FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TECHNICAL ELECTRONIC PRODUCTS RADIATION SAFETY STANDARDS COMMITTEE

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27TH MEETING

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WEDNESDAY,
JUNE 21, 2000

The Committee met at 8:30 a.m. in the Potomac I and II rooms of the Quality Suites, 3 Research Court, Rockville, Maryland 20850, Dr. Lawrence Rothenberg, Chairman, presiding.

Present:

LAWRENCE ROTHENBERG, Ph.D., Chairman
QUIRINO BALZANO, Ph.D., Member
JOHN F. CARDELLA, M.D., Member
KATHLEEN A. KAUFMAN, B.S., Member
MICHELE LOSCOCCO, M.S., Member
GREGORY W. LOTZ, Ph.D., Member
MAUREEN MURDOCK NELSON, M.D., Member
ROBERT PLEASURE, Member
JOHN M. SANDRIK, Ph.D., Member
STEPHEN SZEGLIN, M.S., Member
JERRY A. THOMAS, M.S., Member
ORHAN H. SULEIMAN, Ph.D., Executive Secretary

FDA Presenters:

DAVID FEIGAL
FRANK CERRA
HOWARD CYR
JERRY DENNIS
ROBERT GAGNE
ELIZABETH JACOBSON
STANLEY STERN

Public Speakers:

JERRY DEVENEY
JOE LEVY
JACK RILEY
DON SMITH

I N D E X

P R O C E E D I N G S

8:40 a.m.

DR. SULEIMAN: Good morning. My name is Orhan Suleiman. I'm the Executive Secretary for the Technical Electronic Products Radiation Safety Standards Committee meeting. And before we get -- as we get started, I'd like to read the following statement: "In accordance with the radiation control for the Health and Safety Act of 1968, Public Law 90-602, the Secretary, DHHS, has established the Technical Electronic Products Safety Standards Committee for consultation on matters relating to technical electronic product 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 four years or less. Five Members are selected from government agencies, including state and federal governments; five Members from the 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 production radiation and safety standards. The primary function of TEPRSSC is to provide advice and consultation to the Commissioner of Food and Drugs on the technical feasibility and reasonableness of performance standards for electronic products, to control the emission 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. Public Law 90-602 and its legislative history clearly indicated that the TEPRSSC Members are expected to represent a wide range of interest with at least one third of the Committee nominated by the regulated industry itself and appointed on the basis of their being able to represent industry-wide concerns. Section 534 of the Federal Food, Drug and Cosmetic Act specifies that TEPRSSC Members are not to be considered officers or employees of the United States for any purpose

including conflict of interest determinations. However, to be consistent with FDA's general policies regarding Advisory Committees, the Agency believes a public disclosure memorandum should be made a part of the public record which identifies each member and provides their employment affiliation. Approved on March 20, 1996, September 15th and 22nd, 1998, August 30, 1999, and June 14, 2000, by the delegated authority of the Commissioner of Food and Drugs, the Members of the Technical Electronic Products Radiation Safety Standards Committee are" -- and I'll just read you a list of the current Members. Mary Marx, University of Michigan Medical Center. She's not here today. John Cardella, State University New York-Syracuse, Health Science Center. William Rice who also isn't here today, American Radiology. Robert Pleasure, Center to Protect Workers' Rights. Larry Rothenberg, representing Memorial Sloan-Kettering Cancer Center. These are the five general public Members.

The government Members are Kathleen Kaufman, Los Angeles County Department of Health

Services. Jerry Thomas, Uniformed Services, University of Health Sciences. W. Gregory Lotz, National Institute for Occupational Safety and Health. Michele Loscocco, Joint Readiness Clinical Advisory Board. Maureen Nelson, Veterans Administration.

The representatives from industry: David Lambeth, Lambeth Systems, Design and Consulting. He was not able to be here today. Stephen Szeglin, PTW New York Corporation. He is not here physically, but he's connected to the meeting via telephone. Quirino Balzano, Motorola Florida Laboratories. John Sandrik, General Electric Medical Systems. And Alice Fahy-Elwood, Lucent Technologies. She is not here with us today because of an imminent birth.

Larry?

DR. ROTHENBERG: Well, I'd also like to welcome you here on behalf of the Committee. I am a new Member, as well as a new Chairman of this Committee, so I'm going to have to rely heavily on Dr. Suleiman and other Members of the staff as well as the experienced Members of the Committee. But I think we will have a good meeting and there's several

interesting topics that we'll be going through.

It might be good at this time if we could just have each Committee Member just say a couple of words, maybe a little bit more detail about their activities. So maybe we could start with Mr. Thomas.

MR. THOMAS: Sorry. I had a Lifesaver in my mouth. I'm Jerry Thomas. I'm the Senior Medical Physicist in the Navy. I'm on the faculty of the Uniformed Services University. My areas of expertise are radiation biology and diagnostic imaging and nuclear medicine.

DR. SANDRIK: John Sandrik, G.E. Medical Systems. My background is in x-ray imaging of various sorts, screen film, fluoroscopics, CT and mammographic.

DR. LOTZ: I'm Gregory Lotz with NIOSH and my background is in physiology and biophysics and a career of research in low frequency and radio frequency non-ionizing radiation. I lead the NIOSH research effort in that area.

DR. BALZANO: I'm Quirino Balzano. I'm involved in radiation dosimetry and non-ionizing

radiation dosimetry and the biological effect of RF energy.

DR. ROTHENBERG: We'll go now to the other end of the table

MR. PLEASURE: Robert Pleasure. I'm Executive Director of the Center to Protect Workers Rights. I am principal investigator on a major cooperative agreement with the National Institute for Occupational Safety and Health on Construction Safety and Health and administer two other major grants, one with the National Institute for Environmental Health Science for workers involved in environmental cleanup work, and the other doing medical screening in facilities of the Department of Energy.

MS. KAUFMAN: I'm Kathleen Kaufman. I'm Director of Los Angeles County Radiation Management. We enforce compliance of both federal and state standards for x-ray and radioactive materials users in Los Angeles County. Los Angeles County is the largest county in the country with a population of about 10 million that we know of and we also make numerous recommendations during inspections to improve image

quality and reduce patient risk.

DR. CARDELLA: Good morning. My name is John Cardella. I'm an interventional radiologist trained in high dose fluoroscopy techniques. I currently am the Chairman of Radiology at SUNY Upstate Medical University. In addition to that I serve as the Chairman for the Society of Cardiovascular Interventional Radiology Standards of Practice Committee which is a large multi-specialty or sub-specialty group involved in international radiology and high dose fluoroscopy type procedures.

DR. MURDOCH NELSON: I'm Maureen Murdoch Nelson. I am a general internist at the Minneapolis VA Medical Center. I'm here probably because of my public health and epidemiology background.

DR. SULEIMAN: I'm Orhan Suleiman with FDA, the Exec. Sec. for the Committee.

DR. ROTHENBERG: I'm Lawrence Rothenberg. I'm an attending physicist in the Department of Medical Physics at Memorial Sloan-Kettering Cancer Center and a former president of the American Association of Physicists in Medicine and I've also

been involved in a number of committees of the National Council on Radiation Detection and Measurement and my major activities have been in the area of physics and diagnostic radiology with particular interest in computed tomography, mammography and patient dosimetry as well.

DR. SULEIMAN: You may want to get Steve.

DR. ROTHENBERG: Steve, while you're with us, can you say a few words about your activities?

MR. SZEGLIN: Yes. Can everybody hear me?

ALL: Yes.

MR. SZEGLIN: Okay, my name is Steve Szeglin. I'm the president of PTW. We are a company that manufactures devices that measure radiation so my area of specialty is radiation measurement, radiation dosimetry.

DR. ROTHENBERG: Okay, thank you. Our next agenda item, we'll have a welcoming address from Dr. David Feigal.

DR. FEIGAL: Thank you. Good morning. Since there's new Members of the Committee, I usually welcome new Members with the following warning. One

of my first introductions to FDA was actually being asked to come and make a presentation to the Advisory Committee. Next thing I knew I was on an Advisory Committee and not too long after that I was employed by the FDA. So in the spirit of full disclosure, some things are habit forming and consumer protection and interest in the public health seems to be one of those and we actually look -- even if we don't recruit you directly, actually, we often get some of our best leads for new leadership in the Agency from our Advisory Committees' recommendations.

You are probably all aware that the Center for Devices and Radiological Health, just by the nature of its title was formed from two streams of consumer protection. One was the device side, the medical devices and some of those, in fact, are devices that use radiation or involve radiation and are the kinds of things that we will bring and discuss with you. And the other side was the consumer protection activities that correlated to radiologic health, whether it was a medical device or not. And that's actually the side of the program that often

gets forgotten in all of the attention and excitement around devices. And the two streams actually came from very different traditions and looking over today's agenda, you're actually going to be having looks at parts of both of those programs and see the breadth of the challenge with dealing with these types of products.

The device side of the consumer protection came very much from, if you will, the drug model. In fact, if you look at the legal definition of a drug, it actually includes devices and before the Devices Amendments in 1976, such things as sutures were actually regulated as drugs with applications as new drug approvals and contact lenses were another example and other kinds of implants.

But in 1976 it was realized that the device world was much broader and the pre-market philosophy approval that you had to actually have your product reviewed for safety and effectiveness, the standard that had been in place for drugs involving forms since the turn of the century was applied for systematically to devices. And that was part of the

origins of this Center.

On the other side was the consumer protection strategy and it's applied to products that emit radiation, whether they're medical devices or not. Now if they're medical devices we will still be doing pre-market review, but for the nonmedical devices, televisions or from your agenda today, sunlamps and tanning applications, there the philosophy very much was a product testing philosophy and even more important than the product testing, setting standards and standard setting.

Actually, these two currents, these two streams are beginning to merge. Standards are being increasingly used in the pre-market application process and standards organizations is becoming a way that the world is harmonizing the approval and recognition of new products.

It's kind of a daunting regulatory scheme to figure out at times, what's covered by what, what do you have to do, what are the requirements and even at a briefing that Elizabeth Jacobson did very capably for the Commissioner last week on the radiologic

health program, it was very easy to ask us questions that stumped us, that we said we'll have to get back to you on that. And some of those related to well, what do the states require? Or what does the Joint Commission require of hospitals? And that's another part of the complexity is the great overlap.

My final comment in terms of a welcome is more of a comment that we really need you and it's particularly a sincere statement in the area of radiologic health. This is a program that within the Agency has been gradually shrinking as the device program and the demands of the device program became more voracious. This program which at one time had over 400 people working full-time on it, now has less than 100. And we rely increasingly on partnerships with external organizations, with the states, with other bodies that have regulatory authority and on our advisory panels and on the experts that help us serve in this area.

So let me close by welcoming you and wishing you a productive meeting and invite you to keep your CVs up to date just in case we have some

opportunities to do some rebuilding in the near future, we'll at least want to have your recommendations, if we can't entice you to join us more formally in this effort.

DR. ROTHENBERG: Thank you very much, Dr. Feigal. Next item on our agenda is an update on open issues from Dr. Elizabeth Jacobson.

DR. JACOBSON: Well, good morning. My job today is to give you some brief updates on three issues that were discussed at previous meetings, and I'd also like to say a few words about our revitalization project for rad health.

Let me start with the updates though. There are two, what I'm going to call good news stories and one that's sort of still in progress and let me start with that one and that's the fluoroscopy amendments to the CDRH performance standard for diagnostic x-ray systems.

In a word, the bottom line here is that our proposed amendments are not published yet. As you know, in 1994 FDA published amendments to the performance standard for diagnostic x-ray systems and

these amendments established an upper limit on the x-ray exposure rate for fluoroscopic x-ray systems when operated in the high level control mode of operation. And at the time of the amendments, we recognized that additional changes were going to be needed to address changes in technology and use and we discussed concepts for those amendments in 1997 with TEPRSSC and the details of proposed amendments with the Committee in 1998 and then again an update in 1999.

During those discussions we had we noted that fluoro is being used for guidance and visualization in connection with a number of, a growing number of procedures and these uses often require exposure times much longer than that for diagnostic procedures, obviously. Unfortunately, radiation burns to the skin continue to be reported as a result of some of these long fluoroscopic procedures and everybody agrees that clearly something needs to be done to help minimize patient exposure.

In addition, the technology of fluoroscopy equipment has continued to evolve and we also need to

maintain agreement between our performance standard and international standards that are being developed.

As I said, we had hoped that the proposed amendments to the x-ray performance standard would be published before this meeting. They aren't. Unfortunately, our progress on them was slowed by another issue that we needed to deal with which was the Y2K issue. We had a lot of activity to insure that medical devices would continue to function properly, computer-driven, software-driven medical devices would continue to function properly.

But I am happy to say that our major driver of the fluoro amendments who had been spending 100 percent of his time on Y2K in order to lead the Agency's effort for medical devices on Y2K is now back on the job putting his full attention on fluoroscopy and currently the draft Federal Register notice is under final review, the very final stages of review at CDRH. We're doing an impact analysis and the Center's fluoroscopy working group, the Center's senior staff, FDA's general counsel and our regs staff are all very committed to moving this rule.

We anticipate to have publication of the notice of proposed rulemaking this summer with a comment period and after the comment period, we'll consider the comments and then proceed with the final rule which would become effective a year after publication. So with our current time line, the proposed rules would become final some time in 2002.

Now although the publication of the proposed amendments has been delayed, we have continued our efforts to raise awareness of users of these systems, regarding the potential for injuries from long procedure times. We issued a public health advisory in 1994.

We had an RSNA exhibit on skin injuries and additional information regarding recording of patient dose information during 1995. And we published a journal article in 1996. In addition, CDRH staff have continued to make presentations and to work with other professional groups to raise awareness of the issue. The AAPM developed their report No. 58, "Managing the Use of Fluoroscopy in Medical Institutions" with consultation and strong encouraged

from CDRH. This report provides a blueprint for establishing a program to assure that fluoroscopic systems are only used by appropriately trained physicians.

CDRH staff are also working with the H22 Committee of the Conference of Radiation Control Program Directors to develop materials that will assist State radiation control programs to implement programs to improve use of fluoroscopy. The initial focus is likely to be a program that will encourage facilities performing interventional procedures to monitor actual patient doses from fluoroscopy.

CDRH has also been an active participant in the IEC Working Group that's developed the draft IEC standard for safety requirements for x-ray systems intended for interventional radiology. This international standard is in the final stages of approval and we intend for the U.S. standard to be harmonized with it.

CDRH staff have also contributed to the development of a report by the ICRP on the avoidance of radiation injuries from interventional procedures.

This report is also in the final stages of approval and it's designed to educate physicians regarding the risks from radiation during interventional procedures and how to reduce those risks.

I'd like to turn now to our efforts with another product, anti-theft systems and this one of the things that I consider to be a fairly good news story. Electronic article surveillance systems and metal detectors were discussed at the 1998 and 1999 TEPRSSC Meetings by -- we had local, federal and government agencies.

We had the anti-theft systems industry and the medical community here. And these are the systems that you walk through when you go into retail stores or at the airport, you're scanned by them. And the concern here was that these systems can potentially interfere with some implanted medical devices.

However, the risk appears to be low and can be avoided through proper communication and design consideration between the EAS and metal detector industries and the medical device industry.

At the last meeting the TEPRSSC Committee

urged cooperation between these groups to resolve the problem, to research the problem, to identify solutions and to reduce the risk of electromagnetic interference with implantable electronic medical devices.

To address those recommendations, we worked with medical device manufacturers to insure that they include information about potential interference and their labeling and the two manufacturing groups, the anti-theft system manufacturers and the medical device manufacturers are cooperating in a number of venues to reduce the potential for interference through proper testing and design.

For example, the Health Industry Manufacturers Association, HIMA, met with both the metal detector and EAS manufacturers to talk about labeling and both industries are members of AAMI's pacemaker committee's EMC working group. This working group is chaired by, co-chaired by Mitchell Shane of the CDRH's Office of Device Evaluation and it's developing a comprehensive EMC testing standard for

cardiac pacemakers and implantable defibrillators.

Some other steps taken by FDA included issuance of a letter to clinicians in 1998, explaining the possibility of interference from anti-theft systems. The letter supported the recommendations of the anti-theft industry and of the medical community that implant wearers not linger in the vicinity of electronic anti-theft systems, that they not go up and lean on the pylons and it also recommended that security personnel with hand held scanners that you have in airports, for example, be aware of the potential for interference.

We also feel that explicit signage on the anti-theft equipment itself, making its location more obvious to patients, again, more counseling to patients to be aware that these systems are out there and to understand whether there's an issue with their particular product, but they need to know that the systems are there. So signage would be helpful.

The idea here is to just simply state on the equipment something to the effect of electronic security system in use or anti-theft system or we're

not really prescribing what the word should be. We're issuing a letter, probably this week or next, to all electronic anti-theft system manufacturers recommending labeling and signage be used on all new and all currently installed equipment. So put it on their new production, but also to go back and put it on their installed base.

The labeling has a clear public health benefit and we're pretty optimistic that retailers won't object because in the case of EAS systems it should also deter shoplifting and that is the main concern for retailers.

In fact, the largest manufacturer of EAS systems has already beat us to the punch and has for the last couple of months been putting that kind of label on all of their new production and they're currently going back and adding it to their installed base.

So we're also going to be ready to cardiovascular and neurostimulator device manufacturers, to notify them of these recommendations that we're making to the anti-theft industry. Another

letter is going out to other clinicians, again, to reinforce the message that patients should be aware. And finally, we're sending a letter to retailers, to explain the recommendations to them, so they'll understand what the purpose is.

In other actions, we recently conducted a study to generate some data to characterize the electromagnetic fields that are generated by these kinds of products. And the data from this study are being used to help formulate some standardized approaches for susceptibility testing for various ambulatory medical devices.

Again, we hope this kind of information will be very useful in future designs for medical devices and our Winchester Engineering and Analytic Center, WEAC, also measured a number of EAS systems, actually in use in retail stores and libraries in the Boston metropolitan area and results from this sort of in the field study are being compared to our laboratory studies and we're going to be publishing those results, again, to assist engineers in designs that can minimize the potential for interference.

I think that the collaborative efforts that we've seen between the electronic security systems industry and the medical community over the last couple of years to mitigate interference with implantable devices has really been pretty substantial and very much targeted towards the recommendations that TEPRSSC made.

We recognize that -- I think we all have to recognize that the likelihood of interference from these types of equipment with implanted medical devices is very low. The number of adverse reports indicates that we relatively small numbers of people that have had any kind of interaction.

Furthermore, the reports describe most interactions as mild or moderate in nature and not of any significant clinical impact to the patient. But it's also important and this was kind of the reason we addressed this whole issue, it's important to be sure that we don't get significant problems in the future as the designs of both industries continue to evolve. So I think the emphasis that TEPRSSC put on communication and cooperation of the industries to

insure that the situation stays under good control is really right on the money.

The third update I wanted to give you has to do with another different kind of electromagnetic interference and that's that involving wireless telemetry systems. And I think this again is another very good news story. Wireless medical telemetry equipment is used in hospitals and health care facilities to transmit patients' physiological measurement data such as heart rhythms and respiration rates to a nearby receiver.

This technology allows patients the freedom to move around without being tethered to a monitor and really helps speed recovery, gets them back on their feet faster and enables medical staff to simultaneously monitor several patients from central consoles.

The primary concern for wireless medical telemetry up until now has been that hospitals and telemetry devices were secondary users of the radiospectrum. This means that under FCC rules they could not interfere with primary spectrum users like

TV stations and in turn, they had to accept any interference that they got from primary users like TV stations.

Well, for a long time that really wasn't a problem. Most wireless medical telemetry systems worked very well within those limitations. The manufacturers and users were very aware of their status as secondary users. Most locations had unused TV or land mobile radio frequencies that were vacant so that hospitals could use those for their wireless telemetry systems, but that's been changing a couple of things.

TV is going digital and FCC is refarming -- I love that term -- that's an FCC term, they're refarming portions of the land mobile radio spectrum for the newer digital technologies that are here and that is very important to them because it allows for many more users and more efficient use of the spectrum which is part of the FCC mission.

But while the radio spectrum is rapidly changing and more users are competing for the frequencies, wire medical telemetry has been stuck

with ever diminishing frequencies in which they can operate without interference. And in fact, the changes brought about by digital TV were widely felt in 1998 in Dallas and later Atlanta, Houston and Philadelphia where digital signals from experimental TV stations that were going on-line shut down some wireless telemetry systems in local hospitals.

Luckily, nobody was injured. They did figure out immediately what the problem was, but the potential for harm was kind of loud and clear at that point.

So we reached out to a number of organizations to help in tackling the problem. There's really been a cooperative effort between -- among, rather, FDA, FCC, the American Hospital Association, the American Society of Health Care Engineers and the affected industry.

In 1998, we sent an alert to all hospitals warning them of the problem. And at the very same time, FCC moved quickly to coordinate with their TV broadcasters, to make sure that they would coordinate with their local hospitals when they were going to go

on-line with digital testing. So they could avoid interference problems with these experimental signals.

The American Hospital Association and the American Society of Health Care Engineers developed information to demonstrate the extent of the potential problem, went out, surveyed their members, what kinds of equipment do you have, what frequencies do they operate at, how old is your equipment, those kinds of questions.

And then the American Hospital Association set up a task force to look at the problem and to develop recommendations to FCC for what spectrum ought to be dedicated to the use of medical telemetry equipment, what kind of bandwidths were appropriate, that kind of thing.

The American Hospital Association also looked at current and future needs in cooperation with hospitals and the telemetry manufacturers and the recommendations that they drew up formed the basis for an FCC proposal, a proposed rule on wireless medical telemetry and this was really a historic proposal because it proposed setting aside a special place on

the spectrum for the sole use of medical telemetry equipment. I think the sense the spectrum is usually auctioned off, it's an incredibly valuable commodity. This really was a change in the way spectrum allocations were done or were being proposed to do.

There was a comment period, of course, and the FCC ultimately adopted the proposed rule as final as of June 8th and they've called this new protected band the Wireless Medical Telemetry Service, the WMTS. And use of this band should prevent interferences with medical monitoring, such as those that were seen in Dallas and other hospitals and it will protect patients.

Of course, there's going to be a transition period to allow the medical telemetry manufacturers to transition to this new service. And to assist in this transition we're committed to working with device manufacturers and to users to facilitate migration as quickly as possible and as least burdensomely as possible.

We're developing a guidance document for industry to help the wireless telemetry manufacturers

meet our regulatory requirements as they make these changes. And to advise the affected community of the transition we'll be issuing a public health advisory. It's going to go out to about 53,000 different types of groups, chemical and biomedical engineers, risk managers, nursing homes, hospital administrators and the advisory urges users to assess the potential vulnerability of their own equipment to electromagnetic interference during this interim period, so don't get caught as people are migrating over to this new band, we still have this couple of year period.

Determining at which frequency band and channel telemetry systems are currently operating, and comparing that data with the sort of sources for interference in their areas and what needs to get done, and FCC is making this easier because they have on their website a list of all of the digital TV allocations posted, so people at the hospitals can just go to that website and look to see what's happening in their area. And they can also find out about changes that are anticipated in the land mobile

band.

We're also issuing a notice to wireless medical telemetry manufacturers, recommending that they establish an action plan to minimize the risk of interference during this period and also that they use the new band for new equipment, so the job isn't completed yet, but I think we have an excellent result so far. We really strongly support the use of the new wireless medical telemetry service and we're going to do all that we can to insure that it's a great success. And I might point out that the latest issue of AAMI's journal has the cover story on this called "Managing the Airwaves, New FCC Rules for Wireless Medical Telemetry." So there is a fair amount of discussion about this.

Okay, well, I'm almost done. My last topic is I wanted to just take a very -- just a couple of minutes to talk about our revitalization effort for rad health. Dr. Feigal kind of referred to that in his opening remarks and the Committee has been briefed at its previous meetings by our re-engineering team leader, Joanne Barron, and she is on the agenda again

tomorrow to give you some more specifics, but I wanted to give especially for the new TEPRSSC Members, just a bit of perspective.

As Dr. Feigal said, at the peak of the rad health program we had about 400 CDRH people, headquarters people, and additional people in the field working in this area. The number has dropped in the non-mammography rad health area to about 60 people. So clearly we need to change the approach to the program and we're currently engaged in a grand experiment of sorts to change the paradigm of rad health protection. And this for us means moving from the approach that was really typified by the work I described for diagnostic x-rays for the fluoro amendments.

It's a very hands on, driven by the development of mandatory and federal performance standards and the subsequent enforcement of those standards to a new role that's probably best typified by the medical telemetry example I described where we act as public health protector in kind of a catalyst role. We identify the problem, sound the alarm, bring

together the right parties to solve it and then move on. It doesn't mean that we would never do mandatory performance standards.

That would be part of our armamentarium of things that we could use if we need to take a more strictly regulatory route, but it is a new way of thinking for us, a new paradigm and we are in the process now of trying to move into that. This role is -- it's hard to do that. It's hard to change the paradigm and we've been extremely fortunate in having a great deal of interest in our situation and support for our need to change by our stakeholders.

They've been very wonderful about talking to us, giving us suggestions and based on their input and the analysis we've done ourselves, we intend to become a national information resource for rad health issues. We want to return to our roots and work more as an educator, work more closely with States and other federal agencies and actively communicate with the public and other stakeholders about radiation risks from products.

So to that end we have quite a few

projects ongoing now and lots more in the pipeline. We've developed a long-term training strategy for the center and field staff. Eventually, we're going to expand that to include State, State personnel to fill a long standing request from the States. We're looking at CD ROM and web-based and other distance learning techniques and we're going to have an internal kickoff meeting to launch this new training initiative this coming Monday.

We've piloted an internal survey of in-house expertise to help with succession and other planning that we have to do in terms of what types of people do we need in the program. Like a number of other government programs about half of our remaining rad health experts can retire within three years. So we're looking at some staffing strategies to figure out how to handle that.

We're also developing a website to enable us to fulfill this role of national information resource. Right now we have a button for rad health on our home page, but most of the information we have is still pretty scattered throughout our webpages and

it's very hard for people to find their way to the information they need so we're going to be pulling that together in a very coordinated way.

And finally, I guess my message is just know we have a lot of internal attention to this effort. We have every intention to succeed. We also have a very hard job ahead of us and I'd like to thank you very much.

DR. ROTHENBERG: Thank you. At this time I guess we're moving along well so if any of the Committee Members have any question I'd like to address them.

MS. KAUFMAN: Kathleen Kaufman. I was wondering if FDA had received any more reports of injuries, erythema from fluoro and also relative to the anti-theft systems, if there have been any reports since our last meeting of outliers and interactions?

DR. JACOBSON: That's a good question. I'll let Tom answer the fluoro question. We have gotten in the anti-theft area, yes, we've continued to get a few reports, the numbers have been sort of in the teens per year. It's not a lot and it's going

down, so I think it looks like that issue may be, I think as I said I think it's being gotten under control.

The one type of product that we probably will be continuing to see reports on in the anti-theft area for a while are the neurostimulators. That seems to be the best proportion of things that we're seeing right now. That proportion is a very small number, but that's what we're seeing.

DR. SHOPE: With regard to the reports of injuries from fluoroscopy, yes, we're continuing to get occasional reports through the MDR reporting process, although I think that is not an extremely reliable way to catch all the reports. In fact, I think I've gotten more reports as a result of calls from lawyers or legal aides asking questions and the more we investigate the questions and the reason for the questions we find out about a few more incidents.

So I've been attempting to put all our information together in a little bit of a data base. I'm a little bit behind on that, but I think the numbers are certainly beyond 60 at this point over the

last six or seven years. So that's sort of where it stands.

Unfortunately, a number of these reports are injuries that occurred long after our 1994 public health advisory, so we know we didn't reach everybody and if we reached them it didn't take. Somebody always doesn't get the message, I'm sure. So I think we have some more education that's appropriate for the users of this equipment.

DR. JACOBSON: I can give you the numbers, actually, for the anti-theft. We had 17 reports in 1998; 15 in 1999; and 6 in 2000 to date. And the ones in 2000 are all neurostimulators.

DR. ROTHENBERG: Any other questions? Yes.

DR. LOTZ: When you were describing a couple of the things you referred to generating new data, in house, and yet when I heard you describing the future directions of rad health, it sounds to me like research is probably going to be a casualty of the limited resources. Is that --

DR. JACOBSON: No, I really didn't mean to

imply that at all. I think information generation and serving as an information resource are very much part and parcel.

DR. ROTHENBERG: I just have one information question. I don't know who are the right people here to answer it, but with these medical telemetry devices do they have to be replaced to change the frequencies that they use or are they programmable in some ways so they can be retuned?

DR. JACOBSON: Some of them are programmable and some of them, the older models may need to be replaced. In fact, that was one of the -- I don't know if Skip Witters is here, but one of the pieces of information that the American Society of Health Care Engineers got for FCC and us was that kind of information. What does the installed base look like? How old is the equipment? What's the impact of having to do these kinds of replacements?

Don, did you want to add anything?

MR. WITTERS: The new frequencies that are allocated for the WMTS include channel 37 which is in the frequency ranges of some of the newer equipment,

so they can go to that channel now if they so choose, programmable-wise. Some of the other frequencies which are much higher require new equipment and that will have to be replaced.

MS. KAUFMAN: The protected band, I'm not sure how broad this protected band is. Is it broad enough that it will be able to handle future needs of large urban areas, like, for example, Los Angeles?

MR. WITTERS: The AHA recommendations included looking at that as Liz mentioned, the numbers of patients, the numbers of parameters measured, which approximately was about 6 megahertz worth if everything was combined in a small geographic area. These are low power, small geographic area type transmitters, a few hundred feet at the most, usually.

Even so there are areas like Los Angeles, Boston, San Francisco, Chicago, some other areas where these facilities can be close. They recommended at least double that, 12 megahertz.

The new band, in fact, has 14 megahertz. It also allows not only one way which is what is up to now been allowed from the patient to the central

monitor, but they are now allowing bi-directional. So it is possible that communication will be from the patient back to the monitor and then from the monitor or some controlling system back to the patient for possible treatment.

DR. JACOBSON: Let me just say this is Don Witters who spearheaded this effort for CDR.

DR. ROTHENBERG: Any others? Thank you very much for your report.

(Pause.)

MS. KAUFMAN: Larry, can I -- I guess my question is for Tom Shope. On the fluoro reports have they all been strictly erythema or has anything been worse than erythema?

DR. SHOPE: I would say that most of them are worse than erythema. We're talking desquamation and severe kinds of injuries requiring flap grafts and those kinds of things.

MS. KAUFMAN: How about -- I know we're going to talk later on about the CT fluoro, but have you seen any reports from that yet?

DR. SHOPE: No, other than kind of an

anecdotal report about from one institution of a little erythema.

MS. KAUFMAN: Uh-huh.

DR. SHOPE: I suspect we'll eventually hear some of those, but whether they'll be worse than erythema is a good question.

Those systems can be run at a low mA and hopefully that's what people are doing when they're doing those fluoroscopic type procedures.

MS. KAUFMAN: I guess I really question how much reporting is occurring because when I talked to facilities about other -- what sound like more serious incidents to me about reporting, they don't seem to be aware of reporting or how to do it or that it might be a good idea. They always seem surprised when I mention it that we reported this to the FDA, it's something they might like to know about.

So I'm wondering if FDA might want to do some more outreach kind of efforts in terms of notifying people of the ability to report, when they should report and how to go about it.

DR. SHOPE: I don't know, you may be aware

at one point there was some discussion and we have the authority, I think, and I'd have to check on this to be sure from the changes to the MDR reporting requirements.

We were given some authority to describe other adverse events that we wanted reported and at one point we were talking about specifying in addition to the current definition of serious adverse consequences and those kinds of things, some particular kind of events, analogous to infections or burns of any sort or implants that cause problems of a particular nature. We could specify some particular kind of things that would be mandatorily reported. We haven't done that. So that's one opportunity that was discussed at one point and this administration of radiation therapy would be another kind of event like that.

But I think that's sort of taking a low priority or recently I had some hope, I think, initially that we have a clear statement of reporting and have some authority to say even though -- see the device in these cases doesn't necessarily malfunction.

The device, the x-ray machine works perfectly. It's not a problem with the device. It's sort of the way in which it's used, although user error is a reportable event if it leads to serious injury. It's -- I think the health care community is not real clear on that reporting hierarchy requirements.

MS. KAUFMAN: I agree. Would it be helpful for this committee to make recommendation regarding mandatory reporting on those events?

DR. SHOPE: I'm not sure I could answer that question, but I'm sure the committee could think through that and give us a recommendation if they wish.

MS. KAUFMAN: Can I make a motion? Is that appropriate? I'd like to make a motion and open for discussion the issue of making erythema and more serious effects from fluoro, including CT fluoro be mandatory reporting requirements for facilities or doctors.

DR. CARDELLA: I'll second that motion.

DR. ROTHENBERG: Okay. Do we have discussion?

MR. THOMAS: I have a question, please. Tom, in the -- you said we were beyond 60 incidents. Have you had the opportunity to break those out by frequency by year or are we seeing an increasing trend recently or is this total since you first became aware of this about eight years ago?

DR. SHOPE: Yes, I think the answer is that's kind of a cumulative number. I think it probably has slowed down a little bit, but we haven't done a real detailed analysis of those trends, so I wouldn't want to answer that specifically.

MR. THOMAS: The types of injuries that you've seen, you said that they're worse than an erythema dose. Are we looking at dry and moist desquamation?

DR. SHOPE: Yes, in many cases.

MR. THOMAS: That's fairly serious.

DR. SHOPE: Yes.

DR. SULEIMAN: Let me add a clarification that Dr. Jacobson pointed out which these reports are mandatory. The hospitals do it much more -- or the manufacturers seem to be doing it much more regularly,

but it's more of an education, letting people know that they're supposed to do it.

MS. KAUFMAN: I can tell you hospitals certainly are not aware of that, if it is mandatory.

I thought on these kinds of issues it was not mandatory that it was advisory, it wasn't mandatory reporting since there was not actually defect in the --

DR. SULEIMAN: No, I think medical device reporting requirement is that any serious adverse incidents and I think that we've defined that these are, in fact, serious enough to be reported, but it's always this initiative to report.

DR. SHOPE: I think one could debate whether erythema is a serious injury that needs to be reported. There's an issue here.

DR. CARDELLA: John Cardella. There may be a little bit of misunderstanding about that in that the institution where the owner of the equipment believes that it is their responsibility to report it if the radiation burn was the result of malfunction of the equipment. In other words, a patient receives a

skin burn injury because the machine was improperly tuned. Everybody thought it was delivering 20R a minute in high dose mode and in reality it was delivering 25R per minute because of a malfunction.

The issue of mandatorily reporting an adverse event that occurs because of prolonged use of a properly functioning machine may be the hair that's being split and I'm inclined to agree with Cass that the occurrence of those types of injury should be reported whether or not the machine works properly or is improperly functioning.

I don't know if that's a distinction that maybe -- my sense, Tom, is that 60 reported cases is substantially under reported. We've had three in our hospital and it's a small -- it's not a big place. I personally know of probably now a dozen or 18 of these and you're right, it comes in attention through the legal system mostly.

My guess is that 60 is substantially under reported.

DR. ROTHENBERG: Michele?

MS. LOSCOCCO: I'd have to agree that I

think most people think that it's a malfunction of the equipment, not in standard use and that typically you don't receive these over one procedure type thing. It's somebody that has returned multiple times that then receives a range burn.

MS. KAUFMAN: I have a question probably for Dr. Cardella and other physicians and that is do you think and I don't know the answer to this, are there instances where erythema or something more serious may be occurring in the physician who actually did the fluoro procedure may not even be alerted to that by the primary care physician?

DR. CARDELLA: I hate to say this in a public forum. I think that that occurs. I have the sense that -- I wouldn't use "frequently" but occasionally injuries are identified by other than the radiation deliverer and they're not appreciated for what they are. I think that's problem number one because if the propositus physician, the guy that catches the thing is not a radiologist or is not a cardiologist or is not a neuroradiologist, they may not appreciate it for what it is. I have some concern

that that occurs.

I think the answer to your question is yes.

MR. THOMAS: Orhan, or maybe somebody else from the FDA. Focusing back on Cass's proposal that's on the table here, I'm unclear that making this mandatory is anything other than what we currently have from what you've said. It might help a little bit to let the Committee be a little more clearer as to what the current reporting requirements are in this particular area because I think there's some misconfusion here.

If we're looking at a device that isn't operating correctly, that's a manufacturer's requirement for reporting. If it's misused in -- misused is the wrong word. If it's used in the delivery of care in such a fashion that it causes injury to the patient it may or may not be known to the individual that's using the piece of equipment. That's a different set of circumstances for reporting. I'm unclear as to what the regulations require today.

DR. SHOPE: I think I can summarize close

to the words, but I probably won't get it exactly right. The mandatory reporting requirements are for reports of deaths or serious injuries associated with the use of a medical device or in which the use of the medical device contributes to the death or serious injury. It's not a requirement that the device malfunctioned.

The question of judgement gets to be what do you mean by serious and how close is that connection or contributed to and in the preamble for the medical device reporting it was explicitly stated that user error that results in an injury associated with the use of a medical device is a reportable item. The idea is to learn about mistakes made because users didn't understand the instructions, didn't understand the use of the device. That makes it clear that that was a reportable event.

I think the question with regard to these kinds of injuries is the question of is it serious enough to be reported. It's clearly the moist desquamation kinds of injuries I think no one would argue that those are reportable events. They're

erythema and maybe the dry desquamation could be issues of whether that's serious enough that requires the immediate medical attention and the definition of a serious injury.

DR. CARDELLA: Tom, the -- John Cardella. The other issue that maybe at play here is with the heightened awareness of the radiation injury potential, I would not say many, but I would say some physicians are beginning to include that in the informed consent process and they say, "Mrs. Jones, we're doing to X, if our fluoroscopy time goes over an hour and a half, you may end up with a skin injury. We're going to save your life by fixing your coronary artery, but you're going to burn some skin."

If the patient says, "yes, doctor, I understand that. Let's go for it" that may not get reported either because everybody thinks that's part of the procedure and it's been discussed by the patient and the patient agrees to it, so there is another side to that coin in terms of -- I'm trying to be balanced in what I present, but I think probably under reporting occurs and that may be one of the

factors.

DR. SHOPE: Not necessarily, we wouldn't think of that situation as a user error. That was a complicated process that the user made a decision, a professional judgment decision to keep proceeding.

DR. CARDELLA: It was planned. It was intentional. It was done with forethought and they may not view that they want to tell anybody they made an error or had an adverse event. That was part of the complex procedure. That's the other side of it.

DR. SHOPE: Clearly.

MS. LOSCOCCO: I believe that's also the case is that a number of times it is multiple procedures that causes this, so it is a reasonable expectation that you would receive a erythema dose with the length of fluoroscopy so it was not a user error. And I don't think that would fall under reporting category.

MS. KAUFMAN: I guess I'm kind of thinking that though there may be things that could be done that would result in less of those effects, but that people aren't going to initiate taking those actions

unless we know that those are occurring and that it may be helpful to have reports of those events even though they may not have been avoidable under present circumstances that might assist FDA and the States to come up with procedures that might assist in reducing those events.

For example, encouraging training. I believe California is the only State in the country that has some certification requirements for physicians who use fluoroscopes and so if we were -- if the country was aware of more of these incidents occurring it may be that more States might move in that direction. It may be that additional training would reduce that number of incidents.

I guess what I'd like to see is more communication between FDA on reporting and perhaps some more definitive descriptions of what is reportable and what is not so that there's less confusion out there and it's not -- it may be similar to have a misadministration in nuclear medicine, where it's not a violation to have a misadministration.

It's only a violation not to report it.

So I don't think people should think that because something is reportable that something negative is going to occur from that. It's just a matter of data keeping and influencing future decisions, just to know about it.

DR. ROTHENBERG: So it sounds like with regard to our initial motion it's not really a question of requiring mandatory reporting, the majority exists, but to restate in some way with further educational materials what types of things should be reported.

MS. KAUFMAN: Yes, and perhaps give some examples such as erythema, whatever FDA thinks is appropriate. But to be more definitive I think than just to say adverse occurrence.

MR. THOMAS: Then we're going to have to restate your motion because the way the motion is right now we're going to have to amend it and restate it, I think, is what we probably need to do, Cass. I don't disagree with thoughts, but the motion as stated, I can't support because it's already required by law from what I was just told by Tom, but what

we're trying to say is we are very concerned about this public health issue and what I'm hearing is a trend toward education, toward better communications and encouraging reporting. We can't say that something is required that's already required.

MS. KAUFMAN: Would you like to amend my motion?

MR. THOMAS: Yes, I guess maybe I better since I raised it. May I amend your motion, and instead of saying that we have required reporting that we highly encourage the FDA to continue their educational efforts in this area, to encourage reporting of incidents to include erythema and other more complicated -- and other complications associated with these high dose radiation procedures.

MS. KAUFMAN: I accept the amendment.

DR. CARDELLA: Accept the second?

DR. ROTHENBERG: Is there any further discussion?

DR. SANDRIK: Question, Tom, regarding the -- you mentioned a 1994 health advisory. Did that mainly go to practitioners of radiology or did that

also include the primary care physicians, could that affect, like you say the reporting back on what was happening?

DR. SHOPE: We used our hospital mailing list primarily and it also includes, I believe, free standing clinics and each of those addressees received four of the advisories. One addressed a risk management. One addressed the Administrator. One to the Director of Radiology and one to the Director of Cardiology. Now whether they reached those individuals and got read of course is an entirely different question.

We also actively promoted those publications to the various professional societies and requested that those groups highlight a warning to their members and their various newsletters and things and we know that in a number of the professional society newsletters, the issue was raised for their membership. So I think we're fairly comprehensive in trying to get the word out. There was a little bit of press coverage, but I think we haven't pursued that with great vigor since the 1995 time frame.

DR. SULEIMAN: Let me add something from a professional point of view. I'm involved with a review paper where we're looking at trends, basically just looking at articles in the literature and it's -- a lot of it is anecdotal, but clearly prior to the 1990s there were no such reports. In the 1990s, there were significant number of reports int he literature and there seems to be increased awareness. I think for those of us who have been involved with this for over a decade, it's a little bit frustrating when we keep on discovering these pockets of ignorance in the professional communities.

There's a traveling road show. Ben Archer, Lou Wagner from the AAPM who put together an extremely nice, you know, training course for fluoroscopy and they have the pictures of the radiation burns and there's just a lot of effort, you know, but it's patchwork, but I think the community, the awareness continues to be increasing, but it's far from where we would have liked it. I think the safety alert and the two advisories that we issued in 1994 and 1995 keep on getting cited and referenced

routinely that this is not a new issue, people, that FDA brought it officially to everybody's attention many, many years ago.

So this is just a continuation of something that's really unfortunately not new.

DR. ROTHENBERG: It sounds like we're asking for additional clarification to the usage.

Maybe we should vote on this. It seems like everybody is pretty much in favor of -- can we have a show of hands, I guess, all in favor of this proposal?

Steve?

MR. SZEGLIN: (via telephone) Yes, my hand's up.

(Laughter.)

DR. ROTHENBERG: So it seems like among the Committee Members it's unanimous. This is our feeling as to how to proceed.

I would just like to take the opportunity while we still have Dr. Jacobson and other's here to ask whether there's -- what the current situation with the FDA is with regard to something that we're all

very much aware of and that's the cell phone situation. Are there any active initiatives and maybe there are some you have already reported on that I may be unaware of.

DR. JACOBSON: No, the latest in the cell phone story is that we have just signed a research and development agreement with the Cellular Telecommunications Industry Association. That's the trade association for the phone manufacturers and the carriers.

And we're going to be -- the industry had had supported a -- a five year research effort that was done by a group called WTI, Wireless Technology Industry, Inc., I think was the name, and they both put together reviews of the literature, came up with some research agenda and also did some studies and they had two kinds of batches of studies that we thought warranted follow-up.

They did a genotox test battery with cell phones and basically found all negative results except for the micronucleus assay which came up positive every time they looked at it. And this -- none of

this has been published. It's kind of been reported at meetings and reported in the newspaper so it's a little frustrating that we don't have a full article to look at, but the bottom line is it seems to be a legitimate finding.

It is -- there is some concern that micronucleus assays may be sensitive to heating and there may have been some exposure concerns about heating in these microwave exposures that were done and so we think that needs to be followed up on and the CRADA is -- will enable us to pull together experts from around the world to look at what research was done at least to the extent we can see that from what's published, what -- come up with a protocol for how to proceed to examine that finding and then we'll put together a sort of a request for proposals.

That request will then go out from the CTIA, the Cellular Telephone Industry Association. They will then fund -- they'll get proposals back in. The expert group that we're managing, we'll take a look at those and then the industry will fund studies in the area.

And then the other area of finding was that -- I'm a little rusty on this so the -- it was epidemiology studies where they looked at the industry-funded research looked at cell phone exposure and induction of brain cancer which actually was the initial question that actually got this whole thing started.

When you look at brain cancers in total, cell phone exposure, there was no association. When you look at -- they then broke it down to many different types of individual types of brain cancer and did find an association with one of those types, but it was one of very many and it was very small numbers. They were looking at one or two cancers and so the questions were many.

I mean there was a whole question of the latent period and is there even time, given how newer technology phones are. Is this a finding by chance alone? The numbers you're dealing with, the statistics are very small numbers which is very tricky. So we thought that also merited follow up and we're going to pulling together another expert group

to give recommendations in the human studies area. So we're very excited about that.

We have the details of the CRADA is published on our website. We have the assistance of lots of the other public health agencies and an interagency working group that's helped us develop the interactions we've had with the industry to date. So there's a lot going on. I think the public health bottom line right now is the same as it's always been.

There are a lot of questions that have been raised. We don't see any indications that there is a public health problem and we also think that it's very important to continue to do research and make sure that that continues to be the case. It's a very attractive technology, lots of people use it, want to use it and are thinking of new ways to use it every day and we want to make sure we're not putting the public at any risk.

DR. ROTHENBERG: Yes.

MS. KAUFMAN: Was that micronucleus effect observable at all cell phone energies? Because I read years ago that there had been some mid-energy range

window where people weren't seeing effects.

DR. JACOBSON: You know, I don't have the details of the study, but as far as I remember there was no window effect. And I don't know, to tell you the truth which frequencies they looked at offhand and we have the sort of reports from the meetings and reports in the paper, but we'd like to see the final study so we could evaluate that. But there wasn't any mention as I recall of any window effect this time.

DR. ROTHENBERG: Okay. Thank you, again. We're now scheduled to take a break so I guess try to reconvene.

DR. SULEIMAN: Right after we break could we have all the -- could I have all the public speakers who are scheduled to speak later today come up and talk to me right after -- or right after we break for the break?

DR. ROTHENBERG: So we'll take about a 15 minute break at this point and reconvene at 10:05.

(Off the record.)

DR. ROTHENBERG: Okay, let me just make a brief announcement that people who want to have lunch

here in the hotel, there will be a box lunch that you can purchase outside the door, I guess, at the time of the lunch break. The cost is $8.

I think we should move along with our agenda now, the next item is amendments to the laser standards and Mr. Jerry Dennis is going to address us on this.

MR. DENNIS: Good morning. It's good to be here. Whoops. I'll try that again. Again, it's good to be here. I'd like to update you this morning on where we are in amending the CDRH laser standard.

I'd like to begin by going back to last September when TEPRSSC last met and go over a brief summary of what I presented at that time and then bring you up to date on where we are today.

I also would like to talk about those things that you discussed last September. Again, in September, I gave you a motivation for wanting to amend the standard, primarily to harmonize with the international standard so that there would be one standard for radiation safety of laser products worldwide.

I gave you the history of how we got to the point where we were then, discussed the high points of the proposal that we put int he Federal Register last year to amend the standard, and the status of amending the international standard which is IEC 60825-1 and to also discuss the options that were open to the Agency.

In our discussion last September, TEPRSSC recommended or they had a motion which was approved to wait to see what the voting then in progress in the IEC was going to be and then to proceed with all due haste to amend our standard.

We also -- you also discussed the possibilities of CDRH taking the lead in the amendment process and attempting to lead the world. You also recommended that we did not follow the lead of IEC by including LEDs in the standard and you were very much in agreement with reducing the gap between the IEC standard and CDRH.

One thing that we did not -- that TEPRSSC did not bring up in their discussion was the idea that we presented at that time to include a vertical

standard for toy and novelty laser products.

Now since we're talking about harmonizing with the international standard, let me fill you in on where we are today. A CDV means a Committee Draft for Vote. It is the final stage before going to a final standard for voting.

That CDV was approved at the end of September of last year by a vote of 15 to 1 so it looked like a very sure thing. The TC76, the technical committee responsible for optical radiation safety met in Milan and on November 12th they voted to distribute a final draft international standard in April of this year.

I'd like to insert at this point that I wear two hats in the IEC. I'm the chairman of that technical committee and I'm also the chairman of the U.S. technical advisory group for the U.S. National Committee of the IEC. I must say that our technical committee did meet its deadline. It got the final draft standard to the IEC central office in Geneva on March 1st as we promised and we expected that we would see the final draft international standard out for

vote by the end of April.

I had hoped very much that I would be able to report to you this morning and tell you how the outcome was coming on that voting. However, the central office has not yet released the final draft standard for vote. I'm promised that it will be out this month. That means that the voting will close in August. It's the 16 day voting period and if approved the amended international standard will be published in October of this year, if again, the central office can meet its publication schedule.

Now in the briefing package that was distributed and is now available on the web, I gave you a draft of the revised proposed amendments to the CDRH standard to achieve close to harmonization. And those revisions are based on a presumption that the IEC final draft standard will be approved, but I can't emphasize strongly enough that the draft is not complete. The draft is as it was on May 5th when I sent it to Dr. Suleiman. I've done additional work on it since then. We still have quite a bit to do.

And why are we reproposing at this point?

Well, we've made considerable changes and significant technical changes since our 1999 proposal and to recap what I said in September, the 1999 FDA proposal was based on a scheme that was issued by the IEC as a CDV in 1995, but unfortunately was not approved by them. It seemed like a very good and reasonable approach, but it wasn't passed.

In 1999, again, we had a new CDV for amendments that we hope will be approved for the Year 2000. Now these amendments will include a new scheme for classification of laser products, revised measurement requirements and new accessible emission limits for short pulses and they will also differentiate between photochemical and thermal hazards of optical radiation.

One of the things that you said last year was you recognized that we really needed to update the science space of our standard. Over the years, it certainly has become obvious that the interaction between tissue and optical radiation is extremely complex.

The differentiation between photochemical

and thermal hazards is not something new. We first heard about it as a result of research by Dr. Ham at the University of Virginia back in the late 1970s. At that point it was called the "blue light hazard." That hazard was recognized in some of the other safety standards, namely that of ANSI, and also the IEC in which they introduced a correction factor to their limits of exposure. We called it "red relaxation" at the time. Now it's being referred to as photochemical limits.

The highlights of those revisions are that the classes, instead of being what we have today of 1, 2, 3A, 3B, we're now going to introduce two new classes. Class 1M and Class 2M. And what do the Ms stand for, but magnification. And these are products for which the use of collecting optics such as telescopes, loupes and that kind of thing would either create a hazard for Class 1M or in Class 2M increased an already recognized hazard.

The emission limits are also being extended on the short end down to include pulses as short to 10 to the minus 13 seconds. And as I said

earlier that we're introducing or incorporating the distinction between a photochemical and thermal hazards.

The other thing that we are proposing at this point is something that we said in our advanced notice of proposed rulemaking several years ago to change our criteria for human access. Right now, any laser radiation which is accessible is accessible if you can reach it by any part of the body. The problem is with low level laser radiations, if you can only get a hand into it and the hazard is strictly an ocular hazard, do we have to consider that to be accessible? It's not really a hazard for the part of the body exposed. So one of the things that we have in our draft proposal is to change our criterion for human access. This is an area in which we're going beyond what IEC is doing at this time, but it seems like it's a relaxation and a reasonable direction.

Our classification measurements are going to be different from what we proposed last year. We're picking up on what IEC is proposing in their final draft international standard. We're also

changing the wording of our requirement for user information. I'm sorry, for service information. We've had quite a bit of discussion over the years and I've done some research on this and I've found in the old preambles that the requirements as they were discussed for service information related really to radiation safety information that service people could use. Several people, mainly independent service organizations, have taken the words in the standard to mean that we -- that the manufacturers must provide upon request complete service manuals. Clearly, the preambles to what we have published in our proposals years ago made it clear that we were talking about radiation safety procedures during service.

Some friends in the Navy have suggested that we clarify the exemption from the standard for products procured by the Department of Defense that are used in combat, combat training or that are classified in national security interests. They're having a difficult administering that. The authorization for manufacturers to use the exemption has to come from the DOD contracting offices and quite

often in the military they lose sight of that, so the Navy specifically would like us to put that up front in our standard to make it more obvious to the world.

Our present tasks, obviously to complete our draft amendments and what we've been doing in that area, we have been taking the material that will be in the IEC final draft standard and work it into the format that we have used in the CDRH standards for the almost 30 years that we've had them. I think we'll have a much more orderly document as a result.

We also still need to prepare the preamble to the proposed rule and we have to get to the analysis of comments from our 1999 proposal in the Federal Register.

The tasks in the future will be to get the Agency clearances, our Office of Chief Counsel, the Office of Manpower and Budget and released by FDA. We're going to have to do an impact analysis and then if all that runs smoothly then we get into roll out of the new CDRH standard. We've got to train our own staff in it, that's both our Headquarters people and our field people. We've got to revise our guidance

documents and reporting guides. We've got to train people in the field and we've got to provide education for the industry. It's going to be a big job.

So what we would like from TEPRSSC is we would like you to discuss the direction in which we are proposing to go. We would like to get your agreement. We would welcome your technical comments and we would like you to consider what we should do if the IEC does not approve its final draft standard. And those could be modifying our reproposal or continuing, hoping that IEC will correct whatever problems prevented the approval of their new standard and hope that they will catch up.

And that concludes my prepared remarks. Do you have any questions?

MS. KAUFMAN: I'm trying to find the slide. It seemed like we didn't talk a lot about the novelty toys issue.

MR. DENNIS: Okay, novelty and toys. I brought two novelty and toys with me, but they're light-emitting diode products. I have this little thing. One of the things that's happened in the IEC

standard is that they did in 1993 increase their scope to include LED products and products like this, here's a little key chains with LEDs in it, subject to the same standard as laser products. And even this very dangerous, where is this, this infrared remote control that doesn't work for the projector is subject to that standard.

What about the toy and novelties? We have these pointers. They're all over the place. We find them being promoted for indications that we don't like at all. This can be used extremely safely as a pointer by somebody who is giving a presentation. But they're not toys. They shouldn't be in the hands of children. Many of the states have enacted legislation to restrict the sale of these devices and we have some in California -- has legislation on the books, New Jersey has many municipalities have -- and it's helter skelter. Sales are restricted to people below 18 years of age. We see some of the promotional materials. They say take them to athletic events. Take them to discos. Take them to parties. Have fun. Dazzle your friends. There's a public outrage against

them. And they fall into the hands of children who can't read. This one I have has all the required labeling and I think it's a very good example of what can be done in the industry, but we've -- it's been a very large exercise for FDA. We have put tens of thousands of these products on imports' attention if they're properly labeled. It's a very large effort. The hazard, the hazard is there. The risk though is very small. The experts in the photobiology really believe that a fixated staring into a 5 milliwatt laser for a time greater than 10 seconds would be necessary to cause a permanent injury. And then we have LEDs. LEDs, there's a -- your advice last time was not to include LEDs. We still believe that that's sound advice. There was a paper published in Health Physics this month, June 2000, that talks about the relative hazards of semiconductor lasers versus LEDs. Although little products like this, what happens is you get a problem where the market often will require third party certification and that's a terrible burden on the industry and people like ourselves who are trying to administer standards.

We have to watch the LED technology very closely because they're coming out with new technology. They now have things that are called super-radiant LEDs which are getting closer and closer to lasers in their radiants. And radiants is really the property that distinguishes between lasers and other light sources.

So I hope I answered your question.

DR. BALZANO: Quirino Balzano. Can you tell me what is the power of emission of that device in your hands, that little ball?

MR. DENNIS: The little ball?

DR. BALZANO: Yes.

MR. DENNIS: Looking at -- it's probably on the order of hundreds of microwatts.

DR. BALZANO: So it's less than a firefly because a firefly is about half a milliwatt.

MR. DENNIS: It's pretty bright. It's pretty bright. Because it has a little collimating lens on it. Usually pilot lights are designed to emit into a very large solid angle so you can see them from just about anywhere in the room. This has a little

collimating lens on it, but then the light is scattered by the rather diffuse surface of the ball.

So I would guess that the total power of this is probably less than a milliwatt.

DR. ROTHENBERG: I have a question, unfortunately, since this is my first meeting I'm probably getting into some of this a little late in the game. This is not my area of expertise. But when I got this information I asked -- I'm at Memorial Sloan-Kettering Cancer Center and we have a laser safety program going and I asked the person running that to just take a look at this and see if he had any comments. The first thing he mentioned is that currently, at least in medical facilities, many people are following or most people, I guess, are following an ANSI standard that was put out in the mid-1990s and the question is are -- he didn't go into any detail about major differences, but he mentioned a couple of things. He said some of the class definitions are different and he was wondering whether this was going to cause confusion.

MR. DENNIS: Okay, I can respond to that.

I also sit on the Executive Committee of ANSI Z136. Z136 has several standards. It's got the dot-one which is the basic across the board standard. There's dot-two which is for fiber optic laser and LED communication systems. Dot-three is American National Standard for the Safe Use of Lasers in Health Care Facilities. Dot-three is now in the process of revision. Dr. Trokel at Columbia Presbyterian is the chairperson of that subcommittee and they're hard at work coming up with new revisions.

The ANSI standards are primarily user safety standards. Z136 has gone out for vote for version 2000. It has been approved. It will be published very shortly. I received a copy of that this week to take one final editorial look at it before it goes to press.

The people -- this is a rather small community. Many of us sit on the IEC Committee, the ANSI Committee and I sit here as well. We're working closely together. We know what's going on. We're prepared that if the IEC amendments are approved to move in the ANSI Committee to also incorporate the new

classification scheme there.

As far as product goes, the ANSI standard really only impacts on products that are manufactured in-house for the use by the people who put them together, but predominantly the product safety standard in the United States is our CDRH standard.

DR. ROTHENBERG: Another thing you mentioned is there's a wavelength range, I guess at the low end of the wavelengths that's not addressed here that -- unfortunately, I don't have my notes with me. At the lower end of the wavelengths they're not addressed in the IEC or at least in this one. They're not address in the --

MR. DENNIS: We all go down to 180 nanometers, all of the laser and optical radiation safety standards start there because then you get into the vacuum ultraviolet.

DR. ROTHENBERG: He thought it didn't go that low, but maybe --

MR. DENNIS: No, we all start at 180 nanometers.

DR. ROTHENBERG: Maybe he misinterpreted

that.

John?

DR. CARDELLA: Is the delay with the IEC laser, is it just an administrative or a resource issue?

MR. DENNIS: I believe it is.

DR. CARDELLA: With a 15 to 1 CDV vote, you would anticipate that it would not have been bogged down because there were such egregious changes that they were worried about it not getting approved. It's not the case that it's being held up because of substantive change and the likelihood of passage, is it?

MR. DENNIS: It's not allowed to be substantive change, but editorial clarification. Where you draw the line is kind of murky and we do want to have the best quality IEC document we have. That's one of my agendas in the IEC to improve the overall quality, readability of the documents that the Technical Committee publishes.

DR. CARDELLA: I guess what I was trying to lead in to is if there is a real likelihood that

the IEC laser standard does not get approved, then I think that TEPRSSC should probably give the direction to CDRH that you go forward with your own anyway. I'm not sure that it would wait and wait and wait for harmonization. I don't think that the standards will be that much different. I think if there's a likelihood that it would not be published I think we ought to talk about that. If you think it's -- if you just brought that up as an editorial comment or a comment on somebody slipping up on their administrative responsibilities then we can leave it alone.

MR. DENNIS: One of my favorite jokes on that subject is that I say that I'm old enough to remember President Dewey.

(Laughter.)

It's not over until the votes are in. We have been surprised before. We were surprised in 1995. We really thought that those amendments to the IEC standard were going to fly and we just missed the necessary majority and then we started working on the approach that's being -- going to come out for vote

this month.

So yes, I appreciate that and I think that eventually the IEC will go that way if the voting nations do provide enough technical problems with the existing document that they can't vote for it, I'm sure that then they'll be another policy and probably just another final draft standard. I don't know whether we'd have to go through another CDV stage first though.

DR. LOTZ: This is Greg Lotz. And I just thought I'd second that because, John, I was thinking exactly the same thing that particularly compared to last year when you came to us and we said well, wait and see what happens with the next IEC step. It seems to me at this point you're at a stage where you can proceed regardless of what happens. If the IEC bogs down a bit at this point over final points that you could proceed anyway.

MR. DENNIS: And if we go that way, then it would provide motivation for them to move in the same direction because basically we're going with their idea.

MR. PLEASURE: Are you comfortable with the -- with your capacity to define the DOD exemption in ways that won't spill over to subsequent use when the procured object, the procured laser is disposed of, for example, or when the user may be by civilian employees or by employees of contractors for DOD who may or may not have notice of dangers.

MR. DENNIS: There are two answers to that. The first is that these products that are exempted or for combat, combat training or that are classified. They're not going to be used by the run of the mill DOD employees except perhaps in a depo maintenance type of -- or repair type of situation. They're not going to be seen by such people. The other thing is that our DOD exemption contains a requirement that the products that have been exempted cannot just be dumped into the surplus market and they're labeled that way as well.

MR. PLEASURE: But are you satisfied that contractors who are engaged by DOD, let's say construction workers who come on to a nuclear site, and they're there for just a few days. They may have

some general clearance, security clearance for entry onto the site. But are you satisfied that you can exempt all of those workers from coverage, particularly considering that perhaps the vast usage will be by these contract employees, rather than by combat troops?

MR. DENNIS: Let me clarify that a little bit more in that the -- we're not talking about a classified site where it takes a cleared person to have entry. We're talking about a product which itself is classified. So that general purpose contractors would not have access to these devices which themselves are classified. So there's that additional level of control and certainly those kind of personnel are not going to be, we hope not in the combat situation.

MR. PLEASURE: But in the draft that I'm looking at, there isn't anything -- there's no reference and it might be useful considering the Navy is asking for clarification, there's no reference to subsequent use in the surplus area.

MR. DENNIS: Except that these products

which are exempted cannot be disposed of as normal surplus.

MR. PLEASURE: What I'm getting at -- the notice that you're being asked to actually provide by the Navy is giving notice as to all the requirements of the law with respect to let's say to the security of a particular piece of machinery or the dumping into the surplus market in the reg.

MR. DENNIS: If I hear you then, correctly, you're suggesting that we make that specific in the proposal.

MR. PLEASURE: Yes, I would say that there is no reference to either of these two issues in the proposal. One is assuming a great deal of knowledge on the part of the reader of the reg and the request came from the Navy to provide clarification, so it doesn't answer the matter to say well, if one knew the body of security laws one would know X and Y.

MR. DENNIS: Your point is well taken.

DR. ROTHENBERG: Any other questions or comments?

John?

DR. SANDRIK: John Sandrik. You brought up the issue of relaxation of the human access definition. I guess I have some curiosity on that. I noticed one of the directions you went, particularly I guess from the 1 through 3R class, I guess two aspects. One was talking about direct -- access to human eye and also a direct undeviated access. I was just wondering is that sufficient? If somebody with one of these type lasers or just to put a mirror at the exit for it, does that then define that as providing no human access even if the beam is directed off of a mirror or prism right at the exit? Does that somehow reduce the risk that it becomes not human access again?

MR. DENNIS: Right now what we have is -- if we have low class which I'll call Class 2 and Class 3A. If you can be -- if any part of your body can be exposed it's considered accessible. If it's higher class, then we worry about reflection from a single flat reflector put within the product. Usually this criterion is used for determining the adequacy of the protective housing. Many laser products that are

Class 1 for example know hazard in use, contain higher class lasers. They may contain Class 3B or 4 and as far as judging the adequacy of the housing we use this accessibility test, that if it is Class 3B or 4 on the interior, if the reflection from a single flat surface could come through an opening in the housing at a level in excess of Class 1, then the protective housing would not be adequate.

Now when we do the classification, we look at the level to which human access is possible during operation. And what we're proposing -- what we're planning to propose is that if you could only expose a part of the body other than the eye, whether that needs to be considered to be accessible for the purpose of classification.

DR. SANDRIK: Okay, I guess I agree with the part of the eye as probably the most sensitive organ for the lower level, but as far as say design the housing, if the manufacturers say we're just to put a mirror at the exit port, would that indicate that there's then no human access or do you still measure the level that could go into the eye through

this mirror. I guess that's what I'm wondering about.

MR. DENNIS: Okay, let me get specific and try to describe a product. Let's say that we have a product that incorporates a bar code scanner and bar codes on things are being read as they go along a conveyor belt or they get dropped down a shoot or something like that. Yes, it's possible, physically that somebody could reach down, if they could reach down into this laser field with a mirror and they could reflect it out and expose their eye. It's possible.

Is there enough of a risk of that happening to require that that condition be considered human access? Or it's not a high enough level to exceed the exposure allowable for the skin. It's something we proposed in the advanced notice of proposed rulemaking and mea culpa, I didn't put it into the 1999 proposal. It was an oversight on my part, but we have it in the draft proposal that we distributed in your briefing package.

So yeah, it's a case, yes, there's a hazard. Yes, this could happen, but is there a risk

if it -- a significant risk of it happening?

DR. ROTHENBERG: Jerry.

MR. THOMAS: Jerry Thomas. In the package that you handed out, I've got a couple of questions regarding the DOD exemption. It says that any exemption should have specific authorization by the cognizant DOD purchasing authority for deviation from requirements of 1040.10 or .11. Does that also include the labeling requirements? I would think for combat systems that it would still be appropriate to label them.

MR. DENNIS: The way the exemption works is the products are required to comply to the extent that's practicable. They're only exempted from those requirements which are specifically inappropriate in the military application.

MR. THOMAS: Okay, I understand that, but that's not what I read. And that, I think, is a concern. I'm sure Bob is concerned with after market use of war-related devices. If we have a classified device at some point in time that could be unclassified, or the laser component could be removed

from that device and then it goes into the after market and I'm not sure that that's as clear as it might be. I appreciate and understand why the Navy asks for that exemption, the individuals that asked that. I think that it's reasonable from what they're asking that potentially what you've just said may or may not need to be expressed in your language of your final rule.

MR. DENNIS: I'd like to address one of your other concerns and that is the removal of the laser from -- and sold from an incorporating product. Laser products that are sold as components are excepted from the standard anyway. One of the things way back when it was recognized that -- to impose labeling and engineering controls on components would very often duplicate labeling and controls that would be necessary on the incorporating product, so therefore the components were excepted from the standard.

MR. THOMAS: Okay, I had forgotten that. Thank you.

DR. ROTHENBERG: Any other questions,

comments?

Thank you very much.

MS. KAUFMAN: I guess I'm a little confused on that last statement because I'm looking at the section under removal laser systems, how does that apply to what you just said? It seems kind of contrary to --

MR. DENNIS: Okay, removable laser system is a definition, specific definition in the standard. Basically, when that requirement was originally written it was intended to apply to things like thallium neon lasers that were bolted into larger products and then plugged into a convenience outlet. Then they could be just pulled out, plugged into the wall and used by anybody.

If the components are permanently installed and think about the lasers that are buried way down deep inside of laser printers and that kind of product, they're not really removable in the sense of that term.

Usually, we have drawn the line. If a laser system is hard wired into an incorporating

product, it's not removable.

MS. KAUFMAN: Is that clarified in the definitions?

MR. DENNIS: We believe it is. It should be definition B something.

MS. KAUFMAN: I don't see a definition for removal.

MR. DENNIS: Let me wander over. That's essentially unchanged.

DR. ROTHENBERG: Could we get a page?

MR. DENNIS: 14.

MS. KAUFMAN: 14. I guess this doesn't seem to say to me what you just said.

MR. DENNIS: It says, granted it says what it says and the way I related it is the way that we have been interpreting that portion of the regulation to mean for the last 24 years that we've had the standard.

MS. KAUFMAN: Because it really isn't under the definitions.

MR. DENNIS: No, no.

MS. KAUFMAN: It's under the

classifications.

MR. DENNIS: It's a separate thing under classification.

DR. CARDELLA: Just to be clear about it as an example, let's say you had a firearm that had a laser sight on it. The laser part of it was used for targeting, was not the destructive part of the tool, but it's removable. You can take those laser sights off. They just unscrew. Is that a removable laser in your mind?

MR. DENNIS: Oh, definitely. But -- and those products are as far as we know certified and classified as required by the paragraph of the standard. So it's not a problem there. These are strictly, really removable and one of the eternal questions again to be a little bit humorous is the eternal question is where does the product end? If we put a laser gyroscope on a 747, we don't want the airplane to be a laser product. And we don't want the gun to be a laser product. The laser product is the aiming device and it's independently certified and it's labeled and has the performance requirements of

the standard.

DR. ROTHENBERG: Okay, we don't have any public speakers for this item on the agenda. I guess the question -- I suggest we continue.

MR. THOMAS: We probably do need to put on record with a formal motion of -- since Cass and I are good at that, I'll start.

I think that what I would like to propose is a motion that we encourage the FDA to proceed forward with the regulations independent of the IEC. However, we would like them to wait for the review that's due in August prior to moving forward. I guess what I'm trying to say is I don't want you to stop if the IEC does not approve.

MS. KAUFMAN: I'll second that.

DR. ROTHENBERG: Any additional discussion?

DR. BALZANO: (Speaking from unmiked location.)

MR. THOMAS: I agree with you. However, my guess is from what Jerry has said to us is an international standard is not going to drag beyond August, is that a true opinion that I've gotten?

They're either going to approve it or not approve it. If they don't approve it, I think we should go ahead. I don't think we should wait another year for them to go ahead.

MR. DENNIS: Right, the voting document is coming out before the end of June, I'm told. The voting will then close 60 days after that and the publication date should be 60 days after that if approved.

DR. LOTZ: I guess my sense is that from the picture you've shown us today that you actually hardly even need the August delay, that there's plenty for you to do that will not be undone if no matter what happens with the IEC in August and so that even the simpler idea of just proceed is I'm certainly supportive of.

MR. PLEASURE: I would concur with what's been said. With the proviso that the colloquy that we

had about needed clarification to which the presented indicated point well taken that some clarification is needed is incorporated in the work that's going forward.

So I would as Kathleen suggested, I will suggest an amendment to the motion that the work go forward with the understanding that clarification as has been indicated in our discussion this morning is included.

MR. THOMAS: I don't have a problem with that.

MR. PLEASURE: On the military exemption, yes.

MR. THOMAS: I accept that as a friendly amendment to the motion. Thank you.

MS. KAUFMAN: The seconder accepts too.

DR. ROTHENBERG: Okay, is there any further discussion?

MS. KAUFMAN: I did have one question and I'm trying to recall at the last meeting if there were any issues that FDA wanted that might be more stringent than what IEC was proposing. Were there any

issues that FDA thought needed to be included that weren't included in here because they wouldn't result in harmonization?

MR. DENNIS: At that point the main sticking point between IEC and what we had proposed in 1999 was that IEC at that point had much more stringent measurement requirements as far as what radiation had to be counted for the purpose of classification. I have that slide in my briefcase, but basically they collected a very large solid angle of emission for the purpose of classification that we thought was unreasonable, but now with their new classification scheme they're coming up with something that appears to be very reasonable.

MS. KAUFMAN: Okay, that does bring recollection to my memory, that the issue is the measurement.

MR. DENNIS: Yes.

MS. KAUFMAN: Is what they're proposing now conform to what FDA is proposing relative to measurement?

MR. DENNIS: That's correct.

DR. ROTHENBERG: Yes.

DR. BALZANO: You do not expect any surprises on classification or measurements, do you?

MR. DENNIS: As I said, I remember President Dewey. It's not over until the votes are in. We're optimistic, but we've had surprises in the past. We -- I was at the -- I presided at the IEC meeting in Milano in November and the vote to go to the final draft standard was unanimous.

DR. ROTHENBERG: But just to clarify, the vote itself that people will be taking will be yes/no?

MR. DENNIS: That is correct.

DR. ROTHENBERG: So if it passes it can't contain new things?

MR. DENNIS: It's not allowed to have any substantive changes from what was approved at the CDV stage. So there have been a number of clarifications between then and now. And there may be some minor clarifications between the vote and the final publication, but nothing substantive.

MR. THOMAS: If that's the case then, there's absolutely no reason that the FDA shouldn't

move forward.

DR. ROTHENBERG: Everyone, all in favor of this motion, as amended, signify by raising your hand.

Any opposed? Steve?

MR. SZEGLIN: I'm in favor of it. I agree with Jerry.

DR. ROTHENBERG: Okay, so it looks again like it's a unanimous vote of those present, including by telephone.

John?

DR. CARDELLA: I have another issue that I wanted to ask about. Not to countermand or revisit what this august body has decided previously, but the issue of LEDs, I would like to ask a question about more than anything. They're becoming far more ubiquitous. They're being used for traffic lights. They're being used for the brake lights on commercial vehicles, buses, big 18-wheel rigs, that sort of thing for the following reason. They last longer than a light bulb. They are brighter and they're focusable is the information that I've had given to me --

MR. DENNIS: More than that.