

1 It's easier for the manufacturers.

2 MR. HERMAN: Well, in terms of actual
3 technical ease, it's not particularly, you know, any
4 easier. It's about the same level. You still have to
5 do scans with a hydrophone. European manufacturers,
6 you know, know about it more. It means they only have
7 to do one set of tests they want to market in both
8 Europe and the United States. I think that's probably
9 the major advantage. They don't have to comply with
10 two sets of technical specifications.

11 In terms of actual "technicalese," I would
12 put them on a par actually -- it would be hard to say
13 which one would be better. It would depend upon the
14 specific set-up that any particular manufacturer had.

15 If they had to change from one to the
16 other, obviously it would be difficult, but in an
17 absolute sense I really wouldn't say that one is much
18 easier than another.

19 MS. KAUFMAN: Okay, and in terms of
20 submitting the application, they only do that one
21 time, right? So whatever time is involved, it's an
22 application to FDA and then that's it, right?

1 MR. HERMAN: Plus whatever --

2 MS. KAUFMAN: I guess I'm still having a
3 hard time figuring out what the advantage is to
4 everyone to go with the IEC standard.

5 MR. HERMAN: They could market in the
6 Europe and the FDA without doing two sets of tests.

7 MS. KAUFMAN: So the issue is two sets of
8 tests?

9 MR. HERMAN: Well, that's one of the major
10 issues, yes.

11 MS. KAUFMAN: And that's what I'm saying,
12 is that testing is something that just submit one time
13 to FDA, right?

14 MR. HERMAN: Yes.

15 MS. KAUFMAN: Okay, and then the other
16 advantage would be that IEC can change their standards
17 more easily than we can. Is that another advantage?

18 MR. HERMAN: It might be, yeah.

19 MS. KAUFMAN: Okay.

20 MS. BARRON: For us it is because it's
21 resource intensive for us to do any amendments at all
22 to the mandatory standard.

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1 MR. HERMAN: So the more we can utilize
2 some other body's expertise, the better we leverage
3 our technical expertise. I assume that's the
4 rationale.

5 CHAIRMAN ROTHENBERG: Yes.

6 DR. BALZANO: In terms of preventing skin
7 burns, wouldn't the FDA methodology or measurement be
8 better in characterizing the surface of the applicator
9 than the European that just looks at if you want the
10 far field (phonetic) and extrapolates back at the
11 surface? Instead you may need a measurement pretty
12 close to the surface of the applicator.

13 So should you get an idea of the closing
14 energy in case that the --

15 MR. HERMAN: Studies have shown that,
16 again, for a single plane wave transducer the IEC
17 technique is actually more accurate than the FDA
18 technique for that transducer in terms of getting an
19 effective radiating area.

20 Now, the powers are -- excuse me -- both
21 measured similarly. The intensity is a function of
22 the area, and one might say that the IEC is actually

1 better in terms of surface skin burns because it does
2 limit the applicator to a 16 degree temperature rise.

3 Someone could, you know, coming up with
4 under the FDA -- I assume that we'd stop them if the
5 applicator rose by 100 degrees C. We'd have some
6 mechanism by which, you know, we could prevent them
7 from marketing, but there's nothing in the standard
8 that precludes a high temperature rise of the
9 applicator itself.

10 So one might say that in that sense, at
11 least for surface burns, the IEC might be a, quote,
12 safer, unquote, type standard.

13 CHAIRMAN ROTHENBERG: Jerry.

14 MR. THOMAS: Kind of coming back to the
15 title of the presentation that John's making, a
16 question for you. This is a proposal to shift from a
17 mandatory to a voluntary standard. I think really
18 what you're asking for is guidance as to whether we
19 think this is a good direction for you to be going.

20 I'd be more than happy if the committee is
21 willing to take a motion, to throw a motion on the
22 table. We've discussed this. I personally think this

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1 is a good idea. So I'm going to put the motion in a
2 positive way here, and that is that TERPSSC encourages
3 FDA to proceed with a pilot study to -- well, pardon
4 me -- a pilot program to recognize the IEC standard,
5 with exceptions in the area of therapy ultrasound.

6 CHAIRMAN ROTHENBERG: Do I have a second?

7 PARTICIPANT: Second.

8 CHAIRMAN ROTHENBERG: Yes. Clearly we're
9 encouraging them with this motion to proceed with this
10 specific project and then review with us the
11 results --

12 MR. THOMAS: Yes, sir.

13 CHAIRMAN ROTHENBERG: -- and see whether
14 similar efforts should go forward in the future.

15 MR. THOMAS: That is correct, and then
16 after we finish discussing this one, I've got another
17 one to throw on the table.

18 CHAIRMAN ROTHENBERG: Yes?

19 MS. KAUFMAN: I'm concerned about what may
20 be your second motion because with over 20 years of
21 compliance history under my belt, voluntary compliance
22 is incredibly ineffective in my experience, and the

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1 very facilities who need compliance the most are those
2 least likely to comply with voluntary compliance.

3 And in fact, I've had numerous facilities
4 come to me and say that under managed care, that they
5 more and more need compliance issues rather than
6 voluntary; that with the issue of health care going
7 more and more to cost issues, that unless it's
8 required by law or regulation, their facilities will
9 not allow them to do some of the things that we think
10 are essential.

11 So this motion, I just want to make it
12 very clear, is specific only to the ultrasound
13 therapeutic pilot project.

14 MR. THOMAS: Yeah, that's exactly right.
15 I think it's important that we look at a demonstration
16 of this concept and get a better feeling for where the
17 pitfalls are. I think we've discussed some of the
18 pitfalls, but I'm not sure that until we go down this
19 road a little bit further we know where all of the
20 pitfalls are.

21 CHAIRMAN ROTHENBERG: John.

22 DR. SANDRIK: Maybe it's just my

1 perception, but I think we may be suffering under a
2 bit of a naming problem here because I don't think
3 it's a matter of a voluntary versus a mandatory
4 standard. There will be a standard. You must follow
5 something. The only voluntary part is going to be IEC
6 or FDA. So it's going to be one or the other. It's
7 not going to be arbitrary.

8 MR. HERMAN: The FDA is using a formerly
9 voluntary standard as, I guess, a regulatory standard.

10 MS. BARRON: De facto.

11 MR. PLEASURE: Yeah, I have to confess to
12 a certain amount of confusion in the way the issue was
13 first presented. It was presented as an alternative
14 between the FDA's regulatory process and the consensus
15 standard process, which is the ANSI process. But as
16 I understand this pilot, and if I understand it this
17 way, I'm willing to support the motion, it's really an
18 amalgam of a mandatory standard and a consensus
19 standard in an effort to harmonize it and end up with
20 a mandatory standard; that we're moving toward a
21 standard that will be enforceable. We're not simply
22 deferring to the consensus process.

1 And the early slides that were presented
2 were about the consensus process and the lack of legal
3 enforceability, and so I initially thought that's
4 where we were going in deferring to an ANSI process
5 and ending up -- but, in fact, as I understand it,
6 there's an effort to harmonize the two and end up with
7 a mandatory standard.

8 If that's correct, then I think I would
9 support it as a pilot.

10 MS. BARRON: I would say, in essence, by
11 using the device authorities, that's correct. If we
12 did not have the device authorities, we would be
13 looking at some other alternative, yes.

14 CHAIRMAN ROTHENBERG: Could we have a vote
15 on that now?

16 All those in favor, and this is to go
17 ahead with this pilot project; all in favor?

18 (Show of hands.)

19 CHAIRMAN ROTHENBERG: Opposed?

20 (No response.)

21 CHAIRMAN ROTHENBERG: Okay. I see no no
22 votes of those present.

1 Now, you said you had a second one?

2 MR. THOMAS: I've got a second issue, and
3 before a motion goes on the table, really what I'm
4 hearing is a trend to less prescriptive standards, and
5 by that I'm looking kind of at a broad brush issue
6 here where the FDA is saying we would like to set
7 limits with tolerance levels, but we don't want to
8 specify how one goes about measuring those, but to use
9 established protocols by recognized authorities,
10 whether they be the IEC or whether they be
11 professional activities for measurements of the
12 established standard.

13 Currently we have a number of standards
14 within the regulations that are quite prescriptive.
15 They give a value, and then they state how it is to be
16 measured. One of the problems we have within the
17 United States is changing that process easily.

18 The IEC, because it's regularly reviewed,
19 and other professional standards bodies allow that,
20 allow recognition of new technologies and new
21 measurement methodologies as ways to evaluate
22 compliance with a standard.

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1 So when I think about what we talked about
2 yesterday, we talked about these personal security
3 scanners where we're looking at the establishment of
4 new regulations. This might also be -- and I want
5 before we say anything just to discuss it in general
6 -- this may be also another area where development of
7 a standard through industry of what the performance of
8 those devices should be. Should they be ten
9 micrograms? Should they be 25 microgram, you know?
10 Where should those numbers sit?

11 I think that was one of those -- you know,
12 those type of limit numbers was what they were looking
13 at. So I just throw that out for general thoughts
14 before I throw a motion on the table and get shot
15 down.

16 CHAIRMAN ROTHENBERG: Any comments from
17 the Committee? Yes, John.

18 DR. SANDRIK: I think part of this goes
19 back to probably the first talk where you mentioned
20 getting the consensus of the stakeholders involved,
21 and I think that's one of the important aspects of
22 this.

1 You know, from one side there's the
2 comfort aspect. When you look through some of the
3 current performance standards and say, "Here's the
4 standard. Here's how compliance will be tested," I
5 know with some interactions I've had with some of our
6 manufacturing people, they feel very comfortable with
7 that because it tells them exactly what they have to
8 do to show compliance, and that's comforting.

9 On some other regulations where all it
10 says is, "Here is the required performance. You
11 figure out how to show that," there's a very high
12 level of discomfort under that because we have no idea
13 what's going to be acceptable and what's not.

14 So I think, again, from this point of view
15 if you have, say, the performance requirements that
16 you're looking for and then through interaction with
17 the stakeholders you just say IEC Standard XYZ, ANSI
18 Standard whatever. These would be acceptable ways to
19 show compliance with this, and people buy in, and they
20 say, "Yes, we agree that this is a good standard to
21 show this." I think it maintains the comfort level on
22 all sides.

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1 You'll probably be able to aim the
2 regulations towards the most important aspects of what
3 needs to be attended to, and those who have to do the
4 tests can use methods that work best for them,
5 everybody sort of converging towards something that
6 works for both sides.

7 But I think, again, it's a matter of
8 including all those parties who are involved in this
9 to get that consensus built.

10 CHAIRMAN ROTHENBERG: Cass?

11 MS. KAUFMAN: Well, regulations don't
12 occur in a vacuum. I mean there's a huge, you know,
13 opportunity, I think, certainly at the federal level
14 and, as far as I know, in every state program, an
15 opportunity for comment including industry.

16 And any smart regulator knows that you
17 need to include industry when you write regulations.
18 So I don't think that it doesn't occur now. I think
19 that it does occur, that there is communication.

20 I agree with the comment that a lot of
21 manufacturers -- and I can tell you at a lot of
22 facilities also -- are much more comfortable with more

1 prescriptive regulations because it does tell them
2 exactly what they have to do, what they don't have to
3 do, and one of the most common complaints we as
4 regulators and compliance people get has to do with
5 different interpretations and variables amongst
6 inspectors, and the more prescriptive the regulations
7 are, the consistency and uniformity you have in
8 enforcing those regulations.

9 I think that the issue is best handled on
10 a case-by-case basis, and it depends what you're
11 looking at, you know, how appropriate it is to be
12 prescriptive and how appropriate it is to reference
13 other materials. I just don't think you can make kind
14 of a general statement that it's always better to do
15 it one way or another.

16 I think it's a case-by-case issue.

17 CHAIRMAN ROTHENBERG: I think maybe one
18 aspect of John's comments is by the time things get to
19 the printed and comment stage, you don't always get to
20 maybe have the full input that you would if things are
21 discussed with appropriate parties at an earlier stage
22 in the game.

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1 Greg.

2 DR. LOTZ: I was just going to reinforce
3 Cass' comment about the case-by case basis, but maybe
4 even with a little different angle that the case by
5 case depends as much on what the technical quality is
6 of the protential consensus standard that you're
7 dealing with in terms of whether it adequately
8 describes the procedures, the instrumentation, and so
9 forth.

10 And I'm thinking that there will be
11 situations where it might be very desirable to use the
12 consensus standard for those procedures, but you just
13 look at it and say, "It's not up to what we're looking
14 for in this case," and so in a case like that you'd
15 have to say, "Yeah, there exists one, but we're not
16 going to use it because it's just not up to level of
17 par."

18 So if that's the case-by-case aspect, I
19 would put it even more on the technical level of
20 evaluating what the options were.

21 CHAIRMAN ROTHENBERG: Yes.

22 DR. BALZANO: If I can echo what Greg just

1 said, I hope that this doesn't become a way for the
2 FDA or for CDRH to somewhat estrange itself from the
3 technical aspects because you're going to have less
4 people, fewer funding. Relying on technical standards
5 in which the FDA has had very few inputs is certainly
6 not to the advantage of the public, and this is
7 something that we're really very much concerned.

8 Normally if you just leave it to the
9 industry or that side of the stakeholders, you might
10 end up with technical methodologies that might have
11 been sufficient as Greg allowed.

12 So, again, the input and the active
13 participation of the FDA in this standard setting,
14 volatile standard setting efforts, should be as
15 intense as necessary for the promulgation of technical
16 standards that do make sense and protect the public.

17 CHAIRMAN ROTHENBERG: So where are we with
18 regard to a motion?

19 MR. THOMAS: That's always tough. Can I
20 make another comment? And then I'll try to figure out
21 a motion here.

22 Cass and I share, I think, a similar

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1 concern. Voluntary standards tend only to work when
2 somebody says, "Yes, that makes sense to me
3 personally." I've seen changes in the way the Joint
4 Commission and hospitals are establishing standards,
5 and quite frankly, the end users and people are going
6 to go to the lowest common denominator, and if it's
7 not required, they're not going to do it.

8 A concern that I have additionally is with
9 the mindset shift from mandatory prescriptive type
10 standards to less prescriptive and voluntary
11 standards, that requires to monitor compliance
12 technical expertise. I'm not concerned not only with
13 the HHS organization, but also with the DOD
14 organization and, frankly, the loss of that technical
15 expertise in the next few years. We're seeing it
16 across the federal sector, not just within the CDRH.

17 So with that as a general background
18 statement, what I want to do is to try to word a
19 motion that encourages the center to recognize that
20 voluntary standards, although nice administratively,
21 may be a problem.

22 So the motion I'll state in the following

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1 way, and that is TEPRSSC strongly encourages the CDRH
2 to critically evaluate any voluntary standard to
3 assure that they have the technical competence over
4 the long period of time to assure compliance with
5 those voluntary standards or voluntary standard bodies
6 that they may identify as being acceptable standards
7 to the FDA.

8 CHAIRMAN ROTHENBERG: Do we have a second?

9 MR. THOMAS: It's going to die.

10 MS. KAUFMAN: I guess I'm not quite clear
11 on the motion. Could we narrow --

12 MR. THOMAS: Would I be more crisp in my
13 vague motion?

14 PARTICIPANTS: Yes.

15 MR. THOMAS: Okay. TEPRSSC encourages the
16 FDA to carefully consider the movement from
17 prescriptive to less prescriptive standards and the
18 adoption of voluntary standards without assuring the
19 -- pardon me. Back up.

20 TEPRSSC encourages, strongly encourages
21 the FDA to critically evaluate the proposed changes to
22 the regulatory process from prescriptive to voluntary

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1 standards.

2 MS. KAUFMAN: I'll second that.

3 CHAIRMAN ROTHENBERG: Further discussion?

4 Yes.

5 MR. PLEASURE: Yeah, I support that, and
6 I would just like to say one point that I don't think
7 has been made in support of that concept, and that is
8 that this device that's being used on a pilot basis,
9 as I understand it, avoids the ANPR process and the
10 proposed rulemaking process, which means that the
11 American public doesn't have an opportunity to
12 participate in this harmonization process. So we're
13 doing this as a pilot, recognizing the necessity
14 perhaps, but I would say on balance that it should be
15 carefully watched.

16 And I don't think that moving in this
17 direction wholesale will serve the purposes of the act
18 that the regulations are intended to implement. It is
19 a move to a vote for the American people by an ANSI
20 chairman or chairwoman, and the Federal Administrative
21 Procedures Act is comforting in many ways and provides
22 opportunity, for example, organized labor representing

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1 operators who may be affected adversely by
2 introduction of certain machinery that they'll be
3 expected to use, others who are not adequately
4 represented always in the ANSI process, and have an
5 opportunity through a notice of a proposed rule to
6 formally participate if they choose.

7 So I think actually this Committee is
8 showing a great deal of confidence in the staff of the
9 FDA in watching closely how this develops and whether
10 in the long run it will serve the purposes of the act.

11 CHAIRMAN ROTHENBERG: Any other comments?

12 Yes, John.

13 DR. SANDRIK: I guess, you know, some of
14 the details have to be worked out, but I guess, you
15 know, it may not be clear that we are moving away from
16 that process necessarily. I mean part of the proposed
17 rulemaking could be that the rule is we will have this
18 FDA standard or this IEC standard, which will be how
19 the tests or whatever shall be done.

20 That would still be published. People
21 would still have the opportunity to comment on that,
22 I would suspect, but it's true they would not have had

1 the input on the IEC side of things in the formation
2 of that standard, but I would suspect they would still
3 have the opportunity to, say, speak out against it if
4 they found that it was not protecting the public
5 safety.

6 MR. PLEASURE: If I may, as I understand
7 this proposal, we are using an administrative process
8 that will not follow the usual ANPR and publishing a
9 final rule, that we're using another administrative
10 process that will shortcut that; is that correct?

11 DR. SULEIMAN: Let me try to clarify
12 because I know I'm going to have to interpret a lot of
13 this discussion subsequently. My understanding is
14 that the federal performance standard is still in
15 place for ultrasound diathermy. So that performance
16 safety feature is still in play.

17 We will be exercising some of our medical
18 device authority to exempt under the radiation
19 authority and adopt this document that's out there
20 that happens to be a voluntary IEC standard, and if
21 they're not complying, we can exempt it, and it will
22 get kicked back under the mandatory performance

1 standard.

2 So it really isn't very simple. It's not
3 mandatory versus voluntary. It's not prescriptive
4 versus nonprescriptive.

5 The other issue that I think John Sandrik
6 is referring to is conceptually is it opting for the
7 mandatory safety related features of this Advisory
8 Committee on the Radiation Safety Act, using that, but
9 then not going into a very prescriptive definition in
10 terms of writing a performance standard that is going
11 to be, you know, 50 pages long that may make it more
12 difficult to amend, you know, on a routine basis
13 because it's difficult to amend this thing on a
14 routine basis, but then defer to the IEC or other
15 committees and documents that are updated more
16 frequently and just sort of adopt those as ways to
17 meet the measure.

18 And so you come up with a safety number,
19 but how that number is derived, how that testing is
20 done is up to -- is not spelled out.

21 Have I confused things or have I
22 clarified?

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1 MR. PLEASURE: Well, if I may, Mr.
2 Chairman.

3 CHAIRMAN ROTHENBERG: Please.

4 MR. PLEASURE: There's a device being used
5 here on a pilot basis to provide a new exemption to
6 opt for an ANSI standard with limitations, and that
7 will not go through a rulemaking process. There will
8 be an opportunity with perhaps public notice to the
9 industry that they have new opportunity to get an
10 exemption from the FDA standard with limitations, and
11 it's mandatory that they then follow the ANSI standard
12 with exceptions as noted.

13 So it's an opening to go around the
14 rulemaking process through an exemption process that
15 you have the authority to exercise, and it's
16 interesting and I think it still has the policy issues
17 that I mentioned as an issue.

18 CHAIRMAN ROTHENBERG: Yes.

19 DR. BALZANO: I've been to too many IEC
20 meetings to be really comfortable in the acceptance of
21 IEC. I mean, I've got a real problem with that one.
22 So the only thing I can add to the comments of my

1 colleague is that the CDRH continues the utmost
2 attentive technical vigilance in any of the IEC
3 actions because otherwise, again, the protection of
4 the final user, which is the patient, might be lost in
5 the process.

6 I've seen that happen too many times.

7 CHAIRMAN ROTHENBERG: Okay. Are we ready
8 to vote again on this?

9 We've already approved or recommended
10 approval for the pilot project. Now we're talking
11 about utilizing or safeguarding the process that's in
12 existence and just urging caution in proceeding with
13 other projects like this until we know some results
14 from the pilot project.

15 All those in favor of this proposal?

16 (Show of hands.)

17 CHAIRMAN ROTHENBERG: Okay, and it looks
18 like we have a unanimous proposal.

19 So that is the last item on our agenda.

20 I want to thank you two for your excellent
21 presentation. I guess that's the end of our agenda.

22 I just wanted to, with the help of our

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1 Executive Secretary, review some of the things we've
2 looked at. We looked at the laser performance
3 proposals, and we've basically concurred with the
4 recommendations there.

5 On the sunlamps, we recommended proceeding
6 with certain of the suggestions from the center and
7 not with others.

8 With people scanners, we just reviewed
9 some of the activities going on in putting together
10 recommendations, and we still have to decide whether
11 there should be a standard at some point.

12 And CT fluoro, we wanted to make sure
13 that's not coupled in and holding up the fluoro
14 standards, but we might want to recommend some things
15 for that in the future once part of it will be based
16 on some data that hopefully we'll get from the next
17 survey.

18 Are there other future issues that anyone
19 on the committee would like to recommend that we take
20 up in our future meetings, things to keep an eye on
21 for the next agenda or other comments relating to
22 this?

1 Yes.

2 DR. BALZANO: You can expect in the
3 immediate future an explosion of electronic devices
4 emitting RF in the house. The technologies have blue
5 tooth (phonetic) that allows at a distance which are
6 known electro-domestics and all sorts of devices
7 "intranetting" (phonetic) the house. If there is an
8 area that you can expect in the next very, very near
9 future to have an explosion similar to the one of the
10 cellular telephones, it is, indeed, the technology of
11 RF communication between devices in the house.

12 You're seeing somewhat of a glimmer with
13 the telemonitoring for cardiac and so on. I suspect
14 an explosion coming there in the market for the house
15 and, therefore, a personal interest.

16 So in case that you see the cellular
17 telephone caught you by surprise, this may be another
18 case where there is an explosion in five or six
19 months.

20 CHAIRMAN ROTHENBERG: Okay. So we should
21 keep this in mind for next year's or next meeting's
22 agenda, whenever that will be.

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1 Yes, Cass.

2 MS. KAUFMAN: Now, the number one issue
3 that came before FDA on the reengineering had to do
4 with accelerators, and so I'm wondering if FDA might
5 think at our next meeting about presenting us with
6 what their plans are for addressing that issue as it
7 was raised as the number one issue.

8 And the second thing had to do with
9 analytical X-ray equipment used in the industrial
10 setting because I don't believe FDA regulates that
11 right now. They just have cabinet X-ray, and in fact,
12 those units often results in some very serious
13 injuries to workers, and so that might also be
14 considered as a presentation by FDA, is whether or not
15 they have any plans regarding analytical X-ray
16 equipment..

17 CHAIRMAN ROTHENBERG: Any other proposals?

18 MR. THOMAS: Looking on the other side, I
19 think it was the top one on the right-hand side, is
20 the change that we're seeing in medical imaging in the
21 area of direct digital detectors, teleradiology, soft
22 copy reading. It's all kind of wrapped up into that

1 one that was adjacent to accelerators in the other
2 column.

3 We've got, I think, in the next two or
4 three years tremendous technology that is using the
5 electromagnetic spectrum in ways that we're not
6 currently using it that probably it might be just a
7 good idea to have here's an overview of the futures
8 and the directions of what's happening in the
9 electromagnetic spectrum so that the committee has a
10 feel for what areas might, indeed, become significant
11 public health risks.

12 CHAIRMAN ROTHENBERG: Any other
13 suggestions?

14 MS. KAUFMAN: Well, I'm just wondering
15 with some of these issues on the table. I don't know.
16 Maybe this committee needs to meet more often than
17 just annually.

18 DR. SULEIMAN: If necessary, you could
19 meet.

20 CHAIRMAN ROTHENBERG: It sounds like at
21 least for some of the proposals that were just
22 mentioned there won't be information really to deal

1 with, let's say, in six months. It's going to be
2 possibly within a year. So unless there are more
3 pressing items, I guess we can always -- what is our
4 ability to call a meeting?

5 DR. SULEIMAN: Well, whether you remember
6 or not, you only met here six months ago. So we
7 have --

8 (Laughter.)

9 MS. KAUFMAN: This is our annual meeting.

10 DR. SULEIMAN: When the Committee had gone
11 through the five or six year hiatus of not meeting at
12 all, I think senior center management felt very
13 committed that as a minimum it would meet annually.
14 If we need to meet more frequently we're capable of
15 doing that, but we don't want to meet just for the
16 sake of meeting.

17 I think the issues should be driving. If
18 it's less than once a year, it's going to be the
19 requirement to go ahead and meet once a year, but if
20 the issues mandate it, we'll meet more frequently.

21 MS. KAUFMAN: Well, one advantage to
22 meeting more frequently is it does drive FDA to

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1 perhaps move a little bit more quickly on some of
2 these issues if they know that there's a meeting
3 coming up and we want to hear a report on what's going
4 on.

5 So there is an advantage to having more
6 frequent meetings. I'm not suggesting that we always
7 need to. I'm just saying that it's something we might
8 consider.

9 For example, on accelerators, you know, I
10 don't know what, if any, work FDA has already done on
11 analytic. It may be that work is already in progress
12 that we just haven't heard about, you know, that FDA
13 might be prepared in six months to report back on.

14 But at any rate, I do know that a lot of
15 work takes place just prior to the meeting, and so the
16 more frequent the meetings, the more impetus there is
17 for FDA to work on some of these activities.

18 CHAIRMAN ROTHENBERG: Any other comments
19 or suggestions?

20 I think we'll have to keep this in mind,
21 but I don't think there's anything we can specifically
22 point to right now to --

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1 MS. KAUFMAN: Oh, I absolutely agree.

2 CHAIRMAN ROTHENBERG: Yes?

3 MR. PLEASURE: This is my first meeting.

4 I just wanted to comment on the very high quality of
5 the presentations, the work of the Chairman, and with
6 Dr. Suleiman's help for a new member coming on. I
7 think it was a great experience for me, and I hope it
8 was -- well, we'll see -- I hope it will be useful to
9 FDA.

10 CHAIRMAN ROTHENBERG: Well, this was also
11 my first meeting, and coming in as the Chair, I
12 certainly want to thank all of you on the Committee,
13 Dr. Suleiman, all of our CDRH and FDA people for
14 making this run so smoothly, and I think we got
15 through quite a bit, and we accomplished quite a bit.
16 So thank you all very much for your cooperation.

17 I think at this point, I guess, unless
18 Orhan has any closing remarks, we can --

19 DR. SULEIMAN: No, the only -- well, I
20 guess I will make a closing remark, but keep it very
21 minimum. I think the essence of the Committee
22 functioning well is getting quality people on the

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1 Committee, and we've been very pleased with you as
2 Committee members.

3 I'm also pleased to say that next year
4 we're not going to lose anybody. So we're going to
5 have everybody coming back intact. The way we have
6 everything going is we'll be rotating five people off
7 in a year, but we've got everybody with a four year
8 term. So next year we take a little bit of a
9 breather.

10 And we will have a meeting internally
11 pretty soon to discuss what happened here at the
12 meeting, and at that time we'll make an assessment
13 whether we need to have or when we'll have the next
14 meeting. That target date was just one that I said,
15 "Let me go into the meeting and have some target
16 date."

17 I'm sure I would have checked the CRCPD
18 thing, but I'll check if there's a conflict, but I
19 assume I would have, but I'll find out if I did or
20 not.

21 But if we need to meet early, if there are
22 some issues that would require the Committee coming

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1 earlier, we'll seriously consider that. It may be a
2 one day meeting to discuss some specific issues, but
3 that's fine, and I think this committee is very
4 instrumental in the reengineering activities as well.

5 We're not necessarily driving the
6 Committee as much as the Committee may be driving us.
7 So I think there's some synergy there, I think, in
8 terms of the process.

9 That's really all I have to say.

10 CHAIRMAN ROTHENBERG: Okay. Well, thank
11 you all. I guess this meeting is now adjourned.

12 (Whereupon, at 11:39 a.m., the meeting in
13 the above-entitled matter was concluded.)
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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: TECHNICAL ELECTRONIC PRODUCTS RADIATION
SAFETY STANDARDS COMMITTEE MEETING

Before: CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH

Date: JUNE 22, 2000

Place: ROCKVILLE, MARYLAND

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.

Rebecca Davis