and there is really
7 no way to test that in an objective manner.

8 So, we could keep the UV limits the same,
9 but for the visible region, we would like to
10 propose a more quantitative definition, and that is
11 that the luminous transmittance shall not be less
12 than 1 percent over the 380 to 780 nanometer
13 wavelength region.

14 We have suggested this to IEC and it has
15 now been adopted in the IEC standard.

16 Just to give you an idea of what the
17 luminous transmittance is, here is the formula. It
18 is a little complicated, but it is really based on
19 the amount of light that the eye can perceive.

20 So, the quantities which are spectral
21 functions in this formula, the $Y(\lambda)$ is the
22 relative luminous efficiency of the human eye, and
23 then you also need to use a standard light source
24 in order to do the calculations, and you include
25 the spectral transmittance of the eyewear to get a

1 number for the luminous transmittance.

2 We are proposing that a floor of 1 percent
3 be the cutoff point for this value.

4 In addition, we don't want too much
5 visible light to be transmitted because there is a
6 chance, especially in sunbeds that have
7 high-pressure lamps which are very small lamps of
8 high intensity, there is a chance for damage to the
9 retina from visible light. So, we want to
10 institute a cap of 5 percent on the unweighted
11 spectral transmittance from 400 to 550 nanometers.
12 This requirement is also part of the international
13 standard and has been in there for several years.

14 However, we have had our FDA laboratory in
15 Winchester, Massachusetts, do testing on eyewear
16 recently and we found out that there is some
17 eyewear currently on the market that cannot meet
18 the 5 percent cap. It is not a large percentage of
19 the market, but there are some products that can't.

20 So, since it is really only a hazard when
21 you are using it with a high-pressure lamp, we are
22 proposing that these products that can't meet the
23 cap be required to bear a tag reading something
24 like the following: "Does not provide adequate eye
25 protection in sunlamp products with high-pressure

1 lamps in the facial area."

2 In addition, it is a requirement in the
3 standard that two pairs or however many people that
4 you think might be using the product, that number
5 of pairs of eyewear must be sold with the product.
6 So, high-pressure lamps, some of their products
7 could not include this type of eyewear that doesn't
8 meet the 5 percent cap with their product.

9 As I said, the rationale is because the
10 high-pressure lamps are more likely to be pose a
11 hazard than the fluorescent lamps are.

12 Proposed Amendment 5. I am breaking this
13 into two parts, A and B. They really go together.
14 We would like to change the action spectrum that we
15 are currently using. Right now we are using
16 something called the CIELYTTLE erythema action
17 spectrum.

18 At the time we published our standard,
19 there was no standard, no internationally accepted
20 action spectrum for erythema or sunburn. So, what
21 certain people at the Agency did was take the data
22 that was in the literature and adjust it, and used
23 that as the action spectrum.

24 But now there is an internationally
25 accepted spectrum, it has been well tested and it

1 is used by many organizations. FDA uses it in
2 their Sunscreen Monograph. It is used by the
3 National Weather Service, who define the UV index,
4 and, of course, it is also used in the IEC
5 standard.

6 So, we would like to update our standard
7 in that way and change to using what is now the CIE
8 reference action spectrum for erythema.

9 Here is a plot of the two spectra. They
10 look very similar especially on this plot, which is
11 a log plot here, but there are slight differences
12 in this region, and this region, but they are not
13 significant, but we feel it would be an improvement
14 to incorporate the standard that is more
15 internationally accepted.

16 Part 5B is to not only change the action
17 spectrum that we use, but to also change the value
18 of Minimal Erythema Dose that is used in defining
19 the timer, and it is also used in setting the
20 exposure schedule.

21 FDA is currently using a value of 156
22 joules per meter squared. Since the time when we
23 published our standard, a lot of research has been
24 done, and there is a CIE standard in progress that
25 is going to recommend 200 J/m² be used as the

1 minimum erythema dose for a skin type 2 person,
2 which is the person with high sensitivity that
3 would be expected to use a sunlamp product.

4 This is a weighted dose. This dose is
5 supposed to be determined with weighting the output
6 of the lamp with the erythema action spectrum.

7 In the FDA standard, the Maximum Timer
8 Limit is currently 4 MEDs, where the MED is 156.
9 So, in order to maintain the same biological dose
10 in our standard, we are proposing using 3 MEDs now,
11 which is approximately still 600 J/m² effective
12 dose.

13 The last amendment deals with replacement
14 lamps. As I said, the current situation, which is
15 defined in a policy letter, relies on a relative
16 comparison between two lamps. In order to be
17 considered compatible, these two individual lamps
18 must be within plus or minus 10 percent of both
19 erythemal and melanogenic or tanning effectiveness
20 in order to be considered compatible.

21 That system is not very desirable and we
22 would like to have an absolute system that can be
23 tested by independent laboratories, as well as a
24 lamp code on the lamp, so that people could
25 immediately see if it's the right lamp that is in

1 the product or not.

2 Just to give you an idea of this is an
3 example of a lamp. This person's face has been
4 blotted out to protect her identity. Here is the
5 number that we will be modifying or we hope to
6 modify to use for UV coding.

7 It says right now 62W-R. What that means
8 is 62 watts and R implies that it is a reflector
9 lamp, as many lamps today have reflectors built
10 into them. This text down here just tells you what
11 is written on the lamp.

12 What is being proposed now is we have a
13 code that consists of wattage, reflector code, and
14 then a UV code. Of course, the wattage is just the
15 nominal lamp wattage marked watts or W. The
16 reflector code is one of these following letters,
17 either O for non-reflector lamps meaning open, B
18 for lamps with broad reflector angle, N for narrow,
19 R for regular, and these are defined by an angle
20 alpha that refers to the angle of open surface area
21 in the lamp.

22 Lastly, the UV code consists of two
23 numbers. We are calling them X and Y where X is
24 the total erythemal-effective irradiance from 250
25 to 400 nm, and Y, we need to use the NMSC action

1 spectrum to determine Y. It is actually a ratio of
2 the NMSC effect of irradiance from 250 to 320 over
3 320 to 400.

4 The reason we are including this action
5 spectrum in the lamp code is because as I mentioned
6 before, the IEC standard requires that sunlamp
7 products be classified in one of four classes, or
8 five classes now, based on what their balance of
9 UVB and UVA is, and in order to ensure that when
10 you replace the lamp, you don't end up putting it
11 at a different class, it is necessary to have this
12 kind of ratio information be on the lamp, as well.
13 The IEC standard is using this action spectrum to
14 classify products.

15 So, in addition to coming up with the
16 coding scheme, we also had to develop standard
17 operating procedures for lamp measurements, and
18 this has been worked on by a lot of lamp
19 manufacturers.

20 There is an existing standard out there,
21 that is an IEC standard called the Method of
22 Measuring and Specifying Fluorescent Ultraviolet
23 Lamps used for Tanning. However, this standard will
24 be modified in the near future based on the results
25 of this working group that met with us at our last

1 IEC meeting because it needed to be updated.

2 It had been written based on making a
3 measurement of total flux which is a method that
4 not many people are using, so they are going to
5 refine that and base it on an irradiance
6 measurement. These are the lamps the lighting
7 engineers are mostly going to be working on.

8 So, the readings that will constitute part
9 of the code will be based on an irradiance
10 measurement from a single lamp, and it shall either
11 be measured at a distance of 25 cm from the center
12 of the lamp, or if a manufacturer chooses to
13 measure at a distance other than 25 cm, he must
14 correct his measurement value to what it would be
15 at 25 cm. That is possible to do either
16 mathematically or just by simply making a
17 correction factor with simple measurements.

18 Just to show you what the non-melanoma
19 skin cancer action spectrum looks you, it is shown
20 in pink here, and comparing it to the erythema
21 action spectrum, which is simplified for
22 mathematical purposes because in the days when it
23 was first developed, spreadsheets were not very
24 common, so they made it into a curve with three
25 different slopes.

1 But anyway, this non-melanoma skin cancer
2 action spectrum has been developed in mice. It was
3 developed by research in labs both in the U.S. and
4 in Holland, and it is now an accepted international
5 standard in the CIE Standards Committee

6 The tolerances that we would like to see
7 on this UV code, similar to what we have been
8 accepting up until now, we would like to see a plus
9 or minus 10 percent limit on these numbers.

10 Therefore, as an example, if the original
11 lamp in the sunbed had the code of 100 watts, R
12 reflector type, and then 47 where this was the X
13 number and 3.2 was the Y number, which as you
14 remember is a ratio, suitable replacements would be
15 as follows:

16 The same numbers here and then this number
17 could range from 42 to 52, this number could range
18 from 2.3 to 3.8, and this is more than 10 percent,
19 but that is because when you take the ratio of two
20 numbers, those two numbers can deviate by 10
21 percent, it ends up being a 20 percent allowable
22 deviation in the ratio.

23 We see that on the sunlamp product itself,
24 there will be a label that would say something like
25 use only lamps with these ratings, and these are

1 examples of suitable replacements for that product.

2 We probably will have some future
3 proposals. This standards amendment process is a
4 very long process. We have already published an
5 ANPRM. The next step would be to publish a Notice
6 of Proposed Rulemaking, but before we can do that,
7 a lot of things have to happen - an economic impact
8 analysis has to be done, other types of analysis, I
9 believe it is called the Regulatory Flexibility Act
10 has to be done to see if we have looked at all
11 alternatives, and it will take probably three to
12 four years.

13 But, anyway, in that time, we anticipate
14 finishing our study, so we believe we will have
15 recommendations for the revised exposure schedules
16 before we go to the proposed rule stage. If there
17 any additional changes instituted by the
18 International IEC Committee, that also may result
19 in a few new proposals.

20 So, after you hear comments from people in
21 the audience, I would like to request a vote from
22 the committee on the six proposals that I
23 presented. If you have any other questions, I can
24 take them now or take them later.

25 Thank you.

1 DR. ROTHENBERG: Yes, at this time, we
2 should have any questions about the presentation as
3 opposed to consideration of the amendments. We
4 will have following this presentation and a break,
5 the open public hearing. At this time, if there
6 are any questions for Sharon Miller about the
7 technical aspects or definitions, anything related
8 to the presentation. Yes, Michele.

9 CDR LOSCOCCO: I guess I had two
10 questions. One, I remember there being I guess
11 very specific questions about the responsibility of
12 the manufacturer regarding the lamp replacement.

13 So, you think that the new information
14 that would be required, you alluded to like a
15 manual like you would replace your light bulb in
16 your car, is that the type of thing--

17 MS. MILLER: That is what is being used
18 currently is the manual kind of system.

19 CDR LOSCOCCO: So, you think that would
20 simplify it by having these?

21 MS. MILLER: Oh, yes, definitely. I mean
22 that is what we hope. What happens now is that the
23 manufacturers of individual lamps submit what they
24 call a compatibility declaration sheet, and it is a
25 very long list saying, you know, if you have lamp,

1 you know, beautiful tan, 23567, you can use one of
2 these 10 lamps as replacement lamps.

3 Then, there is a long list for all the
4 lamps they manufacture. Like I said, we foresee
5 that there would be a clear label on the bed saying
6 use only lamps of this type, and then that code
7 would be on the lamp, so it will be more universal.
8 You wouldn't have to use only that manufacturer's
9 lamp.

10 CDR LOSCOCCO: I guess the concern was not
11 necessarily for the larger tanning bed salons, but
12 the person that has one in their house. Is the
13 person that then is the homeowner that is replacing
14 their lamp then considered the manufacturer,
15 because they are replacing a lamp?

16 MS. MILLER: No, no, and if anybody
17 replaces a lamp with an acceptable lamp, they are
18 not required to report to us or consider to be a
19 manufacturer for that purpose. So, as long as they
20 use the right lamp, it is not a problem. Of
21 course, a homeowner would not be considered because
22 they are not exposing the general public. Thank
23 you.

24 DR. ROTHENBERG: Dr. Cardarelli.

25 DR. CARDARELLI: Two quick questions.

1 One, I do like the simplicity of the new label.
2 The one question I had, though, is the change from
3 the word "Danger" to "Warning" in that it does
4 breed a little bit of inconsistency with that, that
5 the manufacturers put on the bulb, the bulb itself
6 or the lamp itself has the word "Danger" on it.

7 So, in terms of communication to everyone
8 out there in the world using these, it would be
9 good to have some level of consistency. I don't
10 know if the word "Warning" is consistent with the
11 international.

12 MS. MILLER: That got changed a few years
13 ago, I can't remember exactly what the reasons were
14 that we decided to go from "Warning" to "Danger."
15 Do you remember, Howard?

16 DR. CYR: It was a question of
17 harmonizing.

18 MS. MILLER: I wasn't sure if it was a
19 conscious decision that it was not as much of a
20 hazard as we thought it was.

21 DR. CARDARELLI: At least then for the
22 manufacturers, you may want to maintain some level
23 of consistency.

24 MS. MILLER: On the lamp, whatever you are
25 going to have, have on back, too.

1 DR. CARDARELLI: The other question I had
2 was, what was the basis for the 10 percent
3 compatibility rule?

4 MS. MILLER: Well, it was I guess more to
5 be in agreement with what is achievable in
6 production and to try to build in as much safety as
7 possible.

8 DR. CARDARELLI: So, even if they were 10
9 percent over, set at the maximum time, it won't
10 result in some sensitive person getting burned.

11 MS. MILLER: Most likely not. From the
12 research we have seen, you really have to usually
13 go at least 20 percent over to see a difference in
14 reaction.

15 DR. CARDARELLI: Thank you.

16 DR. ROTHENBERG: Dr. Lambeth.

17 DR. LAMBETH: I wonder if you could shed
18 some light on the aspect of the spectral changes in
19 the lamp with lifetime. Is this more than 10
20 percent, does it fall within that same sort of
21 category?

22 MS. MILLER: Definitely.

23 DR. LAMBETH: Pardon?

24 MS. MILLER: Yes, over the lifetime, I
25 mean I can't say "lifetime" because--maybe someone

1 from the audience would like to speak about this,
2 someone who has day-to-day experience with it--but
3 I know that before the lamp has totally failed,
4 they can easily drop by half, if not more in their
5 output, in the effective output.

6 DR. LAMBETH: I wasn't so concerned about
7 the wattage as I was about their spectral content.

8 MS. MILLER: Well, I believe what happens
9 normally is that the shorter wavelength spectrum
10 drops quicker than the longer wavelength spectrum.
11 In any event, they are getting less powerful, their
12 sunburning potential is going down with life, with
13 time.

14 DR. LAMBETH: So, would a salon operator
15 change this when it is down by 50 percent, or is it
16 down by 10 percent?

17 MS. MILLER: You had better ask the salon
18 owners here, they could tell you that.

19 DR. ROTHENBERG: Dr. Caswell has a
20 question.

21 DR. CASWELL: Sharon, just a
22 clarification. Do I understand that you want to
23 use the CIE erythema action spectrum for 5A and
24 then the non-melanoma skin cancer action spectrum
25 for Proposed Amendment 6?

1 MS. MILLER: Amendment 6, which is the
2 lamp rating, you use both, both erythema and the
3 non-melanoma skin cancer. The first number is the
4 total erythema-weighted output, which used the CIE
5 erythema action spectrum.

6 DR. CASWELL: The X value.

7 MS. MILLER: The X value, right, and then
8 the Y value is based on the non-melanoma.

9 DR. CASWELL: Why would you use both of
10 those, what is the thinking behind that?

11 MS. MILLER: Well, we want to use the
12 erythema action spectrum because we feel as long as
13 we keep the lamps within the limits of that value,
14 we can prevent people getting burned, whereas, if
15 you only use the non-melanoma skin cancer action
16 spectrum, there is a slight chance--you know, there
17 isn't a huge difference in the two, but there is a
18 slight chance that you might have a lamp that
19 agrees with the non-melanoma skin cancer action
20 spectrum number, but doesn't agree on the erythema
21 number and someone could get burned.

22 As I mentioned before, the reason we want
23 to use the non-melanoma number in addition to the
24 erythema number, is to allow that the IUC
25 Classification System is preserved, because they

1 classify their sunlamp products, the sunbeds, based
2 on non-melanoma skin cancer-weighted output in the
3 UVB and UVA.

4 So, it is really just to make sure that,
5 like I said, we don't have lamps being changed and
6 have the product accidentally go into a different
7 class.

8 DR. ROTHENBERG: I have just one question
9 about the wattage. Is it specified somewhere that
10 only the same wattage bulb, because you don't
11 address the wattage itself?

12 MS. MILLER: Yes, well, that is part of
13 the code, so the first number that was shown there
14 was--either on the lamp I showed--it was 62 watts,
15 so, yes, you would have to use lamps of the same
16 wattage, same reflector type, and same UV code, or
17 UV code within 10 percent.

18 Dr. Lipoti.

19 DR. LIPOTI: I have got four questions.
20 The first one has to do with the warning label
21 also. Based on the classification of skin cancer
22 as a known cause of cancer, the label says
23 ultraviolet radiation may cause skin cancer. I
24 wondered if you needed to take into consideration
25 the work of the Toxicology Institute.

1 MS. MILLER: Well, the reason we prefer to
2 have "may" on there is because not every person who
3 is exposed to UV either from tanning lamps or from
4 the sun will get skin cancer. So, it is not a
5 definite given and conclusion.

6 I mean ultraviolet radiation can cause
7 cancer, it doesn't always cause cancer in an
8 individual.

9 DR. LIPOTI: The second question has to do
10 with timer accuracy. Is there a standard for timer
11 accuracy?

12 MS. MILLER: Not currently, but I believe
13 it will come out of--

14 PARTICIPANT: [Inaudible comment.]

15 MS. MILLER: Well, that may be what the
16 industry standard is, but it is not really written
17 in the FDA standard, but I think when we have the
18 standard operating procedures for lamp
19 measurements, there will be accuracy requirements
20 on that. That will in effect lead to accuracy
21 requirements on the timer value.

22 DR. LIPOTI: But your measurement
23 procedure is not part of a regulation. Wouldn't
24 timer accuracy be an important thing to put in the
25 regulation?

1 MS. MILLER: Well, if we accept the IEC
2 measurement standard or recognize it as part of our
3 standard, then, it would in effect become part of
4 our standard.

5 DR. LIPOTI: It would be enforceable.

6 MS. MILLER: Yes.

7 DR. LIPOTI: On Proposed Amendment 5, you
8 seem unconcerned with the deviation between the
9 current standard of 4 minimal erythema dose units,
10 which comes out to 624 joules per meter squared,
11 versus the new standard, which would be 600.

12 That deviation, what is the uncertainty in
13 making these kinds of measurements, and why are you
14 unconcerned with that deviation?

15 MS. MILLER: Well, there is two reasons.
16 There is quite a bit of uncertainty in making these
17 measurements. Measurements of ultraviolet radiation
18 are difficult to make in an accurate manner.
19 Probably most very experienced laboratories could
20 do it best, say, 15 percent accuracy.

21 Another reason we are not too concerned
22 about this difference of 600 to 624 is because
23 there is a difference in the action spectrum, and
24 depending on the lamp spectra, that will slightly
25 change the resulting effect of dose that you get.

1 So, between the weighting function being a
2 little different and the accuracy being less than
3 10 percent, it is really about the same. You are
4 talking about apples to apples there.

5 DR. LIPOTI: The last question. This was
6 not on your slide. You mentioned that it was three
7 to four years is your time line for writing a
8 standard.

9 MS. MILLER: Not for writing it, but for
10 getting it in a final published, enforceable form.

11 DR. LIPOTI: So, that includes--you have
12 already done Advanced Notice of Proposed
13 Rulemaking, so you must do the proposal, respond to
14 comments, and finalize it.

15 MS. MILLER: Yes.

16 DR. LIPOTI: And that takes three to four
17 years?

18 MS. MILLER: Well, before we get to the
19 proposed rule stage--and maybe someone else in the
20 audience would be better to explain this in
21 detail--but we need to do a lot of different
22 notifications--not notifications--but we have to do
23 economic impact analysis. That is a pretty lengthy
24 procedure. I believe it has to be approved by
25 General Counsel. There is just a lot of

1 bureaucracy that has to be taken care of before it
2 gets to the proposed rule stage.

3 DR. ROTHENBERG: Dr. Cardarelli.

4 DR. CARDARELLI: I have one follow-up
5 question. If I heard you correctly in your
6 presentation, you suggested that some research that
7 you are conducting may result in a reduction in the
8 exposure schedule.

9 MS. MILLER: In what was that?

10 DR. CARDARELLI: The amount of time it
11 takes to get a tan and keep a tan.

12 MS. MILLER: Yes.

13 DR. CARDARELLI: Now, if that is the case
14 and FDA comes out with some recommendation that
15 says the exposure schedules can now be reduced for
16 the same effective outcome in terms of tanning,
17 does that imply anything that the current schedule
18 is harmful, that they are overexposing people, and
19 there could be ramifications down the road for
20 that? I don't know if you can answer that now, but
21 wanted to bring that up.

22 MS. MILLER: Well, I would just say that
23 that is really part of the driving force why we are
24 doing this study. In 1986, we published guidance
25 for exposure schedules and we kind of came up with

1 the formula as to how a manufacturer could develop
2 an exposure schedule that would be printed on the
3 bed.

4 Since then, the research that we have
5 done, and also research that other people have
6 done, have led us to believe that the doses that
7 are currently recommended are too high and that
8 they could be reduced, so that is partly why we are
9 doing the research.

10 You might say that they are currently
11 excessive, but the other problem is that in
12 addition to the recommendations currently being
13 excessive, people will sometimes go to salons more
14 frequently and get more of a dose than is even
15 recommended. That is another issue we have to I
16 think educate the public about.

17 They don't need to get as much exposure as
18 they might think they do, and I think part of the
19 problem is a lot of the people who go to tanning
20 salons want to see quick and immediate results, and
21 you just can't force the skin to produce melanin
22 immediately, it takes some time to develop, and
23 hopefully, if we can educate people to take it
24 slow, that they can get the same result with less
25 dose.

1 DR. ROTHENBERG: I have just two
2 clarifications I would like. If you go back two
3 slides previously, to the one just before Proposed
4 Amendment 5A, the previous slide to that, you talk
5 about the smaller image size. What is the
6 definition of image size?

7 MS. MILLER: Well, these high-pressure
8 lamps, they are called "high-intensity" lamps.
9 They have an arc which is about this large. So,
10 the image that they form on the retina is much
11 smaller than you would get, say, from a fluorescent
12 lamp. Because of that you have, in a similar
13 intensity being focused to a very small spot on the
14 retina, and visible light can cause either subtle
15 retinal damage or even retinal burns.

16 DR. ROTHENBERG: And the second question
17 is, do you have an idea, typically, how often do
18 these bulbs get changed, is it once a year, twice?

19 MS. MILLER: You mean fluorescent lamps or
20 high-pressure lamps?

21 DR. ROTHENBERG: Well, let's say for
22 either type.

23 MS. MILLER: I really don't know about the
24 high-pressure lamps, and it probably would be best
25 for someone in the audience to answer this, but I

1 would say less than once a year. How long?

2 AUDIENCE: It depends how many people.

3 MS. MILLER: Yes, it really depend on the
4 throughput.

5 DR. ROTHENBERG: The question is, is it
6 something that happens so often that it makes a
7 difference, whether it happens every month, once a
8 year, once every five years type of thing.

9 AUDIENCE: Most people recommend changing
10 it when they degrade it to 70 percent of the
11 original output.

12 MS. MILLER: How often would that be in a
13 busy salon?

14 AUDIENCE: Once a year.

15 MS. MILLER: Once a year in a busy salon,
16 she says.

17 DR. LAMBETH: Perhaps a simple statement
18 about the lifetime of the bulb would help.

19 AUDIENCE: Most bulbs have 1,000 hours, so
20 if you change them every 700 hours--

21 MS. MILLER: It's a value of 700 to 1,000
22 hours.

23 DR. ROTHENBERG: I just wanted to get a
24 feel for the typical frequency.

25 Yes, Dr. Platner.

1 DR. PLATNER: I just had two short
2 questions or one comment and a question. The
3 comment is on the label. I agree with the previous
4 member who commented on the "may cause." To me,
5 that implies that it is uncertain whether it does
6 cause, whereas, I think we are fairly certain that
7 it can cause. I would suggest maybe changing "may"
8 to "can" just because "may" sounds like cigarette
9 smoke cause lung cancer.

10 MS. MILLER: I am not sure. It that what
11 the warning label on cigarettes says? But, anyway,
12 you would have good company because a lot of the
13 dermatologists also have suggested that. We will
14 have to discuss it among ourselves, I think, to see
15 if we feel it is required to go that route.

16 DR. PLATNER: My other question is in
17 reference to your standard operating procedure for
18 irradiance measurements where you refer to the IEC
19 1228 method. As you mentioned, that is currently
20 in the process of being modified, and I was curious
21 how this kind of international standard or
22 consensus standard is reference in a regulation
23 because it seems to me that if you just reference
24 it without including it, or including the date,
25 then, you are basically delegating your rulemaking

1 to what is potentially a small committee.

2 MS. MILLER: Well, this is kind of new
3 ground for us because at least in this area, we
4 haven't approached standards that way before, by
5 adopting other international standards, but we
6 certainly would include the date, so that it would
7 be clear which version we were talking about.

8 As far as the enforceability, like I said,
9 this is a new area, so some of those details are
10 still being worked out. Lillian mentioned this
11 morning with the laser standard, that we have run
12 into some copyright issues when we tried to just
13 put the language of the IEC standard in our
14 standard. So, we are going to try to make it as
15 understandable and as clear as possible.

16 So, it is still a little bit up in the air
17 which way is best to go.

18 DR. ROTHENBERG: Dave Lambeth.

19 DR. LAMBETH: I had a couple of others
20 that came up. In your Proposed Amendment No. 4,
21 the wording is the spectral transmission shall not
22 exceed. When I first read this, I was a little
23 concerned. I understood later from your other
24 slide, but you really mean the integrated spectral
25 transmittance, which is what you do on the next

1 page, explain for us.

2 MS. MILLER: No, actually, the way it is
3 written in the IEC standard is not the integrated
4 transmittance, but the spectral transmittance
5 itself shall not go over 5 percent at any
6 wavelength, and as it is mentioned here, it needs
7 to be measured at less than or equal to 5 nanometer
8 intervals.

9 DR. LAMBETH: Well, under your Proposed
10 No. 4, spectral transmittance shall not exceed a
11 value of 0.001 over the wavelength region. I don't
12 think in that, there is anyplace in there that
13 specifies the bandwidth of that measurement.

14 MS. MILLER: That's the current standard.
15 We would also probably be modifying just to make
16 sure that all the measurements have to be done at 5
17 nanometer intervals or less for the UV and the
18 visible.

19 DR. LAMBETH: My other question was why
20 does one of these stops at 400 nanometers and the
21 other one begins at 380, so that there is this
22 overlap?

23 MS. MILLER: Well, that is really just
24 because, you know, there is a standard function
25 that describes the response of the eye and some

1 individuals can see down to 380, not very many, but
2 it is just in order to use what is already out
3 there in other standards, and that use another eye
4 protection, you know, safety standards, but we want
5 to make sure that the UV region is adequately
6 covered, and that pretty much stops at 400.

7 But I don't think it affects safety or
8 anything to have the small overlap.

9 DR. ROTHENBERG: Kim Kantner.

10 MS. KANTNER: My question relates back to
11 the labeling and some follow-ups on the word of use
12 of "may." It was mentioned here to consult your
13 physician. I was wondering if you can elaborate a
14 bit on what types of conditions or situations would
15 a user consult a physician on. Are we looking at
16 duration, limitation, avoidance?

17 MS. MILLER: What we really intended was
18 since it follows the phrase about medicines, we
19 really meant for that to be if you are on
20 medications, you should consult your physician
21 before using a product like this, because certain
22 medicines make you more sensitive to UV.

23 MS. KANTNER: So, to add to that, then,
24 instructions to the users would only say generally,
25 if these cosmetics or medications, which then they

1 would have to be referring back to a physician to
2 help make those judgments on their safety, on
3 whether or not to use?

4 MS. MILLER: Are you saying are we going
5 to change the wording?

6 MS. KANTNER: Just if there was more
7 explanation needed on the labeling since it is
8 consulting your physician, I think you had
9 mentioned that there might be some room for
10 elaborating a bit.

11 MS. MILLER: I mean we want to keep it
12 short, so we have the balance of trying to keep it
13 short and provide enough information. We could, I
14 suppose say something like if you are taking
15 medications, consult your physician because
16 medications and certain cosmetics may increase
17 sensitivity, just to make it more clear as to what
18 we are referring to.

19 DR. ROTHENBERG: Dr. Lipoti.

20 DR. LIPOTI: I have one more. All of
21 these regulations are regulations that would not
22 affect any equipment that is currently in use, it
23 would only be for equipment that is manufactured
24 after the four years when it goes final.

25 MS. MILLER: Right, and four years is a

1 ballpark number.

2 DR. LIPOTI: Right, but I think it is an
3 accurate number given FDA's past history of getting
4 these things through, so I will go with the four
5 years. I guess I am wondering in that case why you
6 need to put tags on the eyewear that doesn't
7 provide adequate protection for the sunlamps, for
8 the high-pressure sunlamps.

9 It seems to me that you should be able to
10 simply not allow that eyewear to be used. I mean
11 if the manufacturer has four years in which to
12 change their product, so that it can provide
13 adequate protection, why are you being so careful
14 about putting a tag on this? As you put it, it is
15 only a small portion of the market.

16 MS. MILLER: Right, but on the other hand,
17 should we restrict the manufacturer of products
18 that don't create a hazardous situation for the
19 majority of the products on the market. The
20 fluorescent lamps are the major portion of the
21 products that are out there. They don't pose a
22 retinal hazard.

23 So, in order to not stymie development of
24 eyewear that is not a problem with the vast
25 majority of products out there, we thought it made

1 more sense just to allow that they can be produced
2 for those types of beds, but in the cases where
3 there is a potential hazard with the high-pressure
4 lamps, that this tag would pretty much take care of
5 that problem.

6 We thought about having two different
7 standards for eyewear to be used with fluorescent
8 lamps versus eyewear to be used with high-pressure
9 lamps, but that seemed to us more cumbersome in a
10 way and since it is a small percentage of the
11 market, it might be simpler just to have this type
12 of tag system.

13 DR. LIPOTI: But would the tags stay with
14 the eyewear, or are the tags going to be taken off
15 the first person who uses it?

16 MS. MILLER: But they are only supposed to
17 be used by one person. It is not something that is
18 given out to--

19 DR. LIPOTI: It's disposable.

20 MS. MILLER: Yes, most--I would say all
21 the cases are disposable. Supposedly, when the
22 salon owner gives it to them, it would have the tag
23 on it at that time, and if they want to tear it off
24 after that, there is not much we can do about it,
25 but at least they would see it initially, and

1 hopefully, the salon owner would be educated enough
2 not to give somebody this kind of eyewear when they
3 are going in a high-pressure bed.

4 DR. ROTHENBERG: John.

5 DR. CARDARELLI: Just a quick follow-up
6 from a previous comment regarding the statement
7 consult your physician. Most physicians may or may
8 not be expertise in the area of skin and skin
9 disorders. Hopefully, if they are not, they would
10 consult with a dermatologist to answer any
11 concerns.

12 I would then offer this, that
13 consideration be given to the addition to consult
14 your physician or a dermatologist, or consult a
15 dermatologist, go to who the experts are on these
16 issues.

17 MS. MILLER: Yes, I guess that is probably
18 a pretty good idea. The only concern I would have
19 is that most people don't have a dermatologist and
20 that they would be more likely to go to their
21 primary care physician, who could then refer them,
22 I suppose.

23 DR. CARDARELLI: I would agree, but having
24 the word "or a dermatologist" would also give them
25 some intelligence, educate them that there is a

1 specialist in skin disorders.

2 MS. MILLER: I think that is a good idea.

3 DR. ROTHENBERG: Dr. Caswell.

4 DR. CASWELL: A follow-up, Sharon, a
5 comment I guess on the label. There are really
6 three different types of skin cancers - squamous
7 cell carcinoma, basal cell carcinoma, and melanoma,
8 and as Dr. Cyr pointed out, the relationship
9 between squamous cell carcinoma and ultraviolet
10 radiation is very clear, a direct relationship.

11 Basal cell carcinoma, certainly there is a
12 relationship there. We don't really know what that
13 relationship is, but it is clear that there is a
14 relationship.

15 Melanoma, as you pointed out, is a little
16 more problematic and contentious certainly in the
17 scientific literature.

18 So, I think the clarity of saying "may
19 cause skin cancer" is clear, it's precise, and the
20 user understands what that is, and you retain
21 scientific credibility with that.

22 MS. MILLER: I agree with that, because if
23 you just say causes cancer, people may think that
24 without a doubt they will get melanoma or basal
25 cell cancer, and as you said, the relationship

1 there is not crystal-clear.

2 CDR LOSCOCCO: One more follow-up about
3 the replacement of the lamps. The one gentleman
4 indicated that a salon would replace a lamp if it
5 was down to 70 percent. Is there an actual test
6 that is done that verifies that? Is it hours of
7 the lamp use? I am really concerned more about the
8 in-home user that takes a lamp out that is now down
9 to 30 percent and puts a lamp in that is plus 10
10 percent, how would they know that, is it
11 calculated, do they know the hours?

12 MS. MILLER: No, there is really no way
13 they can know. Some salon owners may have ways of
14 measuring the output of a bulb, a homeowner would
15 not although there are some new meters on the
16 market that are not extremely expensive that could
17 be used, but I seriously doubt a homeowner would go
18 to the trouble of purchasing one.

19 There is more of a risk to the homeowner
20 who would put in a new bulb, and even in salons, we
21 know that when bulbs are replaced, people are more
22 likely to get burned because it is different than
23 maybe what they had been used to.

24 But we haven't seen too many reports of
25 severe burns, so we hope that it is not a huge

1 issue, and we don't have any really good
2 alternative methods since there is not an easy way
3 to measure the output.

4 CDR LOSCOCCO: So, is there anything in
5 the literature that comes with the bed that says
6 replace lamp after so many hours?

7 MS. MILLER: I don't think so, no.

8 CDR LOSCOCCO: And you think that when you
9 go back to that plus 10 percent, you had indicated
10 that typically, you don't get a--

11 MS. MILLER: You wouldn't see a big
12 difference, no.

13 DR. ROTHENBERG: Dr. Benson and then Dr.
14 Mabuchi.

15 DR. BENSON: I just have another follow-up
16 question about the protective eyewear phrase in the
17 proposed revised label. It says, "Wear protective
18 eyewear provided." Is this too vague for a
19 homeowner who might lose or break the ones
20 provided? Since you have an eyewear standard,
21 could you not just change the phrase to read
22 something like "Wear only eyewear certified for use
23 with sunlamps," or something to that effect, so
24 that, you know, replacement eyewear, they would
25 have an idea of what to do.

1 MS. MILLER: Yes, I think that is a good
2 idea. When the standard or the warning label was
3 originally written, we have just kind of made
4 slight modifications to the original language,
5 there really wasn't a clear definition for eyewear.
6 So, if we update the standard and make the eyewear
7 requirements part of the standard, then, we could
8 do something like that, just so that people don't
9 try to wear sunglasses.

10 CDR LOSCOCCO: Right. That is what I
11 worry about.

12 DR. ROTHENBERG: Dr. Mabuchi.

13 DR. MABUCHI: I tend to disagree with the
14 characterization of epidemiological data on skin
15 cancer, you know, cell types, et cetera. My take
16 is that epidemiological evidence is that all types
17 of skin cancer are caused by ionizing radiation
18 even there is uncertainty about the types of
19 exposure, either intense or chronic, but it is
20 certain that UV exposure is capable of causing, not
21 only basal cells, but squamous cells, all types.

22 MS. MILLER: You say it is capable, which
23 to me means it may cause.

24 DR. MABUCHI: It can, yes.

25 DR. ROTHENBERG: I think at this time, we

1 will take a short break. Let's try to reconvene
2 about 10:40. I would ask that if the following
3 people--I know some of you are here--could the
4 following people who are going to participate in
5 the open public hearing, the ones we know about so
6 far, John Overstreet, Jim Shepherd, Joe Levy, Joe
7 Schuster, Rick Mattoon, Donald Smith, and Laura
8 Edwards, during the break, just let us know that
9 you are here.

10 I understood that possibly the first three
11 mentioned wouldn't all speak for the Indoor Tanning
12 Association. Would you please let us know, so that
13 we will know how many people are planning to speak
14 and then how much time we will be able to allocate
15 for each person.

16 MR. KACZMAREK: It also might be a good
17 time to load any slides you have into the computer
18 during the break.

19 DR. ROTHENBERG: We will take a 15-minute
20 break at this time.

21 [Break.]

22 MR. KACZMAREK: There have been some
23 questions about getting copies of the handouts and
24 the overheads or the slides. My endeavor is to get
25 everything from the speakers and get them posted on

1 may have with the sponsor, its product, and if
2 known, its direct competitors. For example, this
3 financial information may include the sponsor's
4 payment of your travel, lodging, or other expenses
5 in connection with your attendance at the meeting.

6 Likewise, FDA encourages you at the
7 beginning of your statement to advise the committee
8 if you do not have any such financial
9 relationships. If you choose not to address this
10 issue of financial relationships at the beginning
11 of your statement, it will not preclude you from
12 speaking.

13 Thank you.

14 Our first speaker will be Joe Levy from
15 the Indoor Tanning Association.

16 MR. LEVY: Good morning, Mr. Kaczmarek,
17 Dr. Rothenberg, and committee members. My name is
18 Joseph Levy. I represent the Indoor Tanning
19 Association.

20 ITA is the world's largest association of
21 indoor tanning facility owners and suppliers,
22 representing nearly 100 percent of all lamp and
23 equipment manufacturers in the United States and
24 abroad and, through our relationship with the
25 International Smart Tan Network, the owners and

1 operators of approximately 6,000 tanning facilities
2 in the United States.

3 Thank you for this opportunity to speak
4 this morning. In the spirit of constructive
5 cooperation with FDA's Center for Devices and
6 Radiological Health, I want to focus primarily on
7 this: The real world efficacy of what is being
8 proposed.

9 The spirit of the proposals introduced
10 here today make sense, of some of them, but what we
11 are concerned about is that several of these
12 proposals would mandate changes that may not
13 actually positively affect public health, but which
14 would potentially create detrimental economic
15 effects for the indoor tanning industry.

16 We are concerned that several of these
17 proposals are harmonizing with voluntary
18 international standards simply for the sake of
19 harmonization, but not, in fact, for the sake of
20 better advocacy of public health. That, of course,
21 is our common goal, so let me go through these
22 proposals one by one.

23 First, is the FDA warning label language.
24 I have put a sheet in front of you that shows the
25 proposal as we saw it last year, as you saw this

1 morning, the sentence "Consult your physician" has
2 been added to the medications and cosmetics portion
3 of that, and that is not reflected on what I
4 reported to you as FDA's warning label.

5 We have suggested a year ago three
6 revisions to that label. The first revision you
7 see in bold and the first bullet under the warning,
8 "The injury to unprotected eyes." Simply, we feel
9 that this change accomplishes the goal, which is to
10 get the user to understand they need to wear the
11 eyewear. Simply leaving it as "Injury to the eyes
12 and skin" does not connote that message that you
13 need to wear the eyewear.

14 The second change, we believe that the
15 term "Avoid overexposure" should be on this label
16 because that is our common goal, we want to teach
17 people to tan, but not to burn.

18 The third change that we suggested, and I
19 think was also suggested by a committee member,
20 "Wear federally compliant eye protection intended
21 for use with this device" - an important
22 distinction from simply the consumer having the
23 belief potentially that they could wear sunglasses
24 or any other type of eye protection.

25 The term "Consult your physician" was

1 added in relation to medicines and cosmetics that
2 may increase your sensitivity to ultraviolet
3 radiation. I would make the suggestion that that
4 be "Consult your physician or pharmacist."

5 I think it is pretty well documented in
6 the photobiology community right now that the list
7 of photosensitizing agents is losing its meaning
8 because there are so many medications on the list
9 that are simply added for liability purposes. The
10 people who seem to have the best grasp of this are
11 pharmacists.

12 The second point I would like to go over,
13 inclusion of the warning label that we just
14 discussed in catalogs. We have an important
15 concern here. FDA proposes a warning label in all
16 catalogs, specification sheets, and descriptive
17 brochures.

18 ITA agrees that the end consumer needs to
19 be properly educated on the use of tanning
20 equipment. In professional tanning facilities, we
21 believe the consumer already had proper access to
22 this information on several levels.

23 Consumers who purchase home units should
24 be provided material prior to purchase educating
25 them on the use of the equipment. We do not

1 believe this education needs to be in the form of a
2 warning label similar to cigarette warning labels,
3 which was discussed when this concept was first
4 introduced in 2000. That would send the wrong
5 public health message. It would overclassify the
6 risk in relation to lung cancer, which kills
7 160,000 Americans annually, and the American Cancer
8 Society believes is related to 1 in 3 cancer
9 deaths, to ultraviolet light, which the risks of
10 overexposure are nowhere near that, so it should
11 not be overpromoted, and I don't think that sends
12 the right public health message.

13 We would like to know exactly what
14 materials--and this is important--that FDA would
15 like published, and specifically, in what
16 publications they should appear. This needs to be
17 distinguished with some level of certainty before a
18 proposal is written, and we did not get that level
19 of certainty this morning.

20 Our third concern, the protective eyewear
21 - visible transmission requirements. Some
22 important clarification and quantification is
23 needed on this amendment. Our current FDA
24 regulations for eyewear only limit the transmission
25 of light up to 400 nm. Although IEC suggested

1 regulations place an additional restriction from
2 400 to 550 nm, we are not familiar--this is
3 important--we are not familiar with any data
4 showing that tanning lamps emit dangerous levels of
5 light in this range. We ask data supporting the
6 need for this change be made available.

7 Creating eyewear that is compliant to this
8 new proposed standard will considerably reduce the
9 vision of the user. It may be more difficult to
10 see and operate the controls in the unit. That
11 also needs to be evaluated.

12 This proposal could add significant
13 additional costs to the manufacturing process by
14 requiring retooling and other changes without clear
15 indication that it will improve public health.

16 Our goal is to avoid regulations that are
17 unnecessary and, at the same time burdensome, so
18 the trade-offs in this change should be evaluated
19 and substantiated before going forward.

20 Fourth point regarding the definition of a
21 manufacturer. Extreme care is required to develop
22 this proposal. There are some very important
23 distinctions. The language of this proposed
24 amendment needs to be very clear and very specific.
25 Salons should not be restricted in any way from

1 conducting basic maintenance or from changing a
2 unit's lamps to a certified compatible lamp.

3 Anyone who modifies a unit by
4 intentionally changing the unit's lamps to models
5 that are incompatible or who makes a change that
6 significantly increases the output of the unit
7 should become a manufacturer and assume the
8 manufacturing-related liabilities including, but
9 not limited to, re-certification and
10 re-identification of the product.

11 We are not opposed to salon owners making
12 basic modifications that do not affect the spectral
13 output of the tanning system. Changing parts
14 including, but not limited to, such items as
15 shocks, ballasts, starters, sockets, cooling fans,
16 pistons, or acrylics--and these need to be very
17 specifically outlined in this proposal or it is
18 going to create many problems I assure you--that do
19 not significantly increase the output of a unit, do
20 not pose a threat to compliance.

21 Our next concern, major concern, with
22 proposals to replace the FDA erythema action
23 spectrum with the CIE erythema action spectrum, and
24 change the MED to maximum timer interval from 4
25 MEDs at 156 joules per meter squared, to 3 MEDs.

1 On both of these proposals, we would like
2 to ask you to ask the FDA exactly what we are
3 trying to accomplish.

4 Is the expected gain worth the
5 considerable effort and expense required to
6 implement such changes?

7 ITS is not confident that all of the
8 real-world ramifications of these changes are being
9 considered at this point.

10 Has the FDA considered the many costs to
11 industry, such as changes in specifications, new
12 labeling, changes to supporting documentation,
13 brochures, the potential impact on state
14 regulations, and perhaps most important, confusion
15 and reeducation for consumers and salon owners in
16 the retail sector.

17 Lamp manufacturers have decades of
18 accumulated data using the FDA erythema action
19 spectrum. This data could become useless if the
20 standard is changed.

21 We would therefore suggest to hold a
22 stakeholder meeting with FDA to be conducted to
23 reveal these issues prior to developing any written
24 proposal.

25 Our next concern regards the IEC proposed

1 X/Y lamp coding system. Again, we do not believe
2 the FDA has demonstrated a clear need for this
3 change.

4 Our constituents believe that use of the
5 non-melanoma skin cancer weighting function in this
6 standard has the potential of causing major
7 economic problems in the future, and we believe
8 the utility of enacting this change needs to be
9 more clearly examined and taken into account.

10 This is important. Health Canada, the
11 Canadian equivalent to FDA, has not proposed this
12 change in its current rule review, according to the
13 Joint Canadian Tanning Association. This would
14 create two different standards in the North
15 American market.

16 Now, we talked about the goal of
17 harmonization being to facilitate international
18 trade. This would create a very confusing
19 atmosphere because a lot of equipment from the
20 United States goes into Canada, and this would
21 create two standards.

22 The system introduces the non-melanoma
23 skin cancer action spectrum into the lamp rating
24 systems.

25 DR. ROTHENBERG: One minute.

1 MR. LEVY: Okay. This spectrum is most
2 certain to change in the future as more studies
3 develop additional information about UV and
4 non-melanoma skin cancer. This is going to change.
5 Therefore, this change could result in a situation
6 where the current standard is changed for no
7 apparent reason and will have to be changed again
8 in the future if that standard changes.

9 We are strongly opposed to pursuing
10 international harmonization simply for the sake of
11 harmonization. ITA in January of this year hosted
12 the first-ever World Summit of Indoor Tanning Trade
13 Associations in New York. We had 33 delegates from
14 12 countries joined us in discussing the state of
15 world tanning regulations.

16 It is important to note that based on
17 conversations in the past year with our European
18 counterparts, IEC standards, which are voluntary,
19 are not even followed in Europe. In addition,
20 where IEC standards are required, regulations based
21 on these standards have had severe negative impacts
22 on the industry.

23 The standards were developed without
24 organized comprehensive input from the indoor
25 tanning industry. That is why so many of them

1 don't make perfect sense in the real world
2 environment.

3 I will let you read the rest of my
4 comments for the sake of time.

5 Thank you.

6 DR. ROTHENBERG: Okay. Thank you.

7 I think we will go to the other presenters
8 and then see what questions the committee may have
9 overall, if you could just stay here for the
10 remainder, we would appreciate it.

11 Our next speaker is Joe Schuster.

12 MR. SCHUSTER: Good morning,
13 ladies and gentlemen, the TEPRSSC Committee. I am
14 Joe Schuster with Light Sources and also
15 representing the Suntanning Association for
16 Education.

17 Comments that I wanted to share today
18 basically will be for your information, background,
19 additional support when you are considering the
20 various proposals that have been made today.

21 I represent the Suntanning Association for
22 Education in addition to Light Sources, and I think
23 it is important for you members to know that there
24 are educational bodies that are out there that are
25 teaching accredited indoor tanning operator

1 training throughout this country, the Suntanning
2 Association for Education, as well as two other
3 groups, National Tanning Training Institute and
4 Smart Tan, make up the core of education in this
5 country.

6 I think the comment was made earlier about
7 education. That is where I would like to see some
8 direction. There are certain states that have
9 mandatory educational requirements in this country,
10 not all, but some - North Carolina, South Carolina,
11 Florida, Oregon.

12 These are good things where the indoor
13 tanning operator is required to go pass an
14 accredited operator training program. I would like
15 to see more of that. I know it is not an FDA
16 recommendation, but you need to consider it when
17 you are looking at these different proposals.

18 Let's talk a second for the state of
19 technology in this industry. The indoor tanning
20 lamp, it has developed over the past few years.
21 Research that has been presented to the FDA has
22 primarily relied upon solar simulators and FS40
23 sunlamps that emit pure UVB.

24 For the first time, we are seeing lamps
25 that are used by Sharon Miller, Howard Cyr, that

1 are good. They are indoor tanning lamps being used
2 to look for study purposes, but the industry grows
3 and chances, currently maybe as much a 25 to 30
4 percent are using much more effective lamps now for
5 producing a sun tan, lamps that are also known as
6 very high output reflector lamps.

7 You heard the comment about reflector and
8 degree of reflectivity. These are good things, but
9 it changes what goes on now. So, now the time
10 frame that is needed, we talked about 20 minutes,
11 you are hearing 20 minutes a lot. Maybe it is now
12 as short as 8 minutes, 9 minutes. So the lamps are
13 becoming much more effective.

14 Here is what happens. We talked about
15 maintenance. The lamps don't last as long, we
16 heard 1,000 hour comments. These lamps are run
17 typically through much higher wattage systems. The
18 lamps don't last as long. The end result is the
19 output goes down as the maintenance curve drops,
20 the output goes down. The end result to the tanner
21 is a less or a lower dosage than what was
22 originally given when the lamps were new.

23 How often do salon owners change lamps?
24 You asked that question. Good question. I would
25 love to say they change them as per manufacturer's