This PDF version has yellow highlighting added to help readers find discussions relating to laser pointers, consumer lasers, and laser light shows.

UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

+ + +

TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

+ + +

October 26, 2016
8:30 a.m.

Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, MD 20879

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INDEX

INDEX

M E E T I N G

(8:30 a.m.)

DR. LOTZ: Good morning, everyone. I'd like to call this meeting to order of the Technical Electronic Product Radiation Safety Standards Committee, Day 2 of our proceedings.

I'm Dr. William Lotz, Chairman of the Panel, also known by middle name as Greg at times. I note for the record that the voting members present constitute a quorum as required by 21 C.F.R. Part 14.

Yesterday, the Committee discussed and made recommendations regarding possible FDA performance standards for the following topics: radiofrequency or RF radiation products, such as microwave ovens and wireless power transfer; laser products, including an update to amendments to the laser rule, light detection and ranging, or LiDAR, laser data, light fidelity (Li-Fi), energy transfer, illumination applications, and infrared applications; sunlamp products, including an update on the performance standards amendments; and noncoherent light sources, such as LEDs and UVC lamps, including new initiatives.

For today's agenda, the Committee will discuss and make recommendations regarding possible FDA performance standards for the following topics: International Electrotechnical Commission (IEC) standards versus performance standards for medical devices; computed tomography, or CT; radiography and fluoroscopy; diagnostic and therapeutic ultrasound; and radiation therapy.

Before we begin, I would like to ask our distinguished panel members and FDA staff seated at this table to introduce themselves. And I'll begin by indicating that I'm recently, a few months ago, retired from a career as a commissioned officer in the Public Health Service, working for the Centers for Disease Control, National Institute for Occupational

Safety and Health. I'd been there for 24 years, the last 10 of -- or 9 of which I'd served as the Director of the Division of Applied Research and Technology for NIOSH. So as that would indicate, I have expertise and interest in occupational safety and health in general, but specifically a background in biophysics and physiology, with an emphasis on research in radiofrequency and extremely low frequency field bioeffects and exposure assessment.

With that, I'll change up the order a little bit from yesterday and begin with Dr. Stein at the far end of the table.

DR. STEIN: Thank you so much. Toni Stein. I am here on behalf of Environmental Health Trust. I have a Ph.D. in environmental engineering and specialize in air quality control. And as well, I have a master's in process controls and systems and a bachelor's, all in engineering. In addition to that, I have worked for 7 years for a government entity, in air quality control and public health, as well as writing contracts and specifications for engineering green design for built environments. I also spent 7 years working in industry for General Electric, writing, doing protection of corrosion and other materials. I am representing, as well, Occupational Environmental Health and Safety Alliance, OEHSA. Thank you.

MR. MURPHY: I'm -- excuse me. I'm Patrick Murphy. I'm the Executive Director of the International Laser Display Association, an association of people who do laser light shows. I should say that almost none of the regulations we're discussing affect laser light shows, including laser pointers. You could eliminate laser pointers, and we wouldn't care. But we're here to help out.

MR. SAVIC: My name is Stanley Savic. I was employed by the University of Chicago as a staff scientist at the Radiology department, and prior to that at the Argonne Cancer Research Hospital under the contract with the, at that time, Atomic Energy Commission on cancer research. Following that, I joined the industry at Zenith Electronics Corporation,

where I was Director of Product Safety and Vice President of Product Safety. And following that, I have my own company, Stanley V. Savic Consulting, LLC, dealing with product safety basically. Thank you.

DR. FARAONE: Good morning. My name is Antonio Faraone. I have a Ph.D. in electrical engineering. I work for Motorola Solutions, Incorporated. My title is Chief EME Scientist. EME stands for electromagnetic energy. My expertise is in the areas of antenna technologies, RF technologies, radiofrequency dosimetry, bioeffects, and animal research. Thank you.

DR. LINET: Good morning. My name is Martha Linet. I have long worked for the National Cancer Institute. My training is in medicine. I am board certified in internal medicine and general preventive medicine. My work at the National Cancer Institute has focused on both non-ionizing radiation and ionizing radiation exposure. I've led studies on power frequency, residential magnetic field exposure and childhood leukemia, on cell phones and brain tumors, on ultraviolet radiation and cancer risk, and more recently on medical radiation workers and cancer and other serious disease risks.

MR. ALDRICH: My name is Robert Aldrich. I work for the United States Navy and Marine Corps. I am a laser safety expert and focus my efforts on the use of lasers outdoors. I am the Chair of the American National Standard for the Outdoor Use of Lasers, and I've been involved with laser safety through that organization, through the Navy, through ICAO, and through the SAE G10T subcommittees on laser safety issues, and have been doing so for some years.

CDR ANDERSON: My name is Commander Anderson. I am serving as a Designated Federal Official for this meeting. I work for the Food and Drug Administration. I'm also an officer in the United States Public Health Service.

DR. LAMBETH: Good morning. I'm David Lambeth. I am currently retired but have

my own company, Lambeth Systems, that I work through. I got my undergraduate degree in electrical engineering and my Ph.D. in physics from MIT. I then went to work in industry for about 16 years, working in a variety of areas, data storage, optical and magnetic, exotic radiographic systems, cameras and sensors, rangefinders for those. After that time, I managed to make my way to Carnegie Mellon University, where I was a professor there for roughly 24 years and worked largely in the field of data storage, magnetic recording and optical again, but also to a large extent in sensors, taught courses and did research in those, including chemical sensors, and then finally became emeritus.

DR. McCOLLOUGH: Good morning. My name is Cynthia McCollough, and I am a Professor of Medical Physics and Biomedical Engineering at the Mayo Clinic in Rochester, Minnesota. My expertise is in CT imaging, both the evaluation of new technology, development of new technology, and then translation of that technology into clinical practice.

As to today's topic, I have quite a bit of experience relevant to today's topic, having -- and still am, a member of the IEC CT maintenance team, which is involved in all of the CT-related standards, and am on the project team for development of a new standard on a topic we'll be discussing today. I'm also Vice Chair and incoming Chair of the AAPM CT Subcommittee and the AAPM's Alliance for Quality CT, where I've chaired that since 2010, and it is a group of all the stakeholders. We've got radiologists, technologists, the FDA, and all the manufacturers at the table. And we have helped prepare or had major input on pretty much all of the materials developed by the manufacturers at the request of the FDA after the brain perfusion overdose incidents.

MR. KEITH: I'm Larry Keith, and like Greg, like to go by my middle name, Sam, Sam Keith. I'm a Senior Health Physicist in the Centers for Disease Control and Prevention in the Division of Toxicology and Human Health Sciences. I specialize in radiation and chemical

toxicology, but I have special interest in x-ray imaging and radiation protection in medicine, partly due to an experience with my wife going through cancer therapy. And I have had the opportunity and pleasure to chair the Medical Workgroup at the Interagency Steering Committee on Radiation Standards, which produced Federal Guidance Report Number 14, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures. Thank you.

DR. IRWIN: Yes, good morning. My name is Bill Irwin. I am Radiation Control Program Director for the State of Vermont. As such, I'm responsible for all ionizing and non-ionizing radiation sources in the state. My academic background is a Doctor of Science in work environment engineering, where my dissertation was on the radiofrequency radiation from cellular telephones. I also have a master of science in radiological physics. I'm a certified health physicist. I'm on NCRP Council and on several committees, including the Committee for Radiation Protection Guidance for the United States.

Prior to my start in Vermont, I was a health physicist at MIT and Harvard, where I assisted researchers like Dr. Lambeth, trying to make sure they were safe while they were using all sorts of things along the electromagnetic spectrum. And I started as a naval nuclear submarine radiation protection technician.

DR. OCHS: Good morning. I'm Robert Ochs. I'm the Director for the Division of Radiological Health at FDA.

DR. MILLER: Good morning. My name is Donald Miller. I'm the Chief Medical Officer for Radiological Health at the Center for Devices and Radiological Health. I'm an interventional radiologist, and I'm board certified in diagnostic radiology and interventional radiology. I was in practice for 30 years before joining FDA, first at the NIH Clinical Center and then at what was Bethesda Naval Hospital and is now Walter Reed. I am Co-Chair of NCRP PAC 4, which deals with radiation protection in medicine, and Vice Chair of ICRP

Committee 3, which also deals with radiation protection in medicine.

DR. LOTZ: Thank you, everyone. I'd like to remind members of the audience that we would like you to sign the attendance sheets that are on the tables just outside the door, if you have not done so already, to register your attendance with us.

Commander Anderson, the Designated Federal Official for this TEPRSSC Committee meeting, will now make some introductory remarks.

CDR ANDERSON: Good morning. In accordance with the Radiation Control for Health and Safety Act of 1968, Public Law 90-602, 21 U.S.C. Section 360k(k), the Secretary, DHHS, has established the Technical Electronic Product Radiation Safety Standards Committee for consultation on matters relating to technical electronic radiation safety.

As specified by Public Law 90-602, the Committee consists of 15 members, including the Chairman, who are appointed by the Commissioner of Food and Drugs for overlapping terms of 4 years or less. Five members are selected from governmental agencies, including state and federal governments, five members from affected industries, and five members from the general public, of which at least one shall be a representative for organized labor. Members must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation and safety standards.

The primary function of TEPRSSC is to provide advice and consultation to the Commissioner of Foods and Drugs on the technical feasibility and reasonableness of performance standards for electronic products to control the emissions of electronic product radiation from such products and to review amendments to such standards before being prescribed by the Commissioner.

The Committee is not requested to review individual applications or particular products of specific firms. No vote will be taken at this meeting. I note for the record that this meeting is a meeting of particular matters of general applicability.

Public Law 90-602 and its legislative history clearly indicate that TEPRSSC members are expected to represent a very wide range of interests, with at least one-third of the Committee nominated by regulated industry itself and appointed on a basis of them being able to represent industry-wide concerns.

Section 532 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 360k(k) specifies that TEPRSSC members are not to be considered officers and employees of the United States for any purpose. This includes for the purpose of conflict of interest determinations. Regular government employees who are members of this Committee have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 U.S.C. Section 208, their employees.

The Agency believes public disclosure should be made a part of the public record, which identifies each member and provides their employment affiliation. Approved by delegated authority of the Commissioner of the Food and Drugs, the members of the Technical Electronic Product Radiation Safety Standards Committee are:

General public - William Lotz, Ph.D., biophysics; David Lambeth, Ph.D., Carnegie Mellon University; Cynthia McCullough, Ph.D., Mayo Clinic, Rochester, Minnesota; Antoinette Stein, Ph.D., Environmental Health Trust;

Government - Robert Aldrich, B.S.E.E., Naval Surface Warfare Center; William Irwin, Sc.D., Vermont Department of Health; Martha Linet, M.D., M.P.H., National Cancer Institute (NIH); Larry Keith, M.S., Center for Disease Control and Prevention;

Industry - Anthony Faraone, Ph.D., Motorola Solutions, Incorporated; Patrick Murphy, B.A., M.B.A., International Laser Display Association; Stanley Savic, M.S., Savic Consulting, LLC.

Thank you.

Before I turn the meeting back over to Dr. Lotz, I'd like to make a few general announcements.

Transcripts of today's meeting will be available from Free State Court Reporting, Incorporated, telephone 410-974-0947.

Information on purchasing videos of today's and yesterday's meeting can be found on the table outside the meeting room.

Handouts of today's presentations are available at the registration desk.

The press contact for today's meeting is Stephanie Caccomo.

I'd like to remind everyone that members of the public and the press are not permitted in the Panel area, which is the area beyond the speaker's podium. Again, I'd like to remind everyone that members of the public and the press are not permitted in the Panel area. I request that reporters please wait to speak to FDA officials until after the Panel meeting has concluded.

If you'd like to present during today's Open Public Hearing session and have not already registered with AnnMarie Williams at the registration desk, please do so.

In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time you speak.

Finally, please silence your cell phones and other electronic devices at this time.

Dr. Lotz.

DR. LOTZ: Thank you, Commander Anderson.

We will now proceed with the first FDA presentation of the morning. Dr. Jung will now present.

I'll remind public observers at this meeting that while the meeting is open for public observation, public attendees may not participate except at the specific request of the Panel Chair.

Dr. Jung, you may now begin.

DR. JUNG: My name is William Jung. I am the Branch Chief for Nuclear Medicine and Radiation Therapy Branch.

And today I'll be talking about the radiation therapy, which will be divided into two specific areas for the external beam therapy and internal beam therapy, which external beam therapies are for a device such as a linear accelerator, particle beam therapy, and some surface electronic brachytherapy, which are the x-ray sources at the tip of the catheter. And internal radiation therapy are basically the same as the x-ray source catheter that could be placed inside the body through internal, intracavity or interstitial.

Currently, we have, under the electronic product radiation control regulations, which apply for radiation therapy devices that produces radiation through electronic circuit, therefore, brachytherapy device such as the ones that inherently has a radioactive source such as radioactive seeds are not part of the discussion here today.

Over the past 30 years, the advancement in radiation therapy devices includes the use of multileaf collimators, advanced patient positioning devices, and the patient motion tracking, as well as specific image guidance that has made the radiation therapy much more sophisticated, which increase the ability to deliver a higher dose with a shorter fraction. And this also increases the importance on quality assurance to validate the dose calibrations, and this causes a -- specifically into our safety concerns regarding the incorporations of different types of accessories and specific tumor deliveries into -- I'm sorry. I'm a little bit -- okay.

So the incorporation of the different types with the imaging modalities to plan specific delivery emphasizes a -- specifically to delivery -- excuse me. I'll just get a glass of water.

So the incorporation of the advancement in radiation therapy specifically raises

safety concerns regarding the capability of delivering doses to a correct location in the prescribed dose. This becomes very important based on the fact that because you are delivering a higher dose in a shorter fraction, the ability to deliver a dose to a correct location becomes much more important, due to possibility of increasing a secondary cancer as a result.

The integration of these multiple components, often a third party, introduces a complexity in the treatment delivery. This includes incorporation of a treatment planning software, which takes in account of multiple imaging modality to plan out and identify tumors that you want it to deliver the radiation therapy.

Currently, there is no specific performance standard under Title 21 C.F.R. Subchapter J, Radiological Health, that applies to the electronic products used in ionizing radiation therapy. FDA currently relies on the existing international voluntary consensus standards for linear accelerators, particle therapy, treatment planning, and radiotherapy simulators, as well as brachytherapy.

What FDA would like to do, we are considering developing specific performance standards applicable to electronic products used for radiation therapy. And we're considering developing additional guidance to facilitate and encourage the use of the relevant consensus standard. We encourage manufacturers to adapt the features that promote patient safety and to conform to existing voluntary standards.

A question, the first is what is the Committee's opinion on the desirability of establishing performance standards for electronic products used for radiation therapy, such as linear accelerators and particle accelerator systems used to deliver external photon or particle radiation?

Okay. And the second question is are mandatory performance standards necessary for electronic products used for radiation therapy, or is it sufficient to develop and

encourage the use of voluntary consensus radiation safety standards?

If FDA develops performance standards for electronic products used for radiation therapy, what functions, systems, products, etc., should we focus on to achieve the largest public health benefits?

And what is the Committee's opinion on the desirability of establishing performance standards for accessories to radiation therapy system (for example, treatment planning software, quality assurance equipment software, patient positioning systems, and patient motion tracking systems) that control the quality, quantity, or direction of the radiation beam?

Are mandatory performance standards necessary for accessories to radiation therapy systems, or is it sufficient to develop and encourage the use of voluntary consensus radiation safety standards?

And if FDA develops performance standards for accessory to radiation therapy systems, what functions, systems, products, etc., should we focus on to achieve the largest public health benefit?

DR. LOTZ: Thank you, Dr. Jung.

We will return to the questions themselves in the discussion period later this morning, but I'd like to ask members of the Panel if you have any questions of Dr. Jung for clarification at this point.

(No response.)

DR. LOTZ: Hearing none, thank you again, Dr. Jung.

We will now proceed to the presentation by Dr. Vaishnav and Dr. Spelic.

You may proceed.

DR. VAISHNAV: So good morning, everybody, and thank you all for coming out today. And I'd like to start actually by introducing myself to you. I am a Ph.D. physicist, my

bachelor's with the University of Maryland, my master's and Ph.D. were at Harvard. I was originally trained actually in theoretical physics, and I did my postdoc at the National Institute of Standards and Technology. And then I was a professor for a year at Bucknell before joining the FDA about 6 years ago.

And at the FDA, I've been doing a mix of research and regulatory work on computed tomography and specifically on the assessment of image quality in radiological medical devices. So that's a bit about me. And I'll be talking to you today about multi-detector computed tomography. And I am presently in the Office of In Vitro Diagnostics and Radiological Health, which is part of the Center for Devices and Radiological Health at the FDA.

So computed tomography is a medical imaging technique, and it uses x-rays to produce cross-sectional images, which are like slices of the human body. CT scans are used all across medicine for a variety of purposes and really used in every clinical application imaginable, from the head all the way down to the extremities. So CT is a very widely kind of a modality with just a number of applications.

Well, here's a picture of a CT scanner, and here's kind of the basic mechanism of operation. You have an x-ray source here, and that emits x-rays that pass through the patient and are picked up on the other side by detectors. And the source emits x-rays, the detectors measure x-rays, and all the while the patient is translating.

So that's how CT works. And the data coming out of the detectors, which does not look like an image that a radiologist could read, actually needs to be reconstructed into images that look like this. And the process, that process is called reconstruction. It's a mathematical operation that's done by software. So those are the big parts of CT scanning, the source, the detector, and the reconstruction.

And CT, in addition to being a very widely used modality, is also a rapidly developing

one. There have been a number of advances in CT technology since '85, although the basic principle of computed tomography has always remained the same. There'll be x-ray source and the detector and the reconstruction. The actual mechanism of implementing that has undergone a lot of changes.

So innovations include multi-slice detectors; automatic tube current modulation, which is a way of reducing the dose necessary to generate a diagnostic quality image; a helical scanning; a cone beam CT, which Dr. David Spelic will talk to you about later, which is a different type of scanning geometry; more recently, we have seen spectral CT, which uses different x-ray energies to give you images that contain more information about the specific tissue that is in the image; and finally, iterative reconstruction. So I mentioned on the last slide that the raw data coming out of the detectors needed to be mathematically reconstructed into a viewable image. Well, one of the new ways of doing this is called iterative reconstruction.

So yeah, we've seen a lot of changes. In fact, we've seen changes since the '80s to all the different components of the CT, of the source, the detectors, and the reconstruction algorithm, although the basic principle, as I said, has remained the same.

So along with the changes to CT technology, we've also seen a difference in how it's used. The use of CT has exploded, with 3 million scans performed in the United States in 1980, and 62 million performed in 2006. By the way, 4 to 7 million of those scans were performed on pediatric patients.

So I started on my timeline before in the '80s, and that wasn't random actually. You know, the '80s were an interesting time, I guess, and '85 was notable as Ronald Reagan and Mikhail Gorbachev held a summit, I entered kindergarten, and FDA's performance standards were published.

Well, life has since changed, and yet the performance standards have not. So the

increased use of CT and new technology -- as said, you know, technology has changed a lot, and CT is used differently and used a lot more, and yet, actually -- so all of this has created safety concerns that in '85 nobody could have predicted.

And so what are some of the safety concerns coming from the new technology as well as more widespread use of CT? Well, the increased use of CT means an increased radiation dose of -- oh, sorry. Okay. Yeah.

The increased use of CT means an increased radiation dose to the United States population. CT, in fact, contributes almost half of the U.S. collective dose received from medical radiation. So that's a, you know, big fraction of the collective dose.

So why is this a safety concern? Well, the radiation in CT uses ionizing radiation, which may slightly increase an individual's lifetime risk of getting cancer. This risk is more pronounced for pediatric patients, first of all, because for the same unit radiation dose, a pediatric patient's cancer risk is actually higher. And also, from the time that they're scanned, the pediatric has longer left to live. So there's more potential because their lifetime is longer. There's more potential for any long-term effects that might arise.

Secondly, in addition to the radiation dose, there are times when harmful radiation overexposure can occur when operators don't have access to the proper safety features as well as information about dose. And that has happened in the past. There were a series of incidents in 2009 when there were accidental radiation overexposures.

So this is FDA's proposal. FDA's goal is to ensure that appropriate safety features as well as user safety information are available for all CT devices. And as such, we propose updated device performance standards as well as adoption of international consensus standards. Our proposals are based on public comments that we received at a 2010 public meeting, as well as recommendations from national and international organizations.

Here I'll give you some examples of safety features that are not contained in FDA

performance standards. One is automatic exposure control. A second one is radiation dose structured reporting, access controls, dose check, improved dose-related user information, and size-specific dose estimates. So these are a series of safety features that have to do with both, you know, alerting the operator if, you know, radiation dose exceeds a certain preset amount and providing information to users about -- yeah, improving information to users about radiation dose. And yeah, so these are a number of features that are not included in the FDA performance standards but are included in IEC and NEMA standards.

And the goal of FDA's proposal is, first, to reduce unnecessary radiation exposure to patients of all ages. The alliance Image Gently, which is an alliance of various healthcare organizations focused on pediatric imaging, recommends that pediatric CT be performed only when medically necessary and then using only the exposure levels necessary to provide diagnostic quality images. Now, actually implementing this recommendation requires, well, first of all, that you know what the dose is, so it requires accurate size-scaled dose estimates that apply to pediatric patients, who tend to be smaller than adults, detailed dose reporting, and also safety features.

The second goal of FDA is to help avoid CT misuse and unintentional radiation overexposure.

And with that, the questions that we have for the TEPRSSC are how should FDA approach safety features and requirements which are contained in the voluntary consensus standards but not included in an FDA performance standard?

Secondly, what about features that are not yet in FDA or voluntary standards?

And the third question we have for TEPRSSC is other than the size-specific dose estimates, which we mentioned, does TEPRSSC have specific recommendations to assess pediatric safety concerns for multi-detector CT systems?

DR. LOTZ: Thank you. Questions from the Panel to clarify at this point?

Yes, Dr. Faraone.

DR. FARAONE: Good morning. Antonio Faraone.

On slice -- slide what, 9, yeah, the second bullet, second bullet, size-scaled dose, so I'm thinking about children, right? So you're quote/unquote "slicing" across the body, so you know the total travel. So height, you can take that into account. So when you talk about size-scaled, are you talking about the size of the cross-section of the body?

DR. VAISHNAV: Well, so size just means patient size in this context, yeah.

DR. FARAONE: That's right. But you know how much the slice travels, so height-wise, you know how much it has traveled, so you know the height of the patient.

DR. VAISHNAV: Right.

DR. FARAONE: So if it's a child, you know, maybe it could be, you know, 1.2 meters, okay.

DR. VAISHNAV: Yeah, right.

DR. FARAONE: So in terms of size-scaled, do you mean to account for the cross-section area of each slice?

DR. VAISHNAV: Oh, I see. So how is the SSDE actually calculated? Roughly?

DR. FARAONE: I guess. I mean, because for me, height is easy to estimate. You can -- you measure it, right. In terms of, you know, cross-section size, so the total area, which allows you then to add the volume, then that would be, you know, something that you would have to estimate.

DR. VAISHNAV: So I think we actually have one of the, you know, experts on this today here is Dr. McCollough. Do you want to talk a little bit about SSDEs and --

DR. LOTZ: Dr. Miller.

DR. MILLER: Donald Miller.

Just to clarify, the answer to your question is yes. It's the cross-sectional area or

cross-sectional diameter, in one way or another.

DR. FARAONE: Okay. Thank you.

DR. LOTZ: Any other questions from the Panel?

Dr. Stein.

DR. STEIN: You had a slide that talked about the consensus versus the FDA performance standards. My question is -- and the question is how to manage the two together. Is there any instance where they are in conflict, you know, where one would have criteria that might be problematic to the FDA's performance standards? And if not, is it just that they're more stringent, you know, more safety provisions and criteria? I'm trying to understand what the concerns would be.

DR. VAISHNAV: They are -- well, okay. Let me answer that backwards. They are certainly broader. The FDA standard is typically confined to radiation dose safety. The IEC and NEMA standards are broader and cover a greater variety of safety features.

Off the top of my head, I'm not thinking of anyplace that I know of where they're actually in conflict with each other, although it's an interesting question that, you know, if that were to happen, then what would we do?

DR. STEIN: Yeah.

DR. VAISHNAV: FDA does not always necessarily recognize all parts of every standard. So they'll recognize specific parts of the standard. So yeah, that's how -- I guess that's how we deal with situations where maybe the thinking of the IEC or NEMA might not be something that we implement. Yeah. So that's one solution we have to that.

DR. STEIN: Okay. Thank you.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

On your slide number 5, you mention that ionizing radiation exposure regarding a

safety concern may be slightly increased, slightly increase a person's lifetime risk of cancer. I think that only partly gets to the point, since medical radiation itself represents more than 50% of the total radiation dose a person receives from ionizing radiation in a year. A CT exposure can represent a significant increase in the radiation portion of the cancer risk. So I think that just needs to be, you know, clarified, that yes, the increase may be slight.

And the second thing is that although the increase may be slight, it's actually dose-dependent because some individuals receive multiple CTs in a year.

DR. VAISHNAV: Right. Right.

MR. KEITH: Those going through cancer therapy, you know, those having operations before and after, and the radiation doses are significantly higher than they were from film screen radiography.

DR. LOTZ: Dr. Linet.

DR. LINET: So data from studies that have been carried out, not so much in this country but the UK, have suggested that overall, the doses from CT have been dramatically dropping over time. However, there are studies suggesting that -- and these are studies mostly in adults, there's a tremendous amount of variability in doses.

So my question is -- I mean, I think this is a much bigger problem than the FDA, but from the FDA perspective, to what extent is that variability a problem with the equipment itself versus the operators? And sort of this gets to the hard hat, if you're going to move from potentially voluntary standards to mandated standards, to what extent would that make any difference? I'm looking at Dr. Miller as well, so --

DR. MILLER: And Dr. Miller is going to answer it.

The FDA regulates manufacturers and devices and products. With specific exceptions, and CT is not one of them, we do not regulate the practice of medicine. So we do not tell operators and physicians how to use the equipment. Our responsibility in this

regard is to make sure that the equipment has the necessary features to enable the operators to understand what the dose is and to control or manipulate the dose to make it as low as reasonably achievable while still maintaining image quality adequate to the clinical purpose.

So while we are involved in education of operators and physicians and so on, we don't regulate what they do. That's a function of the states, and you might address your question to Dr. Irwin in that regard.

DR. LOTZ: Yeah. Dr. McCollough?

DR. McCOLLOUGH: Just a follow-up actually to the question about variability: The half-value layer, which is the amount of tissue that's needed to cut radiation dose in half, in soft tissue, is about 5 cm, 5-6 cm. So every time a patient gets -- not the same patient, but between patients, if one is 5 or 6 cm wider than another, the dose theoretically needs to double to get the same level of image quality. So many of the reports about this huge variability is because they're throwing together, into one pot, doses from patients of all different sizes.

DR. MILLER: Donald Miller again.

I would also point out that, for example, for a CT scan of the abdomen, the dose will, in large part, in any specific individual, depend on why you're doing the examination. You need far less dose to detect, for example, kidney stones than you do to detect cancer or to characterize cancer. So the reason for the scan also affects the dose that you want to use.

DR. LOTZ: Dr. Stein.

DR. STEIN: Yes. You spoke about quality control and that the changes since 1985, much has been -- become digital. And so my question is during the actual procedures, is there any new provisions put in place to do setups, so that it's specific to the person, you know, that there can be something to set for their mass, their ions, and etc.?

DR. VAISHNAV: So I guess, to reword the question, are the CT protocols, are they tailored to the specific person?

DR. STEIN: Yes. Thank you.

DR. VAISHNAV: Okay, yeah.

DR. STEIN: Real time.

DR. VAISHNAV: Real time? Oh, interesting. Let me pass that to Dr. Miller actually, who actually has, you know -- does clinical work.

DR. MILLER: Well, not anymore, but yes is the short answer. And also, you can use something called tube current modulation, which Dr. Vaishnav mentioned, to in real time adjust the radiation dose output from the tube, as the scan is occurring, so that, for example, if you're going through the chest and you go through the shoulders, the dose increases as compared to when you're just primarily looking through the lungs, because the shoulders, the bone, and the soft tissue attenuate radiation more than the lung does because it's mostly air.

DR. STEIN: And just on that, does that include all of the industry products, or are there selective, you know -- just certain high-end that has that capability, that you have to then tailor the standard for the broad range of equipment?

DR. MILLER: I don't do most of the premarket evaluations of CT scanners, so I'm not in a good position to tell you --

DR. VAISHNAV: Okay. I would just say that tube current modulations is pretty standard now --

DR. STEIN: Standard?

DR. VAISHNAV: -- across manufacturers, yeah. And --

DR. MILLER: There is no FDA performance standard requirement for that. That's one of the things we're talking about today.

DR. STEIN: Right.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

The automatic exposure control concept was introduced in the early 2000, so by now it is well entrenched in the technology. And further, a NEMA standard that was adopted by a congressional act and involved in Medicare reimbursement requires that option or they're penalized on their reimbursement. So it really is a ubiquitous feature now.

DR. LOTZ: Very good. Thank you, Dr. Vaishnav.

I'd like to move to the next presentation at this point.

Dr. Spelic.

DR. SPELIC: All right, thank you. I'm David Spelic. I'm a physicist with the Food and Drug Administration, Center for Devices and Radiological Health. I will just give you a quick background. I'm a pure physicist by training. Back then it was called high-energy particle physics. I don't know what it's called now. It's been a while. But I've been with FDA since 1994.

And so this morning, I'm going to be talking about an aspect of computed tomography called cone-beam CT. As Dr. Vaishnav gave you an overview of the general process of computed tomography, I'm going to speak about a particular aspect of computed tomography called cone-beam CT. And this has been more of a general progression rather than a step in technology, where the earlier computed tomography equipment used a narrow fan-beam shaped x-ray beam geometry, the systems have progressed toward multi-slice, wider fan-beam x-ray geometries, to where we are now with x-ray beams that are sufficiently broad that they can scan the entire anatomical area of interest in a single scan, such as the figure shows here.

So what is cone-beam computed tomography, cone-beam CT? From the

International Commission on Radiological Protection, I pulled a nice definition from Publication 129, which I thought kind of well described cone-beam CT as the use of a two-dimensional digital flat panel detector to yield a three-dimensional volumetric image in one rotation.

There are benefits to this type of cone-beam CT equipment compared to conventional CT. For instance, as I just indicated earlier, the scan of the imaged anatomy can take place in a single rotation. These systems now provide fairly good spatial resolution detail. They come with sophisticated software-level features using, for instance, reconstruction improvements, including iterative reconstruction. And they typically can provide patients with lower radiation doses compared with conventional CT, when scanning similar types of anatomical regions of interest.

There are a good number of clinical applications for cone-beam CT. As a feature, which is implemented on fluoroscopic equipment, for instance, C-arm equipment, they can be used in the area of radiation therapy or for interventional procedures. As a dedicated device, these things, these devices are used for dental and maxillofacial imaging, ear, nose and throat applications, as well as imaging of extremities.

I mentioned earlier that these systems can provide patient doses that are fairly lower compared to conventional CT. Here is just one example of the scanning of a head, where cone-beam CT, as you can see by the tabulations here, provide the doses that are on the order of a factor of 10 lower compared to conventional CT.

There are a number of organizations, in the U.S. and internationally, that are looking at cone-beam computed tomography. I list just a small number of them here in the U.S., including the American Dental Association, the American Association of Physicists in Medicine, which has task-group level activities on cone-beam CT. The National Council on Radiation Protection and Measurements has a upcoming report that will, in part, feature a

discussion of cone-beam CT. And there are a number of international organizations as well, looking at this aspect of CT imaging.

So there are some standards that are associated with these equipment. They are -- they fall under the purview of the federal performance standard, 21 C.F.R. 1020.33. There are also a number of international standards that can address cone-beam CT, for instance, 60601-2-44, which is a general safety and performance standard for CT equipment, as well as the last one there, IEC 61223-3-5, which provides acceptance testing procedures for cone-beam CT equipment.

So one area of concern that FDA has with regard to cone-beam CT equipment is the characterization of patient dose. If you look at the federal performance standard now, it really was defined for conventional CT equipment that predominantly has a narrow beam geometry on the order of a few centimeters or less, as well as the ability to characterize with these CT equipment actual tomographic slice thickness. So this definition, as it is now in the standard, is very difficult to apply to cone-beam CT equipment.

There are alternative methods that can be used to specify patient dose indicators, such as kerma-area product, or sometimes referred to as dose-area product, and a number of systems already display these indicators on their equipment. And there's effective dose, which is a computationally involved parameter to calculate. The nice thing about effective dose is that you can compare it across different modalities, but it is difficult to compute, and it really wasn't intended for this purpose of providing patient-specific indicators.

So FDA is currently looking at how to work specifications for cone-beam CT equipment into its standard. The standard currently defines CTDI and requires the reporting of specific values to users in the labeling. The standard currently requires imaging performance information to be provided to users as well. And it also requires a quality assurance program, including the provision of a phantom, that can be used to conduct

those procedures. So, in short, there are aspects of the performance standard for CT that are difficult to apply to cone-beam CT equipment.

One area that is of interest, and I believe Dr. Vaishnav may have mentioned this earlier, is the use of radiation dose structured reports. These are DICOM level objects or actors that provide a good amount of detail on the aspects of the particular exam that is conducted on the equipment. DICOM has a Working Group Number 28, I believe, working on aspects of that for cone-beam CT equipment. And I noted that the ICRP report that I cited earlier in the definition of cone-beam CT includes a recommendation. While it specifies it for fluoroscopy and cone-beam CT, it was nice to see that it indicated that the inclusion of a radiation dose structured report should be implemented on equipment like this.

So, in summary, the federal performance standard for CT lacks specific content that is addressed to cone-beam CT devices. The dose metric for cone-beam CT is not fully standardized across the industry, and the professional organizations are currently refining this, but there is good progress on that, I believe. And the scope of cone-beam CT continues to grow, for instance, the use of these devices for pediatric imaging applications.

So we have several questions that we'd like the Committee to consider for cone-beam CT equipment:

First of all, in order for us to regulate the product, we have to have a good definition of it. So we would like the TEPRSSC Committee to consider a recommendation for how to define cone-beam CT equipment so that FDA can specify standards for these devices.

And we would like to know how the TEPRSSC Committee feels about the development of standards that include the specification of image quality and dose metrics that are specific to these devices. And if so, should FDA require the inclusion of these parameters, to some level or extent, in the device labeling, such as currently is done for

conventional CT equipment?

Are there any specific pediatric safety concerns that FDA could address?

And how does the Committee recommend that FDA attempt to ensure that radiation dose structured reports and other safety features are available on all types of CT equipment?

Thank you.

DR. LOTZ: Thank you, Dr. Spelic. We're available for clarifying questions at this point. Dr. Irwin?

DR. IRWIN: Yes. Bill Irwin.

I appreciate the presentation on Slide 6 about patient dose. And given the changing geometry of cone-beam CT, I'm particularly interested in the interventionalist's dose, when you change that geometry. Is there a greater probability of higher doses for interventionalists or others using CBCT close to the patient as compared to conventional CT?

DR. SPELIC: I'm not a practicing radiologist, so I can't say to what extent, for instance, that the clinician is in the area during the use of this type of modality on fluoroscopic equipment. Certainly, for conventional CT, you know, staff are typically, you know, remote from the device. So there's good opportunity probably for people to be near the patient during that type of imaging acquisition.

DR. IRWIN: Right.

DR. LOTZ: Dr. Miller.

DR. MILLER: Let me just amplify a little bit. I am an interventionalist. With a conventional CT scanner, there are two ways to do an interventional procedure. You can use what's called CT fluoroscopy, which is not fluoroscopy, but involves real-time CT imaging while you're manipulating the needle. And the radiation dose to the operator can

be substantial, particularly to the hands. Or you can manipulate the needle, step away, do an image, come back, in which case the dose to the interventionalist is essentially zero.

With a cone-beam CT mode of operation of a fluoroscope, because of the way the gantry swings 360 degrees or 180 degrees around the patient, it's impractical and sometimes dangerous to stand right there. So usually you move far out of the way, and the dose to the interventionalist is relatively low or zero.

DR. IRWIN: Thank you.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: On Slide 6, what are the units of dose?

Cynthia McCollough.

What are the units of dose on Slide 6?

DR. SPELIC: Oh, they're in millisieverts there.

DR. McCOLLOUGH: Okay. One comment I want to make, having compared these modalities, is the differential in dose there is in part because this is dental exam, and the dentists are looking for teeth and bone, jaw structures. Within radiology, there is more of a responsibility to pick up soft tissue tumors that might be in the field of view. And we can operate a conventional CT at that low dose if we wanted just that level of image quality. We don't because there are other findings that can be seen. So the technology doesn't have to run at that dose differential. It's more of a clinical practice choice that they do.

DR. SPELIC: Yes, yes. Thank you. And as was discussed earlier regarding, for instance, tube current modulation, that feature can further reduce a patient dose where it is able to. Yes.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

On your Slide 9, you address effective dose, and you say it's computationally

involved. And I would agree with that. However, so is the imaging. I mean, it's very complicated, the physics of the interaction of radiation with matter as it passes through, and the imaging and recreating the -- producing the image from the data. And so if the equipment and software is capable of producing an image, isn't it also capable of identifying the dosimetry to, let's say, any particular organ? Shouldn't that be able to be created very easily from the data that's available?

DR. SPELIC: I think these devices are computationally powerful, yes, and can provide a wealth of information probably. But I think you also need to consider what would be done with that value to improve, you know, the quality of the exams. Effective dose is, as I indicated earlier, yes, computationally intensive, but there are other indicators of dose as well that can provide a good indication of patient doses, without the computational intensity of, say, effective dose.

MR. KEITH: Well, I think it's more of tracking the dose over time, because as people get more and more studies performed, their cumulative radiation dose increases, and it's a way of tracking how much dose a patient has received and gives the clinician, the dentist an ability to say that perhaps maybe they can avoid a particular procedure, or maybe they need to add a procedure based on the historical dosimetry of the patient, the patient's history.

DR. SPELIC: I think effective dose is also -- was intended -- correct me if I'm wrong, for instance, Dr. Linet, it was intended for populations, a standard population. And so I don't think it's really intended to be applied to individuals.

DR. LOTZ: Dr. Miller.

DR. MILLER: Effective dose was developed as a concept by ICRP for radiation protection purposes, for the public and for workers. It uses a phantom that is part -- well not -- a computational phantom that's part female and part male and incorporates in the

calculation estimates of detriment. And because it contains no uncertainty and doesn't represent any actual human being, it is specifically not intended for use as a dose metric for individuals. So that's why it's not appropriate in this situation.

DR. LOTZ: Dr. Faraone, you had a question?

DR. FARAONE: Thank you, yes. Antonio Faraone.

Two clarifying questions: On page 12, you highlight some issues, for example, the federal performance standards lacks specific coverage, and then dose metric for CBCT ongoing effort. So given this uncertainty, is this an experimental procedure? Or is this an approved procedure? I mean, is this classified as an experimental procedure right now?

DR. SPELIC: Are you referring to the actual practice of cone-beam CT?

DR. FARAONE: That's right.

DR. SPELIC: No. It's not a experimental procedure. There are devices out there now that are conducting cone-beam CT. However, the federal performance standard lacks items in the standard that specifically apply to that type of imaging computed tomography modality.

DR. FARAONE: Okay. Thanks.

DR. SPELIC: So there are aspects of the standard that do apply, but there are other aspects of the standard that are just difficult to apply to cone-beam CT.

DR. FARAONE: Thank you. Then your very last question, it's not clear to me what is the ask. So when you say how does the Committee recommend that FDA ensure that radiation dose structured reporting, so do you mean -- what kind of recommendation are you looking for, like the format? Or should it be published? Should it be made available? Or you looking for a recommendation about the proper administrative instrument to be used by FDA to enforce that this reporting is done and produced?

DR. SPELIC: Well --

DR. FARAONE: Or something else?

DR. SPELIC: CT equipment is capable of recording the parameters that were used to conduct the cone-beam CT exam, okay, a variety of parameters, the kVp, the exposure times, the current, the product of mAs, among other aspects that can be helpful to reconstruct a patient dosimetry. And so what we'd like to know is if we -- how the Committee feels about incorporating that type of information into these specific pieces of equipment so that users have available that information as a DICOM report, that they can use to go back and understand the dosimetry of specific cases, or in a broader sense, the dosimetry regarding the practice of cone-beam CT.

DR. FARAONE: Thank you.

DR. LOTZ: I want to thank both Dr. Vaishnav and Dr. Spelic for concise, timely presentations and sticking to our schedule.

DR. SPELIC: Thank you.

DR. LOTZ: We will now move to a presentation by Dr. Fang.

DR. FANG: Good morning. My name is Yuan Fang, and I'm from the Diagnostic X-Ray Systems Branch at Division of Radiological Health. And a little bit about my background: My background is in electrical engineering, where I received my Ph.D. And I'm also a licensed professional engineer, with R&D experience with radiographic equipment.

So today I'll talk a little bit about radiography and fluoroscopy x-ray systems.

So we'll start with an overview of the diagnostic x-ray products that's covered in this presentation. That includes radiography, which includes dental applications. Radiography can be used for generating 2-D projection images of the anatomy. And these can be, for example, extremities like elbow and also dental.

In addition, we have fluoroscopy, which is real-time imaging of the body, which includes the motion, and fluoroscopy also includes interventional fluoroscopy procedures.

So one of the things to note from these are, according to the NCRP 2006 report, over 300 million radiography and fluoroscopy procedures are performed each year. So we have a huge number of procedures that's performed.

In addition, in this presentation, we'll also talk about handheld radiographic equipment. So in this picture here, you see the operator holding the handheld radiographic unit very close to him. And the proximity also poses challenges to radiation exposure to the operator.

In this presentation, we'll also talk about third-party components.

So one of the big concerns for the FDA is radiation safety for radiographic equipment. You have heard from my colleagues Dr. Vaishnav and Dr. Spelic about the dose reduction initiative that's being done for CT equipment. And this is similar for the radiography and fluoroscopy equipment as well.

So, in addition, there is this tissue reaction, which can cause acute radiation injuries from interventional procedures. So on the picture, you see the acute radiation injury that's caused. And then for stochastic processes, you have dose delivered to the patient and, in addition, to the operator as well. And this can cause cancer.

So there are several performance standards that's applicable to diagnostic x-ray systems and also radiography and fluoroscopy equipment. These are covered under 1020.30, .31, and .32, and these standards were amended in 2005 to include mode of operation, description, and user instructions; display of fluoroscopy time; air kerma (dose) meters; and also schedule of maintenance.

So what are FDA's current concerns? We're concerned with inadequate quality control information provided to the end user, and also availability of protocols and descriptions for imaging different size patients. We're concerned with insufficient shielding for handheld x-ray systems, and inadequate integration information for third-party certified

components. And, in addition, we have concerns related to reporting of radiation dose. So for each of these points, we'll try to cover in some of the subsequent slides.

So the IEC has a number of consensus standards available, and four of these are related to radiography and fluoroscopy equipment. You have the 60601-2-54, which is related to radiography and fluoroscopy; and also the 2-43, which is related to the interventional fluoroscopy; and the 63 and 65, which are related to dental equipment.

So to assist the Committee in reviewing this list of features, we differentiated between features that are already in existing or proposed IEC standards, and also features that are currently not but is currently under consideration by IEC.

So, first, the FDA would like to require certain features, which includes manufacturer-defined quality control procedures in the user manual, requirement of physics mode in order for the end user to be able to perform these quality control tests, and easily removable anti-scatter grids in order to image smaller-size patients, and size-specific presets. This will also include radiation dose structured report, which you have heard from the previous presentations.

One thing to note here is that for CT and radiography and fluoro, radiation dose structured reports are already included in the IEC standards; however, this is not included for the cone-beam CT.

In addition, the FDA would like to require additional features, including standardized quality control tests and user access control to parameters that can affect dose and image quality, and this also includes a description of the actual parameters so that the end user knows what's being modified. And this also includes skin dose mapping for interventional fluoroscopy equipment.

For handheld systems, you learned about our concerns related to operator safety and the dose received by the operator. So one of the concerns is that there isn't a specific

performance standard that exists for handheld systems. So, therefore, I would like to consider a performance standard for handheld x-ray radiography units, which can ensure that handheld devices include safety features, such as shielding of the unit housing itself in order to prevent leakage radiation and identifying necessary safety precautions and also provide additional shielding or a means to reduce the distance between the operator and the unit. So one of the issues also is with the backscatter of radiation, which could also cause radiation dose to the operator. So this is to address that.

This is related to addressing integration of information with third-party certified components. So sometimes third parties can produce add-ons or upgrades to existing systems, existing systems that are made by the original manufacturer. So when you try to integrate the third-party component into a pre-existing system that were originally designed by a different manufacturer, this poses issues, especially when the third-party component can change and affect the quantity, quality, and direction of the radiation, then that becomes a really big concern.

Therefore, we would like to ask for clarifications as to how connections are made from the third-party component to the existing system, and also provide a list of compatible systems for the third-party unit to the list of compatible systems in the labeling for the end user, so that end users, including assemblers and people that have to maintain these type of equipment, knows what type of equipment is compatible for the third-party certified unit component.

So I have a list of questions for the Committee:

What is your opinion on the value of requiring manufacturers to include a quality control phantom with radiographic and fluoroscopy x-ray equipment free of charge, which is currently existing for CT?

What is the Committee's opinion on including the proposed features above for

radiography and fluoroscopy system in a performance standard?

And are there additional safety improvements that should be pursued for radiography and fluoroscopy?

What information is necessary to ensure adequate integration of third-party certified components? And should third-party component integration issues be addressed in a performance standard?

And what is the Committee's opinion on the importance of regulating handheld x-ray systems through a specific performance standard? And does the Committee have any additional concerns with the use of handheld devices?

And should FDA include requirements for radiation dose structured report for all imaging equipment that generates ionizing radiation? This includes radiography, fluoroscopy, CT, and dental cone-beam CT in the performance standard.

Thank you very much for your attention.

DR. LOTZ: Thank you, Dr. Fang. Quite a few questions there for us to consider later in the discussion period. For now we'll have questions from the Panel for clarification.

Dr. Stein.

DR. STEIN: You brought up backscatter. Can you speak more specifically about it? Is there a time element to that? Is there -- if the entire room is shielded, is it, you know, dampened out? If there's another person in the room, what is the features of backscatter?

DR. FANG: So when I mention backscatter for the handheld x-ray equipment, it's mainly concern was the x-rays coming out of the x-ray unit and backscatter into the operator. So that's mainly due to the proximity of the operator because they are so close to the x-ray equipment.

DR. STEIN: But you also brought up that you have shielding of the handheld device.

DR. FANG: Yes.

DR. STEIN: If that's fully shielded and the room is shielded, do you have backscatter bouncing around or not?

DR. FANG: So we can use this picture to illustrate that point. So you have the patient here, the operator, which is holding the handheld equipment. So we talked about the shielding for the housing, which protects the operator. But in this case we have, for example, this additional shield, because once the x-rays are produced, it can potentially backscatter into -- yeah. So that's why we have this additional shielding which can try to block out the backscatter. So that's why it's related to the close proximity of the operator to the actual equipment and how the x-rays are -- although the x-rays are shooting towards the patient, they may backscatter into the operator.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Yes, Bill Irwin.

I wanted to ask, from page -- Slide 9, could you just explain what the physics mode relates to relative to your requirement?

DR. FANG: Yes. So, also I wanted to thank Dr. Irwin about the gas station example that were brought up yesterday. So the example related to when the gas station were built versus say 10 years later, how well does that perform? And I think QC procedures, what we're asking for is exactly related to that, performing tests routinely to make sure that the image quality performance is maintained so that we're able to also use the same, for example, radiation dose that can be achieved.

So, particularly here, we're talking about specific features that allows the end user to access information from the radiographic equipment, that allows them to use the data, access the data that is needed for performing the QC tests.

DR. MILLER: Dr. Miller.

DR. LOTZ: Dr. Miller.

DR. MILLER: Donald Miller.

Just to clarify, fluoroscopes in particular, and some radiographic systems today, are so automated that you cannot manually set a specific tube voltage or tube current, which makes it very difficult for the medical physicist to actually test the system under certain circumstances. The physics mode is a special mode that is password protected so that it's not available to the ordinary user and gives the physicist freedom to set these techniques manually in order to do the testing. And it's password protected partially because it's possible to overload the tube if you don't do it properly.

DR. IRWIN: Excuse me. Thank you. Bill Irwin again.

I just had a second question, and that is, regarding the RDSRs, the radiation dose reports, what is the universality of usage of these reports? This is the -- I've heard these reports a couple of times referenced, and I was curious. Are these used commonly? Is this a new kind of report, this radiation dose structured report?

DR. FANG: So very good question. So radiation dose structured reports is developed by DICOM, which is a NEMA standard. So the DICOM committee develops the format for radiation dose structured reports. Currently, these reports exist for projection of radiography and angiography systems and another format for CT. So the reason for this new geometry, which is why currently -- DICOM is working, the Work Group 28 is working on developing a format for the cone-beam CT. So for radiography, fluoroscopy, and also CT, that already exists. And I believe IEC already cites this as a part of its standard.

DR. IRWIN: Thank you.

DR. LOTZ: Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

On page 13, I was just curious why you specified that the phantom should be free of charge.

DR. FANG: Okay. So currently the -- for CT, under the performance standards require that the firm, the manufacturer provides a QC phantom free of charge. And one of the reasons, it's also because, for example, on Slide 8, we talk about requiring the manufacturer to define the quality control procedures. Different manufacturers may have different quality control procedures and they may use different phantoms.

So depending on the type of phantom that's being used, the end user, which is, for example, a medical physicist, has to perform those tests based on that phantom. So if the compatible kind of QC phantom is provided with the equipment, then that could really make the QC procedures done easier.

DR. FARAONE: So is this a loaner, or is a permanent gift?

DR. FANG: It's provided as a part of the system. So it's --

DR. FARAONE: So it's permanently provided? Okay.

DR. LOTZ: Dr. Stein.

DR. STEIN: Is there any special provisions -- you have one of the questions of what else on safety, for thyroid shielding during procedures for any interventionist or -- so that's number one question. And the second is -- I'll remember it in a minute.

DR. FANG: Sure. So I'll like to, you know, direct to Dr. Miller, who's our interventional expert.

DR. MILLER: Donald Miller.

Are you talking about thyroid shielding for patients or for staff?

DR. STEIN: All of the above. And procedures that are regular business, you know, that everyone does it.

DR. MILLER: The answer is the same for both. We don't regulate patient or operator radiation protection. We regulate the equipment and the manufacturers. If thyroid shielding is to be a regulation, it would have to be from one of the states or all the states.

That's not in FDA purview. And we also do not regulate the radiation protection limits for anybody.

DR. STEIN: Right. And the question about the phantom, does NIST get involved in anything with it, and of certifying the actual phantom for the equipment and --

DR. MILLER: Donald Miller. No.

DR. STEIN: No?

DR. FANG: And something related to this phantom. We're also working with, for example, AAPM, which is the American Association of Physicists in Medicine, which are the end users that have to perform these QC tests. And we're coming up with, for example, a list of recommended tests for radiography and fluoroscopy equipment. And the actual phantoms are discussed in that report as well. We have a range of options.

DR. STEIN: Okay.

DR. LOTZ: Thank you, Dr. Fang.

Yes, Dr. McCollough.

DR. McCOLLOUGH: Most states, but not all, have radiation protection regulations and hence monitor the ongoing quality assurance of the equipment once it has been purchased and installed. And having a manufacturer provide a phantom, and likely software to analyze a phantom, puts in the hands of users a particular quality control program, but it may not necessarily be that of the state's. And it also may not be adequate from the point of view of the medical physicist. I'm glad to hear you're working with the AAPM because putting it in the hands of the manufacturers, with all due respect to my colleagues in industry, is a little bit like having the fox guard the henhouse.

So my question there is, is there a conflict between federal and state authorities if the federal performance standards requires a specific QC program and then the states require a different one? Is it within the purview of the FDA to take on what is currently a

state authority?

DR. MILLER: Donald Miller.

We try very hard to avoid conflicts between federal and state regulations, as I think Dr. Irwin will agree. The states may or may not have the ability to mandate provision of a specific phantom. We do. So in these kinds of situations, we try to work together to determine what is the best course of action.

DR. FANG: And just in addition, for CT, this is already currently required. So we're only asking for something that's similarly -- that's being implemented in the -- that's existing in the performance standard to be done for radiography and fluoroscopy equipment as well.

DR. McCOLLOUGH: Cynthia McCollough again.

And interestingly, the phantom in CT, the CTDI, CT dose index phantom, was developed by the FDA, who took a leadership role in that, and then the states followed.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Yeah. Just to follow up on Dr. Miller's comment and Dr. McCollough's question, the states work with the Food and Drug Administration through what's called the Conference of Radiation Control Program Directors to develop suggested state regulations. And these suggested state regulations are provided to the states as models that they can adopt. They can adopt them whole or in part. And because it is a collaborative effort between the states, representatives from the states, the Food and Drug Administration, and other agencies and professionals, typically the best of both worlds, the states and the FDA, get factored into those suggested state regulations.

And it does provide for fairly good uniformity across the nation relative to quality control assessment over the course of time. But it is a freedom to choose whether to adopt those suggested state regulations. So not every state will have done so.

DR. LOTZ: Thank you. I'm going to ask the Panel to hold additional questions until our discussion period. It's time for our morning break, and then the next segment of the meeting will be our morning Open Public period. So we will take a break at this point. My phone says it's 10:03. We will convene again at 10:15, and so a 12-minute break. Thank you.

(Off the record at 10:03 a.m.)

(On the record at 10:15 a.m.)

DR. LOTZ: Back to order, please. We will now proceed with the Open Public Hearing portion of the meeting. Public attendees are given an opportunity to address the Panel to present data, information, or views relevant to the meeting agenda. Commander Anderson will now read the Open Public Hearing disclosure process statement.

CDR ANDERSON: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

Thank you.

DR. LOTZ: For the record, we have received four requests to speak for today's first session. We ask that you speak clearly to allow the transcriptionist to provide an accurate transcription of the proceedings of the meeting, and we appreciate that each speaker remain cognizant of your appointed time and note the lights on the podium -- green, yellow, red -- indicating when your time is up.

It's been indicated to me that Mr. Miller of Palm Beach has asked to speak again, and he will be the first in this session.

Mr. Miller.

MR. MILLER: This is related to indoor tanning equipment. There were a couple of comments that I heard from the group here yesterday that I thought required some kind of a response.

One is a comment that's really -- that indoor tanning equipment's not really a very serious matter, certainly as compared to using lasers to knock airplanes out of the sky, because it principally is cosmetic. And it is true that some of the customers of indoor tanning salons come there for cosmetic purposes. But recent scientific papers that have done scientific polling show that 85% of the people that come to indoor tanning salons come there for purposes of getting a protective tan. And that is important because sunburns are -- you don't get melanoma unless you get a sunburn, and that's what the current science also shows. So sunburn prevention is critical in preventing melanoma.

The second comment that came out of -- one that's common, I've heard many times before, which is, well, melanoma's on the rise, and so is indoor tanning, so the two must be connected in some way. The incidence of melanoma was first measured in 1935 in the Connecticut Tumor Registry. And since that time, if you plot the incidence of melanoma on semi-log paper, you get essentially a straight line, which shows that it has been advancing at a cumulative, compounded rate of 4%, from 1935 to the present, taking the incidence from

roughly 1 per 100,000 to 23 per 100,000. The indoor tanning salon didn't appear on the scene until 1980, so whatever is causing this increase in melanoma is not the result of tanning salons.

The third point I'd like to make is that until very recently, all of the data on the relationship of skin cancer with tanning equipment was under the heading, quote, "indoor tanning." And that conflated data of home use of the tanning equipment with commercial tanning salon use of the tanning equipment. As we all know, the FDA has calculated how much UV radiation a person can get without burning. And that's on the equipment, and those rules are followed in the tanning salons but probably are not followed at home.

Very recently, studies now show, it is a current science, that home use is associated with a doubling of melanoma risk, whereas commercial tanning salon use of tanning equipment is not related to any increase in the risk of melanoma.

And then that concludes my comments.

DR. LOTZ: Thank you, Mr. Miller. It looks like we have a couple of questions from the Panel.

Mr. Keith.

MR. KEITH: Sam Keith.

You gave us a percentage of people who use tanning beds for protective tans. First is about how many sessions does it take to get protective tans, and out of those people, how many -- what percentage stop the tanning booth visits at that point, after they have protective tan and don't need it anymore?

And the second is what fraction of the individuals who use tanning booths do so expressly to avoid vitamin D deficiency?

MR. MILLER: We don't have -- we don't know how many people use tanning beds to

avoid vitamin D deficiency. We have no way of knowing that. We're not permitted to ask questions like that, and we don't.

With respect to people who come to get a protective tan, they gradually ramp up their exposure so as to avoid burning, but once they get fully tanned, they tend to want to keep that tan, maintain it year round. So they continue to come month after month, perhaps as little -- depending on the skin type, as few as maybe one visit a month or two visits a month is enough to maintain the tan. For almost all the tanning equipment, one session is approximately equal to 20 to 30 minutes of noonday sun on the Mediterranean in the summer.

MR. KEITH: So in other words, they do it to build up a protective tan, perhaps for the summer, before they go out into the sunshine and risk getting burned. But then after the summertime and after the potential for sunburn is greatly reduced, they keep on using the tanning bed just to maintain the cosmetic look?

MR. MILLER: Yeah. Well, it is a seasonal business. I'm talking about the commercial tanning salon business. It's a seasonal business, heavily in the spring, as people prepare for the summer. But it is now common for many people to take winter vacations and fly to Mexico or the border or to someplace where they sunbathe, and they're going to the beach. And so they will use our services to prepare for that as well. And we are -- the best measure we have of that is that we have monthly memberships that are cancelable any time. And so most of our customers maintain their memberships year round.

We have a program where they can cancel them and hold their place, and we have some special programs and discounts and whatever that are depending on how long you've been with us. But we have some programs that say, well, you can cancel and hold your position if you want to, but we don't see any of that kind of pattern. People tend to use the facilities fairly steadily and maintain their tan year round.

DR. LOTZ: Mr. Murphy, did you have a question?

MR. MURPHY: Yes. I had a similar question about protective tans. If 80% of people are going there for protective tans, it must be important to them. I just did a search online under the word "protective tan," and I basically found no results for that. I went to your website, and everything that it talks about sunbed tanning is getting the just-off-the-beach look, a light sun-kissed glow, find your perfect shade.

Even under "Tan Wisely," it does talk a little bit about the sun being important in melanin production, but then it's tan a shade smarter, the golden rules, know your skin type, apply skincare products. I see nothing about the healthcare benefits of tanning. So it seems incongruous to me, if 80% of people are going for healthcare benefits, that's not what you guys are selling, and I can't find it on the Internet.

MR. MILLER: It's widely believed within our industry that we are not permitted to advertise any health benefits, just nationwide. And with respect to Palm Beach Tan -- I gather you're reading from Palm Beach Tan's -- in Texas, it's illegal, there's a law in Texas that makes it illegal, it's a misdemeanor, for us to advertise any health benefits of any kind.

MR. MURPHY: If that is the case, then it would seem that maybe there would be other, you know, internet forums or discussions or something about protective tan, not necessarily to get around it but just because people are interested in this topic. And again, I can find nothing about it. I'm not disputing that there may be health benefits. Can you tell me a little bit about why --

MR. MILLER: Well, I can refer --

MR. MURPHY: -- they feel that it's not, you know, legitimate to advertise health benefits?

MR. MILLER: The industry is under a Federal Trade Commission consent decree that forbids it from advertising any health benefits.

MR. MURPHY: Just as a layperson, it would seem that maybe the FTC thought there was something wrong about doing that.

MR. MILLER: Well, yeah, there's a good reason for doing it because back, way back when this happened, there were some tanning salons advertising all kinds of health benefits and doing things that weren't right, saying hey, this cures cancer, it reduces your --

MR. MURPHY: But FTC didn't, FTC did not stop certain claims. Apparently they stopped all health claims? You can't make any health claims?

MR. MILLER: Well, they have an exception that says if you can scientifically prove what you say is true, you're permitted to advertise it. But after the horrendous event of being sued by the FTC, which, I said, not a pleasant experience, the industry decided to just completely back off of that.

MR. MURPHY: Okay. Well, I appreciate the clarification and the information that I can't find on the Internet about protective tans.

MR. MILLER: Well, in our filing with this Committee, we referenced a recent article, a scientific article that surveyed customers that had the 85% figure in it. That's in the filings that we made with the Committee.

DR. LOTZ: Thank you, Mr. Miller.

I'd like to move on to our next speakers. My indication is that they -- I'm not sure exactly how they're going to present, but that Sarah McKenney and Alan Cohen are here on behalf of the American Association of Physicists in Medicine. I guess Dr. McKenney will be first.

Go ahead. And please do pay attention to our time.

DR. McKENNEY: Thank you for the opportunity to appear before you today. Alan Cohen and I will be speaking on behalf of the American Association of Physicists in Medicine in regards to the adoption of IEC Standards.

Just for a brief introduction, I'm a medical physicist and radiation safety officer here in D.C. at Children's National Hospital, but I'm representing the AAPM today.

MR. COHEN: And I'm Alan Cohen. I have got board certification from the ABR in therapeutic medical physics, and I'll be representing the therapy side. I have background in both industry and clinic in radiation therapy, as well as currently serving as chair of the IEC 62C Committee.

DR. McKENNEY: All right, so just some brief background. Medical physics is the application of physics principles in medicine for both diagnosis and treatment. The American Association of Physicists in Medicine has a variety of goals, one of which includes the promotion of standards of the practice of medical physics, and that's why we're here today.

So the primary objective of the IEC standards is to standardize testing and to minimize variability among different standards from different organizations and nations. The IEC develops standards for all electrical and electronic-related technologies. Adoption is voluntary, although they're often referenced in national laws or regulations around the world. Experts from all over the world develop these standards.

These standards are a technical description of the characteristics to be fulfilled by the object in question. And an object is a product, which could include services, processes, bodies, people, or systems, for example, management systems.

IEC standards are widely adopted at regional or national levels and are applied by manufacturers, trade organizations, purchasers, consumers, and testing laboratories, and governments, and other interested parties. The people who participate in these standard developments are companies, industries, governments, and they meet to discuss and develop these standards that they require for their different objects.

All IEC standards are fully consensus-based and represent the needs of key

stakeholders of every nation participating in the IEC work. Every member country, no matter how large or small, has one vote and a say in what goes on in the IEC standards.

So once these standards are developed, we then have to assess its conformity. Conformity assessment is any activity that determines whether or not an object meets the requirements contained in a specification. A specification is a technical description of the characteristics which are required to be fulfilled by an object.

Officially, the CA is a demonstration that specified requirements related to a product, process, system, person, or body are fulfilled. But note that the conformity assessment does not limit or classify the activity in any way. So a consumer who buys an appliance and, at home, checks that it's conforming to the technical description is, in fact, carrying out a conformity assessment.

The AAPM is not necessarily opposed to the FDA proposal to incorporate, reference IEC standards; however, we have several concerns. First, the AAPM believes that additional clarification must be set forth to justify this path forward. Of major concern to not only the AAPM members but to many others in this room is the lack of public availability, without significant cost, of the IEC standards. It is difficult as a member of the public or an end user of a product to be able to effectively review and comment on proposed guidance and ultimately regulations if the documents referenced are not available for public review and comment. This is especially true for the AAPM task groups creating recommendations. Each member of a task group would have to purchase these standards.

While the AAPM does have members present during the development of IEC standards, the IEC process is heavily dominated by manufacturers and their representatives. We are not saying that this is wrong, simply stating a fact. In addition to the purchasing of IEC standards being costly, it is not inexpensive to participate in the development of the process of itself. However, the AAPM believes this is important to our members and the

public, to have medical physicists involved with the development and review process.

Although there is an opportunity for the public to comment on IEC standards, it is not without significant cost. Clarification is needed on how the public comments received during a public comment on the standards would be addressed, since changes to the standards would not be allowed during that process.

From a clinical perspective, it is challenging, if not impossible, to remain knowledgeable and up to date with IEC standards. For example, if a manufacturer states they conform to an IEC standard, which section of the standards is that? As IEC standards are developed, many are interrelated and rely on sections of other IEC standards. There is no discussion on transition time for this to be effective or how manufacturers would continue to comply with revised IEC standards.

Would this require declaration of conformity with each and every standard and its subsequent revision? If not, how can one enforce or comply with potential standard changes to existing equipment, or even to develop a regulatory framework that would allow for prospective agreement of change without knowledge of that change and its potential impact?

It is also unclear how manufacturers would address situations where the FDA recognizes multiple versions or editions of the same standard. Currently, the FDA recognizes Edition 3.0, 3.1, 3.2 of IEC 60601-2-44, Medical Electric Equipment, Part 2-44. Here, that would be the particular requirements for basic safety and essential performance of x-ray equipment for computed tomography.

To which section would conformance need to be stated? How would a medical physicist, a state regulator, or a member of the public know which section each manufacturer has stated conformance to? Would the manufacturer have to revise its existing 501(k) every time a revision was issued? Would state regulations have to be

modified to reflect every revision, and what would the timeline be for regulations to be effective? If the FDA is incorporating by reference the IEC standard, what is the timeline for effectiveness, the timeline for transition from existing regulation to IEC conformance?

MR. COHEN: So along those lines, as Dr. Miller stated earlier, the FDA does not try to regulate the medical usage of the devices, and it's the same thing with the IEC. They don't try to ensure the ongoing safety that the end user must do. And this is where the issue starts to come in with the enforcement of these regulations by the states for those that do just point to what the FDA's doing and say you in the clinic must do this on your annual basis.

So let's take, for example, the linac standard, 60601-2-1. Within that, it references the general standard, 60601-1, and the other list that you can see there. So to start with, if I was to be using these as a guideline for my QA program in the clinic, I would have to purchase all of those to know what they're asking the manufacturer to satisfy. But wait, it gets worse.

So in 60601-1, you have a whole list of normative references that it refers to. You can see plus 52 more, I think there's about 60 of them there, that also get referenced. Now we're looking at anywhere from 70 to 90 standards that would all go into one device.

In addition, if you're going to reference these, you need to be clear as to what standards apply to which pieces of equipment. So, for example, we have here 60601-2-68, which is x-ray-based image-guided radiotherapy, and you have 60601-2-44 for computed tomography. Now, I can take a CT and put it in the room and use it for image guidance. The things that I'm going to require for that are not the same.

And so, for example, in the one document, you talk about beam-on for consistency. On the CT, you talk about loading state. You have the coordinate systems are different. Latency, how long does it take the images to be generated and processed? It doesn't

matter for a CT. Spatial accuracy requirements, and of course, the other big one, 60601-1-3 does not apply for the IGRT standard, but it does apply for the -2-44. So you have to be very careful to know which standard you're referencing. And it is the one thing that I've noticed in a lot of the documentation so far; a lot of imaging standards are referenced, but there aren't very many on the therapy side.

In addition to this, we have the testing procedures in the documents. So not all IEC safety and performance standards have corresponding testing standards. Also, the values that have to be met are not clearly stated. A lot of times it just says the manufacturer must provide what number they measure. So how will this impact the medical physicist's ability to develop and maintain a quality assurance program to demonstrate compliance with regulations as they apply to the end user? And, of course, that also brings up, as the versions of IEC documents change, when or if do they apply to the equipment that I currently have installed?

Now, there is a little bit of hope here because there are two main types of testing within the IEC test. There's a type test, which is a representative sample of the equipment, with the objective of determining if the equipment, as designed and manufactured, can meet requirements of this standard. These are tests that typically need to be done in the factory. They cannot be done on site. So that, at least, gives one easy line for the states to try to divide the testing required.

A site test, after installation, test of an individual device or ME equipment, to establish compliance with specified criteria. Okay. That sounds a little bit better, but we have those divided as well. There's a Type Test Grade A, which pretty much says, look at the documentation and see if it's there; Type Test Grade B, which is a test that means you need to measure something on the machine, but you should be able to use the machine as it's intended; and then there's a Type Test Grade C, which as it says within the description

really should only be conducted with the assistance of the manufacturer. Which one of these would apply to the site medical physicist for their ongoing QA?

So here is an example. Verification of the functioning of the dose-monitoring systems at up to twice the specified absorbed dose rates for the ME equipment in which they are used. Functioning may also be verified with the systems removed from the ME equipment and tested by other means.

What this is saying is that your dose-monitoring system, measuring the output from the machine, needs to be tested to see that it's accurate for twice the dose rate that the machine's capable of. There is no way that an installed device can be tested for this requirement.

Here's another one. Statement regarding how to ensure that the capability for termination of irradiation is tested between or prior to irradiation. Well, definitely very important, but the only way to really test this is to look at the manufacturing's engineering documents and look at their risk assessments and what they've come up with in order to ensure this requirement's met.

Three, means shall be provided to terminate irradiation before an additional absorbed dose of 0.25 Gy is delivered when, at the depth specified for flatness measurements, either the absorbed dose is distorted by more than 10% or the signals from the radiation detectors change by more than 10%. This is basically a test to make sure that if the output distribution in the machine changes, that the system will throw an interlock. Well, in order to test this, you would then have to adjust the machine to generate those conditions and see if the interlock holds, definitely not a test you want to do without the manufacturer's engineer on-site to help with.

So unlike the FDA performance standards, IEC standards, unto themselves, lack enforcement and must be adopted into regulations to be enforceable. And this is where

the issue comes in. In the U.S., this means the individual states. How would the states enforce this for the remainder of the life of the device? What system would be in place to know which model of a device conforms to which version of the standard? And whose responsibility would it be to develop a database for tracking which standards apply to which devices at which point in time?

There's already lots of instances that we've run into, as clinical medical physicists, where we've had requirements put on us by the state that are outdated for the equipment, but yet we're forced to somehow try to show that it complies.

So, in summary, we need clarification on how these would be incorporated into regulations or legislation and thus be enforceable. AAPM does agree with the concept of harmonizing with IEC standards; however, we should not move forward without resolution to implementation issues.

AAPM looks forward to continued dialogue on this initiative and urges the FDA to consider all comments received today and submitted in response to the proposed guidance document.

Thanks.

DR. LOTZ: Thank you, Dr. McKenney and Mr. Cohen.

Questions from the Panel?

Dr. Irwin.

DR. IRWIN: Yes, Bill Irwin.

So I feel like a little bit of this is creating a Wild West of regulatory enforcement issues. And I'll just ask, real simply, do you have a suggested alternative?

MR. COHEN: Well, we're willing to work and discuss with you as a group how to go about that. The main issue is not so much the FDA adopting the guidelines. It's what the state will do with them once that happens. And that's really the issue that would need to

be addressed.

DR. IRWIN: Yeah. I think that there is a mechanism, I described it earlier, whereby the states -- and most of them do, adopt suggested state regulations that are created in a collaborative effort amongst the states, the FDA, and others. And that does help.

The companion issue associated with this is one that you very well describe in your slides, and that's the ever-changing nature of the technology and the standards. And as someone who has attempted to use suggested state regulations that are based on FDA performance standards and on consensus standards and on issues of practice and lessons learned through decades of experience, I find them to be so complex and so specific and prescriptive that it creates numerous opportunities for them being out of date, as you described, and for neither the user community, medical physicists and practitioners using these modalities in medicine, nor the regulators to really understand what's going on and whether it all is matching.

And I feel like that there should be something that is really more fundamentally sound and practical. Specifically, for the most part, this is all about dose as well as performance for the satisfaction of the practitioner of the healing arts. And it would seem that if the physicians and other users are getting their healing arts needs met, they're satisfied, there should be some way that we can demonstrate that we are seeing the dose management techniques satisfied or fundamentals satisfied as well. And it would be useful for FDA and AAPM and others, as well as manufacturers and especially the medical community, to try to identify simpler ways to do this, so that we're not constantly fighting a battle where those who are attacking the wagon train and its circle become much greater in number than those behind the wagons.

DR. LOTZ: Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I am very familiar with the IEC standards development process because we participate in that, either as participants or sometimes in leadership positions. I am acutely aware of the cost of the standards, which are exaggerated. But I don't think that's a big deal because if the standards -- they provide the framework under which you can safely employ instrumentation or produce and sell devices and products. I mean, they're well worth the cost and the complexity that they involve, particularly if you're dealing with issues of, you know, safety. There is nothing wrong in being prescriptive if the provisions are coherent. Now, I assume that you made a case that in some cases they may be incoherent, but I suspect that you are cherry-picking a little bit.

So the positive thing about IEC is that it provides a framework for harmonization worldwide, and I see that many countries can live with that, so I don't see why the U.S. cannot.

Thank you.

MR. COHEN: To answer or comment on your statement, I wasn't necessarily cherry-picking. What I was trying to point out is that depending upon how you're using the CT scanner determines which standard would apply. And that's something that needs to be taken into consideration when you move towards this adoption of making sure that the right standard gets applied to the right device for the right usage.

DR. FARAONE: Sure, but you see, this is no different from, for example, an RF-emitting device. You know, some devices can be used by general public or professionals. They may have different settings that enable them to be used in different, you know, operational modes. And depending on which mode they'll be used in, they may be subject to different standards.

So there is a little bit of complexity involved whenever the level of care, to ensure safety, has to be a little bit higher, for example, for professional use.

MR. COHEN: That is true. The problem, and it's what's happening right now, which is why we wished to present today, is that you do have the requirements for a diagnostic CT scanner being applied to CT scanners used for therapy localization. That is occurring. There are also other states, on the diagnostic side, whose requirements for the site physicist is basically to tell them go look at the requirements on the federal side and do those.

So unless you are going to replace what is currently there with the text of the IEC documents, that then would make it the responsibility of the site physicist in that institution, which could be a small community hospital, having to go out and purchase these.

So we're not saying that this is not a good idea. We're just trying to bring up some of the consequences that need to be thought out and planned for if you're going to move down that path.

DR. FARAONE: Thank you.

DR. LOTZ: Thank you.

I think we will be discussing this more as an issue that the FDA has asked us about in our discussion session. I'd like to move on to our final speaker of the public session.

Thank you, Dr. McKenney and Mr. Cohen.

The next speaker is Megan Hayes on behalf of the Medical Imaging and Technology Alliance.

MS. HAYES: Good morning. My name is Megan Hayes. I'm the Director for Regulatory and Standards Strategy with MITA, which is a division of the National Electrical Manufacturers Association, or NEMA, which you've heard about this morning. I come to you with over 15 years of experience in standards development, both on the domestic and the international side. And I am a previous chair of the American National Standards Institute, Board of Standards Review.

Just a few words about MITA: We represent the manufacturers of medical imaging and radiopharmaceuticals. Our members comprise about 90% of the global market for medical imaging technology. And I also wanted to point out that through our association with NEMA, we are an ANSI-accredited standards developer and that we also serve as the secretary for IEC SC 62B and SC 62C U.S. mirror committees. And the vast majority of the IEC standards that we've talked about with respect to medical imaging equipment would fall under the scopes of SC 62B or C.

The other thing is we also serve as the secretary for DICOM, which we've heard quite a bit about today. So, you know, MITA is very involved in standards development for medical imaging equipment, and we like to think of ourselves as one of the leading organizations in that respect.

We have also heard a lot about sort of IEC standards versus the EPRC. And this slide is really meant to sort of just give an overview. It's really complicated to map from IEC to EPRC or back again because the 601 series of standards has a different structure than the EPRC standards. But as you can see, for each of the requirements of the EPRC, there is corresponding IEC standards that would have the same requirements or additional safety requirements with respect to radiation.

Our members did a bit of a comparison between the two, and I think it's telling to say that EPRC can be difficult to maintain and difficult to update, that it's very focused on radiation control and protection and that it can be difficult to expand into new product areas, whereas the IEC doesn't necessarily face those same challenges. MITA believes that IEC standards would offer the same level or improved protection of public health and safety. IEC standards are developed under a consensus-based process and internationally implemented. Participation in the development of these standards is open to all materially interested parties and currently includes FDA participation. Those standards are

continuously maintained on a schedule that's directed by the IEC directives.

The IEC series of standards is extendable. You can add new product areas whenever it's necessary. And they include requirements additional to radiation control and protection.

I wanted to give a few words about participation in the IEC process because I know there's been a lot of questions about that over the course of this meeting. The first is that throughout the process, there are times when participants in the process can comment and provide input. And that happens at the new work item proposal, the committee draft, the draft for comment, the committee draft for a vote, and literally throughout the process. And at each stage in this process, the IEC directives require that the action or observation for each specific comment be recorded and distributed to the national committees.

So unlike the regulatory process, where it is open for public comment but the government doesn't necessarily respond to each comment, for the IEC process, each comment is given a response.

Additionally -- and this is pretty recent -- maybe in the past 2 or 3 years, the IEC has opened up a public comment period at the CDV stage. I just this morning, before I spoke, went on to the IEC website to make sure that it works. And, in fact, you can sign up for a free account, and you can view all open CDVs within the IEC. You can also get an e-mail weekly that tells you which new CDVs have opened up, and you can look at each of those draft standards in read-only via the IEC website. So if you're very interested in electrotechnical standards, I would encourage you to go and sign up for an account and read all the IEC standards that you like.

Additionally, participation in the U.S. National Committee -- I'm not going to talk to other national committees, but it is open to all materially affected parties, and that is part of the USNC statutes. And one more opportunity for participation in IEC is that IEC does

offer the opportunity for liaisons, either for direct participation or to be kept aware of technical committee or subcommittee activity. And they specify in their directives that these liaisons can be intergovernmental, they can be manufacturer or trade associations or other types of associations, they can also be professional or scientific societies.

And then I just wanted to give you sort of a sense of where MITA is in all of this. It's a very complicated issue, and we think that certainly there is more work to be done before we go down any pathway. But we do believe that reliance on consensus-based international standards would be superior to the reliance on existing federal performance standards, that it would benefit all stakeholders, that it would reduce the burden on both manufacturers and regulators, and that it would support the FDA's mission of protecting the public health.

The FDA, throughout their presentations, suggest the development of mandatory performance standards for a variety of devices, some new and some revised. And we would recommend that whenever possible, the Agency rely on consensus-based recognized standards because developing duplicative or competing performance standards would be a disservice to all of the stakeholders involved.

We believe that the use of consensus standards in lieu of EPRC requirements should be narrowly scoped and include only the aspects of Subchapter J for radiation control and protection, as the ultimate goal should be alignment with international standards and reduction of the burden for manufacturers and regulators while maintaining safety and efficacy.

And finally, you know, a few words on some alternatives to IEC standards: We certainly support all of our members, the IEC standardization process, and we agree that when it's possible to rely on them, that's the preferred methodology. But we also understand that IEC standardization may not be the most efficient and effective means of

addressing pressing standards needs because the process can be long and involved and take more time than a pressing standard need might.

Therefore, we would recommend that the Agency consider a broader perspective and rely on consensus-based recognized standards. And that would allow the Agency to include not only IEC standards but also consider standards developed by other SDOs, such as MITA, NEMA, AAMI, ISO, IEEE or any number of other acronyms that are out there developing standards now.

And we also, as I mentioned, know that additional work will be needed for this, but MITA, as an SDO and as a member of the community, is willing and able to help whenever possible.

Thank you for your time.

DR. LOTZ: Thank you, Ms. Hayes.

Dr. Stein.

DR. STEIN: Yeah. On your final slide, you had ISO. With respect to the SDOs and ANSI, are all of your consensus standards, are the ones that you're dealing with, with IEC, ANSI standards, or only a set, a small set?

MS. HAYES: So the IEC standards are, in and of themselves, not automatically ANSI standards.

DR. STEIN: Right.

MS. HAYES: That requires an SDO that's accredited by ANSI to nationally adopt the standard. And in the case of the IEC standards, under the auspices of 62B and 62C, we have not nationally adopted those standards, although NEMA could certainly do so. But --

DR. STEIN: Okay.

MS. HAYES: -- they do meet sort of the --

DR. STEIN: Thank you.

MS. HAYES: -- consensus-based requirements.

DR. STEIN: And then is there any 17025 accreditations to either your consensus IEC standards or any of the ANSI standards? And what I mean by 17025 is that the entity that's practicing conformance then gets checked to see if they can be -- if they're complying or, you know, they're -- they're accredited to do it. And it's checked and audited. Is there that process?

MS. HAYES: I am aware of conformity assessment schemes for medical devices, which I would assume would follow 17025, but I don't, am not that involved in the conformity assessment process, so I don't want to misspeak.

DR. STEIN: Okay. Thank you.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: So I'm trying to get a sense of the IEC as a representative of various values important to radiation protection. I understand that each country that may be represented on a committee, working group, of the IEC all together has one vote. Can you give me a sense of how many manufacturers there are within IEC relative to electronic products used for medicine or radiation production that have one vote as well?

MS. HAYES: So the answer to that question is that's not really possible because the voting structure within the IEC is country-based. Manufacturers have no vote. Neither do regulators, medical physicists, doctors, any other stakeholder group involved. It is solely based upon the national committee. Additionally, most of the standards development work at the IEC is done in working groups, and the IEC directives specify that participation in working groups is individual based and not company or country based.

So if I go to the IEC to participate in a working group, I'm there representing Megan Hayes, not the United States, not MITA, not NEMA, and not any of my manufacturer member companies.

DR. IRWIN: And as follow-up, are there any guidelines that put some sort of parameters around the membership of these working groups? For example, our Committee here, by its founding documents, describes that five members are from this, from industry, five members from the public, and five members from regulators. Is that sort of balance of power represented in IEC standards, working groups and other functionary groups?

MS. HAYES: No. Because the IEC operates on a country-by-country basis, there is no kind of balance there. Right. It is are the participating member countries involved or are they not? Domestically, in the United States National Committee to the IEC, they have organized themselves into what they call technical advisory groups, or TAGs. You'll hear them called mirror committees as well. The model operating procedures for those TAGs do mention that the TAG administrator, in this case NEMA or MITA, should seek balance of interests on the TAG so that the U.S. position going into the IEC represents a balance of stakeholders.

And I know that MITA does do that. We do invite a balance of stakeholders to participate, although we cannot force anybody to participate. So I'm not sure that our TAGs would be considered balanced by maybe your definition.

DR. IRWIN: Thank you.

DR. LOTZ: Thank -- okay, Dr. Stein.

DR. STEIN: I'm sorry. Just one more quick: Is there any attempt to create an IEC consensus standard on management of, you know, the whole set that have to be put together? You know how you brought up that there can be 6 to 80 standards that have to be drawn together, where there's some inclusion of plan, do, check, and act?

MS. HAYES: Not that I'm aware of. And, you know, the 60601 series and the structure of it, I'm still trying to figure that out, and I've been involved in IEC for 15 years. It can be quite complicated. But, you know, my understanding is that you've got the greatest

minds in the world working on these standards.

DR. STEIN: Thank you.

DR. LOTZ: Thank you very much.

Are there any other individuals who would like to speak at this public session that have not registered previously?

(No response.)

DR. LOTZ: Okay. Not hearing any come forward, then I now pronounce this portion of the Open Public Meeting to be officially closed. And we'll turn to and proceed to the Committee Discussion related to the topics presented by the FDA. And this will be where we'll want to, as a Panel, address the questions specifically posed by our FDA speakers this morning.

Now, I note that while our speakers in the public session have addressed other topics, in one case that was primarily focused on yesterday, and in the case of the question of IEC standards, will actually be presented by FDA later today. So I'd like to draw the Panel's attention back, if you will, for this discussion, to the topics presented this morning by our FDA speakers. So I will open the floor for that discussion at this point.

Dr. Irwin.

DR. IRWIN: Yes, thank you.

Again, I appreciate the effort made by FDA and our public presenters here to focus on very valuable content. And the preparation of questions for our session today is greatly appreciated as well. It does focus a lot on important subjects. And it strikes me that for most all of these, I agree that these are good recommendations, that these are valuable efforts to be made for each of these questions in each of the areas that were discussed today.

What is of greater concern to me are some of the broader ramifications of this, not

necessarily whether FDA proceeds with the directions indicated by the questions asked here. Specifically, can the FDA even keep up with the pace of technological development, whether they're adopting consensus standards, developing their own performance standards, and others?

And then, second, what is the rate of compliance to consensus standards? Compliance can be measured relative to regulations that are based on, to date, primarily performance standards, but I wonder what the international or even national rate of compliance to consensus standards, where there's really no hammer behind the standard like a regulation might have. And I think that without knowledge of that rate of compliance and without having some enforcement capability, it's difficult.

And I would also like to know what has changed since 1985 to make update of the FDA's performance standards, for lack of a better term, possible now when it seemed somewhat difficult in the intervening 30 years. And I mentioned previously the difficulties of prescriptive regulation. Is there a way that the key parties can get together to identify better ways for very rapidly evolving technologies that need to evolve to do better patient care and to manage both user and patient doses more effectively? And I would hope that FDA and others might come to some ways to do that.

And then with some specificity, the handhelds, x-ray devices, I think, are quite difficult. I think there's going to be more and more use of this. We're seeing it not only in medicine but in law enforcement for evaluating vehicles. And I think that the possibilities of misuse and overexposure can be significant, and I think that it is very valuable that FDA is taking great interest in them and trying to find engineering controls that can help manage better use and prevent excessive or overexposure. And those are my key points from this morning, and I hope that FDA will work with all parties to try to solve this really complex collection of issues.

DR. LOTZ: I wonder if rather than sort of put the burden on our individual speakers, whether Dr. Ochs or Dr. Miller might want to comment on the more general issues that Dr. Irwin was just speaking to with respect to keeping up with the technology, with just dealing with the regulatory environment that we find ourselves in these days and some of those factors. Just give the Panel a little perspective on your outlook on that.

DR. OCHS: So this is Robert Ochs.

Yes, the keeping up with emerging technologies is quite difficult. As we mentioned, many people mentioned, I mean, most of the standards have not been updated since 1985. For other systems, even radiation therapy, MRI systems, there are no FDA performance standards. So we're trying to look at the very, very limited resources that we have and say, well, what makes the most sense?

And so the movement to IEC kind of reflects our thought of some of the brightest minds in the world are working on the safety of this equipment; can we leverage that and maybe take some of the resources that are required to write new regulations, to organize a panel meeting, before we even, you know, try and do something like that? Such as TEPRSSC, can we -- how do we focus that? Because as you see, we have a very broad agenda, and we haven't done this in 13 years, and it's very difficult to do something like this and to do it rapidly.

So how can we best leverage it? And so we are very open to the ideas from the Committee or to get your thoughts on some of these, you know, your opinions, what you see as concerns, what things we need to go address to the community as far as their questions. They're all very useful for us as we look at our directions forward.

And do you have anything to add?

DR. MILLER: Well, one of the reasons we haven't done much in recent years is because this Committee hasn't met in 13 years, and we can't do anything without talking to

you first.

At least with respect to medical devices, if a manufacturer declares conformance to an IEC or any other standard, that becomes part of the specifications for the device. If the device doesn't meet the specifications, it's violative, and we can take action against the manufacturer. So that's one way to deal with the enforcement issue that -- I'm not sure. And I'd have to consult with some of the FDA legal people, whether that carries over to electronic products. I know it's true for medical devices.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: Kind of expanding upon what you were saying, as we've -- as I've listened to the speakers, my thought is always what is the problem that is trying to be solved here? The very first speaker, I didn't even get a problem they wanted the FDA to do -- or permission for the FDA to do something. But I didn't see any demonstrated or anticipated harm. And so I would just urge that as we look at this, and as FDA looks at these things, if you can bring us, at least for me, a little more clearly, are people being harmed by these things?

Talking about the cone-beam CT, it doesn't appear that there's a problem that we don't have regulations about cone-beams, because people are using cone-beams somehow -- I hope they're not using it illegally. And if they are using the cone-beams, you know, have there been any harm from that? And so on, with the other topics that we've looked at, are people being hurt by it? Are standards, you know, the kind of informal application of these, pretty much solving the problem and allowing you guys to use your resources on things that really are harming the public?

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

I would respond to your question that people have died because of errors in

radiation therapy. There was a congressional hearing on the matter after some exposés in the media. And so it is, to me, surprising that the modality that delivers lethal doses of radiation is not in any way regulated by the U.S. Government. And people have died in MR scanners, not due to proper use but by accidents and errors.

MR. MURPHY: If I can have a follow-up.

DR. McCOLLOUGH: So these are lethal when used improperly, and we do deserve some protection in our country.

MR. MURPHY: Oh, and -- sure. And I am -- I have heard of some of these cases and things, but just as kind of ongoing, you know, once certain problems are solved, are there other ongoing things? Again, for the cone-beams -- and I'm sorry. I had a specific response to this. Just --

DR. LOTZ: Dr. Miller.

DR. MILLER: Donald Miller.

Just to clarify, radiation therapy devices are medical devices, and we regulate them as medical devices. But there is no electronic product performance standard for these systems at this point. It's not that we don't regulate them. We certainly do regulate them.

DR. McCOLLOUGH: Cynthia McCollough.

Just to clarify that, then when you say they do not have electronic product performance standards, from the medical device side, do they have performance standards?

DR. MILLER: Not in the sense that you mean. Performance standards generally, with respect to radiation, are under the electronic product radiation control provisions, where we regulate aspects of the device -- aspects of the product that control the quality, quantity, or direction of radiation.

We regulate medical devices with respect to safety and efficacy, and whether or not

they're substantially equivalent to predicate devices, depending on how the device is brought to us for approval or clearance. And I know that that wasn't in English. I apologize.

DR. McCOLLOUGH: So to try to put that in words I'm more familiar with, they get premarket 510(k) clearance or approvals, and so they are required to meet the specifications that they, the manufacturers, put forward. They have that sort of regulatory oversight. But they do not have the things that we have in CT, such as the measured dose must be within ±20% of the stated dose.

DR. MILLER: That's correct. And to give you a relatively specific example with respect to radiation therapy devices, we recently looked at all of the medical device recalls for radiation therapy equipment and linear accelerators specifically and its associated components. And I don't remember the exact number, but approximately 80% of the recalls were due to software issues in that one part of the system wasn't talking to the other part of the system, or the two parts of the system were -- one part was from a third-party manufacturer and didn't talk to the original one, or the units got garbled or something else, causing the potential for serious injury or death.

DR. LOTZ: Let's go over here. I'm just --

Dr. Stein.

DR. STEIN: Toni Stein.

It's a piece of cake. I can only draw the analogy to the ISO 14000 series, or the ISO 9000 series for quality, where it evolved into the 14000 series. Those of you who don't know what that is, it's for sustainability and -- but the basic features are to come up with a management system for the specifics of the site. Each and every site would have to do a management plan, to look at their whole life cycle of their equipment and manage it properly, and then plan, act, check, do, and change, respond to everything that's seen.

But the point that I really would like to make is that it's important, I think, first off,

that FDA consider, in its own activities, as well as for any consensus standards that it wants to adopt or use, that they encourage and promote conversion or using ANSI standard, since the ANSI standards provisions require the balance that's been brought up by several speakers and by several discussions here in terms of the voting structures on the final standard.

And it's really important because the representation can't be biased to one, you know, sector that's involved in composing the standard. So I highly recommend that. But since we've seen that it's a multiple standard compilation, it's really important that there be a management plan. Otherwise, it's chaos. And that shouldn't be. And in terms of looking at what the goals are for the management plan, it has to be to reduce damages, you know, to try and reduce, as Dr. McCollough brought up, incidences of fatalities or any kind of damage to workers, to patients, and that should be number one.

It seems as though there needs to be encouragement by the federal government to begin that process of creating a management plan standard that puts all these together, that requires those that are in practice, using the equipment, that to check that its certification can be audited, and that those involved in operating the equipment are accredited and are legitimately qualified to operate the equipment, and that that's audited and checked for the safety of the individuals having to go through possible damages.

That's my suggestion.

DR. LOTZ: Dr. Linet.

DR. LINET: So from a little bit different perspective, I'd like to return to Dr. Irwin's question and Mr. Murphy's issues that he raised. So as a population scientist, you know, we can't study everything. We have to make priorities. And the way we make priorities -- and I'm speaking to the choir here, with Greg, is based on the proportion of people in a population that are affected seriously. I mean, you know, we would love to look at

everything, but we can't, so we have to make priorities.

So one of the priorities that comes up in all of this is, in order to identify harms, which Mr. Murphy raised, I mean, what are the harms; we can't really quantify the harms till we know dose. So identification requiring that equipment produce doses is not only valuable for research and for public health importance, but it gives information to patients. People need to know their doses from various procedures, from -- they even need to know if equipment, you know, emits radiation, as we talked about yesterday, with microwave ovens. But I think dose is the primary requirement.

The second issue is what is the size of the population being affected? And we've talked a little bit about the issue of CT scans, responsible for half the dose to the population of the United States in terms of radiation exposure. So that has to be one of the priorities.

Second, cancer risk, now responsible for 1 out of 5 new cancer cases is a secondary cancer due to often treatment but not always treatment. It is due to other risk factors. So we have to be worried about people who might be at risk for second cancers.

But I think the third is, in terms of standing back and thinking about lifespan, the most sensitive members of the population are children. And they're going to have the longest lifespan and the greatest chance of developing late effects, so we must focus on children. So it seems to me that for the FDA, which has all these things to be concerned about, I think the big picture needs, in part, to be taken into account, and we need to worry about serious late effects and those that cause not just death, but disability, morbidity, this sort of thing.

DR. LOTZ: Let me go to Mr. Keith.

MR. KEITH: I want to applaud FDA for reaching out at this time and recognizing it's been a long time since these standards have been updated. Sometimes it takes an act, a happening to kind of shake us up and make us realize that, you know, things need to be

taken care of. It's just like when during the anthrax, and staff, congressional staffers and the press saw us doing mass spec work in a Quonset hut with holes in the roof, with a tarp over the mass spec and a half pipe taking the water out through a hole in the side, that we realized that our premiere public health agency was under-funded, and we got funding.

And now FDA is recognizing that it's important. You know, there's a CT brain perfusion study in which patients were exposed to like eight times the radiation dose that was intended. You had epilation and, you know, there could be further complications down the road.

In order for FDA to do this with limited resources, I think that the use of consensus-based standards is very, very important to being nimble and being able to stay current. It's stated in here that FDA incorporates standards into the U.S. regulatory framework through a standards recognition program, and once a consensus standard has been established, it can be recognized in whole or in part by FDA. That's very important, in whole or in part.

See FDA is represented on the IEC work groups. That means that even though a standard may be a consensus standard, there may be aspects in there that FDA does not think are strict enough or are relevant enough, but by having membership on that, FDA knows what aspects of those, of each standard, should be applicable or not applicable to their guidance and their regulations. So they are a step ahead. And if they use those and cite those but only use relevant portions, it helps them stay current with the current needs of society and medicine, in keeping us safe in an area where there are not enough federal resources to do a totally adequate job in a vacuum.

I hear that IEC has heavy industry involvement, and yet it's a country-by-country thing, which dials a lot of that out. I hear that IEC standards are costly and not readily available, and AAPM addressed that. Yet I look at AAPM standards, and they address NCRP,

ICRU, and ICRP, and yet I don't see the standards posted on their website. So it's a progression. And I thought of each IEC standard has its references. And you go to each one of those, and it has its references.

When an organization develops a document like this and has all these references, it means they have utilized that to educate themselves. And then they developed the document as essentially a standalone, based on their knowledge of the science at the time and the needs of the publication. So the idea of going to secondary and tertiary and quaternary references is irresponsible, unnecessary. But providing aspects of those references, or perhaps even like Dr. Miller mentioned, having the reference up there on the website where you can read it but you can't copy it -- Health Physics Society does some things like that, and so does IHS, who Health Physics Society uses to distribute publications. But the important thing is that the references -- are the guidances out of date? It's important to put it in date because people are being harmed, as Dr. McCollough has so adequately addressed, and we want to avoid harm. We use the ALARA process, concept, you know, and if we see harm, we try to address it. If there's a potential for harm, we try to address that, too.

So even though there are issues with addressing IEC standards versus FDA guidance and requirements, when you use the 17011 and 17025 accreditation body and accredited organization concept, when you go in there to audit, you give the requirement to the auditee to give you a roadmap of where their requirements match with the requirements of the regulatory agency. You put that on the medical facilities. It can be done. It's a joint effort.

It's very important for us to work together because I don't know of anybody in this room -- can anybody in this room stand up and say they have never had an x-ray, medical x-ray, that they do not know anybody who has undergone therapy? It comes home to all of

us. It's us, our sisters, our brothers, our cousins, our mothers, our fathers, our grandparents, our children. So we should want to figure out how to skin this animal in consonance. Let's not put roadblocks in the way. Let's not come up with concerns and issues. Let's come up with solutions.

It's like JFK said: Ask not what your country can do for you; ask what you can do for your country. I ask you to think about if you have an issue, how can you help FDA? Think about solutions. State a problem; come up with a solution. Don't come to me with a problem unless you have a solution. And that's how I try to live. If I have a problem with my agency, I try to come up with a solution.

DR. LOTZ: Let's turn to Dr. McCollough now.

DR. McCOLLOUGH: I absolutely agree that we have a problem that needs a solution. We do need FDA to represent current technology and be effective in their regulations. FDA has a history of leading in protection. But that history is not current. The CTDI concept came from the FDA. And I hold FDA to a higher standard than I do IEC, in part because I have been a part of IEC for the CT maintenance team for 15 years now, and it is absolutely dominated by the manufacturers. Let me give you -- and so I do not want to see FDA address its limited resources and its being out of date by handing over our problem and say, IEC will fix it, because they won't.

They do a lot that is good, but like we saw yesterday with the laser product standard, the solution needs to be the FDA coming up with its own sets of things where they accept this and don't accept this, add this, and not just say we recognize it by this. You're in compliance with IEC 60-da-da-da, and you're good.

An example that hit home to me is with the CT dose reduction emphasis. We are busy coming up with technologies that reduce the typical dose by 10% here, 20% here, 30% there, and with the safety standards most recent amendment in CT -- we have two

representatives from the AAPM on this Committee. We are the only end users on the Committee. And we fought very hard, and the AAPM as a society funds all of our travel to go there and pays our ANSI dues to participate. So we are extremely dedicated to being a part of this.

There are an FDA representative and a regulatory person or two from Europe; all the rest is manufacturer representatives. So we are always out-spoken -- or outnumbered and often out-spoken. We addressed the issue that the limits on dose accuracy are ±20% in the federal regulations, and we were readdressing what the number ought to be, and everyone in the room that's measured on a CT scanner says that is ridiculous. It can be ±5%. We have our own data; we show da-da-da-da-da, we brought them data. And they kept saying, no, no, no, no, we cannot do this. In fact, some modes, it's ±40%, at which we were shocked and said how can it be ±40%? The FDA requires ±20%.

And they said, well, the IEC document says ±20% unless otherwise stated in the accompanying documents. And then they had us go look at the accompanying documents, and they said, for these modes, it can be ±40%. And here we're trying to shave off 10s and 20 percents of doses, and the manufacturer is saying your dose on your scanner can be ±40% of what we told you it would be.

And that got very heated. I have at times, whichever way the manufacturer group goes at the meeting for lunch, I go the other way because they do work to represent their interests, and those interests are not the same as the end user. And handing over our power and our authority to them strips the U.S. medical community, the providers, the regulatory people, the medical physics, the states, of our ability to address limits and have in performance specs that we think are critical because we are outnumbered at the table.

DR. LOTZ: Mr. Savic.

MR. SAVIC: Stan Savic.

I'm trying to understand a little bit better which wheel is the one that's squeaking? Specifically, with respect to radiation therapy, but it may also apply to diagnostic imaging, does FDA have any idea whether some of the horror stories are more of a quality of equipment issues that may be addressed to performance standards, or are they more issues of practitioners' training and ability to do a radiation treatment plan that might not result in either excessive dose to unwanted organs or areas?

DR. MILLER: Donald Miller.

For therapy, it's both. For diagnostic equipment, it tends to be more an incorrect understanding of how to use the equipment. But our desire to use IEC standards for diagnostic equipment is based largely on our realization that the IEC standards are at least equal, and frequently better, in terms of assuring safety than our performance standards because our performance standards are so old.

And I will give you a concrete example. Full disclosure: I'm a member of two IEC maintenance teams, and I'm also an honorary member of AAPM, so all such -- I have served on the maintenance team for interventional fluoroscopy for the past 6 years and also another 6 years before that, before I joined FDA.

And when I first joined, I was the only physician. I still am the only physician on that maintenance team. And while the rest of the team was composed primarily of manufacturers, they were aware that none of them were end users or really understood how the equipment was used. And so when I said something, they paid attention. Now, of course, when I say something, and they know I work for the FDA, they pay even more attention. But even then, they paid attention.

One of the things that was introduced in the last edition of that standard, 60601-2-43, is something called an emergency fluoroscopy mode. The idea is that if the equipment crashes in the middle of a procedure, you should be able to get it back up and

running as fast as possible. And if you've got a balloon or a coil in somebody's brain and you're trying to deploy it, you don't want to use fluoro. It's a bad thing to have happen. You want to get that up as fast as possible.

And the manufacturers came up with something called an emergency fluoroscopy mode, and the specification was you get it up and running and as close as to the way it was working beforehand. And they said, well, but if we have to show you all of the radiation dose requirement stuff from the FDA standard, performance standard, it's going to take longer.

And so the FDA wrote a guidance that said, I tell you what, if you have an emergency fluoroscopy mode on your device, we won't worry about that part of the performance standard because it's a clear advance in safety. And there's no way we're going to change our performance standard anytime soon because we know how long that takes. And of course, we'd have to come and talk to you first.

So there are many circumstances -- and you'll hear more about it this afternoon, but there are many circumstances where the IEC standards have advances in safety in them that we do not have in our performance standards. And that's what's important to us is advances in safety.

DR. LOTZ: I'm going to ask a question here that, I think, relates to that, Dr. Miller. And it occurred to me in the earlier presentations. And that is with respect to the whole question of updating the performance standards, are there any standards now on the books that are blocking, say, technologies that are safer than what the standard requires? And by that, I mean, I know of an example -- and I won't go into the details, in occupational safety and health where technology to do a particular task that's dangerous to the worker has progressed, but there are actually regulations that prohibit the use of that technology because they require a different procedure.

I'm not sure if that's a good analogy, but I'm wondering if FDA is struggling with any of that sort of thing, where what you have on the books is actually blocking the progress.

DR. MILLER: I think the best people to ask would be the manufacturers, who may or may not be introducing new technologies because of existing FDA performance standards. But I can tell you that the same fluoroscopy guidance, the draft guidance that I just mentioned has another clause that deals with termination of fluoroscopy that also deals with another safety issue that's being advanced in the IEC but that would conflict with our existing performance standard.

And that's just radiography and fluoroscopy, which are my areas of particular interest. I won't speak for CT or mammography or dental or ultrasound or radiation therapy.

DR. LOTZ: So with that as an opportunity for me to intervene, let me also see if we can push us back to the questions of this morning's presentations a bit more than we have been so far. I think Dr. Faraone has been waiting to speak, hopefully to one of those questions.

DR. FARAONE: Thank you. Antonio Faraone. Exactly.

So I wanted to go through some of the questions. Some of them are common among several presentations. In particular, there is a question that's regarding about the desirability of establishing performance standards for electronic products used for radiation therapy, different kind of, you know, different kind of products.

Well, my advice would be that if there are IEC standards, international standards that could provide the required technical information to ensure the safe use and the efficient use of these devices, they should be adopted. If they require variances, like improvements, FDA could get involved for the development of those standards.

Based on my experience, a U.S. regulator -- in my case, the FCC -- has enormous

influence on a IEC committee. People really listen to what the FCC has to say. So I would suspect that FDA could have a similar kind of clout within an IEC standards committee.

Now, obviously, if there are pressing issues that cannot be addressed in a timely fashion by an IEC committee -- you know, sometimes it's true, like one of the public presenters said, that they are kind of slow sometimes; you know, there are 3 month circulations for CDVs and so on, or 5 months maybe. So, you know, if there are pressing issues, clearly, you know, they require immediate action.

But in a more like, you know, managed kind of a framework where, you know, issues are identified with enough time and they can be worked on, also for the introduction, the safe introduction of new technologies, you know, the IEC is a good vehicle and ensures harmonization and vetting by a lot of experts worldwide.

I have a specific item that I, you know, I wanted to bring up, which may be related to this question. And there is -- this is the fact in one, maybe the initial presentation, there was a reference that sometimes these systems comprise different parts, like software from a third party, so something that I would, in my world, I would call modules. You know, we are used to have to deal with modular systems, for example, a radiofrequency transceiver.

Sometimes you buy a whole chip set from a certain vendor because they provide parts, different submodules that are designed to work together, let's say, for a smartphone. Okay. Qualcomm provides you with a chip set that does the base band and the RF and then various other chips that can do, for example, antenna tuners. And they're all designed to work together. They've been optimized to work together. The single vendor provides you with a reference design, and most companies like to go with this low-risk approach because everything has been pretested.

Now, the moment, instead, where you try and assemble different modules from different vendors, then there is a risk that some things may not be fully compatible. So in

these instances, I wonder whether IEC standards can be useful. Maybe they are not. Maybe they have not been -- they are not standards that have been developed with the intent of ensuring the functional and safe combination of different modules from different vendors. Should that be the case, this could be an area where FDA could certainly provide guidance, given the experience and expertise.

Again, I don't know if this is a problem. I'm just wondering, given my experience with, you know, electronic products, this could be a problem sometimes, the combination of different modules from different vendors. For example, what if it has to do with the actual dose being delivered? What if a certain software used to manage exposures, somehow used in combination with a certain manufacturer's machine, may not necessarily produce the amount of dose that is prescribed? So obviously that could be an extreme case, but should that be, you know, a question about the reliability of these modular systems? I think that's an area where FDA should be vigilant.

There were other questions. One in particular related to these handheld x-ray systems, about the opportunity to protect the user, the operator. For me, it's almost like a no-brainer. I mean, if there is knowledge that indicates that operators may be overexposed during the performance of their duties, there should be the possibility then to intervene with engineering means, for example, shielding, to limit that occurrence.

There was another question about cone-beam CTs. It was about children and concern about pediatric safety. Well, given the fact that it seems like these cone-beam CTs, they produce lower doses, I would guess probably not, meaning that if they are used in substitution of the current previous generation of CT scanners, and they expose less, probably there is no reason to be concerned.

So this is the extent of my advice.

DR. LOTZ: I think Dr. McCollough was wanting to --

DR. McCOLLOUGH: Excuse me. Cynthia McCollough.

I will also go through a few of the questions to give the FDA representatives some specific answers to the specific questions. I'll start backwards because my last comment was about the cone-beam CT and safety concerns for pediatric children.

Cone-beam CT can use low doses, but they can use very high doses. It is all on how the operator turns the dials. And so some of the safety concerns and ideas to address them that I would suggest for across the board, even regular CT and radiographic and fluoroscopic, are accreditation of users and requirements of users. You cannot regulate the users, but there can be ways that when the equipment is sold, it has to come with X amount of training and Y training module.

One of the concerns with cone-beam CT is that they are popping up in dentists' office, in orthopedic offices, in all these -- and urology offices, in all these types of medical environments where that physician group and the people that operate them have no background in radiation safety, have no background in imaging. And so they really, it is a Wild West in how they use the device. And so I think some things that you can put in at the front end requirement, so that when those go out into those environments, they are as well protected as if they went into a radiology environment where we have radiation safety knowledge.

With an idea on how we can address safety concerns in multi-detector CT, there is a recently -- very recently approved DICOM standard for protocol, all the details of how the scanner is set up and to be used. And DICOM has put together a standard format to record all that and capture all that. And whatever FDA can do to make sure that that is adopted and goes into the marketplace quickly will help because then best practices can be shared easily.

If you give someone a piece of paper and say these are all my things that I use,

there's interpretation, there's typing, and such. But if somebody can say these are the sets of protocols from, you know, XYZ institution, that has -- well, for example, Mayo Clinic, we have five Ph.D. physicists related -- working just on CT physics. So we go through each and every protocol, and we could use our best practices and share them if protocol standardization means of happening, not standardization sharing, was available.

The qualification and training at time of handover is something that I think could fall into the purview of the FDA because it's the installation in the handover. And the application specialists that do that handover are given a very, very short time window to teach all the new features of the scanner, set it up for that environment, and then go through their handoff checklist.

And the question was asked is there anything in a standard that prohibits safety. In CT we had the opposite experience that Dr. Miller had; the dose check standard, which was a standard that NEMA put forward without much input, if any, from the professional societies, and it became a NEMA standard, and it was very quickly adopted into the IEC standard.

And the dose check idea is that you prescribe something, I'm going to do this scan, and if it sees that the radiation that the scanner will deliver is too high, it gives you a warning. Are you sure you want to do this? You may want to recheck. So it's a pause. It's like that surgical pause. Very good idea. But the standard that was adopted has an upper limit, and it says you just can't run the scanner above this number. And when that was put in, they were thinking typical diagnostic exams. They weren't thinking interventional.

And so at time of turnover, we had scanners with this feature get turned on. We were not notified. And we came to a point in a CT interventional procedure, with needles next to someone's spine, and all of a sudden the scanner says you're done. You've hit your limit. You can't scan anymore.

And so we reported that to the FDA as a device alert. The manufacturers said we can change this within NEMA quickly. We can't change it within IEC quickly. And so the problem is still not fixed. So the only way to deal with that right now is more education at the time of handover, so that people know not to -- you know, there are some workarounds that AAPM has published.

So those are some specific suggestions that I had to the specific questions.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Yes, Bill Irwin.

I'm going to try to make this really quick, but a summary of my response to all of the questions.

First, again, the questions are really well crafted. And in my opinion, if the question asked should we do something, my answer was yes. If the idea was suggested, it was a good one, including the use of both performance standards and consensus standards. But in all of these cases, the FDA assumes a greater role and even greater responsibility.

First, the FDA has to be the arbiter of consensus standard review for adoption for the nation as a whole. It has to identify, very specifically, exceptions and additions to meet the higher standards that Dr. McCollough rightly pointed out the FDA has been representative of for decades, and identify where specific performance standards are needed for safety purposes, when the consensus standard is lacking or inadequate; also, to provide guidance to the states and others, who verify that once possession of these devices is transferred to users, safety is maintained; and then lastly, that they convene collaborative processes to institute checks and balances on all of these processes in order to ensure that these steps that are taken now, with this new initiative to bring safety standards into modern state for technology today, is maintained for all of the relevant parties, the patients, the public, the users, as well as industry.

Thank you.

DR. LOTZ: Let's go down over here.

Dr. Stein and Mr. Murphy.

DR. STEIN: I would like to reemphasize what I mentioned yesterday about C95. It's an IEEE/ANSI standard, and it's used for what we discussed yesterday, for RF energy and radiation. But these standards were an ANSI process. And if you go onto the website today, which is standards.ieee.org/about/get, and you'll see that they disclose -- and this happened in 2010, that the United States Air Force, United States Army, and the Navy all came together to sponsor so that anyone could download and get these for free.

They don't -- you know, it's not an endorsement process, but they came up with a process in which, to participate in the ANSI process, the government took an active role to make and host the ability to get the standards of interest.

You know, I do have to say, that with respect to C95, it was last updated in 2005, so I will mention that it should be updated every 3 years, and the same with the IEC standards. I feel like the C95 standard is ahead of the game because it is an ANSI -- they moved it to host. IEEE began the process, as IEC has, just a consensus standard. And then they moved it into being an ANSI standard. And the process opened to allow all types of sectors to participate in the process. I highly recommend that that be used as analogy and looked at very carefully to move forward with the process for this. It's very valuable.

The important thing that I wanted to point out is the question of was it a mistake -- we heard before in our discussion from Dr. Savic: Was it a mistake by the operator, or was it a equipment error, or you know, what exactly happens in these instances of damages? And the damage reports need to be compiled annually so that we can keep looking and improving and do continuous improvement of the issues.

But what I wanted to point out was in the instances of when there are errors, there

has to be an attitude of prevention first. Of course, it's important to avoid errors, but there also has to be an attitude that we want to prevent an error from ever, ever happening, not just let's respond when the errors happen and change and continuously improve. But there has to be an active role by FDA and all those involved, including the states, because as we heard earlier, that after the first year, FDA's involvement is less than -- you know, it becomes minimal. It's all offloaded onto the states.

And, therefore, there needs to be an active role in prevention, not just do we -- what do we do once there's a problem, which we're all aware of, for safety. It has to be a constant in the minds of everybody involved in the standard, to constantly think and update every 3 years or sooner, to try and prevent the problems that occur, especially as the technology moves forward.

The other thing I want to make sure that we acknowledge is that when you have more than one standard coming together, you have issues of interoperability. And there always has to be interoperability. When one standard interfaces with another standard, you have to have participation from the other standard on when you're developing the new standard or the both -- interchangeability. It has to be involvement to avoid the non-interoperability of the process.

And I think that what I'm hearing is happening is there isn't. It's siloed. There's lots of people working on one particular part of the standard or one standard, but it's interfacing with 80 other standards, and there's no interchangeability of the subject matter experts between them. And that should be encouraged.

And as we heard before, in many cases, the funding issues are big. It's impossible for someone that's in academics to be able to fly or participate in the other standards if they're not being sponsored. And that should be a requirement that the government encourages and supports, not from their own funding but from those involved in the standard

development. There should be a fund created at the beginning of the standard development process, which will support the participation of all parties involved, not just those that have the money to come.

DR. LOTZ: I believe Mr. Murphy wanted to make some comments.

MR. MURPHY: I believe the last two speakers have presented a list of items for FDA's consideration, some very, very good ones. I would like to add -- again, not to harp on it, but when we see these presentations, when you put forth, you know, publish the documents or the proposed regulations, again, what is it trying to solve? What is the demonstrated or anticipated harm? Hopefully a good analysis. I have seen FDA put forth, we're being harmed by -- you know, certain people are being harmed, and then it turns out that it's either something that FDA can't control or it really isn't -- their regulations aren't going to solve those problems.

So I didn't see it in the first two or three presentations earlier today. And I just would like to say again, if you could present that to us and general public, that would help. I saw it well yesterday with the ones about laser pointers and, you know, here's all the airplanes that have been hit and so forth. Just didn't hear it today, so that's why I couldn't really answer accurately some of the questions that you asked today.

DR. LOTZ: Dr. Lambeth.

DR. LAMBETH: My expertise is not really in the radiographic side of things, but as most of us, and was pointed out, we have experienced it, either as a patient or colleague or friend or whatnot. And I find that my fellow Committee members' comments and others have brought up something that's been a sore spot with me for many years. And the sore spot is -- and I do believe that shining a light on things solves many problems. And the sore spot is that the patient does not actually have access to his records.

Now, Dr. Linet mentioned that we need to know our dosages, and she said, and the

patient should know the dosage. Now, I assume when you say that, you really mean the doctor should know the dosages. But I think the patient should have access to his own medical materials. And the medical profession or the manufacturers or someone prevents this from really happening.

The patient does not have access to these materials. And this is not something I understand the -- falls within your purview of equipment. But shining that light's your best advocate to find out about these failure modes, these accidents, these overexposures, or in the case, underexposures, because that information will come to light best when the consumer knows about it. And the only he has to know about it is if those records are available to him.

And it seems to me, from an equipment standpoint, every piece of equipment that we have in today's modern electronics, almost every piece, has the ability of recording all that information, especially dosages. And many of them do record it, but you don't get it. And I would just like to somehow, you know, inject that and say, advocate that if there's a way for the FDA to participate, to make that happen with whatever agency it would be to make it happen, I think it would be great.

I would like nothing better than to be able to -- and by the way, I've had enough serious medical issues in my family and friends to have seen a lot of forms. And in the university environment, the medical hospital, it's not uncommon that the doctor will ask you to sign a release that he can use your materials, okay, for his research, not uncommon at all. And I think that's great, that that knowledge can be spread and used. So it seems to me that -- and I -- and by the way, I have other doctors who have provided me with records as to where I can go look up what has occurred, my history with him, which I think is very useful. These are usually web-based, web-interactive sorts of things.

So if there was a way to encourage that, that that's actually mandatory for the

patient to be able to access his records, I would vote for that.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: You'll be happy to hear, then, that the State of California requires the radiologist to put the dose information in there, in their radiology report, and other states are following suit with that. And the pressures in consumer medicine are such that, at our institution, there's a patient portal. And I can online, go online, I can see all my images, I can see all my reports, I can see all that. So I think that transparency really is --

DR. LAMBETH: It's coming.

DR. McCOLLOUGH: -- is coming. And the way that FDA can assist in this, is in these radiation dose structured reports that were spoken about, it won't be completely easy because they're not interlocking jigsaw puzzles. Each device, whether it's CT or radiographic or fluoroscopy, has different types of geometries and different uses, so that the dose number -- generically it's dose, but it might be entrant skin dose. It might be mean dose at the center of the scan volume. There's all these different types of doses, and they're not necessarily all additive.

So the FDA can definitely help in continuing to participate in what kind of dose metrics we move toward as a community and then requiring those to be on new systems.

DR. LOTZ: Dr. Stein.

DR. STEIN: Yeah. I really appreciate your comment about -- Dr. Lambeth. And the thing that it brought to mind, and I want to make a, you know, analogy again so that people can kind of understand and see what I mean. My kids are both in high school. And in California -- I live in Berkeley -- our high school or the whole State of California has required, put into statute the requirement that the facility, every year, has to report what's called a SARC. It's a report card for the facility. And it includes how many expulsions, how many suspensions, and as well, a facility inspection report with a checklist. And the checklist tells

you whether or not they're in good condition, poor condition, very good condition, excellent condition. And it gives the incidences of how many, you know, OSHA violations, etc.

I highly recommend that we think -- and remember, I was just mentioning this as an analogy, that wouldn't it be terrific if on the door of the facility where the device is, that there was monthly, just like the Public Health Department puts the checkmark on facilities that we eat at, that there was a detailed, online facility inspection report that said how many incidences, how many problems, how many reports of complaints, how many etc. Come up with -- as creative as you'd like. Have they been 17025 audited recently and completed all of their inspections?

So that those that use the facility can become the advocates to advance the improvements to the technology, not just us here in this room, which are, you know, a number of people, but it certainly would help to gain the support and the financial needs of the resources to maintain that process if we had advocates, a lot of advocates that looked at that report and said, oh, boy, we've seen -- you know, this is terrible. I don't want to use this equipment. Or yes, it looks like high, good quality, and yes, they're in good shape, and the safety is good.

I don't know of any safety reports that are available to date, but it certainly would be nice.

DR. McCOLLOUGH: Cynthia McCollough.

They do exist in medicine to the forms of accreditation, and particularly, the Joint Commission accreditation of hospital organizations, or in radiology, specifically the American College of Radiology. Those accreditations have lots of requirements. They check the radiologists and the radiologists', everybody's, the staff's credentials. They check the equipment. They check clinical exams. And then that certificate needs to be displayed in a

public place. So there is quite a bit of that.

DR. IRWIN: If I could, I could just add, and our state publishes our inspections of medical facilities online. So other states do that as well. So there is an effort to make sure that the public is very much aware of the quality of radiographic and other care.

DR. LOTZ: All right. I'd like to draw this particular session to a close. Thank the panel -- pardon?

(Off microphone comment.)

DR. LOTZ: You've also spoken several times, but go ahead. Go ahead.

MR. KEITH: I apologize for the inconvenience, but I think it's important for me to say that I think from my perspective, FDA owns the documents that they produce and everything that's in them, regardless of what they cite. It's their documents. It's not ISO or IEC citing this. They can cite a document, but it's their document, it's their statement, it's their conclusions, it's their guidance, and it's their regulation. So I think if we look at it in that perspective, and it's shared in that perspective in their documents, it should be clear that it's not an ISO document that they are citing. It's their ideas of what is important to include in their documents.

Regarding therapy, are mandatory performance standards necessary for accessories? And I say, it may be that some performance standards should be mandatory and others voluntary. It depends on the system and the risk.

Should we focus on -- what functions should we focus on? Look at the high-risk things first, and focus on those. Make sure that the protocol options are available to the physician when they perform the study.

On CT, how should FDA approach safety features and requirements and NEMA standards? And I think that get a panel to review the NEMA documents and recommend which are relevant and establish a schedule for updating the FDA performance standards.

Regarding access controls, specific users with admin privileges are needed. They should clearly document each change and transition they make and train others.

Are there other specific recommendations to address pediatric safety? I recommend consideration of doing organ-specific dosimetry to provide a database for future discussion and evaluation. Can pediatric bodies be laser sized so that scans could be made very specific to that individual?

How does TEPRSSC recommend that FDA ensure the reporting and other radiation safety features are available to all CT products? Work with NEMA. FDA might propose guidance or propose a regulation, and then let NEMA and MITA find solutions. Let smart people do the walking for you.

Define CBCT equipment. It's a form of CT that uses a tightly columnated cone-beam of radiation to produce 3-D dimensional volumetric image data of ENT, dental, and maxillofacial features.

Should FDA develop standards specific to CBCT? Yes. Although CBCT delivers only 2 to 5% of what a standard CT of the same anatomical area delivers, the dose is about 7 times that of a panoramic. So the dose can be significant.

Are there specific pediatric safety concerns? Yes. Size-specific protocols should be developed and used, since children have longer lifespans left to develop cancer than adults. Use of CBCT on children or adults should only be conducted after review of the patient's medical history and imaging history and a clinical examination and justification of the procedure.

And finally, what's the Committee's opinion on including features proposed for radiography and fluoroscopy? I agree with all of them that the FDA has laid out, and I particularly like small, medium, and large versus age range presets.

Thank you.

DR. LOTZ: Thank you.

Let's break for lunch, then, at this point. I believe the printed agenda says we would convene at 1:30. I want to move that up. And we will begin at 1:15, with the next FDA presentation. So we're adjourned for lunch. Thank you.

(Whereupon, at 12:30 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(1:26 p.m.)

DR. LOTZ: Let me have your attention, please, and ask folks to take their seats. I'd like to reconvene the afternoon session of the TEPRSSC Panel meeting.

Thank you. We are ready to continue with presentations by the Food and Drug Administration. Dr. Nabili is our first speaker this afternoon, and she will now present.

DR. NABILI: Good afternoon. My name is Marjan Nabili. I am a lead reviewer of the Mammography, Ultrasound, Imaging Software Branch at CDRH. I have a Ph.D. in electrical engineering, and I review diagnostic ultrasound submissions.

The products that I cover during this presentation are related to medical and nonmedical ultrasound.

FDA regulatory authority over radiation imaging products includes products that emit acoustic radiation. EPRC regulations identify four categories of these products. These are ultrasonic therapy, diagnostic ultrasound, medical ultrasound other than therapy or diagnostic, and nonmedical ultrasound.

The table from 21 C.F.R. 1002.1 shows these four categories of acoustic products and the reporting requirements. For the purpose of this presentation, we want to focus only on the EPRC product reports as outlined in 21 C.F.R. 1002.1

Ultrasonic therapy products are the ones used for diathermy or physical therapy. There's only one performance standard for ultrasonic therapy products, which is 21 C.F.R. 1050.10, which applies only to ultrasonic therapy products for use in physical therapy. Physical therapy products, also known as diathermy, are intended to deliver gentle, therapeutic heat to tissues. These are used for treatment of pain, muscle spasms, and joint contraction by heating the tissue to up to 40 to 45 degrees.

Diagnostic ultrasound products, these products use high frequency sound waves for

real-time visualization of structures in the body. They produce grayscale images for most soft tissues, such as liver, heart, and also they can be used in combination with Doppler to visualize blood flow. And also Doppler fetal heart rate monitors are used for monitoring the fetus, and bone sonometers are used to assess bone fragility. These devices have a long history of safe use, dating back to 1940s.

There are also medical ultrasound products that are not used for therapy or diagnostics. These products use high intensity focused ultrasound for ablating the tissues. These are -- these can be used for treatment of cancer, such as prostate tumors, or treatment of benign tumors, such as uterine fibroids.

Nonmedical ultrasound products use high frequency sound waves. These are used for pest repellents, industrial cleaning systems, and ultrasonic distance locators.

What are our concerns? Regarding the medical ultrasound, ultrasound energy has a potential to produce biological effects, such as heating of tissue or creation of bubbles in the tissue. Safety and effectiveness issues are considered during the medical device premarket review of diagnostic, therapeutic, and other medical ultrasound products. Regarding a nonmedical ultrasound, FDA has only received a few adverse effect reports for these products.

Current FDA approaches regarding the medical ultrasound is that the safety profile of medical ultrasound products is considered acceptable when they are operated based on their labeling so that the professional is trained, will follow the manufacturer labeling. Safety issues have been and will continue to be handled through medical device premarket regulatory process, as well as other medical device regulatory authorities.

So, again, this table shows the table from 21 C.F.R. 1002.1, indicate the recognized acoustic products and the reporting requirements. However, this table has been out of date and is not consistent with our current policy.

Medical device, regarding the current FDA approaches -- I'm sorry, regarding the medical ultrasound, is that since February 24, 1986, under the authority of 21 C.F.R. 1002.50(b), FDA has exempted all manufacturers and importers of diagnostic ultrasound products from EPRC initial and model change report requirements under 21 C.F.R. 1002.10 and 1002.12 if they have submitted a premarket notification, also known as 510(k), as required by the medical device regulations.

Regarding nonmedical ultrasound, there is a minimal benefit to the receipt and review of abbreviated reports of these products, given the absence of performance standards for these nonmedical ultrasounds and the limited evidence of safety concerns.

So what are the proposed approaches? FDA would like to update the reporting requirements under 21 C.F.R. 1002.1 to no longer require product reports, supplement reports, abbreviated reports, annual reports, test records, and distribution records for medical and nonmedical acoustic products. FDA believes the current reporting requirements and performance standards are an unnecessary burden and a source of confusion for these products. So this reporting is redundant for medical device premarket submissions. Also, there is no performance standard to consider when reports of nonmedical products are reviewed.

Also, FDA believes that the performance standard in 21 C.F.R. 1050.10 is outdated compared with more recent guidance documents and standards. So for all medical device ultrasonic products, FDA proposes continuing reliance on premarket medical device review of safety and effectiveness, using the guidance document and recognized consensus standards. Also, the premarket medical device review process permits an in-depth review of safety and effectiveness of the design, labeling, and performance.

The only disadvantages to limiting the EPRC reporting is the inability to track nonmedical ultrasound products, but we do not have evidence to support continued

tracking. All ultrasound device manufacturers would still be required to submit certain reports underlined here as 21 C.F.R. 1002.20, 21 C.F.R. 1003, and 21 C.F.R. 1004.

So our questions for TEPRSSC is that what is the Committee's opinion of the strategy of relying on medical device premarket review to address safety concerns with medical ultrasound devices and no longer requiring the EPRC product report monitoring specified in 21 C.F.R. 1002.1 and the performance standard?

Is the Committee aware of any nonmedical ultrasound device safety concerns that warrant continuing the EPRC requirement for abbreviated product reports for nonmedical ultrasound?

Thank you.

DR. LOTZ: Thank you, Dr. Nabili.

Questions from the Panel for clarification on this presentation?

Dr. Stein.

DR. STEIN: On the reporting, since there won't be any in the proposal to abolish that, would you keep your own and do it for yourself or, I mean, for your own department?

DR. NABILI: Okay. Let me show you this table. So based on this table, the companies who do have these products are supposed to send us these reports that are listed there, product reports. So we are asking that since we are already reviewing them through premarket when they apply to get the device to market, then they don't have to send us this report. But they still have to provide us reports of the MDRs and such regarding their products that I listed.

DR. LOTZ: I'm going to go here, to my right, to Dr. Lambeth.

DR. LAMBETH: Yes. On the nonmedical devices, and particularly the cleaners, is there a requirement for labeling of the hazards of putting your hands into these instruments?

DR. NABILI: These cleaning devices that I mentioned, they are used for nuclear -- what do they call it there? -- reactors and stuff, so they are not, the person is not involved. And another thing is that we don't regulate nonmedical ultrasound products. So I don't know about the labeling for the nonmedical products.

DR. MILLER: There is no performance standard for nonmedical ultrasound products, so there's no requirement from FDA for labeling.

DR. LAMBETH: But we require this premanufactured -- I mean, it -- there's a report, right? Is that what this -- maybe I missed that because maybe that's a medical part.

DR. NABILI: They're supposed to submit -- regarding nonmedical ultrasound, they're supposed to submit abbreviated reports for us annually.

DR. OCHS: Yes, so -- this is Robert Ochs.

So essentially what we're saying is we don't have a performance standard saying what this device should or should not have as labeling, or what the output should or should not be, but we receive these reports. And what the proposal is, well, we don't really have much to do with these reports, so maybe we shouldn't receive them and use our resources elsewhere. That's the general sense of it.

DR. LAMBETH: Yeah. I found that wanting on simple laboratory cleaners, that there's no warning on them. I mean, not that I'm afraid that people are going to be harmed by them running, but if the -- I mean, when you're cleaning something, it's not uncommon to put your hands into the bath. And it's a sure way to create arthritis in the hands and the joints, if you do this much.

DR. MILLER: You're more than welcome and you're certainly entitled to make suggestions for performance standards that you think FDA should propose or adopt.

DR. OCHS: Yeah. And getting into our question section, this would be a good one to say is there a safety concern for these products that we should be aware of? So thank you.

DR. LOTZ: All right. We'll go around the table this way.

Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

Quick question, where would the safety regulations and safety checks about electrical safety come into play, since they're putting these transducers with gel, cup and gel right on patients' bodies. Where is that taken into account?

DR. NABILI: So we use the -- during the premarket submission review, we look at the performance tests that they did. There's one IEC standard that we follow, that for the performance standard, that we look at their safety and how the transfers are performed in different situations. So I don't know if I answered your question.

DR. McCOLLOUGH: But electrical safety is in that --

DR. NABILI: They're -- also like the EMC performance standard that we look at. Other than that, we don't have a performance standard for these type of products.

DR. LOTZ: Mr. Keith. Oh, sorry.

DR. MILLER: I was just trying to clarify that for medical devices, the electronic product radiation control regulations and the medical device regulations, in large part, overlap. So electrical safety is something considered as part of the medical device premarket review, for all medical devices that have that capability of producing electric shock or electric hazard, independent of whether or not there's a relevant performance standard.

And what we're concerned with here, in terms of presenting to you, is primarily do we need to keep asking for reports from manufacturers that duplicate information we already get as part of our premarket review as a medical device, or for which we've found no real reason to be concerned because we've not had reports that suggest that they're unsafe if they're not medical devices.

MR. KEITH: Sam Keith.

These premarket reports that are submitted to FDA, I'm sure they have some value. I can't -- I don't understand whether these reports are just sent to FDA, and FDA puts them in a file or whether FDA does something as far as evaluating the reports and works with the manufacturer. What is that process?

And the second is, my question is the bubbling. Is the bubbling from boiling of bodily fluids, or is it from chemical reactions induced by the ultrasound that produces gases?

DR. NABILI: Okay. For the first question, the reports come in, but I'm not sure who reviews it. We don't. I don't think we do. I don't.

DR. OCHS: Let me clarify. The report, so the premarket reports, the medical device premarket review is a very structured, highly monitored process, highly -- you know, we have 90 days to review them. We have certain deadlines to meet. We work with industry, and we clear a device to ensure that, with our kind of clearance, that it's considered to be safe and effective. As a predicate for the EPRC --

MR. KEITH: What actually do you do?

DR. OCHS: Yeah. For the EPRC product reports, those are much more of a -- they're sent to us and they're filed. There's none of the same deadlines that we have with the premarket, and our actions that we can take on them are fairly limited, especially if there's no performance standard to say, you know, our regulation states you must do this. Well, if we don't have that and we receive a report, there's little we can do. So did that clarify the question or the difference between them?

MR. KEITH: Yes, it did.

DR. OCHS: Okay.

MR. KEITH: It's like is there actually a reason for having this, the periodic reports?

And it's like there doesn't seem to be any reasons, because if you don't have a performance standard to evaluate anything, it doesn't seem like there's anything you can or should do with them other than you have to put them in a file somewhere and it takes up space. Thank you.

And about the bubbles?

DR. NABILI: And regarding cavitation, yeah, so the ultrasound, when you apply, based on the frequency, the liquid can expand, big and small, and then they generate bubbles. So it is --

MR. KEITH: Microscopically, is that a boiling, a localized boiling of the --

DR. NABILI: No, not. It is local --

MR. KEITH: Or is it actually tearing the hydrogen, oxygen apart in the water molecule?

DR. NABILI: I don't know the hydrogen but I -- it is just a bubble; I mean, it's just the thing expand, then that in its location, it is --

MR. KEITH: What is the composition of those bubbles? They have to be a gas.

DR. NABILI: Yeah. It is just the, yeah, the liquid. But I don't know. It depends on the -- yeah. The bubbles get --

MR. KEITH: What do you get? Localized boiling.

DR. LAMBETH: I don't think you classify it as boiling. It's called cavitation. But it still, it generates the -- it evaporates the gas. It evaporates the water into water vapor, gas, so it creates the bubbles.

DR. NABILI: Yeah. In some -- in --

DR. LAMBETH: It's just mechanical turbulence.

DR. NABILI: In some cases, they use the contrast agent, and then they use this method to deliver drug and stuff for opening blood-brain barriers. So it is not something

that it is dangerous. In the case that the frequency is very high, these bubbles might be very big, and when they burst, they may damage the tissue, but not in the case that we are talking about here regarding medical devices.

DR. LOTZ: Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I had a specific question about the slide number 4, where you mention that therapeutic temperature range of 40 to 45 degrees C. I know you just said that this heating could be used to open the blood-brain barrier.

DR. NABILI: Cavitation, mostly.

DR. FARAONE: Oh, cavitation is used?

DR. NABILI: Yes. Yeah.

DR. FARAONE: Now, I was just wondering, since we deal with similar considerations for RF exposure safety, temperature rise, right.

DR. NABILI: That's true.

DR. FARAONE: So, in short, what are the limits in terms of temperature rise, and for how long can temperature rise be sustained in a safe manner when you use ultrasounds?

DR. NABILI: Sure. So when we are talking about the thermal effect is mostly we are looking at therapeutic devices, which use like high frequency or focus, high density focused ultrasound, that the heat will be in that section. So these diathermy devices are using that, a little bit increase of the heat, which is still safe, to change the tissue structure for removing of the pain and stuff. So it is still safe for this temperature to go above the body temperatures is 37.

DR. FARAONE: And my question was like what is the safe temperature and for how long? Like is there a temperature-time curve that you have to stay within?

DR. NABILI: It is. I believe it is.

DR. FARAONE: Okay.

DR. NABILI: For the diathermy products, I believe it is. And there is also these devices have the risk mitigation, that if like, you know, you are not ablating the tissue, that you don't need, or you turn off as you feel like the heat is so much. But it is safe. That's why it's been used for a long time, the diathermy.

DR. FARAONE: What kind of training do the operators have to undergo?

DR. NABILI: I'm not sure, but I'm sure the training is excessive, that they have to go through training to make sure that they operate the machine. These are not something that the patient use on themself. It needs to be trained for both diagnostics and therapeutic.

DR. FARAONE: Is the acoustic power emitted by these machines, has it been characterized so that under, let's say, normal conditions -- I suppose a normal condition could be defined as 20 degrees C ambient, with a patient without clothes in the region that's been exposed. So has the power emitted, in terms of acoustic power, been characterized so there is an assurance that temperature rise will not exceed certain levels? Is there a flattening of the temperature rise curve over time that can be expected based on, you know, science, scientific analysis of these processes?

DR. NABILI: Okay. I believe, in case of diagnostic ultrasound, it is. But I'm not that familiar with the therapeutic devices. But I'm sure in case of diagnostic, it is. And then in some cases, we see that like they test that if this goes above, what's going to happen. If like what are this, the --

DR. FARAONE: Do they test on phantoms?

DR. NABILI: Yes. They do test on phantoms.

DR. FARAONE: How do they take into account the blood perfusion that tends to cool down the exposed region in that case?

DR. NABILI: I'm not --

DR. FARAONE: Is it like a worst case?

DR. LOTZ: Dr. Miller, were you going to add something there, please?

DR. MILLER: I'm not sure I'm adding anything, but I'll say something. Diagnostic ultrasound, when used as designed, is very safe and, as you know, is used for fetal examinations in pregnant women. And there are guidelines as to how long that examination should last. But typically those transducers are not held in one place for long periods of time.

For diathermy, the transducer is typically moved back and forth over a portion of the anatomy for a relatively short period of time. Because it's designed to heat tissues that are deep to the skin surface, the skin itself doesn't get particularly warm. I've had these as part of physical therapy, and you don't really notice anything when it's used properly.

And I have never been trained in how to do this. It's mostly done, I believe, by physical therapists who are trained in how to do it. And I suspect that as part of the original process of developing these things, they've been tested in a variety of phantoms. But this technology is quite old. It's been around for a very long period of time, for decades.

DR. FARAONE: So you don't have any report of incidents?

DR. MILLER: No.

DR. FARAONE: Thank you.

DR. LOTZ: Thank you, Dr. Nabili.

DR. NABILI: Thank you.

DR. LOTZ: We will move on to our next FDA presentation.

Dr. Stein.

DR. STEIN: Sorry.

I just want to read -- this is from Nancy Evans, health scientist consultant in San

Francisco: "Ultrasound exposes the brain of the developing fetus to heat, vibration, and high intensity sound. Prenatal ultrasound is being performed in unregulated, nonmedical settings, shopping mall boutiques, selling keepsake sonograms. It is not a risk-free procedure, and women need to know that."

And there's other issues of health. I understand that it's not in the purview to talk about the procedures, but the devices, if they're not calibrated correctly, require higher energy. And most of them, you know, with life, degrade, and therefore they have to ramp up the power on the prenatal structures to be able to see the image. And there's really no oversight. It's a free game.

And I'm very concerned because in the years that we've followed the requirements, we've seen -- and, of course, you probably will not like to hear this, but autism has increased to exponential levels. And, of course, we can't say it's that, but if we're going to do the epidemiology to track whether it's that or not that, we need to be able to require that there is levels, and the quality control of the devices are being monitored to be able to monitor whether or not it is from that.

DR. NABILI: Just one note over that autism that you mentioned; there was one paper out a couple of months ago. And AIUM had a statement on that, so which proved that that study was not done right, on the right population, number of samples. So they disproved that, that it's not enough evidence for the number of diagnostics, that it affect the autism.

DR. STEIN: Right. And I agree that it may -- you know, the science of that particular study, along with the 50 other Chinese papers that have been peer reviewed and published, it may not be that. But do you know what it is? And unless we know what it is, we should take a precautionary procedure on children's health and, you know, do what we can to avoid and prevent any possibilities.

DR. LOTZ: Dr. Miller.

DR. MILLER: Just a very brief comment. Donald Miller.

We agree with you completely about keepsake imaging. We have published a safety notice opposing keepsake imaging. Medical diagnostic ultrasound devices are sold to be used on the order of a physician for medical purposes. And if you do a web search on fda.gov and keepsake imaging, you will find our webpage that says that as well. Once the device is sold, it leaves our control, but we strongly oppose the whole concept of keepsake imaging. We believe that the use of ultrasound should be ALARA, just as the use of ionizing radiation should be ALARA.

DR. STEIN: Just follow-up, do you feel that having no reporting then leaves it open for -- I mean, did that help provide at least a -- you know, a step, that there's some sense of, that people care?

DR. MILLER: We care deeply. Just to clarify, we're not talking about eliminating reporting. We're talking about eliminating reporting under the EPRC provisions. Medical device reports are still mandatory for all medical devices where there is a serious adverse event or death, or a malfunction that could result in a serious adverse event or death.

DR. STEIN: Right.

DR. MILLER: Corrections or removals are reported to the FDA.

DR. STEIN: But autism is a pretty serious -- and I don't think that we're able to report it because we don't know that it is. So it never gets reported.

DR. MILLER: Without getting into whether or not any particular stimulus is a cause of autism or not, any individual can file a voluntary medical device report with the FDA at any time.

DR. LOTZ: Thank you.

I think we're ready to move on to our next FDA presentation, which is by

Mr. Robert Sauer, on this question we've heard about some already today, on IEC standards versus performance standards for medical devices.

Mr. Sauer.

MR. SAUER: Thank you very much.

I'm sure it's not a shock to anyone on the Committee that I'm up here talking about IEC standards. I'm sure you've noticed a pattern yesterday and today, but in this talk I'm going to formally propose the policy for diagnostic x-ray systems and IEC standards. And then at the end, I'm going to ask you guys a series of questions about the benefits and challenges with this approach, your opinion on how effective this would be as a voluntary policy versus a mandatory policy, and whether this should be extended to other electronic products and medical devices.

And before we get into the details of the policy, I'd like to give some background on the IEC, or International Electrotechnical Commission. From what I've gathered over the last couple of days, I think several members of the Panel probably have more expertise in this than I do, but I don't want to assume that that's true for every member of the Panel.

So the IEC is a standards development organization whose scope is electrical, electronic, and related technologies. And so they have performance and safety standards for many of the products we've been discussing yesterday and today. From the IEC's perspective, these are all voluntary standards. Some countries have chosen to require conformance, while in the United States it remains voluntary. The membership is composed of about 60 full members and 20 associate members.

There's a detailed formal process for proposing, drafting, soliciting feedback, and approving new standards or standard amendments, and I just want to highlight a couple of the pieces here. The actual work of drafting the standards is carried out by technical committees, and a broad group of stakeholders participates in these technical committees,

and this includes industry members, academics, users or consumer groups, as well as government agencies. And then the final approval, as has been mentioned several times, is voted on by national committees. One other thing I'd like to point out is that many IEC standards are published with stability dates to ensure that they have regular review, and these are typically 3 to 5 years.

So now that we all have at least a basic understanding of the IEC, I'll start to get into the policy a little bit more. First I'll cover our current approach to the performance standards, point out some of the relevant IEC standards for diagnostic x-ray systems, review recent federal government-wide policy statements on the use of consensus standards, review in more detail the proposed approach for moving forward, what we believe are the benefits of this proposed approach, and some of the impacts it has on stakeholders.

I'd like to talk about the scope of this. I know with IEC standards, we've been talking about lots of different types of electronic products and medical devices. For this particular policy, we're talking about x-ray imaging devices. And so, as electronic products, they're subject to the EPRC regulations, which include performance standards, product reports, reporting of radiation-related adverse events, and defects. As medical devices, they must comply with good manufacturing practices. Many of the systems are Class II devices, which means they submit a 510(k) premarket submission. And there are also adverse event reporting more generally, not just related to radiation events.

So I've outlined our current approach to performance standards for diagnostic x-ray systems up here. There are four distinct sections in the Code of Federal Regulations that address different types of equipment. We have one for diagnostic x-ray equipment and their major components, radiographic systems, fluoroscopic systems, and CT systems. These performance standards includes things like control and indication of technique factors, the reproducibility of technique factors, display of air-kerma rates, and computed

tomography dose index. In addition to those, it includes information to be provided in the product labeling and warning statements that must accompany the product.

Manufacturers are then required to certify that their device complies with the performance standards based on a test procedure in accordance with good manufacturing practices. Once they've done this, they're required to submit product reports that include design specifications for radiation safety and related test procedures.

There are other requirements under the EPRC that I've mentioned before, like accidental radiation occurrence and notifications of defects, but they're not directly relevant to this policy, so I'm not going to go in any more detail on them.

Now I'd like discuss some of what we see as the limitations of our current approach to the performance standards. And the first is that, in practice, these performance standards are not updated frequently. There are different reasons for that, and one is the amount of time it takes. You can see the performance standards we're discussing here haven't been updated, in many cases, in a decade or sometimes much more.

A second limitation is that these are limited to radiation protection. Radiation hazards are not the only hazards presented by these types of products. Some other examples are mechanical or electrical hazards.

And a third limitation is that this is redundant information that the manufacturers are sending to FDA. I mentioned previously that many of the system manufacturers already submit 510(k)s because the medical device regulations apply as well. So they're submitting descriptions of their device, labeling, design specifications, and testing descriptions to the FDA twice, and we don't think there's value in receiving this twice or having them submit it twice.

So I've listed on this slide some of the IEC standards that we think are applicable to electronic products that fell under those other FDA performance standards for different

diagnostic x-ray systems. And you can see here, they get into more specific types of equipment. You have an entire standard for dental extra-oral, an entire standard for dental intra-oral, and an entire standard for mammography. And so in addition to being a little bit more specific to different types of devices, they are more comprehensive, too. They do address things like electrical and mechanical hazards.

So we at FDA have done an analysis of the standards I listed on the previous slide, and we've found that they do provide equivalent or improved assurance of safety. And I'd like to point out that it doesn't mean that it's identical. In many cases, it is. In other cases, they may be more restrictive or it may be less restrictive, and as has been mentioned in several of the talks today, they often address aspects that aren't addressed at all in FDA performance standards.

So we've done an analysis of the current state of IEC standards, and one of the benefits is that these IEC standards are updated more frequently than the FDA standards. And FDA is involved in this standards work. We actively participate on these IEC committees. And in my experience and in talking with my colleagues, and their experience, FDA input on these committees is generally well received.

And another point here is that IEC standard adoption isn't something that's automatic at the FDA. We have a standards recognition program where we do a serious, formal review of these standards before we determine to what extent we're going to recognize them. And this could be a recognition in whole, it could be a recognition in part, or we might not recognize it at all.

And so now I'd like to review OMB Circular A-119. This was brought up yesterday, I think. And so this deals with federal participation in the development and use of voluntary consensus standards and in conformity assessment activities. And I've highlighted, you know, one of the big statements right here, and it's that all federal agencies must use

voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.

There are other, a couple other aspects that I want to highlight. It states that agencies should work closely with standards development organizations to determine appropriate access to the standards for stakeholders. I know this has been an issue that's been raised by many stakeholders. It's something that FDA is actively working towards, figuring out how to ensure appropriate access to the stakeholders that need it.

OMB encourages agencies to work closely with the standards development organizations to ensure that the agencies are aware of, and able to consider, updates and alternatives to existing standards. And I think that's really covered by our active participation in many of these different standards committees.

And OMB recognizes that agencies may have good reasons for not using the most recent version of a standard. And that goes with our recognition program, that if there's something in there that we think is a safety issue, we're not required to recognize that part of the standard. And I think we heard yesterday, examples in the laser space, where we do have concerns about the safety and have not adopted IEC standards entirely.

So the proposal is to accept conformance with the IEC standards I mentioned in lieu of conformance to EPRC performance standards for diagnostic x-ray systems. We would consider a manufacturer that submits a declaration of conformity to the appropriate standards to have met certain EPRC standards and to have met the reporting requirements. I know there's been a lot of discussion today about IEC standards versus EPRC performance standards, and I just want to highlight that there is a second part to this policy about considering the reporting requirements met as well. We feel that this is consistent with the OMB circular.

So as far as benefits go, we think that conformance to the IEC standards would provide the same level of or improved protection of the public health and safety from electronic product radiation as certain EPRC performance standards do. And the reasons for this are that the testing for radiation safety stays current. We won't have standards that are from 1985 anymore. IEC standards are more comprehensive. They address hazards that go beyond just radiation. This would represent a convergence of radiation safety regulatory frameworks with the European Union and China. This would also reduce overlapping information in multiple submissions. As I mentioned, they submit this information in 510(k)s and EPRC product reports, and it would result in a lower burden on industry as well.

So as far as the impact on stakeholders, we think this is a positive impact on patients because equipment will be performance tested according to more comprehensive and modern safety standards. We think this is beneficial for industry because it would result in fewer submissions and is consistent with regulations in the European Union and China. At FDA, it would have minimal impact on our workflow. It will require training on new but pretty similar performance standards for our field investigators.

Some of the states have included EPRC performance standards in their state law and inspect accordingly. And we know that this policy presents challenges, and we want to continue to work with the states and other stakeholders to address those challenges. And so we're regularly in communication with CRCPD, and we hope to continue that.

And I know over today especially, we've heard a lot of additional challenges that some of the different stakeholders see, and I just, I want to mention those briefly and address them quickly.

So there was a question about what FDA would do if IEC standards conflict with current FDA performance standards. And we have run into that issue several times, and we

review the issue on a case-by-case basis. And if we feel that the IEC standard is more appropriate, then we accept the IEC standard.

There have been questions about what happens to old devices if a standard goes into effect that contains requirements for new features. In general, the performance standard that applies to any device is the performance standard that was in effect at the time of manufacture, so this wouldn't be retroactive to older systems on the market.

There were some comments about our transition time, and I think this is a really good point and that we need to continue our discussions with stakeholders like RCPD and AAPM to figure out what an appropriate implementation time would actually be.

There was some discussion about confusion with our recognized standards database, and I think that's something that can be cleaned up and clarified.

There have been questions about when more than one standard might apply, and that's not necessarily an issue with IEC standards alone. I think the example was provided this morning when you have a CT system that's used in radiation therapy, what standard do you apply? Does the 2-44 apply, or does something else apply? And that's not just an issue with IEC standards. I mean, you heard this morning with cone-beam CT and fluoroscopy systems, you know, we had questions about how to apply the performance standards.

There are questions where an IEC standard's acceptance values aren't clearly stated, and it's that the manufacturer must provide them. That's also the case with some of the current FDA performance standards, so again, that's not limited to the IEC.

And then there is a question about testing to IEC standards, and I'd like to point out that not every aspect of an IEC standard is intended to be tested regularly. Often there is overlap with the quality control procedures that would apply to a specific device. But we wouldn't expect that anyone would test devices to the entire IEC standard regularly.

And then lastly there was a question about, you know, whether you can trust these

declarations of conformity. And in general, we do. We've accepted the statements that they provide, that manufacturers have provided in their product reports. We accept as truthful and accurate the statements that manufacturers provide in their premarket submissions, 510(k)s, and we have postmarket controls to deal with issues where it may be not truthful or accurate, whether that's intentional or not.

And actually just yesterday, there was a -- they published the draft proposal for the Medical Device User Fee Amendments. And in that, there's a proposal for a pilot for accrediting conformance assessment bodies. And so for anyone who's interested, there's a public meeting on that November 2nd in the D.C. area.

And then lastly this policy that I've proposed here is outlined in a draft guidance document that is available for comment right now. The comment period closes November 1st, so I encourage anyone who's interested to comment there if anything doesn't get said here that you feel is important.

So, in summary, we're proposing to accept conformance with IEC standards in lieu of some of the EPRC performance standards for diagnostic x-ray systems. And we're doing this because we think that conformance to the IEC standards would provide the same level or improved protection of the public health. We think it would increase patient safety and decrease the regulatory burden on industry and that this is consistent with federal law and current policy.

And so just to review the questions that we have for the Committee, what benefits and challenges do you see in the proposal to accept conformance and declaration of conformity to applicable recognized IEC standards in lieu of conformance to FDA performance standards and FDA product reporting requirements?

How do these benefits and challenges change if the policy to accept conformance to these standards were implemented as a mandatory requirement instead of as an option or

voluntary for manufacturers?

And then there are other electronic products that are also medical devices but lack EPRC performance standards. One example that's been mentioned today is MRI systems. And if there are IEC standards for safety and performance for these products, how should FDA approach the implementation of new performance standards?

Thank you.

DR. LOTZ: Thank you, Mr. Sauer.

Since this is a topic that will obviously, I think, generate a further continued discussion, we've had quite a bit already, I want to ask you to limit your questions at the moment to specific clarification questions, and then we'll come back to this in the discussion.

Dr. Stein, go ahead.

DR. STEIN: Toni Stein.

When you say conformance, did you mean self-declaration or third-party recertification of conformance?

MR. SAUER: So as of now, it would be self-declaration. As I mentioned, there is a current proposal in the Medical Device User Fee Amendments, and that would apply here since these are all also medical devices, to set up an accreditation program for conformance assessment bodies. And so if that was something that we determined was necessary to have that extra confidence, that could be something that's implemented. I don't think we can say for sure that we think the extra confidence is needed right now.

DR. LOTZ: Mr. Keith, brief clarification question?

MR. KEITH: Sam Keith.

You're talking about complete conformance, and yet some of the other information addresses complete or partial conformance. What's the difference here? Are you aiming to

say you'll comply with everything? There are statements that said you may not agree with certain aspects of it. So how do you completely conform and yet want to not completely conform?

MR. SAUER: Good question. So I should clarify that that's complete conformance to the currently recognized version of the standard, the current FDA recognized version of the standards. And so through our recognition process, we review the standard, and we publish in the *Federal Register* the extent to which we recognize that standard, and we would call out specific sections that we don't accept conformance to, if that were the case. And so we would expect conformance to the parts that we've recognized.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

To go through this step of reviewing the documents carefully and deciding which you accept and which things you don't, and then putting out guidelines and that, do you have an estimate of how much that would actually decrease the current workload for the FDA?

MR. SAUER: In terms of?

DR. McCOLLOUGH: It seems like it might increase.

MR. SAUER: Oh so, I mean, we already review these standards. Most of them are already on our standards recognition database. We're pretty familiar with them already because of our participations in the standard development. So on that side, that's already something that we do regularly. And then, on the -- I'm not sure if you're talking about the receiving reporting side of it, but that would have little to no impact.

DR. LOTZ: And Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

I was wondering whether you have a requirement for an annual report. You mentioned annual report on Slide 7. Why is there a requirement for an annual report?

MR. SAUER: So there's just different documentation that manufacturers are supposed to provide in annual reports as opposed to an initial product report. That's outlined in the C.F.R. I think it contains information about sales volumes and issues that they've seen with product performance.

DR. FARAONE: Okay. Regarding the OMB circular, you write that OMB encourages agencies to work closely with SDOs. And somebody correctly pointed out that it's expensive to go to these meetings, right. And I know for a fact that FCC sometimes, toward the end of the fiscal year, they run out of money, and sometimes they have to miss some meetings. So I was wondering if -- I mean, this recognition is also supported by funds, to support travel.

MR. SAUER: Yes. We do have funds that support travel, specifically for standards development at FDA.

DR. FARAONE: Okay. Thank you.

DR. LOTZ: Dr. Miller.

DR. MILLER: Thank you. Donald Miller.

I just wanted to clarify something that perhaps wasn't clear on the basis of Dr. McCollough's question. By law, CDRH has established a standards recognition program. We are required to recognize those standards which are relevant for purposes of premarket review, and to allow manufacturers to conform to those recognized standards and thereby demonstrate safety. So this is not a new concept. What we're talking about is applying it in lieu of electronic performance standards. But it's already in place for medical devices.

And we publish twice a year, in the *Federal Register* and available online on our website, a list of recognized standards. And we already go through all of the relevant standards and review them and decide whether or not to accept them in whole or in part or not at all.

DR. LOTZ: Thank you.

And thank you, Mr. Sauer.

I believe this concludes this particular portion of the session. We will now proceed with the Open Public Hearing of the meeting. Public attendees are given an opportunity to address the Panel, to present data, information, and views relevant to the meeting agenda. Commander Anderson will now read the Open Public Hearing disclosure process statement again.

CDR ANDERSON: Good afternoon. Both the Food and the Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking. Thank you.

DR. LOTZ: For the record, we have received three requests to speak at this afternoon's public session. We ask you to speak clearly to allow the transcriptionist to provide an accurate transcription of the proceedings of the meeting, and the Panel appreciates that each speaker remain cognizant of your speaking time.

The first speaker, I've been informed, is Jamie Wolszon, here on behalf of AdvaMed, if I understand correctly.

MS. WOLSZON: You do understand correctly, thank you.

I just wanted to say thanks to everyone for allowing me to speak. I think this is a really important topic, and I'm glad to be here.

So for those of you who are not familiar with AdvaMed, it's the Advanced Medical Technology Association. I'm Jamie Wolszon of AdvaMed, and we represent many of the manufacturers who are being discussed about today. It includes ones that are transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatment, and it ranges from the smallest to the largest and, relevant to today, includes those that manufacture imaging and radiation therapy devices that are being discussed today.

And in my remarks, I wanted to particularly cover two topics. One is what Mr. Sauer just discussed. It was sort of a perfect lead-in. You'll notice a lot of the material that he was talking about I'll also be covering, the IEC versus performance standards for medical devices, and also from this morning, the specific question of performance standards for radiation therapy devices.

So I wanted to touch on the importance of voluntary international consensus standards. I think a lot of this has been said before, but I still think it's very important to reiterate, that it has many benefits, including that it furthers efforts to harmonize global medical technology regulation around the world, that it introduces efficiencies, both for FDA and the device industry, that it can minimize unnecessary costs and delays in patient access to innovative new devices, and that there is an open process. We've discussed some of the challenges with that, but it is an open process that encourages participation by a broad group of stakeholders in the development of standards, including FDA and academia and industry. Yes, there's a lot of us there, but -- and perhaps it could be -- you know, you can always have even broader participation, but I think it really is a very open process.

And one thing that I don't have on my list, but is very important, has been discussed multiple times today, is just how frequently the international voluntary consensus standards can be updated, as opposed to the time, you know, sometimes that it can take in terms of the EPRC regulations.

Again, there's been recent discussion of OMB A-19, NTTAA, which basically codified OMB A-119, again repeating the importance of directing agencies to use standards developed or adopted by voluntary consensus standard bodies rather than government-unique standards, except where inconsistent with applicable law or otherwise impractical. It recognizes that there are instances where it might not be consistent with law or otherwise practical. And it also mentions, which I haven't heard discussed today, that if the agency does decide in those instances to create government-unique standards, that the head of the agency or department is supposed to provide OMB with an explanation of why it was that they did so. And NIST has a role in tracking that information.

So turning to the draft guidance that Mr. Sauer was just discussing, AdvaMed applauds this general concept of substituting conformance with specified IEC standards for compliance with the performance standards established by the FDA for EPRC, 21 C.F.R. Part 1000, Subchapter J. And we've heard earlier and we agree wholeheartedly that there is need for careful implementation, that it's important that it be done right, although Mr. Sauer got to some of the ones I was going to mention, for instance, transition times.

We heard discussion this morning of what you do when there is multiple FDA recognized standards. These, I think, are all things that, with careful and well thought through implementation, can be resolved.

And speaking to radiation therapy, we also think that -- we had mentioned that there isn't an EPRC performance standard for radiation therapy, that this is something where this concept could be extended to additional technologies, such as, in particular, radiation

therapy, which I just wanted to mention a little, which is that I think this is a perfect opportunity to use this approach and extend it to radiation therapy because there are high-quality IEC standards related to radiation therapy.

Oh, and one other thing I wanted to clarify, and it's been said a little bit, but I think it's important to stress, is that there isn't an EPRC regulation for radiation therapy, but FDA very much regulates radiation therapy. Both in the premarket space, in terms of 510(k)s, and also in the postmarket space, they are subject to QSR 21 C.F.R. 820. They are subject to -- Dr. Miller mentioned 803 and 806, corrections and removals and adverse events. Well, I just flipped them, but you know what I'm doing there. You know, they have to establish a registration listing, which will trigger inspections. So I just -- I think it is important to remember that it's not as if these products are unregulated.

So there are high-quality IEC standards related to RT. There are also other high-quality international consensus standards that are relevant to RT, for instance, some of the ISO process-related, cross-cutting risk management or quality systems type standards. You had mentioned the ISO 1300 series and the 9000 series, you know, on the risk side. So that's also something to keep in mind.

And the other thing I would like to talk to this Committee about is that AdvaMed, in conjunction with SDO AAMI, has been working to develop a standard that we affectionately know as RT2, to address certain issues that are not covered by IEC standards, and this is really just a way for me to hand this off to Stan Mansfield, who is the next person on this. I will return for clarification questions after he has spoken, but a lot of -- otherwise I might just say, ask Stan. So I'm going to have him speak first. But he has -- we've made some really good progress on this standard, and we're really excited about it. And with that, I will introduce Stan, and I'll be around.

DR. LOTZ: And we'll move to Mr. Mansfield as the next speaker.

MR. MANSFIELD: Thank you for having me.

So by way of introduction, as you can see, I am employed by Varian Medical Systems. I am the Director of System Safety and a member of the Medical Affairs team there. I've been in the industry for 38 years, most of that in engineering, research and development management, and product management.

I want to talk about some of the applicable consensus standards in radiation therapy. I want to talk specifically about some standards that are being developed jointly by AdvaMed and AAMI that are targeted in radiation therapy and some of the advantages of consensus standards.

We've talked a lot about performance and safety standards of the equipment, but probably the most important standards affecting the safety of medical devices are actually what I would consider process standards. They're things like 13485, 14971, that talk about quality systems and risk management. And these standards are not only recognized with the FDA, but they work quite well in concert with the 21 C.F.R. 820, the QSRs.

Specifically, that includes things like the software development and usability, 62304 and 62366. So all of these affect the quality of the product by controlling the process by which that product was developed. And they're all part of the premarket approval process, and they're also subject to ongoing inspection by the FDA.

You've already heard a lot about some of the applicable standards. I'm not going to belabor them. I've only listed a subset of the ones that actually directly apply to radiotherapy. But of note, you've heard before, a lot of these standards are for individual subsystems. So, for example, a linear accelerator falls under 601-1, a medical electrical device. It also falls under -2-1, which is the particular standard for the medical linear accelerator.

Most of the medical linear accelerators sold in the United States include image

guidance, kilovoltage, typically image guidance on the device. That is a separate standard. And these standards work in concert with each other because they were developed by the same subset, a same working team in the IEC.

There is also standards for gamma beam equipment and for light ion beam equipment and brachytherapy and so forth. And they're all a part of this -2 series.

There is also particular IEC standards associated with the software devices. And Dr. Miller made a comment, which I totally agree with, in that in the area of radiotherapy, the large majority of the issues we're seeing have to do with the design of software. The number he quoted about 80% is consistent with our experience too, that roughly 80% of the medical device reportable events that we've seen have been related to the development of the software and particularly the usability aspects of the software, use errors that better software design can reduce or mitigate. So I definitely would agree with that notion.

The main thing is the IEC standards, as you've heard, are continually evolving. When I entered this industry, the standard was hanging big lead blocks on the end of the machine to shield the radiation. The treatment plans were done with simple contours, two-dimensional treatment planning. That was the standard, the state of the art. That was after the Good Manufacturing Practices Act but before some of the IEC standards actually existed. So the very first particular standard developed by the IEC was the linac standard, -2-1. And that was the environment in which that standard originated.

In the 1980s, we started seeing multileaf collimators and CT scanners being used in radiotherapy. In the '90s we saw IMRT coming online. And as these technologies came in, the standards evolved. In roughly the 2000 time frame, we saw image guidance coming into radiotherapy, volumetric modulated arc. All of these technologies have been, have enhanced the capabilities and safety and effectiveness of radiotherapy, and they've been rolled into the standards where it's appropriate.

I'm going to talk a little bit about some of the specifics. I got this slide from Alan Cohen, who is the Chair of 62C, and it talks about some of the specific things that are going into the fourth edition of the linac standard. As he puts it, the linac is no longer a dumb machine, that radiotherapy is a complete process, from treatment planning, through treatment management, to delivery of the intended course of therapy.

And the linear accelerator, in the earlier versions of the IEC standard, was still -- it still reflected the origins of that standard where the machine was simply being manually programmed by the therapist. That is certainly not the current state of the art. So data consistency checks, and basically the linac has to make sure what the plan it's receiving is actually consistent with what was approved by the physician to treat.

There's a number of performance things that are being added, for example, dark current. If the beam is held or gated off, then you want to limit the amount of unwanted radiation in that event, for example. Accuracy of the mechanical motions during a trajectory, so a lot of the techniques are now quite sophisticated, where things are moving, and there's a series of control points in which you're basically guaranteeing that the dose is going to be delivered in a series, you know, a roadmap of sorts. And this speaks to the accuracy of both the mechanical and beam delivery between these control points.

The stability of the reference frame, external monitoring devices, another interesting one. The linac standard has dual dosimetry built into the standard. In other words, inside the machine, there are two separate ion chambers that have to independently measure the output of the machine, the uniformity of the beam, and the symmetry of the beam. But there are a number of external devices that could also be used for dosimetry purposes. And this is, you know, sort of this interconnectivity world that we live in, so extending the standard to pick up those kinds of devices and make sure that the machine appropriately can respond to them is part of this new standard development.

And improving the interface requirements for data, so the machine -- because it's a smart machine, it receives a treatment plan. It knows this is what I'm expected to deliver. It also knows what it actually delivered, log files and so forth. And that information is retrieved as part of the medical record. So again, recognizing the current state of the art, the standard is continuing to evolve.

Alan actually mentioned latency, so for example, in some of the techniques that are being used, the machine is responding to direct stimulus, for example, respiration of the patient, and the beam is being gated on and off. There's even experimental techniques, not currently cleared, for the tracking in real time. And so system latency becomes an important part of the performance of the system in that case. Imaging doses is being added specifically, and some other details.

The main point here is that this standard is growing substantially. The current draft is at 100 pages. So it's a pretty substantial rewrite to the standard. The point here is the standards do evolve as the technology evolves and, you know, there's active participation on the part of the FDA.

I also want to talk about some other consensus standards that are being developed through AdvaMed and AAMI. Pretty much all the major manufacturers have been involved in these pieces. The key piece of one is RT2, and I'm the chair on that working group. The origin of that standard was what was called the Radiation Therapy Readiness Check Initiative, which is issued jointly by AdvaMed and MITA as part of an FDA public meeting in 2010. It basically -- a promise that industry would incorporate certain safety features based on things that were learned at that point in time. They were a pretreatment quality assurance check, a verification of beam-modifying devices and patient positioning confirmation.

And these initiatives were brought about in specific response to things that had been

learned, specific events, some of them quite serious that had been reported in the press, and things that had been learned through a search of MDRs. The reason for bringing this in as an actual industry standard is, okay, the manufacturers did things, but how is the user going to know what was done other than, you know, what advertising the manufacturer puts forth? There was no standard for defining how this thing was going to be checked or declared, and there wasn't specific requirements necessarily, and there wasn't anything talking about essential performance and safety in the implementation. So that was the impetus for creating a consensus standard around this.

The approach that we took, because of the diversity in the technology involved in the industry, was that there were basic requirements, and that the actual detailed implementations were then to be spelled out by the manufacturer to explain how they met the standard, and it basically is a tool to the clinical community to make buying and use decisions. And it heavily leverages the existing standards. In fact, it uses IEC and ISO standards as normative references. In other words, it says you don't comply with this standard unless you also comply with 14971, for example, or the IEC particular standards.

The three pieces: Again, the first was about QA. Of all of the medical device reportable events that we saw at that point in time, the serious events, in every one of those cases, the machine did exactly what it was told. The treatment plan information that the machine received was very inconsistent with the physician's intent and, in fact, had somehow gotten messed up. The machine did exactly what it was told, and what it did was very seriously wrong. And that's the thrust of what we're trying to get at.

So, first and foremost, we wanted to enforce a QA check that a qualified medical physicist -- that's the term we're using in the standard -- is involved in the QA of that plan before the beam comes on. And the beam won't come on unless that physicist signed off. So that's the underlying thesis behind this QA check piece.

The next piece was that beam-modifying devices be verified. The IEC standard, as existed, included beam-limiting devices internal to the machine, like the jaws and the multileaf collimator, but there are third-party accessory devices that were added on. I think there were some questions by the Committee about accessory devices. So this was a case where that kind of device fell through the cracks of the IEC standard at the time.

And so we explicitly require now things that would -- to be interlocked, independently, even of the treatment management system. If the treatment plan calls for, for example, radiosurgery cone, and that radiosurgery cone requires certain jaw settings, that independently of what the treatment plan calls for, it's going to interlock based on the fact that it now knows, I have a cone, and I have a certain jaw setting required for that cone, because that's exactly what happened in some of these cases. The treatment plan got changed, and the jaws were opened up beyond the settings that were compatible with this third-party device. And it goes into specific technologies that are available and the advantage and disadvantages of some of those technologies.

The last piece had to do with patient identification. One of the most common things that we're finding is Mr. Smith was treated to Mr. Jones's treatment plan. And when they both are prostate plans, it's pretty hard to tell the difference, but it's clearly the wrong patient. And so this one specifically goes into requirements for verify patient setup, accessory devices that are associated with patient setup, and specifically the identification of the patient.

This, it's currently in a final draft. It's had pretty extensive comment and participation from stakeholders, including the CDRH, ASTRO, and AAPM, two major rounds with ASTRO. That was the multidisciplinary QA subcommittee was the group that we referred to. And AAPM, we went through the Therapy Physics Committee. But also add that Bruce Curran, who is the current chair of AAPM, was an active member in this

committee.

We literally received hundreds of comments, and all of those -- because, you know, AAMI is an SDO, all of those are either incorporated or have been addressed formally. It's currently in final draft stage.

RT3 is a little earlier in the process. It's more of a down-in-the-weeds technical standard about developing a mechanism by which a machine and say other devices, like a treatment planning system that requires certain information about that machine, can share information for the purposes of modeling, beam modeling and things like that. It's much earlier in the process. It's currently in kind of a pre-draft stage. So, but that's another example of a RT-specific standard that doesn't fit within the existing IEC.

Again, the existing IEC standards are reasonably comprehensive. They're regularly updated. The FDA actively participates in the IEC committees. The FDA can and does recognize these. In fact, all of the applicable radiotherapy standards in the IEC are currently recognized by the FDA.

DR. LOTZ: Please --

MR. MANSFIELD: And the FDA is always free to recognize other consensus standards.

DR. LOTZ: Please note the red light.

MR. MANSFIELD: And I'm --

DR. LOTZ: You've used up your time.

MR. MANSFIELD: -- just now finishing up.

DR. LOTZ: Okay.

MR. MANSFIELD: And again, the FDA is also welcome and freely able to provide guidance. And the industry actually encourages that. So on that note, I'm done.

DR. LOTZ: Thank you, Mr. Mansfield.

I think, in the interest of the available time, we need to move on to our other speakers. Mr. Cohen has asked to return, spoke this morning.

You have 3 minutes.

MR. COHEN: Thank you.

I took some notes this morning and just wanted to clarify a couple points. First off -- and I am speaking for myself, even though AAPM paid for me to come here.

On the 62C, Working Group 1, Linac Committee, I'm going to agree with what Dr. McCollough has stated. Working on the linac standard right now, there are three people with clinical -- meaning they practiced in the hospital -- background; two of them are from companies with regulatory experience; and then the other eight are industry engineers.

So at the international level, it is, because of the money, highly dominated by the industry. Along the same notes, because I've seen it a couple of times now, about FDA involvement, within the same working group, there has been somebody from the FDA at the last two U.S. TAG meetings, but I have not seen a participant at the international level within that working group since I've been on the Committee, which has been 8 to 10 years now.

There was a comment made that if they claim compliance, the FDA can do something. Well, that is true, because I know of a couple of systems out there that don't claim compliance to certain standards and therefore are not held accountable to them and have gotten through the system.

I want to make the correction; AAPM doesn't have standards. They produce task group reports, which are recommendations to the clinical physicists on how they should use the equipment or test the equipment for whatever it is they're doing on the clinical side.

And with that, I think that'll be it except for the comment I heard about the low risk of using one vendor to do the whole kit and caboodle. And I personally refer to that as

bowing down and praying to the black box. It is specifically why we have medical physicists in the clinic, is to not assume anything and try to make sure that it's all working. I wish that the site I'm now helping provide coverage for had one full-time diagnostic physicist, let alone five. I think we get one coming in four times a year for a day to do the QA. That's about it.

And with that, thanks for letting me have the extra time.

DR. LOTZ: Thank you, Mr. Cohen. And we have one additional request for a speaker. I understand Ms. Young?

(No response.)

DR. LOTZ: No. Are there any other requests to speak?

Okay. Come on up and introduce yourself. You have 3 minutes.

MS. GEORGE: Thank you.

I'm Elisabeth George. I'm with Philips, and I'm the Vice President of Global Regulations and Standards, with more than 30 years working in the medical device industry.

First, I want to thank the FDA for coordinating this meeting and for their presentations and also for their recognition of the OMB Circular A-119. I first want to just touch on a couple of quick points. I'm going to try not to spend too much time on any of them.

Firstly, I want to say that I support MITA and AdvaMed's presentations earlier today. Philips actively participates in both of those industry organizations. We also participate in ANSI, AAMI, IEC, and I have global representation for all of those.

There was a comment made earlier by one of the gentlemen at the table, I forget who, that about the big stick with regards to standards compliance. There is a huge big stick. As a medical device company selling around the world, we can't get into most countries unless we have proof that we comply to those standards. We have to have our

products tested at a 17025 lab. We have to have that data. We have to have it in place. And as John said, if we make the statement of compliance to that and we don't comply, they come and get us. We don't get a free ride on that.

We do declarations of conformity. We do attestations to these documents, and we identify the scope at which we recognize them. We, many times, include standards that are not specifically recognized by the FDA, hopefully in support of getting them to look at those standards for the future.

Many of the standards do include conformity assessment requirements across the total product life cycle. So that includes things that we have to focus on for testing for components, for subassemblies for our systems, and also things that need to be continuously monitored as part of maintenance and quality assurance. So those are important things that we're looking at, trying to expand that. I'm a member of the U.S. National Committee, so I have a strong voice as one of three people in the medical industry that sit there, and really try to drive the U.S.'s position on these things.

There was also a comment about the siloing of standards being developed. It's definitely not a silo. Anytime a new standard is considered, it's presented, it's discussed. There is a plan that each of the different organizations and committees have going forward. But one of the biggest drivers behind it is issues. Safety issues are a big driver. General priorities and so -- and bandwidth; there's only so much bandwidth that can be done.

The recognition program that the FDA talked about does allow for the recognition of the standards. But one of the things that was mentioned was partial or total. That does mean that they can use deviations or guidance documents.

So I want to thank you very much for the time, and boy does that go fast.

DR. LOTZ: Three minutes goes very fast. Thank you for sticking to it.

MS. GEORGE: Any questions?

DR. LOTZ: Does the Panel have any questions of any of our public speakers for this session?

(No response.)

DR. LOTZ: Hearing none, thank you again to the public speakers.

It's time for our afternoon break. I see my phone saying it's 2:52. So we'll convene again at 5 minutes after 3:00.

For the Panel members who are needing transportation or planning transportation later this afternoon, please see AnnMarie Williams at the break to coordinate -- we've been using the word "harmonize" that perhaps fits here -- if you need transportation to the airport. So please see AnnMarie Williams about that during the break, and we will reconvene in about 12 minutes. Thank you.

(Off the record at 2:52 p.m.)

(On the record at 3:10 p.m.)

DR. LOTZ: Let me have your attention, please. Let me have your attention, please. Ask members of the audience to take a seat, and the FDA staff, so we can resume the session. We'll resume the last session of this TEPRSSC meeting. This is a time for Committee Discussion. In contrast to yesterday, I want to assure the Committee members that we will end, as the agenda calls for, at 5 p.m. I realize many of you have urgent need to leave at that time anyway. So I would ask you to make your comments succinct and direct.

We want to deal with the questions that FDA has asked us to deal with. And I would call your attention first to those things related to the speakers at the table before us from this last session. So I will open the floor for discussion to that effect.

Dr. Stein.

DR. STEIN: The place I'd like to start is on the conformance issues. I want to just

caution that self-declaration is sort of risky because, you know, of course, everyone wants to pass tests, right. And self-declaration can be problematic when you have to grade yourself. So, but in addition to that, it's not only that. It's not just, you know, how you grade yourself. It's a question of inclusion of oversight, and from a different perspective, that plays into this, especially those that are with public -- with credentials, that they come with proper training to make those decisions of compliance.

So you have to remember that for the last years, there has been no -- it's been internally done. And so this is going to be a change in venue. And as I brought up with C95.1 as an example, that's an example of -- as I brought up, it's an ANSI standard. And I believe that it became -- or that it was formed as an ANSI standard particularly for that purpose, and that to comply, the compliance process has to be certified from a third party because of commercial term issues.

If you just pick IEC only, one business in which, you know, we're -- as our government is just supporting one business, commercial terms come into play. And therefore it's a process in which once you get the ANSI standard, and then you have SDOs complying to that ANSI standard, you no longer have that commercial terms problem because it's open to NRTLs, any qualified national body like UL or Intertek, in terms of other standards.

But another analogy is, as I brought up, NFPA, the National Electric Code, which similarly is commercial business, get their standards. Whenever it requires compliance, it has to go through an NRTL like UL or Intertek or others. And it's not just only an issue of that oversight, but it's also ability to create businesses and allow more business enterprise, innovation, because there's competition between Intertek and UL and other SDOs that do compliance, and that's important, I think.

That's it.

DR. LOTZ: Thank you.

Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

Regarding your very last question, whether the Committee's aware of any nonmedical ultrasound device safety concern, while I'm not aware of safety concern, but I know that there are some startup companies considering using ultrasounds for wireless power charging of devices. So that could, if those products really, you know, hit the market, maybe that's something you might consider.

DR. NABILI: Thank you. Thanks.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Yes, Bill Irwin. Thank you.

So I'm trying to get a better sense of all of this, and I was telling someone I just now feel like I really understand where I should have been yesterday morning. But I appreciate all the effort over the last 2 days to educate me.

So I have a series of questions. The first is are there experiences at other agencies? I am glad to reference the Consumer Product Safety Commission; I'm somewhat unsure about referencing the Federal Communications Commission to meet the Office of Management and Budget Circular A-119, and they had experiences that might be beneficial for FDA in taking on this, including whether it might infringe on states' rights.

I see, for example, that this is all federal agencies, but if there is incorporation by reference by the states because they are relying on FDA, and then FDA is incorporating by reference IEC or other standards, but nobody's really presenting the public with the transparent regulations that they can read for themselves and understand what their government is doing for them, I'm a little concerned that we're getting so far from the goals of government in the United States that we do have the federal government pushing the

states someplace that they might not like to be, and some states may clearly object to that.

And then finally -- well, actually two more points. The question about is there a part of your plan -- I want to confirm this -- that you will always adopt by reference with exceptions and additions, or do you expect that you'll simply adopt whole?

And then lastly, what's the experience of FDA adopting IEC standards, which you have done for some time? So there's a lot there, but they reflect a lot of the concerns that I have as a state representative, state government representative.

MR. SAUER: Sure. And thank you for those questions.

In regards to the first point, about learning from other federal agencies and their experience with OMB A-119, I'm not aware of other agencies' experiences at this point. It's a relatively new document, at least in terms of compared to our movement towards international and voluntary consensus standards. And so I think we would definitely be happy to learn from other agencies who do have experience with that.

And there was another comment about having documents available to the public so that they understand what is being required of manufacturers. And yesterday, the idea of summary documents was brought up. And, you know, I think that's a good idea. I think there are discussions to be had about who would most appropriately develop those documents, for transparency purposes, and then also trying to decide what information the different stakeholders actually need. I know we've heard a lot of comments from different stakeholders about the needs for these standards, and I think that we need to determine which parts the different stakeholders actually need.

For example, investigators may not need the entire standard every time they go on a on-site. It's possible that maybe all they need are test procedures. And that's just one example, but we're working with CRCPD and other stakeholders to better identify what access and what information they need in order to fulfill their purpose, too.

And the last question --

DR. IRWIN: Yeah. That was about whether you will, generally speaking, always adopt with some exceptions and additions, or is it more likely that you'll adopt whole? I think I know the answer, but I'd like to hear it.

MR. SAUER: Yeah. So it's really hard to say what we would do in the future. It really depends on what gets put in the standard. If it's something that we think is in conflict with public health and safety, then I think we would have exceptions there. It really depends on what goes in the standards.

DR. IRWIN: I understand. Thank you.

DR. LOTZ: Dr. Miller.

DR. MILLER: Donald Miller.

First, the OMB circular goes into some detail about the concept of being reasonably available, in terms of standards that are incorporated by reference. And we certainly have the intention of making those standards that we incorporate by reference reasonably available. How that will happen, we don't yet know. The CDRH standards program is trying to work through that now. I'm not sure that any other federal agency is any further along since this came out in January. But certainly there is the intent that it should be reasonable. And that's one.

The other is that FDA has no intention to cede its regulatory responsibility to anybody else. Whether we adopt a standard in whole or in part or with subclauses or without subclauses will depend on the standard, but there will be FDA review of any standard before we decide whether or not to adopt it. And if there are parts that we think are not appropriate, we won't adopt them. But we will review everything that we subsequently adopt before we adopt it.

DR. IRWIN: Thank you.

DR. LOTZ: Mr. Murphy.

MR. MURPHY: One of the issues that's troubled me on this, Dr. McCollough brought up, and I believe a gentleman from FDA, I don't know if he's past or present, yesterday brought up, and that is the sometimes domination or majority of people being industry representatives. But this is a consensus body, and so does that not mean that everyone has to reach a consensus? All the objections have to be met before, I guess, a unanimous vote is taken? And so a single person of, you know, having problems can have those problems addressed. I wondered if you could talk about that, Dr. McCollough.

DR. McCOLLOUGH: Absolutely. And there are many, many committees, working groups, maintenance teams. And so my comments reflect my experiences over the past 15 years, and others may function differently than this. But it has been my experience that we don't take votes. We often come to an impasse, and somebody says can we just vote on it? No, we can't vote on it. We have to come to consensus.

But there becomes a process, just a social process, that you have 3½ days to get a certain amount of work done, and things come to an impasse, and eventually someone loses. And we don't come to a complete consensus. But the methodology just tends to work out that the majority speaks the loudest. And in my case, that has always been the manufacturers.

And I'm pretty stubborn and stand my ground and still --

MR. MURPHY: Well, good for you.

DR. McCOLLOUGH: -- don't get it.

MR. MURPHY: Good for you. I mean, any process involves compromises, and nobody gets their way all the time. Have you ever felt that they made a completely wrong decision, and this is an outrage, and that type of thing? Or is it just, well, I would have liked to have it this way, but I guess I can live with it this way?

DR. McCOLLOUGH: Again, Cynthia McCollough.

A great example is when I first joined. I joined because I made enough noise about something and hence finally was invited to join. It was in the first days of multi-detector CT, where they had multiple rows on Z, and so things went faster. But you still need the same x-rays to get the same image quality and the same noise. So the amount of dose, the energy per unit mass was no different. But in a very small group of the maintenance team at that time, to reflect the speed and the improvement of this new technology, which was four times faster, they took the CT dose index, which was well defined in the literature, in regulatory, and divided it by four because we cover four slices at once.

And when we got wind of this, I reached out to my colleagues at what's now Public Health England and in Germany and several other people that I knew. And we all said, this is a travesty. You can't just divide the dose by four. You can't do that. You can't redefine this. We had no effect. And they said, sorry, we're doing it. And at that point, I did reach out to Orhan and made lots of calls and found out how do you get on this organization, because they're doing wrong science. They're giving misinformation. It's just wrong. And it took me joining and being at the table and being quite stubborn to get that reversed.

And so it happens. I think that we are -- the AAPM is and the FDA are much more involved players now than we used to be because we saw the writing on the wall. We saw that what IEC did was not just going to stay in Europe. It was going to affect the U.S., and we needed to be at the table.

But still it's the manufacturers who are mostly at the table because it's the cost of doing business to pay for those reports and to pay for the people to travel and to pay for their dues. I'm an academic and a clinical physicist. It's not the cost of my business. Lucky I come from an institution that allows me the freedom to do this and supports it, and the AAPM supports it. But we're the minority because of the financial situation.

DR. LOTZ: I was going to just chime in, in terms of my experiences, which is in totally different areas, but that I think this last point that Dr. McCollough was making, it's a question of resources. It is a priority for the industry people. There was a comment earlier about not seeing any FDA representation at international meetings. Well, I, till recently, worked for a sister agency in a federal government, and I can tell you, in the last 10 years, that foreign travel is very difficult to get approved. So it's a question of priority for the participants, and it ends up, I think, just by virtue of that and resources, being much more participation by industry than by the other players.

Dr. Miller.

DR. MILLER: It's certainly true that government, in general, has made it more difficult to travel, but we do have -- within CDRH, we do have a standards program. And the standards program has a budget for travel. And we realize the importance of FDA presence at these meetings. And we do have to prioritize which maintenance team is more important than others, but we send people all over the world on a regular basis. That's why Sharon Miller, who's not presenting here today or yesterday on sunlamps, because she's in a meeting in China. And I'll be in London in November to talk about interventional fluoroscopy. We send people all over the world all the time.

DR. LOTZ: Go ahead.

DR. McCOLLOUGH: Cynthia McCollough.

I agree. We have -- with Don, we have seen FDA at the international meetings. But as you said, you have to prioritize, so we don't see them at every meeting. And what I've learned is consistency is key, because if you're not at the table, you really have little impact. And I think it was the speaker from MITA that said that everybody has a say to the extent they participate. And hence, participation is difficult, but you also can participate through downloading the drafts and submitting comments. And so your comments will get looked

at, and they have to be addressed.

Well, in my experience, again, those comments that come in by writing by people who have not been involved in the process are often summarily dismissed with a very repetitive note, committee discussed, no change felt necessary, committee discussed, no change felt necessary, because these are comments coming in after much, much, much work has been done. Directions have been set. Definitions have been made. And someone's making these other random comments, and they don't necessarily have impact. You have to be at the table.

MR. MURPHY: I guess, to summarize my concerns, certainly, you know, you don't want to watch how the sausage gets made, but at the end of the day, you got to have some sausage. So do you feel, do other Committee members feel that these problems are so inherent that the IEC and other standards may be inherently flawed or biased by industry? Or is it like, well, it's the best we got, and it's being done free by -- you know, for the government, so as long as CDRH and FDA take a look at this, review it, and make sure, as you said, Dr. Miller, that it -- you know, it's going to be FDA's standard at the end of the day, that you're satisfied with that?

DR. LOTZ: Since I chimed in before, I'll -- this is Greg Lotz.

I think, in general, it ends up being okay, that wasn't necessarily exactly how we would like it to go, but it's the best we've got out there, and it's better than anything else that's there because it is a complete product. I wouldn't say that's universally true, but in general, I would say that's the case, in my perspective.

Mr. Keith.

MR. KEITH: With all the technological advances, it'd be very difficult for any particular agency to keep up with everything that's going on. However, that being said, if there are industry reps involved in developing documents, it's probably because there's an

issue at hand that needs to be addressed. And by FDA taking these documents and using their understanding of the field and the evaluation capabilities, I personally feel that FDA can do a job of sorting through each individual standard and identifying what's appropriate and what's inappropriate, what needs to be amended and what needs to be eliminated.

So I am on the side of encouraging moving forward with taking the IEC standards and utilizing the best parts of those things to keep our science current and our standards relevant. And that since these are not IEC documents, these are FDA documents, so FDA has to live with them. If FDA does a good job, that's wonderful; if FDA doesn't do a good job, then they're going to be belittled. But I think, because of their strength and their interest in public health, that I tip toward encouraging them to utilize the standards and gain the most out of them that they can.

So even though there's industry involvement -- there needs to be industry involvement and also needs to be reading between the lines to get the right information out. I'll leave it up to FDA to do that. I think they will do that. And if they don't, I think there'll be those out in the field, those Cynthia McColloughs out there in the field who will let them know about that.

We're all going to be fallible. And we can make mistakes in accepting or rejecting, but we can always learn from our mistakes and then adjust and move forward. So I encourage adoption, in whatever part appropriate, the IEC standards by FDA.

DR. FARAONE: Thank you. Antonio Faraone.

Well, I can attest to at least one example where the FDA did, I think, a very good job in leading a standard development effort. That was the first ever standard for the testing of the exposure from cell phones. So that effort was started in 1997, and the chair of the committee was Howard Bassen of the FDA and ended with the publication of the standard in 2003.

Being the first ever standard, there were competing technology, or subtechnologies, so there was a robust interaction between the various members of the committee, which was well managed. And it turned out that the standard has had very longstanding value, since it's being used right now with some modification.

So at the time, there was Howard. There was Brian Beard involved. And then subsequently, to validate the assumptions, some of the assumptions that were made, partly validated during the standard development, FDA led an effort, I think was funded through a CRADA, together with the University of Maryland, Professor Chris Davis, and under the leadership of Brian Beard, to validate the conservativeness of this newly issued standard at a time where, you know, cell phone exposure was kind of a hot item.

So that, you know, showed that, you know, an institution like FDA can really produce remarkable outcomes when involved in standards.

Thank you.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: We've heard and discussed a great deal about the needs of the manufacturers and the trade organizations that represent them and then the needs of the FDA to -- what their needs are, and those needs include minimizing paperwork, minimizing redundancy, increasing efficiency, increasing standardization.

And to the extent that the actions that are being proposed help meet those needs, I am in favor of that because those are important goals. I support it, with the understanding and the hope that the FDA will very strategically and with surgical precision go through those documents and make them their own. And that is what I'm hearing the intent, and to that extent, I can support the proposal.

But what we've not really talked about here today, the needs that I've not been heard addressed, is at the very heart of what we're collectively here about, and that's the

needs of the patient. At our institution, our mission statement is summarized in a very simple phrase, "The needs of the patient come first." And I have been at many committee meetings that have been divisive and lots of different opinions on the table, and someone will bring us back to our roots and say, yeah, but what's best for the patient? And then we reach consensus. And even if it's more burdensome or expensive, if it's the best thing for the patient, it's the best thing.

And so what I am seeing here, relevant to this discussion, is that what's best interest of the patient is threefold. Clearly, the equipment has to be manufactured with the best science and the best safety and technology, and then manufactured and delivered and installed with all those things properly functioning. And that is the area the FDA typically has had the purview and will maintain to have purview over. And to the extent where the needs of the patient are met through FDA working with IEC or any other standard organizations to help that happen, that's a good thing.

The second step in meeting the needs of our patients is that the community that uses the equipment has to have the proper tools on the equipment, again, the purview of the FDA. But they also have to have the necessary information and experiences, and so here I'm referring to training. And I think the FDA can definitely step in and help strengthen the manufacturer's responsibility on providing the needed information, because most of the errors, as was mentioned earlier, are not because the machine didn't do what it was supposed to do. It was told to do the wrong things because of these being very sophisticated pieces of equipment and user education level not necessarily having kept up with that.

But the third, and I would argue certainly not the least, if not the most important part of ensuring patient safety, is what happens after the installation, after the manufacturers have walked away from the install, and the FDA has approved, and it's out

there? And there are legions of people, the state inspectors, medical physicists -- there are about 8,500 medical physicists in the U.S. that take daily responsibility for making sure the equipment performs as it was approved, whether by reference by IEC or our FDA standards. And we can't meet some of the first two needs without making sure we don't cripple that third leg of our stool.

We absolutely have to make sure that whatever is done unequivocally makes all the information necessary for those people to do their job, clearly available in completeness, not just one standard, and you've got to go try to figure out what the other ten that it refers to said.

And one of the ideas that I have had today as I sat through this is, as part of this adoption, to have the manufacturers, under the guidance of the FDA or the Alliance for Quality CT, other stakeholder organizations, spell out in a document -- they have to spell out their specifications. They have all this documentation written up for the premarket approval. Spell out exactly what tests were performed, with what equipment, what were the tolerance values, and what is the value for that system, because that gives the end user every bit of information they need, going forward, to make sure the system is -- you know, they don't have to go read the IEC standards. They're being told exactly what went into the premarket approval for the system. And then we have all the tools we need for that third important part, to make sure it stays running that way.

DR. LOTZ: Dr. Miller.

DR. MILLER: Thank you, Dr. McCollough. I agree with you completely on this, the importance of this, which is one of the reasons that FDA proposed, in the most recent revision of the IEC standard for radiography and fluoroscopy, that the manufacturer include with the labeling, with the user manual, test procedures, a schedule for test procedures, how to do the tests, and what the acceptance criteria were for the tests. And that is in the

current version of the second amendment to 2-54.

Of course, it's not in our performance standard, but it is in -- will shortly be, I hope, in the IEC standard. So at least we're moving in that direction, because we realize the importance of doing that. And frankly, there was no pushback from the manufacturers.

DR. LOTZ: Dr. Stein.

DR. STEIN: One of -- a thing that Dr. Irwin brought up was is there any other example? And I have one more. I know I've been coming up. Is ENERGY STAR -- Department of Energy, DOE, ENERGY STAR for battery chargers, give an example, or other -- there's plenty of other ENERGY STAR examples in industry. And in the laptop computer, for example, they've moved -- and they fund and they support the EPEAT standard, which is a UL and IEEE consensus standard, just like this is, IEC. But it's being developed by consensus groups, a consensus group, and then it's called out in specification and in regulation.

And it goes beyond just the ENERGY STAR provisions. It's things like recycled content, it's safety, it's all kinds of things. But that's the best example I can think of, and it's been going on since 2006, several multifunctional devices, cell phones, UL 110, and that's all EPEAT, E-P-E-A-T.

DR. LOTZ: I'll go back to Dr. Miller.

DR. MILLER: Donald Miller.

Very quick response. We have no requirements for that in any of our performance standards or regulations. There is an IEC -- sorry, an IEC standard, I believe it's 60601-1-9, that deals with environmental aspects, which the manufacturers, we hope, will adhere to. But it's neither safety nor effectiveness, so it's not something that is easy for us to regulate.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: So we have -- Bill Irwin.

So we have been asked to, in essence, answer Mr. Murphy's question as to whether

we feel comfortable allowing the FDA to adopt consensus standards of the IEC. And I'm going to try to provide some reflections on that. And I one point was reminded -- I was reminded of it when Dr. Faraone described the work on cell phone radiofrequency radiation and concerns there.

I was studying this not long after the National Council for Radiation Protection published its Report Number 86, which was one of the more authoritative studies of RFR. Simultaneously, there were efforts of IEEE/ANSI C95.1, I believe, to conduct its own analyses, and it was very valuable for myself as a consultant to industry, as someone who was working in academia with people who were using high-powered sources of RFR, as well as someone who would be advising members of the public relative to cell phone tower installations in their community, to have both the IEEE/ANSI consensus standard, if you want to call it that, and the really substantially scientifically oriented National Council for Radiation Protection and Measurements report, not just one.

And I feel like that for the FDA to go onward with the adoption of IEC consensus standards, there needs to be that same kind of check on the industry balance that seems to be really quite obvious and substantial, especially given what Dr. McCollough has described with her experiences in IEC.

So it would be really valuable, in my opinion, to have perhaps TEPRSSC be a means by which there is that check on FDA, as they review and adopt specific either regulations or statements or whatever it's going to be, to actually adopt the IEC standard for these various radiological devices, and not what I saw in some of the history of TEPRSSC, that because TEPRSSC approved something in 2003, regulations were promulgated in 2013 on that approval basis, that it be timely review by a widely varying body that has representation from all of the key stakeholders, as this body does.

And I would continue to appreciate the kind of knowledge and experience that I've

seen here represented in those meetings of TEPRSSC, or maybe there is even the formation of some new entity. I frankly have some concerns that OMB Circular A-119 may also be driven by industry, not simply by government and a representative democracy. And as such, it could be that we have two efforts from industry relating to public health and safety, patient health and safety, and the integrity of whole population of radiation safety professionals, radiation protection professionals that is being -- that could -- is threatened to be controlled by those interests that we ourselves hope to regulate.

So those are the perspectives I have about FDA moving on here. I feel like there needs to be some means by which, as this very new step -- as I'm hearing, it is very new. No other government agency is doing this. We don't know if DOE or CPSC or FCC or anyone else is going to have some sort of challenges that create huge problems.

And while I really appreciate and truly trust the statement of Dr. Miller relative to what FDA, what its mission is and what it will always be, I still like to say, gee, what happens if Don wins the lottery and is off to London and never comes back?

And so I'd like to make sure that there are engineering controls. And the only one that we might have on the regulatory function is a, as much as we can create it, a non-biased panel that reviews on behalf of those who are poorly represented, the public, the patients, and those who may be a reflection of the entirety of the radiation protection community.

DR. LOTZ: Mr. Keith.

MR. KEITH: There is a press in my agency, and perhaps in others, to develop standard operating procedures for some of the things that they do on an ongoing basis. And perhaps putting pen to paper to address how FDA proposes to address IEC standards in their documents may be useful, so that as members rotate off, others following in their footsteps will have a go-by document to help them understand what FDA's current position

is on such a move to adopt.

Also, I wanted to mention to Dr. McCollough that I've seen FDA's strong interest in patient safety. When Federal Guidance Report 14 was being developed, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, FDA was present at all of the meetings. They addressed patient needs and training and credentialing and testing, pulling the best of what is available in the world as guidance, a nice toolbox. But FDA was there for over 200 meetings during its development. So I'm highly encouraged by the dedication of FDA staff to patient safety and clinical staff safety.

DR. McCOLLOUGH: Cynthia McCollough.

Just for the record, I in no way meant to impugn that I have anything but respect for the FDA and their dedication to patient safety. I said it's collectively what we're all here about. And it was the FDA's big stick that helped early on with the CT issues to get the manufacturers at the table. And they did it in the most diplomatic way I've ever observed. I watched and learned. So just for the record, I needed to make sure that was clear.

DR. LOTZ: Mr. Savic.

MR. SAVIC: Stan Savic.

DR. LOTZ: Turn your mic on, please.

MR. SAVIC: Stan Savic.

Having seen the agenda item of basically handing off some of the standards-making powers and using some of the IEC standards, I had a debate in my own head both of these days which way would I be leaning. I have been an industry person, and I would just say that industry people are also consumers, and we do share the same concerns that the rest of the public has.

I have had exposure to two aspects of IEC standard-making. My earliest -- and FDA, by the way, as well as Consumer Product Safety Commission. FDA's, I believe, first

performance standards were issued for television receivers, for ionizing radiation emitted from television receivers. Anecdotally, as I remember, the word was because that was a very popular issue, mandated by Congress, FDA used the television receivers to get the medical devices under control as well. That's basically what I remember why and how that was approached.

In the television receiver standard, extensive testing methods were incorporated, including things like worst-case component tolerances, single fault analysis, and then measurements to be made from that. During that entire time, there was no comparable IEC standard, so the FDA's approach was, I won't say light years, but years ahead of the IEC requirements. And as best as I know, even to the present time, some of the stringent requirements in the FDA's television standards for ionizing radiation are not incorporated in the IEC standard. And therefore, I was very happy to hear Dr. Miller say that they will review and adopt and reject certain portions of it.

My other experience with the IEC standards versus domestic standards is in the area of fire safety. I have participated in the various working groups, and I was the technical advisor on one of the IEC committees dealing with what is presently 60065, which is the performance safety standard for television sets, radio sets, and so on.

For years, the subject of fire safety as well as electrical shock and explosion in electronic products was considered, in the United States, by Underwriters Laboratories. And there were standards that were tightened significantly as the result, again, of congressional action of what used to be National Commission on Product Safety, and then the subsequent successor agency, Consumer Product Safety Commission.

As someone who has sat on the committees, both in the United States and in IEC committees, as we were tightening up the domestic standards, requiring the latest technology, such as silicon rubber, for example, after the Apollo fire, Apollo 7, I believe, and

we were incorporating flame-retardant materials, when we participated in some of the IEC committees, the typical answer that we got for maybe a couple of years after we had tightened up the U.S. standards was, oh, we don't have fires in Europe. Our homes are built of stone, not of 2 x 4's like your homes in the U.S. And then fortunately, subsequently, the IEC standards tightened up also, and they started incorporating flame retardant techniques that we had been using in the United States for a while.

So I would just say that in light of the present situation, and I see it as an overwhelming task to try to get FDA to issue performance standards for all of the machines that are presently being used, with the reduced budgeting considerations, that probably the approach that Dr. Miller is suggesting, which is with a fine comb going through the IEC standards, picking those things that are good, and then using the knowledge that FDA has to perhaps shore up the requirements, I see that as the only possible practical approach.

DR. LOTZ: Dr. Stein.

DR. STEIN: I just want to comment on the concern about the democracy and losing control, etc., and use the example of the C95.1. And in that case, that's an example of a standard, and it's actually ANSI standard, which I wanted to continue to rephrase that there is a difference between consensus standards and ANSI standards in the rule-based of how it functions. And especially if you have complaints of shenanigans in the voting process, etc., the ANSI process is way more sophisticated, way more filled out than plain old consensus standards that are adopted by the companies themselves.

But I really want to point out that in the case of the C95.1, which is back in 2004 that it was adopted, for example, there were exclusions written into that standard that still exist today. And in particular, it said anything that's less than 7 W is excluded for -- you know, that's basically everything we have today. And it needs to be updated because we have so many devices that are less than 7 W that should be looked at.

And in particular, the National Toxicology Program just, you know, finished their studies on rats, which used a SAR level that C95.1 has a 1.6, and found now animals being impacted and brain cancer and heart cancer. And there's just a need to make sure, if we're going to move forward on any adoption of voluntary or consensus standards, that there's provisions and tight stipulations included, that they have to be annually or on a periodic revision process. It can't be held out and held hostage because they don't want to update it, because if they do update it, the truth comes out, and the need to make the standard tighter will occur.

And the industry groups, as well as the government, who is going to be impacted by lobbyists that are, you know, elected -- the officials in the government are elected and impacted by lobbyists. We have to consider this and make sure that the process is more than just government and industry. It has to include advocacy for consumer groups and children and citizens.

So that's my comment. And the example is on the standard today for radiofrequency, RF, and cell phones in particular. And I live in Berkeley, remember. And we're the first city -- I sit on the Health Commission, and we're the first city that have required, had our own city try and get a label put up at point of sale to inform the cell phone users of the distance separation that is in the C95 -- it's in FCC. And we're being sued for doing that ordinance.

So you're absolutely correct, that if it's not stipulated correctly and given the rights to the local communities to take action to protect their own citizens, it won't happen. It will -- and this is the second lawsuit. It was in San Francisco 4 years ago, the same actions. Now we're 5 years down the line, another city. So I do agree.

DR. LOTZ: Dr. Faraone.

DR. FARAONE: Thank you. Antonio Faraone.

Dr. Stein, I just want to clarify that in the last revision of the C95.1 standard for electromagnetic exposure does not have any 7 W exclusion. The 7 W exclusion was in one of the very early versions of the standard. And maybe the last time it was used was in the '82 version or earlier. So it has been a while that the 7 W exclusion is not there anymore. Thank you.

DR. LOTZ: And I would agree with him on that particular point, for what it's worth.

So I think actually we've had a pretty good airing of this particular general point. Dr. Ochs, Dr. Miller, any -- okay, Dr. Faraone, you want to --

DR. FARAONE: Antonio Faraone.

Just a last item. It's about one of the questions, what are the benefits in accepting, recognize IEC standards, but the benefits are various. And one of them is that there is a harmonization at the international level, and without the challenges. So I'm trying to be funny here.

But the challenge that you may have is maybe to try and avoid adopting them in part only, because that makes things much more complicated, at least from our point of view, industry. Typically, standards are taken as a whole. They are coherent if they're well developed. So the need for just taking out some, you know, parts and leaving others, you know, unused, maybe it's very limited. So if at all possible, unless, you know, there are striking reasons to do so, standards should be adopted in total. Thank you.

DR. LOTZ: Dr. Stein.

DR. STEIN: Yeah, just real quick.

I agree that taking parts out, it doesn't work, and it can, you know, disrupt the functioning of the whole thing. But I don't agree that adding, like IEC 60-whatever plus 3, where you add on more stringent additions to it, it works. I've seen it work.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Yeah, Bill Irwin.

I just wanted to get to one of the questions that was asked from the last session, and that's about the standards being implemented as mandatory requirements instead of as an option. I would strongly recommend that they be mandatory as opposed to options. And I would agree with Dr. Faraone that the incorporation by reference in whole, and then a statement as to which portions you exempt yourself from and what additions you might make to that as a part of it, provides for a coherent read of the consensus standard and then also a means by which you can evaluate what are those exceptions and those additions. So it is useful for those who would find a need to use that in their work or other interests. Thank you.

DR. LOTZ: So I was going to make an attempt to summarize where I think we are on this particular thing and this issue of FDA's proposal to adopt particularly IEC standards, but other consensus standards in cases where they're relevant. And it's my summary that this TEPRSSC Panel is generally supportive of that approach as practical and realistic to our regulatory environment of today, with concern about review and evaluation of specifics, and the overall FDA approach to that, based -- as reflected in all of the comments that will be part of the record.

Dr. Ochs, Dr. Miller, any additional comments on that particular issue? We've got other things to discuss as well.

DR. MILLER: No, but I thank you for summing up the TEPRSSC Panel's sense on this.

DR. LOTZ: All right. We've had Dr. Nabili here, she posed a few questions to us. I don't know that we've really dealt with her topic at all, so I wanted to turn to that a moment, make her wait worthwhile. And so on the issues of the ultrasound, we had some discussion, or not really discussion, but questions earlier. Any additional comments from the Panel on this particular topic?

DR. IRWIN: Bill Irwin.

I frankly was a little concerned that there appears to be some incongruence in the approaches that some use, FDA included, for radiofrequency radiation and having a fundamental protection value in specific absorption rate and then applying that to some sort of controls in the workplace. I understand that we're relying on the healthcare practitioner to choose to use these ultrasound devices in a manner that is therapeutic or diagnostic in their best informed perspectives as the healthcare provider, but it also seems appropriate that there be some sort of limits on this, especially when I got the sense from this that, especially for deep tissue heating, there was no sensation of the heat.

And that absent some sort of value that you might monitor during application, and having no patient aversion response, say, sensation of heat or pain or something of that nature, that there could be -- or excessive heat, obviously the heat is applied to 40 to 45 degrees C, that there should be some sort of guidance to make sure that the administrator of this thermal energy is not exceeding some value, that they're moving at a rate that is not likely to overheat certain areas of tissue.

And I'm not sure if that is something that's accounted for in the other documents that you review, etc. Maybe you can help me with that.

DR. LOTZ: Dr. Miller.

DR. MILLER: Donald Miller.

I just want to make it clear that when I was -- when I said earlier that there was no sensation on the skin or in the tissues when diathermy was being used, that's when it's being used properly. I don't want to claim that you can raise the tissue temperature sufficiently high to cause injury and not have the patient be aware of it. I did not say that.

DR. LOTZ: Dr. Nabili.

DR. NABILI: And I just want to add that there are contradictions with the use of the

system. So like, you know, it cannot be used on the open skin or something like that, so they have to -- the operator needs to consider when applying, using the device.

DR. OCHS: This is Robert Ochs.

So perhaps, Marjan, you can clarify a little bit. So those contradictions would be included as part of the medical device review, correct? And then I believe there's also some standards also for those systems that may be relied on in the --

DR. NABILI: Yes.

DR. OCHS: -- premarket medical device review as well.

DR. NABILI: Yes.

DR. OCHS: Definitely in the diagnostic ultrasound, there are international standards related to outputs on the screen of the acquisition system, related to the output of the device as well.

DR. NABILI: That's correct.

DR. IRWIN: Yes, thank you very much.

DR. LOTZ: I believe Dr. McCollough had her hand up, and then Mr. Keith.

DR. McCOLLOUGH: With regard to the discussion about the memorabilia ultrasound industry, I'm wondering what mechanism FDA might have, either under the ECRP or the medical devices, about EP, electronic products -- whatever order those letters are supposed to go in -- on either side of the fence, to require, for example, that these can be sold only to a licensed physician for medical use or something like that. Is there a way to get at legislatively blocking the use of a device for nonmedical purposes?

DR. OCHS: So the diagnostic ultrasound systems are currently all cleared as prescription use devices. Part of the concern would be, again, someone taking them and using them without a prescription. So the actions, the regulatory actions that we could take, in that sense, can be a bit varied. I know we've had some concern about it. There is

some limits, some that -- again, since we don't regulate practice of medicine, some of it actually, we can coordinate with the states as well, to say others, essentially someone practicing medicine without a license.

So there are options. I can't say that we have a very clear pathway or a clear process in place right now, which, you know, how we'd handle a complaint for this. Again, we have done the safety notice. I don't think -- I mean, we're aware of it. I don't think we have other specific instances that we've escalated it to. There is a -- but there is some regulatory that we can take as FDA, and in other senses, we can try and partner with the states to take action.

DR. STEIN: Because it's a very flagrant violation. They've got billboards and signs, so nobody's trying to do it in any clandestine manner. So it seems that there should be a mechanism to say you are not having a prescription and should shut down.

DR. LOTZ: I think --

DR. IRWIN: I'm just going to address the question of the states, if we're adopting --

DR. LOTZ: Okay. Go ahead.

DR. IRWIN: Relative to the states, it's kind of like chasing snake oil salesmen. You can go and you can call them. You can go to them where they're at a hotel and doing these things or whatever, and scare them to the next county, to the next state, but really, to take legal action is difficult for the states as well, in many of these cases. But it is a concern, and people are doing it with a variety of modalities. Thermography for breast cancer screening, for example, is an injustice to women who think that they can do something less painful and have diagnostics of their risk. Thank you.

DR. LOTZ: Mr. Keith.

MR. KEITH: Sam Keith.

I know we've addressed the 45 degree C temperature being achieved, and I was just

kind of interested in the boiling aspect. And so I kind of thumbed through some of the literature on the CDC library. And Khokhlova et al. 2011 addresses that point. And they say that both inertial cavitation and boiling were observed during their exposures, but emulsification occurred only when shocks and boiling were present.

So there's an indication that even though 45 degrees C may be a relevant temperature, at more of a microscopic level, that there may actually be boiling of the fluids within the body to produce those bubbles. So when you're talking about therapeutic ultrasound, it's more than just cavitation. And so, you know, recognizing the boiling within the body and the temperature profiles that can be achieved, we need to be careful on the regulation of -- or of the lack of regulation of the industry.

DR. NABILI: So we are talking about -- if I'm not mistaken, we are talking about two different things. Cavitation is just mechanical effect, and thermal is a thermal effect. So the cavitation may happen at different frequencies, like if it is very hot. And then we are -- for diathermy, we are talking about something that has a very high intensity, so generation of the heat is possible. But the thing is that diathermy depends on which location of the body you are using. If you're using it close to the bone -- and I'm sure these are in the performance guidance -- that if you are close to the bone -- you are not supposed to use it on the head or somewhere on the face near the tooth because those are the ones -- the bones can grab all the heat, and it may heat up the tissue more.

So I'm sure those heat concerns are all listed in that performance standard and the IEC standard that they follow during the review, pre-review of the device. And there's a guidance that they're working on for diathermy device, that it is -- it will come out very soon, right. I don't know if it is clear yet. They're working on it. Yeah.

DR. LOTZ: Dr. Stein.

DR. STEIN: Yeah. On that issue, I think one of the questions you had is, is there any

other safety suggestions. In terms of a time limit to avoid going for hours that would -- you know, if there was a time -- if it were calibrated for different substances, and that you put a time limit on it, it could be overridden by the doctor or -- but at least at a minimum, that there be a time limit available to at least make someone think, should we go on -- you know, put the thought pattern in to avoid problems, especially for pregnant women.

DR. NABILI: I believe they are -- there is a time limit.

DR. STEIN: They're included?

DR. NABILI: Yeah. And then they are not supposed to be used on a pregnant woman and the fetus. It's not.

DR. LOTZ: Dr. McCollough.

DR. McCOLLOUGH: Cynthia McCollough.

One of the questions -- well, you mentioned your concerns about the medical ultrasound and nonmedical ultrasound, and the concern sounded relatively low, hence your comfort level of removing some of the regulations you have on the electronic product side. I wondered what the thought of -- and maybe this is on the medical device side, about the point-of-care handheld ultrasound units that are proliferating. And again, there's user issues that -- because I'm close to the user base, so I see these and they frustrate me, but we're putting these devices in the hands of a lot of untrained people.

And I saw that in the emergency department with my own daughter. The brand new resident was scanning. And I saw on the screen what he saw. It looked like this huge hematoma. And we thought, oh, surgery. And they kind of said would you like to get a CT to confirm? I said, yes, that would be good. Everything's normal. You know, so these point of hand -- or your point-of-care handheld things can be used with all sorts of wrong settings. And I think some smarts in the device need to be there because they're being used by many untrained people.

So maybe that's on the medical devices part more, but they also could be potentially -- well, they may not have the power enough to do harm from the thermal mechanisms, but any comment on where the FDA's thinking is about those devices?

DR. OCHS: I mean, the safety and effectiveness of those devices is part of the medical device review part of it. I mean, that may be an issue. Again, we do have the MDR reporting for medical devices as well. So if, you know, there was reports being filed of, you know, these medical devices, we keep having errors in a certain region, that could be a surveillance issue that we could catch in our medical device surveillance program.

But the image quality and such, the indications for the ultrasound equipment are all premarket issues, so hence -- again, training could be an issue, too. So training -- again, just like to train up any other -- I mean, any medical equipment, it could be handled similar to the training of other medical equipment. So we do note the concern in it. Again, it sounds potentially like a user issue, but again, another important issue that we've heard quite a bit about the need for user training of medical equipment, even if they are a prescription use device. Who knows what the training is, so noted. Thank you.

DR. MILLER: Donald Miller.

We have the ability to require the manufacturers to provide training or training materials or appropriate instructions in the user manual. We don't have the ability to require anybody to read it. That's up to the states to regulate the practice of medicine and the qualifications of individuals to use particular whatever, devices.

DR. LOTZ: Dr. Stein.

DR. STEIN: Just on that note, you do have the capability for the size of the print. Like the cell phone manual that's in like, you know, microscopic print that nobody, of course, reads. So that can help, if it's visible and conspicuous, and you've used that language before.

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Yes. One of the overriding thoughts I've had over the last couple of days about states, and I've heard it several times just in the last few minutes, is that we've had a model in the nation, for example, in mammography, states have a contract with FDA to do probably some of the best surveillance of use of FDA-approved products in medicine for as long as they remain in use. And it's been very effective for all parties, FDA, the medical community, and patients.

For most of the machines that are used for diagnosis and therapy in the ionizing radiation region, we have built a whole paradigm based on fees that are means by which the states work to verify that an approved device is -- remains safe years, sometimes decades after being introduced into a user space.

And I believe that what is clear from what I've heard yesterday with the non-ionizing radiations, especially with some of the systems that have the ability to create acute effects -- and you know, we discussed them with the RF and laser wireless power transfer; we see it also with some of the laser lamps and laser-illuminated projectors -- that a model may need to be adopted by the states to include these kinds of devices in their fee paradigm to warrant having people go out and do what you're describing is vitally important.

You appear to be doing, at FDA, a great job of ensuring that -- as you were just saying, there is a manual and there is training for them to use, but you can't make them use it. The state surveillance programs can, but it cannot be done without people doing it, and they need to be paid.

So that's a message that I think that the Health Physics Society, the Conference of Radiation Control Program Directors, the state legislatures, the state governors association, and others need to recognize is that if there are going to be possibilities of acute injury and potentially chronic effects from non-ionizing and ionizing radiation sources that are not

currently surveilled appropriately for the protection of the public, and workers, that that is likely to come. And it may be very appropriate, given how close a lot of technologies that used to be remote from people are becoming very personalized.

DR. LOTZ: Dr. Nabili.

DR. NABILI: Just to add a quick think about the safety, during the premarket review, we look at the MDRs, the recalls, the inspections that has been done for the predicate of the device, and see what are the issues that is coming up. So we always look at the safety things that happens to the predicate of the device. So we are consider all that when we are reviewing the files.

DR. LOTZ: So I'm going to try and summarize this particular discussion to the question for TEPRSSC of what is the Committee's opinion of the strategy of relying on medical device premarket reviews to address the safety concerns with the medical ultrasound devices and no longer requiring the EPRC product report monitoring.

My sense is that the Panel is cautiously okay with that, with some concerns noted. It seems that perhaps those are covered in the premarket reviews, but maybe ask FDA to look at the transcript and consider those concerns that have been expressed, and review, okay, are those adequately covered as you move forward with this particular proposal.

Dr. Ochs, does that seem like that takes care of that?

(No audible response.)

DR. LOTZ: Dr. Irwin.

DR. IRWIN: Just one last -- relates to that. One of the things that really helps the states to know to go out and inspect a new ionizing radiation device is a form that states are used to getting from manufacturers. And I forget the number of it, but --

DR. MILLER: 2579.

DR. IRWIN: Yeah, the 2579. But it's -- I think that to enable the states to be able to

go out and to help surveil those kinds of devices that may, with misuse or with age, have potential for public or user health effects, to have some means to identify that to the states when they are marketed and sold would be very useful. So that's something to consider is the states cannot go out and look for these things. They need to be notified that they're being introduced into their specific locations.

DR. LOTZ: So, Mr. Sauer and Dr. Nabili, thank you for your participation and presentations. You're welcome to go back to other seats at this point, if you'd like. Or you can stay where you are. That's up to you.

We have a little bit of time left. At earlier times in the meeting, both yesterday and today, we've had to cut off discussion of other matters that were brought before us. So I'd like to open the floor for Panel members to return to any of those topics that we had not completed discussion of previously.

Mr. Murphy.

MR. MURPHY: As I mentioned yesterday, I had a number of questions about the laser pointer regulations, and so I just --

DR. LOTZ: I can't imagine why that came up.

MR. MURPHY: Well, again, I'm with the International Laser Display Association, and we have nothing to do with these. You could get rid of all the laser pointers; we wouldn't care because we use different instruments. But just from a logic standpoint, I have an interest in this, and I've also been working, since 1993 or '4, on preventing lasers being aimed at aircraft. It used to be our industry. We cleaned it up. And now it's idiots with laser pointers.

Just yesterday was the first documented case that I know of, of a person in an automobile crashing because a laser pointer was aimed at them on a road. The person, you know, fortunately survived, and the car's damaged. You know, it wasn't totally serious but,

you know, her car is all banged up, and it never should have happened.

UNIDENTIFIED SPEAKER: What color was it?

MR. MURPHY: It was green. It was a green laser pointer. Excellent question.

And I also wanted to thank Dan Hewett and Patrick Hintz for coming back today because they suspected there may be some questions.

I'm going to kind of rip through some of these. You may or may not want to answer them. Maybe I'm just putting it on the record to try to cram it in before our flight, my flight leaves.

Okay. Number one, I would urge the FDA to look at labeling and especially requiring an aviation safety label on whatever laser pointers you come up with. I'm sorry. Okay.

Two, I notice across my six pages of notes, I keep having these notes of there needs to be a mechanism for people who need to obtain higher power laser powers legitimately, a mechanism for these individuals to be able to get them, you know, relatively easily and yet not fraudulently. This could be some kind of simplified variance that an individual could apply for. Hopefully you wouldn't have to create a licensing type situation where now you have an all new sub-bureaucracy. But I do think that that is important because under your proposal, there will be a lot of people, relatively large number of people, who need higher-powered, higher-visibility green laser pointers.

One of the questions that the FDA asked was about the definition of a laser pointer. I have never seen a definition that included uses such as -- sorry, visual entertainment, vision disruption, startle, and novelty purposes. All the definitions I've seen before related to the size and handholding of it and the fact that it's used as a pointer to point. So I do think that if FDA is going to promulgate this as a regulation, they need to justify and better define these terms. Why are these terms being used? What is included in the terms? What is not?

Oh, here's an important question that was written down twice. Last year there were 7,700 incidents. This year, the information that I just got a few minutes ago says it's going to be a little bit less, 6,727, but that's still about 6,726 too many. And the entire justification for you to limit the power of the green -- or to limit the color of laser pointers, only red, is that these green laser pointers are being aimed at aircraft in 90 percent of the cases, and those are the ones that are annoying the pilots.

My question is how many of these that are aimed at aircraft are -- what you guys call laser pointers -- less than 5 mW, and how many of these are pointers that are above 5 mW?

CAPT HEWETT: Well, I think the nature of that kind of reporting is that the pilot has reported the incident rather than them actually being able to get ahold of the pointer itself or do a measurement. So I would imagine that data would be pretty rare, if --

MR. MURPHY: I'm not aware of it.

CAPT HEWETT: Yeah. I'm not either.

MR. MURPHY: Myself, you know.

CAPT HEWETT: I'm not aware of it either.

MR. MURPHY: And part of the reason that I ask is because --

(Off microphone comment.)

MR. MURPHY: Yes, certainly.

DR. LAMBETH: Dave Lambeth.

So I was concerned about this and thought about it quite a bit last night. Okay. And I basically disagree with the way it's being put forth, okay, I'll say it up front, for two reasons. Okay. One, I question whether or not it's really been a serious issue with the airline pilots. I can believe that they see it. It bothers them. It's -- startled. Okay. Whether or not it's serious is another issue.

The second one is I do not believe you can curtail it. Okay. So I did a quick check.

There is a Chinese website called Alibaba, okay, which sells massive quantities of stuff. It has a sister website called AliExpress.com. If you go there and you just type in laser diode, or laser pointer, okay, you get literally hundreds of places being sold. You can buy a pointer in the blue. And I believe the common wavelength is 405 nm, and you can either choose a 5 mW or a 50 mW blue laser pointer. And the price for the two of them don't vary very much. I believe one was like 2.69, and the other one is like 3.59. Price.

(Off microphone comment.)

DR. LAMBETH: No, it's dollars. That's -- I mean, it's cents.

(Off microphone comment.)

DR. LAMBETH: Well, of course. But I mean, the point is they'll ship it to you for free, okay. So you can buy these things for $2 or $3, okay. The green laser, the red laser, the same thing they had for sale was also 50 mW. The green laser, because it is significantly different technology, was 5 mW, one website I looked at. Okay. It wasn't really available in 50 mW. But other places you can get that. Okay. We know it's more complex in how you make it.

There are only two wavelengths in the green and the blue. It's not like this entire optical spectrum is full of lasers. It's only 405 nm and 532 nm.

MR. MURPHY: At present. 520 is coming up.

DR. LAMBETH: Yeah. So my point is if I really -- it's ubiquitous. I do not think you can eliminate them. That's what I'm getting at. Okay. I think it's a regulation that will have no teeth if you try to make them illegal.

But the other thing is it's very easy to get glasses that will block those wavelengths. And they're very narrow bandwidth. The lasers, by definition, are narrow bandwidth. And so the glasses are clear. They can be made quite clear except for those wavelengths, very specific wavelengths. And I believe if it was really a serious pilot issue, we would be seeing

these glasses show up --

MR. MURPHY: They do.

DR. LAMBETH: -- in the pilots' cockpit. And I fundamentally think that this should be something the airlines -- you know, it's not our purview, but FAA purview, that when the pilots are taking off or landing, they simply slip these on if that's a really serious issue. And I think those individual wavelengths can be knocked out pretty easily, and the glasses -- we the know the glasses could be made very inexpensively. Okay. So I'd just look at that.

So if you want to see a pair of these glasses for -- what are called alignment glasses, for the laser industry, which means they allow some of the light through, so you can see the beam, so you can work on it, Thorlabs has them online. And you -- if you Google Thorlabs, you get the site. If you'll type in LG14, you will find a pair of glasses that will block the green. And it also blocks out all the blue. So they made the glass out of a blue color, UV, and so it has a slight red tinge to it, coloration, a pink color to it, but it's not necessary, okay, at all. It's just they've made it that way to block out everything that's now in the blue.

MR. MURPHY: I'll let you go, but then I want to say a little something.

CAPT HEWETT: Well, you know, this situation has been looked at extensively by people who are in the ANSI committee. They have a color committee that looks at aircraft cockpits. And pilots rely very much on color recognition in an aircraft, so they must be able to see the color of the instrument panel to warn them of certain oncoming hazards. So that committee has looked at this issue.

I know the ANSI G10T committee, laser safety and aircraft, of which I've attended those meetings, and you as well, we've discussed this issue extensively. And I think if there were a simple solution in terms of eyewear being utilized by pilots, we would have already seen that. I mean, that would be a ripe market for a manufacturer of eyewear to move into, and we haven't seen that. I don't think the technology is there that you're speaking of.

And then we also have the color issue.

DR. LAMBETH: I would disagree with you that the technology's not there. It may not be available, okay, but it's quite there. It's a question of getting it.

CAPT HEWETT: Okay.

DR. LAMBETH: I suggest that you contact the people at Thorlabs, which is a scientific optical facility, and ask them to build you a pair. There'll be some price for it, but they will produce it.

CAPT HEWETT: Okay.

DR. LAMBETH: And they do this, okay. If you can convince them there's a big market out there, they will make it for you. If it's just --

CAPT HEWETT: Well, the market's big enough that one firm has even extensively provided the research for films for cockpits. I mean, the market's there.

MR. MURPHY: Cockpit will not work.

CAPT HEWETT: Well --

MR. MURPHY: You need to do the whole glass. It won't work on --

CAPT HEWETT: I mean, as far as the concept is concerned, everyone can't afford a pair of the eyewear even if -- I mean, you know as well as I do, the eyewear is quite expensive at this point. But apparently you have, you know, information, and I'd love to hear more from you on the subject.

DR. LOTZ: Mr. Murphy, you said you wanted to respond further.

MR. MURPHY: I think you've done a great job for the, you know, evening that you put into it. I commend you, and that's kind of what I try to do here, and then I find out that issues are even deeper and have so many more ramifications and so forth.

This committee that I'm on, I personally have done tests with manufacturers who sell eyewear specifically for protecting pilots from glare. And these tests show that the

eyewear works for that. But the problem is in use. They can't wear it all the time. At least commercial pilots can't. You might want to have it in the cockpit if something goes -- you know, you get a call over the air traffic control, there's lasers in the area, maybe you put it on, but you don't want to wear them all the time because they do reduce color discrimination. They reduce the amount of light coming in.

I don't want to go into all the ramifications and so forth, but just to say that whatever solution there is, it's partially due to FDA and whatever they come up with, it's partially due to airlines adopting these things, and special circumstances, say, for police who are going into an active laser situation to try to find a perpetrator, other areas where it will help to ameliorate the number and the intensity of these attacks.

So right now I'd like to concentrate on what FDA can do, which is to try to restrict these lasers coming in. They can't catch them all from China, but they do catch a good number. Robert Aldrich was telling me that he bought three lasers from China, and all three were confiscated by FDA. He was a little bummed out, but on the other hand, they're doing their job. So that's good. Any --

DR. LOTZ: I can tell you, I've bought a lot of a lasers from the Chinese already, and I've never had anyone check anything.

(Laughter.)

MR. MURPHY: The direction that I was going with my earlier question was simply that we don't know the power of the lasers that are being aimed at these aircraft. So if we say green laser pointers, meaning lasers less than 5 mW are causing these troubles, we don't really know. It may be only higher-powered greens. And although a green laser pointer of 5 mW can cause glare at relatively long distances, about 1,500 feet, as I recall, a lot of the trouble may be caused by the illegal, high-powered, over 5 mW lasers. But anything that you can do to get those, you know, off the street or to call those defective or

whatever would be -- you know, is greatly appreciated.

I do think that your color idea of going back to only red is very interesting for a number of reasons. I do think that you should prepare a Plan B if, when comment period comes up, a lot of people don't go for that, for whatever reason. The Plan B, perhaps making laser pointers at 1 mW instead of 5 mW, say that any portable battery-powered laser over that is defective, and you can then use that defective clause to have greater authority, so just a suggestion there on Plan B.

In your definition of laser pointer -- and I'm sorry, I'm jumping around a little bit because of time -- it says laser products are not excluded as laser pointers, blah, blah, blah, blah, blah. I found that a little confusing, and I would just say, instead of not excluded, just say included or whatever wording better captures what you're trying to say.

You also talk about a laser pointer has no associated technological or scientific purpose for the laser's emission. That wording you should take a look at, and at the very least, try to define it better. I understand from, again, Robert, who shoots guns, that there are certain types of laser devices that you actually put in the gun barrel, simply to make sure that everything is aligned with your sights. You then take it out, and when you shoot, much faster, you're right on target. And that is neither technological nor scientific. Maybe technological. But just to make sure that cases like that are properly covered in the, in your proposed regulations.

(Off microphone comment.)

MR. MURPHY: Yeah, bore sight laser. Thank you.

Again, I'm sorry for kind of wandering all over and just dumping all this on you, but I wanted to do it before time ran out.

DR. LOTZ: Dr. Stein.

DR. STEIN: This is not on lasers, so either --

DR. LOTZ: That's all right.

DR. STEIN: Okay.

DR. LOTZ: We only have a few minutes left, so --

DR. STEIN: Well, but I'll start from the laser pointer. If you are actually going to include labeling to that, you know, improving the labeling, I would question, how come just, you know, these cheapy laser pointers are we improving the labeling while we have zero labeling on non-ionizing radiation, routers, cell phones, the list goes on. There is no labeling.

So I'd say, you know, why are we selectively so improving a laser pointer when we have other products that -- we should be consistent, is all I'm saying, is if we're going to do the laser pointers, we should equivalently provide labeling for all of the other products included.

I'd also like to point out that I had second thoughts when I woke up this morning, about thinking about the sunlamps. And remember I said -- I was the one who said we're siloing our thought process on just thinking about the UV light emissions. I question, you know, these are vacuum tubes or these are tubes with cathode and anodes that are separated by how many -- how far, how long is the -- has anyone measured the non-ionizing radiation, as you're sitting with tubes below and above you, and where is the ballast, and is it magnetic, and you know, what's the distance from your brain?

And I question that as opposed to just going out in the sun and getting your dose for vitamin D, you know, and whether there's the value for the medical purpose. I had some trouble saying that I was okay with everything on that one. I felt like it was risky for, especially teenagers or children with lifespans, to go be doing this for years or something. It's scary to me, especially when we don't -- I don't know of anyone who's measured it.

And from what I know about fluorescent tubes, they're high EMF levels. And so I

wanted to point that out, and also ask the same question about the other devices, you know, such as the ultrasonic. What's the exposure with respect to the non-ionizing radiation? And it should be checked and meet that.

And I also had the reservations about the C95 or the RF standards that we have today and the updating issue, that we're at a level in which the NTP has now studied on animals and said that it's problematic in causing cancer, as well as since 2011, it's been IARC listed as a carcinogen, and on the WHO list for neurological disability issues.

So I just question that the weight that we have in not updating that standard, and feel that I want to put those comments in that it should be definitely looked at as soon as possible, especially when we have the open docket that I listed for that standard. It's still open and has been open for many years. And there's, you know, hundreds to thousands of comments there to ask for it to be updated. And those in charge -- it was somehow offloaded to FCC instead of -- even though it's in the purview of FDA. And FCC is run by, you know, Mr. Wheeler, who comes from the industry. And I question that that's a big concern that we're not updating that important standard on health and safety.

DR. LOTZ: Any further comments on this topic or others that anyone wants to make? Questions of our FDA staff, who has, as I think Mr. Murphy pointed out, graciously come back for a second day to sit here all day waiting to see if we had any other questions.

Mr. Keith.

MR. KEITH: Sam Keith.

Does anybody know the technical effectiveness of glasses for green lasers? You know, green, I think, extends from like 5- to 550 on a normal scale. And the green laser lights are a much narrower frequency. Do the green laser lights glasses, do they, can they filter out just that narrow band and leave the rest of the green spectrum available for pilots to actually see green in front of them? Green and red.

DR. LAMBETH: If you will look at that --

DR. LOTZ: Just lean in a little bit.

DR. LAMBETH: If you will look at that website that I mentioned, they'll show you a spectral curve for the green laser. So typical laser bandwidths are a nanometer or two, okay, even bad ones. And when you make a gas laser, the mirrors that you put into a gas layer, or it's called dielectric mirrors, okay. They're coatings of oxides and metals. And they're designed, the stack is designed just for that wavelength. And they're typically never more than 10 nm wide, okay, or even less.

MR. KEITH: Well, how about the glasses that -- the protective --

DR. LAMBETH: Well, the glasses are --

MR. KEITH: -- glasses against that. Do they --

DR. LAMBETH: So the way the glasses are made, they're very -- most glasses are made to block everything. They're made out of a glass that has chemicals in it. Okay. And so they're going to block everything. But if you'll spend a little bit more money, you can buy laser glasses which will knock out a particular line very accurately, okay, because they put a dielectric coating on it. And the ones that I just referenced to you, they put into the glass, a material that blocks out everything from 400 nm down, just almost everything, by just absorption. But the dielectric is a mirror. So when the light comes to it, it reflects off. Okay. And it's the same technology that you would use to build the old-fashioned glass lasers. Okay. You just make this coating, and it reflects that wavelength.

And that's the reason I say you wouldn't want to put this on the windshield of an airplane, okay, because they have some directionality to this dielectric coating. The beam needs to be coming towards you. In a startle situation, where the light is flashing inside the cockpit, then that light is actually being scattered off surfaces. The laser is not pointing right at your eye. It's hitting something, and suddenly you see this scattered light. And if it

were relying on just hitting you in the eye, you wouldn't see it until it was dead nuts on.

So that light comes pretty much straight into the glasses, the scattered light off the walls and whatnot. But if I tried to block it at the windshield, now I've got to get the windshield lined up with the laser to get it to work well, and besides it being prohibitively expensive to coat the entire windshields this way because it's done in a vacuum system.

But, you know, that's the technology. You can put more than one mirror stack on top of each other, and then you can block more than one wavelength. And as far as that, you know, the bottom line, you know, it's just a question of what you put it on for a glass. Is it going to let light through or not? Normal glass does, right. So you can do that.

That's the reason I was saying, okay, if I had a pair of glasses, it's just going to reflect, you know, the 532 and reflect the blue laser, then they're not going to come in. And I can make that of -- almost of arbitrary quality. I can make it reflect 90% of the light pretty easily. I can make it reflect 1000, so only 0.1% of the light comes through. I can take it all the way down, 1 part in a million. It's just a question of cost.

So when you buy alignment glasses, okay, they, in point of fact, let a certain amount of light through. They're designed so that if you're going to work with a 1 W laser, they're not going to let, you know, a lot of that through. Maybe they let 1 mW through, so you can see the beam. Anybody that's ever worked with lasers knows that if you put on a pair of glasses, it's full of dyes, or through the metal dyes, and you go in there, and there's no laser light coming through, first thing you do, when you go to do the alignment, you take the glasses off so you can see it. Okay. So you don't buy them like that. Okay. So they're designed to let some light through. But this --

MR. KEITH: So they're like green landing lights. You're being --

DR. LAMBETH: A little bit of it, not a lot of it. You design -- but as far as seeing your panel and all that, that's broad spectrum, so you're still going to see all those things.

DR. LOTZ: So I think we could probably go on and discuss this much longer, but we are about running out of time, and I wanted to turn to Dr. Ochs and Dr. Miller and see if you had any final words for the Panel.

DR. MILLER: No specific words, but again, we want to thank all of you. Many of you have come from a considerable distance and are spending a considerable amount of time, both here at the meeting and before the meeting, reading that enormous stack of briefing material that we sent you. We deeply appreciate your presence. We deeply appreciate the ability to mine your knowledge and experience for our benefit and for the benefit of the people of the United States.

We'd also like to thank the public speakers and the public who have been sitting here for the past 2 days. I find it hard to believe you couldn't find something more interesting to do, but all right. And I would very much like to thank all of the FDA presenters who have put in an enormous amount of work preparing for this meeting. Thank you very much.

DR. LOTZ: Dr. Ochs, any final words?

DR. OCHS: No. Just reiterate my thanks for the Panel and the presenters. So thank you. Your comments have been very useful and will be considered.

DR. LOTZ: And I would like to add my thanks to the Panel and to our public speakers, and particularly to the FDA staff for both that volume of briefing materials ahead of time and your efforts, not only in this meeting but in general all the time.

So with that, I now pronounce Day 2 of the October 25th-26th, 2016 meeting of the Technical Electronic Product Radiation Safety Standards Committee adjourned.

(Whereupon, at 5:00 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

October 26, 2016

Gaithersburg, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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