

1 DR. LAMBERT: I am talking about right off
2 the production line.

3 CPT DAWSON: Oh, no, it wouldn't come off
4 the production line that way. In fact, a lot of their
5 quality control is for image quality. They look far
6 more at image quality than they do at the possibility
7 of some kind of radiation I think.

8 But as far as we know, almost never is
9 there a set that has a radiation hazard.

10 SECRETARY SULEIMAN: Let me clarify.
11 Phase I is routine t.v. operating properly; and Phase
12 II is the knobs may be misadjusted; and Phase III is
13 a worst case scenario, where you actually cause some
14 component to fail.

15 CPT DAWSON: When the standard was
16 written, yes. So, Phase I was basically misadjust any
17 user control to maximize x-radiation. In Phase II,
18 they had to adjust the user controls on any service
19 controls.

20 And in Phase III then, they had to
21 introduce a worst case fault, plus misadjust all the
22 user end service controls.

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1 DR. LAMBERT: But that is the test that
2 the manufacturer runs on a per lot, per shift basis?
3 He actually makes it a worst case component fail?

4 CPT DAWSON: That is what he is supposed
5 to do to follow our policy. We find sometimes that
6 they don't actually find the worst case.

7 MS. KAUFMAN: I remember that we heard
8 earlier today that they don't inspect manufacturers.

9 CPT DAWSON: One problem is sealed
10 controls. Well, they may say they are sealing a
11 control, but our laboratory finds that they can break
12 the seal and adjust the control, and that can lead to
13 a noncompliance, where the manufacturer said he didn't
14 test it by adjusting that control, because he
15 considered it sealed.

16 But we say that if you can adjust the
17 control, you have to adjust the control during the
18 test. So now one question that we get today is with
19 electronic and digital controls that can be pre-
20 programmed into the set.

21 It is not something that the user could
22 readily adjust, but perhaps the serviceman could

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1 adjust it if he has the proper code to put into the
2 chip. Is that a sealed control or isn't it? Well,
3 that is a question for us.

4 DR. CARDELLA: I guess what would be a bad
5 situation is if the manufacturers, as the units came
6 off the assembly line, they randomly pull one out and
7 do a Phase I test on it, and declare it meeting the
8 specification; when the requirement was that they
9 should be sampling these and doing a Phase III test on
10 it.

11 Do you think that goes on? Because if
12 that goes on, whatever we say here wouldn't much
13 matter. That was my first point. And my second point
14 is when you said, or when you pull sets and do Phase
15 III testing of your own, you do occasionally come
16 across one that doesn't meet the requirement.

17 Are those recent vintage sets or are they
18 legacy sets that might be 15 or 20 years old that you
19 are testing?

20 CPT DAWSON: On the second one, as I said,
21 we have one right now that is still being resolved,
22 and we had another one about 6 years ago, but we are

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1 only testing right now about 40 sets a year.

2 So if there are 70 million of them
3 produced, you are getting down to 1 in 2 million that
4 FDA tests.

5 As to the first question do manufacturers
6 just do a Phase I test, they shouldn't do it, and if
7 we find that they are doing it in an inspection, we
8 have the authority to disapprove their testing
9 program, which would prevent them from certifying
10 their sets, which makes it illegal for them to sell
11 them in the U.S.

12 If they are not doing an adequate test, we
13 can disapprove the testing program and that is a big
14 stick that we have.

15 CPT THOMAS: How many testing programs
16 have been disapproved?

17 CPT DAWSON: There have been a few in the
18 last few years, yes.

19 CPT THOMAS: Specifically on this issue?

20 CPT DAWSON: Specifically on that issue?

21 CPT THOMAS: Yes, the issue of radiation
22 or x-ray emission from the systems?

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1 CPT DAWSON: On the basis that the test
2 was not adequate to ensure that it was not x-ray
3 emission, yes. And without really finding x-ray
4 emission over .5.

5 DR. LAMBERT: There seems to be two issues
6 that are coming into play, and one is the television
7 versus computer monitor; and I think the technology
8 between those two is -- well, while the CRTSS are
9 similar in concept, the electronics that are running
10 them are a lot different, and a significant difference
11 over what they might radiate or what might fail
12 because of what they might radiate. Are they really
13 asking for relief on the computer monitors, or just on
14 the t.v. sets?

15 CPT DAWSON: We regard the video monitors
16 as the same as a t.v., subject to the same standard,
17 partly because today you can put a video card in your
18 computer and receive video signals, and partly because
19 computers generate pictures for video games, and so
20 you are watching a t.v.

21 DR. LAMBERT: I understand that, but you
22 would not sit at your desk and look at a t.v. monitor

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1 with text on it because the resolution is so bad.

2 CPT DAWSON: Right. I would not use a
3 t.v. for it.

4 DR. LAMBERT: You wouldn't do computer
5 work on a t.v. You might watch a t.v. from a computer
6 though?

7 CPT DAWSON: Right.

8 DR. LAMBERT: And the frequencies are
9 higher, and I am not an expert, but there are a lot of
10 other things that may be different, too.

11 CPT DAWSON: That is correct. The
12 frequencies for the monitors are higher.

13 CPT THOMAS: Why is there not a reduction
14 or changes to any of the testing of frequencies? You
15 have not asked for the standard to change.

16 MS. KAUFMAN: When you say this is
17 guidance, do they have to do this, or is it strictly
18 guidance?

19 SECRETARY SULEIMAN: Guidance is one way
20 of doing things, and if they follow it, then they are
21 usually safe. They can do it another way, and they
22 can deviate from it.

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1 But it is the old philosophical argument
2 about even though you recommend or you give guidance,
3 some people are going to mandate it, and a lot of the
4 companies, I think they really want to follow
5 guidance, and they want to follow it to the T. I
6 think we are going to look at this, and we will take
7 it into consideration.

8 CPT DAWSON: Well, the question for them
9 is would we disapprove their testing program with what
10 they are proposing. Right now our policy has been
11 that it is a minimum of one set per shift per day.

12 If they have a line that would produce two
13 different models in the same day, they should test one
14 from each model. But one of our problems is that we
15 want all of the tests to be representative of units
16 produced by the same people, and tested by the same
17 people.

18 So if you go to a week's production, for
19 example, you might have several different shifts in
20 there of different people assigned to different tasks
21 on the production line. So you don't have the same
22 expertise in doing the production or the testing of

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1 the sets on the production line.

2 MS. KAUFMAN: Well, one suggestion,
3 because this obviously impacts, and it obviously is a
4 significant amount of work for the manufacturer, and
5 the t.v. sets obviously impact a significant number of
6 people, is to perhaps visit a few manufacturers
7 unannounced and just see what they are doing in the
8 way of testing.

9 If they truly are following your Phase III
10 testing and they are not finding anything, you know,
11 that would give you more support in terms of changing
12 your guidance.

13 On the other hand, if you go out there and
14 they are not doing Phase III, and they are maybe not
15 even doing Phase I, they might not even be following
16 the weekly guidance.

17 CPT THOMAS: You want to be careful. They
18 may be doing Phase III testing, but not at the
19 frequency that is dictated.

20 MS. KAUFMAN: Sure, but the only way you
21 know what they are doing is to go out, I think, and do
22 some unannounced visits.

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1 DR. LAMBERT: I am not sure where you are
2 going. I don't think you are going in the United
3 States, and I am not sure where you are going to do
4 this testing.

5 MS. KAUFMAN: There is one manufacturer in
6 the United States isn't there? Isn't there one?

7 CPT THOMAS: Orhan has indicated that we
8 will look into this. Now, should this committee make
9 a motion or I don't know, but we have discussed it a
10 little bit.

11 And I am very confused quite frankly with
12 what I have heard; in that in getting a regulatory
13 answer, in terms of what is currently done, and what
14 you can do to terminate a person or disapprove a
15 company's QA program.

16 But that is not the question that is being
17 asked, and I am not sure that the focus of the CEA's
18 request has been truly discussed. I think we are
19 talking around it. And do we need a motion? I mean,
20 what are you guys going to do with this piece of
21 paper?

22 SECRETARY SULEIMAN: All right. Let me

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1 comment. First off, this is a statement for the
2 record. Now, they could have also submitted this some
3 other way.

4 Number 2, I look at this and I don't see
5 enough. They are asking for relief from daily to
6 weekly, and there are other questions that are
7 unanswered in my mind in terms of what is their sample
8 size, and are they looking at one set a day, a
9 thousand sets a day?

10 In other words, if they want the advisory
11 committee's opinion on this, give us your opinion. I
12 am pretty confident that we are going to look at this,
13 but I don't know the specifics of this, and what
14 impact this has.

15 CPT THOMAS: Well, that was one of my
16 first questions, is that I don't think we have enough
17 information, and at the same time I don't know what we
18 are going to do with this.

19 SECRETARY SULEIMAN: We are looking at it.
20 We have looked at it already today. The staff will
21 look at it. We have given it more attention than
22 probably if it would have come in privately. So,

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1 their intent has been fulfilled; raising the
2 visibility of the question that they are asking.

3 I suspect the staff will look at this and
4 come to a very reasonable decision on what to do and
5 what not to do with this.

6 SECRETARY SULEIMAN: Why don't we just
7 make a motion that the staff look at this?

8 CPT THOMAS: That is a good motion.

9 CHAIRMAN ROTHENBERG: And wrap it up,
10 because there is not much we can do about it.

11 CPT THOMAS: There is nothing that we can
12 do about it, but I will --

13 DR. SZEGLIN: I will make the motion.

14 CHAIRMAN ROTHENBERG: Is there a second?

15 DR. LAMBERT: I second it. I would like
16 to make a comment.

17 CHAIRMAN ROTHENBERG: Yes.

18 DR. LAMBERT: There seems to me to be a
19 couple of issues here from the manufacturers'
20 perspective, and that is that they are saying that it
21 is a must that they would like to avoid, or that they
22 would like to reduce.

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1 And I can understand that. Between 1968
2 and now the profit margins on television sets or
3 monitors are significantly scaled down, and if they
4 have to continue with tests, they represent a
5 significant cost.

6 So I have no perspective of how many sets
7 come off the line per shift. So if they are doing a
8 lot of testing on one set out of 1,000 or doing a lot
9 of testing on one set out of a hundred-thousand, which
10 I don't think really comes off, that may make a big
11 difference.

12 The second thing that I would like to see
13 and to investigate is in point of fact that under the
14 Phase II sort of tests, as opposed to this very
15 extreme test, what are the number of failures that are
16 observed.

17 And if there is never one found under a
18 Phase II test, then it looks like maybe it is being
19 over-tested. That really requires a systematic
20 investigation and well thought out aspects of what is
21 going on, and not something that happens in five
22 minutes at the end of the day.

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1 CHAIRMAN ROTHENBERG: Well, I think that
2 the intent of the committee is well -- can we have a
3 vote now? All in favor?

4 (A show of hands.)

5 CHAIRMAN ROTHENBERG: Opposed? Abstain?
6 Okay. Then the motion carries. We have completed our
7 intended business and it is four o'clock.

8 DR. ELWOOD: Wait, I have another motion
9 I would like to make, and I would like to do it with
10 the laser product performance standard. I wasn't here
11 at last year's meeting, and I don't know how much was
12 discussed then, but the year before we talked about
13 the potential for harmonization with IEC, and we were
14 going to wait or going to recommend wait and look at
15 IEC.

16 Now, IEC has passed, and it is published,
17 and I would like -- my motion is that I would like to
18 move that the committee urge that the Center expedite
19 the publishing of the notice of proposed rule making
20 on this performance standard, because we have a big
21 disconnect now between what is going on in the U.S.
22 and everywhere else in regard to laser products.

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1 So I would like to see that pushed through
2 as quickly as it can happen.

3 CHAIRMAN ROTHENBERG: Is there a second?

4 DR. SANDRIK: I second.

5 CHAIRMAN ROTHENBERG: Okay. Any other
6 discussion?

7 MS. KAUFMAN: Let me just clarify. The
8 motion is simply that we are urging FDA to expedite
9 publication of proposed regulations?

10 DR. ELWOOD: And I guess the next step I
11 understand is the APRM?

12 AUDIENCE: We have already done the APRM.

13 DR. ELWOOD: Then it just needs to be
14 published. Let's expedite the publishing then.

15 MS. KAUFMAN: And these would be proposed
16 regulations and would be for comment, right?

17 CHAIRMAN ROTHENBERG: Right. Okay. All
18 in favor?

19 (A show of hands.)

20 CHAIRMAN ROTHENBERG: Okay. Opposed?
21 Abstain? Okay.

22 MS. KAUFMAN: Thank you.

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1 CHAIRMAN ROTHENBERG: Let's keep in mind
2 that some people have early flights that they can get,
3 and we seem to have covered most of the business.
4 Does anybody have suggestions for any new topics that
5 they would like to see discussed next year? I am sure
6 the Center will come up with plenty of things to
7 present to us. Yes?

8 MR. PLEASURE: It would be helpful if we
9 knew by an indication by the members of the committee,
10 or as a topic that it might be more efficient just by
11 communication to those of us to spell out where ALARA
12 comes in and where it doesn't, and pre-market and
13 post-market issues.

14 Because although we had an interesting and
15 a useful discussion today about feasibility and what
16 we consider, it still would be helpful, and I sense
17 that there are many of us who are still uncertain
18 about when ALARA comes in and when it doesn't.

19 SECRETARY SULEIMAN: Okay. I think since
20 to the extent that it is so perfectly clear to so many
21 other people, but clearly we will make an effort to do
22 that.

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1 DR. SHOPE: I would just make a comment on
2 that. There is nothing in our law that says ALARA
3 anywhere that I am aware of. It talks about
4 identifying radiation hazards and reducing unnecessary
5 radiation in the case of products whose intended
6 purpose doesn't involve radiation, or minimizing it in
7 the case of diagnostic systems for a purposeful
8 exposure of patients.

9 But in addition to our Radiation Control
10 and Safety Act, we also have all the other
11 administrative procedures and executive orders, and
12 environmental assessments, and small business impact
13 assessments, and all those other things that get into
14 looking at the cost benefit issues for any regulation
15 that we propose.

16 And so those have to be dealt with as part
17 of the standards amendment process or the new standard
18 promulgation process. So those kinds of issues come
19 into play. But we don't have any clear direction in
20 our statute about ALARA necessarily and specifically
21 spelled out.

22 And so it is meant to be a judgment based

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1 on technical feasibility and the risks associated with
2 the products, but it is not very well -- and it is
3 something that the committee and the staff here, and
4 the public commenting on our proposals we all kind of
5 have to wrestle together with I think.

6 MR. LEASURE: That is very helpful. It is
7 sort of like best available, and in other contexts, I
8 think the view that was used was cultural -- and I
9 don't want to hang you on that, but it seems to me
10 that --

11 SECRETARY SULEIMAN: Be my guest.

12 MR. LEASURE: It seems to me that when one
13 is talking about exposing the entire population to a
14 certain level of radio frequencies, and doing so
15 intentionally, and we don't go into some detail of
16 assessing the technology that is available, all we
17 talk about is the state of the bio-medical studies
18 that are available.

19 And we are leaving out a considerable area
20 of necessary information to make a judgment if there
21 are cultural issues involved, and ALARA and safety
22 technologies is at issue. That's all I need to say,

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1 and it seems to me that it is a very important issue
2 that we took up today. And if there is further
3 discussion, it should be revisited.

4 SECRETARY SULEIMAN: I guess the standard
5 to some degree is defined by this committee, and you
6 have advocates on both sides. You have some groups
7 that say you have got to get it as low as possible,
8 absolutely possibly and technically possible.

9 Then you have other people or
10 professionals with opinions who say that is not a
11 hazard at all, and they are completely contemptuous of
12 any potential risks.

13 And probably reality is somewhere in
14 between. But clearly I think a lot of people on this
15 committee have dealt with this in various forms or
16 other, but the more frequent the product is used, ala
17 t.v.s or cell phones, you know, the more concern there
18 is about the more subtle effects, because they may
19 manifest themselves on a large scale population.

20 But we are plugged into that I think a
21 lot, but do we have definitive answers? No. And as
22 I think culture does have something to do with it, and

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1 how people perceive it, but I think this committee and
2 you, yourself, contribute to setting that bar.

3 MR. PLEASURE: Well, that is very helpful.
4 So appropriately it was raised by the agency, and it
5 was put on the agenda, and it wasn't on the agenda
6 last year, and I think it is excellent that it was
7 this year.

8 I am just saying that my sense was that we
9 didn't have enough information, and we looked only at
10 the bio-medical science, and we are considering
11 intersecting factors like cost, and cost benefit, and
12 size of the population.

13 All we considered was whether there was a
14 bio-medical threshold, and that's how we approached
15 it, and I think there needs to be more on the
16 engineering side to make some kind of considered
17 judgment is my view.

18 DR. RICE: I think to make the radiation
19 more user friendly for the public in general, and for
20 us as professionals, some people have advocated the
21 use of the Burke Formula as a background equivalent
22 and radiation tide.

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1 We have coupled the radiation with the
2 background that we all get normally, and for example,
3 one physicist said that a chest x-ray is equivalent to
4 one to two weeks of background of radiation, and so
5 everybody can understand that. And I think that would
6 help in some discussions, and also with some public
7 information.

8 DR. BALZANO: That may not work for the
9 rest of us, because there you are dealing specifically
10 with what you might call a chemical insult. With RF,
11 we are talking about additional molecules, and the
12 addition is accomplished in one extent in nano
13 seconds, and so the ordeal is over at that point.

14 So what probably should be done is that
15 indeed it is a pleasure to submit some more of the
16 background of what information so that you can
17 appreciate -- and for the committee it might also be
18 interesting, and I guess that can be organized.

19 But quite a bit of effort went into it,
20 and it gets to the point where people may not buy the
21 device, and that is potentially one of the issues.
22 And the other issue indeed is the fact that if there

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1 was ever a curative effect process, and there was a
2 mechanism for a cumulative effect, then the question
3 that was brought up by Dr. Rice would be entirely
4 correct.

5 But right now we don't have the cumulative
6 effect and it is as simple as that. The basic proof
7 of science has got to be the point of right to left,
8 and that is what we are looking at.

9 CHAIRMAN ROTHENBERG: Okay. John.

10 DR. CARDELLA: On an unrelated topic,
11 comments made earlier this morning about the sun
12 tanning issue, we did not specifically discuss that at
13 this meeting, but comments were made that in the
14 coming years time that there were several photo-
15 biology and the biological effects of UV radiation on
16 skin meetings to be held.

17 And I would like to make the suggestion as
18 a follow-up to the question that I asked earlier this
19 morning, that the American Academy of Dermatology be
20 specifically solicited to participate in those,
21 because what I am a little concerned about is if they
22 have become distant from the deliberations, is that an

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1 indication that, (a), they are disenfranchised, or
2 (b), the science is beginning to indicate other than
3 their original position, and it is awkward for them to
4 come back and say, well, you know, we change our
5 minds, and it is no big deal anymore.

6 And I think that if that is the case, we
7 ought to find that out formally, and then draw a
8 closure to it. You know, sun tan lamps are okay
9 because the science that was in play 3, 4, or 5 years
10 ago has changed.

11 I would make that as a recommendation;
12 that if the FDA is involved in those upcoming meetings
13 that it would be nice to solicit AAD participation;
14 and if they say we don't need to send a
15 representative, and we don't want to come, you might
16 engage them in a dialogue about whether they have
17 changed their position.

18 DR. NELSON: Or as a follow-up to that,
19 invite them to one of these meetings.

20 MS. KAUFMAN: They are coming out with
21 some innovative therapeutic devices that use mega-
22 voltage x-ray as a source, and for example, I think

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1 they have a 4 or 6 mv robotic thing for radiosurgery,
2 and there is in prototype I think at the University of
3 Wisconsin a CT scanner that uses 4 mv for therapy.
4 Has the FDA ever considered regulating the
5 manufacturer of therapeutic equipment?

6 SECRETARY SULEIMAN: Well, first off, if
7 it is a medical device, it has got to go through
8 our --

9 MS. KAUFMAN: But you don't have any
10 regulations on it?

11 SECRETARY SULEIMAN: We don't have any
12 performance standards.

13 MS. KAUFMAN: Right. There are no
14 performance standards.

15 SECRETARY SULEIMAN: But getting back to
16 the culture. In the Radiation Act culture, we are
17 saying performance standards, but we do regulate, and
18 we do have quite a bit of authority under the Medical
19 Device Act.

20 MS. KAUFMAN: Have you ever considered
21 performance standards?

22 SECRETARY SULEIMAN: I am not sure that we

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1 have formally considered them. I am sure that we have
2 probably discussed it.

3 DR. SHOPE: If your question is about
4 radiation therapy delivery systems, and electronic
5 products that delivery radiation therapy. Yes, that
6 has been considered a number of times.

7 Not a lot recently, but in the more distant
8 past, and the conclusion there was in terms of
9 priorities not based on the magnitude of the radiation
10 exposure, but the priority based on the kind of public
11 health problems that were presented and could be
12 controlled by a performance standard.

13 Those were not thought to be high
14 priorities, primarily because there were good
15 international standards, the IEC standard, for
16 accelerators used in medical therapy.

17 If there is some new types of products
18 that are out there that are different and perhaps not
19 covered by voluntary standards, and where it could be
20 shown that there was a potential for radiation risk
21 and concern, and that a performance standard might
22 have some benefit, then that would be appropriate for

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1 the agency to consider.

2 But I don't think we have seen things
3 rising to that level at this point. So if you have
4 some information that would help us relook at the
5 situation, that is something that we could consider.

6 MS. KAUFMAN: I don't think that there are
7 many States that have a mis-administration rule on x-
8 ray therapy. So I honestly don't think we know what
9 problems are occurring out there, and I know that they
10 are reporting guidance and requirements,, but I just
11 am not sure that it is actually occurring.

12 My only suggestion is that it might be
13 something for future committees to think about, and
14 meeting to think about, is performance standards on
15 therapy.

16 DR. SHOPE: Right. But I think we have
17 to also look at mis-administrations are due to many
18 sources, and we can control only the machine
19 performance aspect of those.

20 MS. KAUFMAN: Absolutely. I have another
21 question, too, because someone had said something
22 about film screen systems, and processes, and I know

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1 that they are not electronic products, but I thought
2 they still came under medical device control.

3 Has anyone thought about writing
4 performance standards for those? Would those come
5 under this committee if they were to have performance
6 standards, or under some other advisory?

7 SECRETARY SULEIMAN: We have guidance for
8 processes under the Device Authority. We work
9 collaboratively with outside groups regarding
10 standards and stuff, and guidance, and protocols.

11 We have never really addressed it under
12 the Radiation Control Act.

13 MS. KAUFMAN: I know that I mentioned
14 these being topics maybe for future thought or future
15 subjects, because we all know that there are a lot of
16 problems with processes out there.

17 And it may be an area where performance
18 standards would be helpful.

19 DR. CARDELLA: The other potential future
20 topic that comes to mind as I was thinking through
21 some of the things that we do in our practice that are
22 new, and this may be getting regulated, but I don't

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1 know, or being looked at, is that there is radio
2 frequency tumor ablation that is becoming fairly -- I
3 would say not common, but a new therapy in which
4 probes are passed into various tumorous structures,
5 and they are connected to a radio frequency generator,
6 and then you basically cook a sphere of tissue, to
7 include the tumor, with the idea of thermally
8 necrosing it.

9 I am not sure that there has been any
10 discussion of that in any of the years that I have
11 been here, and I don't know if that is something that
12 should have some discussion and maybe a performance
13 standard or not.

14 MS. KAUFMAN: I overheard a discussion
15 relative to the fluro time they use.

16 DR. MARX: Normally that is done under
17 ultrasound or CT, but not fluro.

18 MS. KAUFMAN: They used to do it always
19 under fluro, and it was very long times.

20 DR. CARDELLA: The guys at our place do it
21 under ultrasound targeting. The RF part of it is an
22 electronic device that is being used in the body.

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1 DR. SHOPE: Those devices come under FDA
2 oversight through premarket approval of medical
3 products. We actually have some in-house laboratory
4 work related to those kinds of products, and ways to
5 manage and measure the heat delivered and the thermal
6 conduction properties of tissue, and those kinds of
7 things.

8 And so it is an area that we do have an
9 interest in. I am not clear -- again, it could be
10 looked at as a radiation emitting product clearly. It
11 is one of those products that has dual coverage under
12 our laws, both medical device and radiation.

13 I think the question would be if there is
14 a problem, is the problem the kind that could be
15 addressed by a performance standard addressing
16 radiation emission, or is it better addressed through
17 the premarket approval, PMA, scientific evidence of
18 safety and effectiveness.

19 There is a provision in the Medical Device
20 Act that also allows the establishment of performance
21 standards for medical products and that is somewhat
22 more cumbersome than our radiation control authority.

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1 And we have not used it except I think
2 once or twice, and one of those times, we did not go
3 all the way with it. So it is a different process and
4 the interpretation up to now has been that when you
5 make a standard for those products, it applies to all
6 of them, including the ones in use.

7 It doesn't have the grandfathering aspect
8 that we have under the Rad Health Act. So that has
9 presented us some problems to actually do a standard,
10 because it makes everything out there basically
11 illegal that doesn't conform with the standard, and
12 that has presented us some problems in really going
13 full blast with standards under the Medical Device
14 Amendment.

15 So we have to sort of watch that issue a
16 little bit. So if it emits radiation, then it is an
17 electronic product, and it certainly could be looked
18 at under the Rad Health Act, and therefore would be
19 under the pervue of this committee.

20 I think the question is what is the level
21 of problem presented, and is performance standard the
22 way to deal with that.

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1 And I guess at this point that we haven't
2 seen those issues rising to the significance that we
3 would want to do those rather some other things that
4 we are doing.

5 DR. MARX: I think one thing to keep in
6 mind with those devices is that as they are currently
7 used, they are typically applied to people who have
8 terminal diseases. It is a relatively small
9 population of people who have a relatively poor
10 prognosis.

11 I think one thing that would be worthwhile
12 with FDA sort of keeping their ear to the ground about
13 is that sooner or later this technology -- that people
14 will push the envelope with the technology into more
15 prevalent benign diseases. And that at that point, I
16 think it bears closer scrutiny.

17 DR. CARDELLA: Or if there is any
18 potential risk to the users, the operators of it,
19 because they would be doing maybe 10 a month, and one
20 patient would be subjected to one in a lifetime.

21 And you are right; the patients are in
22 terrible shape basically, and their expectation for

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1 living is short. But the operators have repeated uses
2 of it. It was just a thought.

3 DR. SHOPE: One of the advantages there is
4 that you are not trying to transmit energy somewhere
5 else.

6 DR. BALZANO: There is radio coming out of
7 the volume, and unless there is micro selection, then
8 it goes to the tumor and that is it.

9 CHAIRMAN ROTHENBERG: Okay. I think we
10 have got some thoughts, and Orhan has some remarks
11 that he would like to make.

12 SECRETARY SULEIMAN: Two things. I want
13 to thank -- there will be five people whose terms
14 expire this December, and since it doesn't look like
15 we are going to be meeting before then, I want to
16 thank Kas Kaufman, Jerry Thomas, Dr. Cardella, Vickie
17 Marx, and Steve Szeglin, for serving on the committee
18 for the last four years, I guess. It was 1998.

19 And now that you are about to rotate off,
20 I want to -- Dr. Cardella and Dr. Marx were my first
21 real challenge, because we got them approved two hours
22 into the meeting that they were in. We had a slight

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1 problem with the Commissioner signing off on it.

2 It turned out that there was a holiday or
3 whatever. Oh, that's right. That was the consumer,
4 and because you were general public representatives,
5 accidentally, you got cycled through our consumer
6 selection process, and we had to argue that you
7 weren't consumers, and here you were general public
8 representatives.

9 The other thing is that we are going to
10 have five vacancies, and so as you should know by now,
11 I would appreciate any nominations, any additional
12 names that you have.

13 We are a very diverse, balanced committee,
14 and we also have this general public industry
15 representation, and government representation quota
16 system that we have to adhere to as well.

17 So if you have any names, any
18 professionals that you think could contribute, I think
19 some of the issues coming up in the next year or two
20 clearly deal with photo biology and some hazards there
21 that I think we need to buff on.

22 It looks like we are very strong in terms

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1 of medical x-ray, but we are losing a number of
2 experts after this round. We also need some people to
3 stimulate the meeting, Kas. So I think it is
4 important to have people to keep others awake.

5 MS. KAUFMAN: You are going to miss me.
6 You may not believe that, but --

7 SECRETARY SULEIMAN: So, again, I want to
8 thank these five people for their terms, and I want to
9 thank the rest of the people as well. But again it
10 would really help out if I could get some additional
11 names for prospective candidates.

12 CHAIRMAN ROTHENBERG: Okay. Well, again,
13 my thanks as well for your participation, particularly
14 the five who have put in such an effort over the
15 years, and thanks to the rest of you for coming here
16 today, and giving up your valuable time to
17 participate. I think we can adjourn the meeting at
18 this point. Thank you.

19 (Whereupon, the Committee Meeting was
20 concluded at 4:28 p.m.)
21
22

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 Safety Standards Committee

Before: DHHS/FDA/CDRH

Date: May 17, 2001

Place: Rockville, MD

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


