

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

+ + + + +

TECHNICAL ELECTRONIC PRODUCTS RADIATION

SAFETY STANDARDS COMMITTEE

+ + + + +

TWENTY-SEVENTH MEETING

+ + + + +

Thursday, June 22, 2000

+ + + + +

**This transcript has not  
been edited and FDA  
makes no representation  
regarding its accuracy**

7018 00 JUL 19 P2:00

The Committee met at 8:30 a.m., in the Potomac I and II Rooms, Quality Suites--Shady Grove, Three Research Court, Rockville, Maryland, Dr. Lawrence Rothenberg, Chairman, presiding.

PRESENT:

LAWRENCE ROTHENBERG, Ph.D., Chairman

QUIRINO BALZANO, Ph.D.

KATHLEEN A. KAUFMAN, B.S.

MICHELE LOSCOCCO, M.S.

GREGORY W. LOTZ, Ph.D.

MAUREEN MURDOCH NELSON, M.D.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE. N.W.  
WASHINGTON, D.C. 20005-3701

PRESENT: (CONT.)

ROBERT PLEASURE

JOHN M. SANDRIK, Ph.D.

JERRY A. THOMAS, M.S.

ORHAN H. SULEIMAN, Ph.D., Executive

Secretary

FDA PRESENTERS:

JOANNE BARRON

BRUCE HERMAN

KIMBER C. RICHTER, M.D.

**NEAL R. GROSS**  
COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

C-O-N-T-E-N-T-S

	PAGE
Introduction . . . . .	3
Radiological Health Reengineering Activities in CDRH, Joanne Barron . . . . .	5
Review of Medical Device Approval Process, Dr. Kimber Richter . . . . .	34
Ultrasound Diathermy, Joanne Barron and Bruce Herman . . . . .	55

## P-R-O-C-E-E-D-I-N-G-S

(8:34 a.m.)

CHAIRMAN ROTHENBERG: Okay. I'd like to call the meeting to order this morning. This is day two of our TEPRSSC meeting.

And before we begin with our first speaker, Dr. Suleiman would like to discuss the date for our next meeting.

DR. SULEIMAN: Yeah, I was looking at the calendar. This would be tentative. At least everybody can mark it down in their calendar. I think May 16th and 17th.

MS. KAUFMAN: Do you know when the CRCPD meeting is?

DR. SULEIMAN: I don't.

PARTICIPANT: I think might be those dates.

DR. SULEIMAN: I may have selected knowing that, the 16th and 17th. So let's -- I'll look. Well, let's mark that down, and then we can check back.

PARTICIPANT: What are those days of the

1 week?

2 DR. SULEIMAN: Wednesday and Thursday.

3 MS. KAUFMAN: May 16th and 17th?

4 DR. SULEIMAN: Right. Just mark it down,  
5 and then we'll resolve any conflicts because we've got  
6 people, you know, in different specialties. So there  
7 may be some conflicts or whatever. May is a bad  
8 month, but for some reason I thought --

9 MS. KAUFMAN: May is a bad month.

10 DR. SULEIMAN: But it's a 30-day month.  
11 So I only selected two days. So will everybody check  
12 and see if there are any conflicts or whatever?

13 CHAIRMAN ROTHENBERG: Okay. So everyone  
14 will check against that.

15 We've having some laptop problems, but Ms.  
16 Barron said she can proceed at this point. So we'll  
17 go ahead with the first talk, "Radiological Health  
18 Reengineering Activities in CDRH," and the panel has  
19 handouts of the slides for this, and I guess there are  
20 a few extra copies.

21 MS. BARRON: Dr. Stern has extra copies  
22 for anyone in the audience.

1           The purpose of my presentation today is to  
2 update you on the radiological health reengineering  
3 activities and to request your comments on a couple of  
4 the ideas that have come up.

5           As Dr. Jacobson mentioned yesterday, we  
6 have approximately 60 people working in radiological  
7 health, and as a result of the reduction of people  
8 working in the program over the years, it's become  
9 fragmented and lacks the coordination.

10           So that was the reason why we began our  
11 reengineering process. If you'll notice the one slide  
12 on the history of the FTEs, it shows that we're  
13 holding somewhere close to around 60 to 65 FTEs or  
14 full-time equivalent personnel.

15           I am not going to be addressing the  
16 mammography quality portion of the work that we do in  
17 the center but only the radiological health activities  
18 other than mammography.

19           I'd like to give you a quick recap of the  
20 reengineering process we've been following,  
21 particularly for the new members. So first we went to  
22 the stakeholders and asked for their input on just

1 what their needs were, what we were trying to achieve  
2 in the first place.

3 We found that there were two stakeholder  
4 groups that naturally fell out. One was the user  
5 group that was the people we were trying to protect,  
6 and then there was the groups of industry, which is a  
7 little bit unique, and all of our other stakeholders,  
8 the states, professional societies and support.

9 But what we found is their needs were  
10 basically the same. So we kind of grouped them  
11 together. You'll notice on the bottom of the one  
12 slide it says "stakeholder needs: to provide  
13 guidelines and policies and have good communication."  
14 That seemed to be across the board regardless of  
15 stakeholder.

16 For the users it was maximum benefit to  
17 risk. For the rest of our stakeholders it was  
18 reliable data to test methodologies, and some  
19 responsiveness issues as well.

20 We started to analyze the program and put  
21 together kind of a picture of what this might look  
22 like to convey. So we end up at the bottom here with

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the stakeholder needs, if I can boil it down to  
2 reliable data, risk perspective and guidelines as the  
3 stakeholder needers.

4 Then two years ago, we asked this  
5 Committee to give us information on what they felt was  
6 important for us to be doing, and it comes out to  
7 national uniformity, characterization of emissions,  
8 training the states and others, and then doing some  
9 liaison in different ways than we've been doing to  
10 obtain information and exchange information other than  
11 just our traditional methods of reporting to  
12 manufacturers and the like.

13 So then we updated the model to add what  
14 we boiled that down to. The direction for the  
15 program, and that being the national direction and  
16 uniformity for radiological health, emissions and  
17 exposure trends and training.

18 Then we mapped and analyzed 28 major  
19 processes. We divided the processes and the effort we  
20 were putting into each of the processes among five  
21 functional areas, and you'll see the process functions  
22 in the boxes.

1 We determined their relationship to one  
2 another. We found several processes that cross over  
3 multiple functional areas, and so we split those out  
4 so that we could see what was actually taking place in  
5 them. You can see that we're spending the bulk of our  
6 time on assessing conformance and generating new  
7 information. That includes product testing, by the  
8 way.

9 A little bit less on setting criteria and  
10 very little in disseminating information or policing  
11 conformance.

12 When we looked at the specifics of each of  
13 those, we found that policing conformance, even though  
14 it was very small, had very good procedures in place  
15 and seemed to be working well because we have such a  
16 cooperative program with our industries. So we're not  
17 concerned about that one.

18 We were concerned, however, about  
19 disseminating information and trying to figure out how  
20 we can make some improvements and efficiencies in the  
21 other areas.

22 So the one with the circles, we set some

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 goals for each of those functional areas and then  
2 found where we had not been meeting those goals.

3 And so, for example, in the large circle  
4 in the middle we were not always targeting the highest  
5 priority products. So we'd like to make improvements  
6 there.

7 In setting criteria, we found that we were  
8 not updating our criteria. We're not staying up to  
9 date with policies and procedures. We're not putting  
10 out an adequate amount of information in the  
11 disseminating circle.

12 So we then updated the model down at the  
13 very bottom again and added in all of the areas where  
14 we thought we needed to make some improvements. We  
15 found several gaps and inefficiencies and decided that  
16 those are the places where we needed to start.

17 If you look at the bottom right of that I  
18 think it's slide number 12, some gaps cut across  
19 several of the processes. So we determined that we  
20 needed to reengineer some of those cross-cutting  
21 processes or functions before we could actually do a  
22 lot of good implementation of new specific processes,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 and that turned out to be management prioritization,  
2 response to emerging or new issues, and how we deal  
3 with information, its surveillance and exchange  
4 process.

5 So when we looked at what that meant for  
6 us, it kind of builds a structure for us if we can  
7 kind of think of it as a frame of those four issues to  
8 help the coordination and eliminate some of that  
9 fragmentation.

10 Then what we did was we looked at specific  
11 processes that needed to be fixed, and they're listed  
12 in the middle of that Slide 14, the manufacturer  
13 reports, product testing, database management, and so  
14 forth.

15 We started looking for ways to make  
16 improvements and asking stakeholders for inputs on  
17 both the structural program reengineering issues and  
18 the process reengineering issues.

19 First of all, we went to our own  
20 management and we told them what was going on and what  
21 we needed, and actually they took it very seriously.  
22 As you heard Dr. Jacobson yesterday, they implemented

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 some major changes in the way we're managing the  
2 program and really trying to revitalize it.

3 We started with the information  
4 surveillance and exchange process. Our goal was to  
5 gather, consolidate, and distribute up to date  
6 information on product performance, exposures, uses,  
7 health effects, and risks.

8 That process is a little bit nebulous  
9 because it's basically a leveraging process. We're  
10 trying to figure out how do we do the liaison and how  
11 do we get our stakeholders to share in the  
12 responsibility of public health and get it carried out  
13 so that we're all working together, but we're not  
14 dealing with extraneous information.

15 This pilot tested the concept of obtaining  
16 that information with hopefully a mechanism eventually  
17 of disseminating it, and we haven't quite figured out  
18 that end of it just yet.

19 What they decided to do was to look at the  
20 television standard, which is 30 years old, and  
21 basically asked the question: should we still be  
22 spending time on it? Is the standard still valid? Is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 there something that's changed? Is there new  
2 technology and so forth?

3 This group put together a list of  
4 questions that they needed to know to answer that. So  
5 they basically targeted specifically what they needed  
6 to try to resolve and put together a list of  
7 questions.

8 They then put together a list of  
9 stakeholders that they thought could help answer those  
10 questions and participate in whatever the solution  
11 might be. Those questions were then targeted, groups  
12 of those questions, targeted to each of the  
13 stakeholder groups, and they contacted them, first of  
14 all, by telephone to make sure they had the  
15 appropriate contact person.

16 Then they sent the questions by E-mail,  
17 got their responses by E-mail, and we had a whopping  
18 77 percent response rate, and they answered 80 percent  
19 of the questions that we posed. So we were very  
20 pleased with the results. We think this is something  
21 that we can implement on a much larger scale.

22 The second pilot that we tried is to

1 develop a set of criteria for prioritization. We  
2 tested it with about a dozen people within the center  
3 and determined that -- tried to determine if we could  
4 come up with a top ten list, which is what our  
5 management was asking for.

6 We listed about 30 products and the  
7 various problems they had and then tried to figure out  
8 how to do the process. The first part of the process  
9 was a decision tree. What we were trying to find out  
10 is can we eliminate some products already because we  
11 know they're so egregious we have to do something or  
12 so innocuous we know we'll never do anything.

13 We also found that we needed to figure out  
14 some method of dealing with those ones where we think  
15 there might be something going on, but we don't have  
16 enough information to even make a risk determination.  
17 So we wanted to at least put them on the list and know  
18 that we need to do some -- have some kind of attention  
19 to them.

20 Then the second part of the process,  
21 number 21, is that we took the remaining products and  
22 scored them on several factors of consequence and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 probability to categorize each of them in one of four  
2 levels of risk according to IEC Standard 513.

3 We also tried to look at very briefly the  
4 decision tree for which processes would work best for  
5 that. As a result, we came up with a tentative top  
6 ten list because, again, this was a limited sample of  
7 people scoring and a limited number of products that  
8 they scored.

9 On the left-hand side -- I'm sorry -- on  
10 the right-hand side of Slide No. 25, I'll take a look  
11 at those first. We came up with a list of products  
12 where we don't have enough information on which to  
13 make a risk judgment, but we had a concern because the  
14 products are highly used. So we've got a lot of  
15 people potentially being exposed to something, and  
16 we're not sure what the final effects issues are. So  
17 we thought they should be on the top ten list.

18 Then on the left, the ones that scored in  
19 Levels 1 and Levels 2 came out on the left-hand side  
20 to give us the rest of the top ten. Accelerators came  
21 out in our number one, Level 1 risk. The others  
22 there, CT radiology and sunlamps, all came out in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Level 2.

2 So we think the model works, and we can  
3 probably use it, but we also found that we needed to  
4 revise the criteria because there were some issues  
5 that we were not taking into account that we thought  
6 were important.

7 The third pilot we looked at is the  
8 manufacturer reports. This now is a specific process.  
9 The others were program issues.

10 Manufacturers submit reports to us  
11 according to what we've published in the regulations.  
12 They report on the products and how the products  
13 comply with standards. They also report their  
14 radiation quality control and testing programs to us.

15 So we were looking for efficiencies and  
16 alternatives, which ones we should maintain and  
17 eliminate, which ones -- what data elements should be  
18 in those reports if we keep them, and then is there  
19 some mechanism for facilitating electronic submission?

20 The group broke it into two parts. The  
21 products they're required by regulation to submit  
22 reports for which we have reports submitted, but there

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 aren't any performance standards. There's less than  
2 a dozen of those types of products.

3 Their recommendation is to eliminate all  
4 of the reports and the records, and instead require a  
5 periodic updated registration and listing, basically  
6 contact information, and to have this submitted  
7 electronically primarily so that we have a way of  
8 corresponding if an issue comes up and we can contact  
9 them.

10 Our internal staff talked about this last  
11 week. They have some reservations about some of the  
12 products. They also have some reservation about  
13 eliminating the record keeping. So we're still  
14 looking at those issues.

15 For the products with performance  
16 standards, they think that we need to keep some  
17 reporting, but what they'd like to do is to figure out  
18 a way to do it by exemption so that we can more  
19 specifically target what we need to know at any one  
20 particular time.

21 They do want to go to electronic  
22 submission and come up with some criteria for that.

1           A couple of ideas that have come out of  
2 our external stakeholders were also considered by  
3 them, and that's the last two down here: to improve  
4 the industry knowledge by providing some kind of  
5 training that's recognized by CDRH, having some kind  
6 of accreditation process so that some number of  
7 employees or factories or such might be accredited in  
8 such a way that perhaps their reporting burden can be  
9 reduced.

10           And the other is to shift from the  
11 reporting to a third party conformance assessment  
12 since much of what is done for the reports with  
13 standards is to assess conformance. So maybe there's  
14 an alternative there to some of the reporting.

15           Another specific process we're looking at  
16 right now we haven't gotten too far on, and that's the  
17 X-ray field testing. Now, this is a subset of one of  
18 the others that we had recommended. We think all of  
19 product testing needs to be relooked at and  
20 reengineered, but we wanted to bite off something a  
21 little bit smaller. So we started just with the X-  
22 rays.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   Particularly to make better use of  
2 technology, such as electronic submission of data or  
3 combined databases; finding some other ways perhaps of  
4 calibration support, how often we test products, and  
5 the like.

6                   This group is still ongoing. So I don't  
7 really have any results to report.

8                   Our biggest success, of course, was the  
9 management revitalization. Their mission is at the  
10 top of Slide 30. Their goal is to revitalize the  
11 program to be the point where we resolve policies and  
12 get policy determinations out to the rest of the world  
13 and to provide oversight to this committee to our  
14 liaison with the states and oversight for the  
15 reengineering.

16                   And the ones at the bottom are the  
17 activities that they've implemented as Dr. Jacobson  
18 mentioned to you yesterday.

19                   In January we held an external  
20 stakeholders meeting sponsored by the Food and Drug  
21 Law Institute, FDLI, and we asked them this question  
22 in Slide 31. If you could design a new electronic

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 product radiation control program today, what would it  
2 look like? What would be the elements? What would be  
3 important? How would stakeholders be involved?

4 And we opened it up in such a way that we  
5 got a lot of good comments, and basically more filling  
6 in of the direction that we need to be going.

7 In Slide 33, the roles are on the left-  
8 hand side, and as Dr. Jacobson mentioned yesterday,  
9 they want us to be an information clearing house,  
10 providing leadership and training expertise and  
11 guidance. So it's basically that function of  
12 providing technical information as needed.

13 The second part is on the right on the  
14 activities. They had some specific recommendations  
15 for us to get the message out about radiological  
16 health and what's our goal and what are we trying to  
17 do, and basically get more of the stakeholders  
18 involved, but also get people to understand in the  
19 general public what their role is and what we're  
20 trying to achieve.

21 They also said when we go to make policy  
22 determinations that we don't need to do that all by

1 yourselves anymore; that we need to find some way of  
2 perhaps a consortium, partnership, something to get  
3 others to participate in that process.

4 They also suggested making some shifts in  
5 the resources from conformance assessment to training,  
6 advertising, whatever our prioritization process is,  
7 and the end results, particularly if we're going to  
8 continually update our priorities.

9 And then of course, to put all of that  
10 information out available to everybody, and in  
11 particular, start with the Web.

12 On Slide 34, you can see the depiction of  
13 what they run in terms of shifts. They want more  
14 emphasis on setting criteria, less effort on assessing  
15 conformance and more on disseminating information.

16 Slide 35, we also posed these questions to  
17 a group at the Conference of Radiation Control Program  
18 Directors last month. Their concepts were interesting  
19 because the first two, having focus groups on new  
20 technology and early relationships with the  
21 manufacturers in the federal and state agencies,  
22 basically looking at new ways of handling new

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

[www.nealrgross.com](http://www.nealrgross.com)

1 technology. Find some way of keeping up with it and  
2 dealing with some of the issues that we need to deal  
3 with.

4 We tend to isolate ourselves, I think.  
5 The federal government tends to handle premarket  
6 issues with the manufacturers one way and the states  
7 handle them a different way, and sometimes I think  
8 we'd be a lot more efficient if we'd work together.

9 The third one, guidance on use control, is  
10 a policy issue that we need to work better on what are  
11 we doing with new uses of products, particularly non-  
12 medical, intentional exposures of radiation, X-ray,  
13 microwave and the like. We haven't tackled too many  
14 of those kinds of issues, and we need to figure out a  
15 way to do it.

16 And the last one has to do with new  
17 approaches to the information we provide, getting some  
18 perspective on the radiation exposures for folks.

19 We then also took these same questions to  
20 the Consumer Electronics Association, and they took  
21 some of the concepts a little bit farther than some of  
22 the other groups that we'd talked to so far. So we're

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 interested in kind of fleshing these out and see if  
2 there's really something we can use.

3 The first one was we took this third party  
4 concept from the FDLI conference, which basically was  
5 to have third party laboratories -- now we've dealt  
6 with third parties in the center, usually consultant  
7 groups and the like, but their suggestion was  
8 laboratories be the third parties because they're  
9 already in the factories to perhaps do inspections or  
10 evaluations of products for the CE mark in Europe and  
11 the UL mark in the U.S., that kind of thing; that  
12 perhaps those laboratories could do some of that  
13 conformance assessment for us.

14 Well, CEA suggested one step further.  
15 They said have the third party laboratories involved  
16 in any of the standard setting so that then they can  
17 interpret it consistently across those laboratories,  
18 which seems to be one of our concerns.

19 The second issue they brought up I think  
20 is worthy of note and, in particular, for this  
21 Committee to consider, and that is the distinction  
22 between how we might use mandatory standards and

1 voluntary standards, and we're going to present  
2 something later this morning on one possible way of  
3 shifting from mandatory to voluntary, but they had a  
4 concept that I think is a little different.

5 What they're suggesting is that if there's  
6 any safety issue, that we should have a mandatory, but  
7 that that mandatory standard should set the limits  
8 only and reference voluntary standards for  
9 particularly instrumentation, test methodologies, and  
10 the like, and that we separate those two processes so  
11 that the voluntary standards, which are updated every  
12 two to five years, would take place on a more routine  
13 basis and would have a participative process, and we  
14 wouldn't get bogged down in a regulatory standard that  
15 needs updating and we can't update them quickly  
16 enough.

17 So it has some merit, I think, but we're  
18 not quite sure how to make it work. So we're still  
19 looking for concepts there.

20 As I mentioned in one of the previous  
21 slides, they're also looking for some mechanism of  
22 decreased reporting according to some kind of training

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 accreditation process, and they specifically are  
2 urging that we go to electronic reporting.

3 So as you can see in the last slide where  
4 we've got several projects underway, we're still  
5 looking for some things that need to be added in. We  
6 think the prioritization probably has to be our first  
7 issue to resolve because it seems like everything else  
8 is linked to that. So we need to particularly spend  
9 time there.

10 We are planning to have an open public  
11 meeting in the fall with some workshops, and at that  
12 point I suspect probably start the process of getting  
13 stakeholders involved more heavily in how we're  
14 reengineering and figure out the more specifics of how  
15 we would implement some of these pilot ideas.

16 So at this point I'll open it for  
17 questions and any comments.

18 CHAIRMAN ROTHENBERG: Okay. Any questions  
19 from the Committee? Greg.

20 DR. LOTZ: Joanne, what do you see as  
21 being the practical impact<sup>\*\*</sup> of the top ten list, sort  
22 of both positive and negative? If you're on it, if

1 you're not in terms of what happens with the  
2 radiologic health program?

3 MS. BARRON: We've had a lot of  
4 discussions internally about that, and we think that  
5 it has to be very well documented to make it clear to  
6 the outside world what we intend with it and what it  
7 means and what it doesn't mean.

8 Because what we want to do is make it  
9 dynamic, it would be updated on some periodic basis;  
10 that it would give hopefully the manufacturers who  
11 make products that are not on it know that they're not  
12 on it only temporarily.

13 It also would help, we think, for our  
14 external stakeholders to help focus their efforts in  
15 the same direction at the same time. So if, for  
16 example, accelerators are at the top of the list, we  
17 basically get everybody started on whatever needs to  
18 happen on accelerators all at the same time, hopefully  
19 so that we get a resolution within a couple of years,  
20 and it comes off the list. Something else moves up  
21 the list.

22 It also helps to target our resources so

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that we're not too scattered within the center on too  
2 many different issues at the same time. We get more  
3 of the fragmentation and lack of coordination because  
4 we're trying to do too many things all at once.

5 CHAIRMAN ROTHENBERG: Cass.

6 MS. KAUFMAN: I'm wondering what the plan  
7 is for monitoring the success or failure of the  
8 reengineering. As someone who's worked with FDA for  
9 over 20 years and knows the kinds of things that you  
10 all used to do that you no longer do or knows the  
11 things that you used to be able to do in a more timely  
12 manner than you can currently do, I think NEXT results  
13 being, you know, a good Exhibit A, as we all would  
14 love to have that data much more quickly than FDA is  
15 able to produce it just simply because of lack of  
16 staff.

17 And so I'm wondering if there's some  
18 mechanism within this whole planning system to be able  
19 to determine, you know, where it's succeeding and  
20 where it's failing.

21 MS. BARRON: That is one of the goals of  
22 reengineering, is that we have measures of success,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 and that we measure them on occasion to see where we  
2 are, and the other is to make sure that all the staff  
3 are trained at following the new processes.

4 As I mentioned about the top ten, the  
5 prioritization, the goal is that we're all working on  
6 the same activities, and that our stakeholders know  
7 which activities we're working on so that you're not  
8 expecting us to be finishing NEXT, and in fact, we're  
9 not working on NEXT. We're working on fluoroscopy,  
10 for example.

11 So everybody will know where we're working  
12 and what the status is. They'll know what our  
13 priorities are and how much we can get done, how much  
14 we cannot get done.

15 MS. KAUFMAN: Well, and I guess what I'm  
16 hoping is that somewhere in this mix there's some  
17 record keeping of the things that are not getting  
18 done. So that what I would be concerned might happen  
19 is that people would look at this streamlining and  
20 say, "Whew, this is going great. You know, you wanted  
21 to do accelerators, and<sup>\*</sup> by golly, you've done  
22 accelerators," and not pay attention to all those

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 things that aren't getting done.

2 And I would like to see kind of the gold  
3 standards, the bar be set not at what FDA is doing  
4 today or even last year, but maybe what they were able  
5 to do 20 years ago at their highest, at their peak  
6 staffing level.

7 And so that it's very clear where it's  
8 working and where it's not working. I guess I'm a  
9 little nervous on the streamlining that we all do that  
10 people think, "Hey, this is great. You know, you can  
11 get just as much done with half the staff," when in  
12 reality you're not. You're ignoring a lot of other  
13 issues that don't get done or they don't get done in  
14 a timely manner.

15 And I just want to make sure that that's  
16 not lost in this whole process, that at some point we  
17 look back and say, "You know, had we had another 20  
18 percent of staffing, this is what we could have done."

19 CHAIRMAN ROTHENBERG: Jerry.

20 MS. BARRON: I'll make a note of that and  
21 take it back. And I can assure you that the staff is  
22 very much aware of what the gold standard is, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealgross.com

1 they're having a hard time with this reengineering  
2 because they don't want to do less.

3 MS. KAUFMAN: Me, too.

4 MS. BARRON: So we're trying to find the  
5 best in between there that we can get. We're trying.

6 MR. THOMAS: Joanne, I find that  
7 interesting with the thought process of moving from  
8 mandatory to voluntary standards, human beings tending  
9 to be what they are, if it's voluntary they tend not  
10 to do it. Has the center thought about some  
11 safeguards, that if we're going to rely on voluntary  
12 standards, that there's some mechanism to encourage  
13 adopting and compliance with those standards?

14 MS. BARRON: That is what we're looking  
15 at. As you'll see from the presentation later this  
16 morning, we are taking that into consideration as  
17 we're looking at making the shifts. We think some  
18 cases we can let the voluntary standards be the method  
19 of direction and guidance without enforcement, and  
20 that sometimes when we need the enforcement. So I  
21 think it's going to be a case by case.

22 CHAIRMAN ROTHENBERG: I just wanted some

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

[www.nealrgross.com](http://www.nealrgross.com)

1 clarification on your Slide 27. You talk about the  
2 manufacturers' reports and possibly eliminating for  
3 products without performance standards. Which types  
4 of products would not have performance standards? Is  
5 it do they not have performance standards purposely or  
6 are the performance standards just not developed up  
7 until this point?

8 MS. BARRON: It's some of each. Products  
9 like RF sealers, microwave security, ultrasound, non-  
10 medical products like motion detectors and the like,  
11 some of our analytical X-ray equipment, things like  
12 that.

13 CHAIRMAN ROTHENBERG: Yes.

14 DR. BALZANO: We are in an age where  
15 electronically reporting and data storage is  
16 increasingly simple and cheap. So why decrease  
17 reporting? If anything, the current state of  
18 technology would allow you to have closer report and  
19 have more often reporting and continuous updating.

20 And I'm saying why should there be  
21 decreased reporting at a time when actually it should  
22 be simpler, faster, and less expensive to store so

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that you have some very good traceability of the  
2 products.

3 MS. BARRON: It may be less expensive to  
4 store, but it's more expensive to develop. Our  
5 databases are 30, 35 years old, and they have an awful  
6 lot of data. If we continue to keep that and we want  
7 to build a new system to do this, it's going to be  
8 very expensive.

9 So we're looking at getting the reporting  
10 down to the minimum first and then build the new  
11 database around that.

12 DR. BALZANO: Yet if you really want to do  
13 more with less, these are the tools that are going to  
14 allow you to do that. The databases and the storage  
15 are probably going to be your main tools of achieving  
16 much more with less.

17 So if you don't make that investment, you  
18 have a real problem to achieve more with less.

19 MS. BARRON: Well noted.

20 CHAIRMAN ROTHENBERG: Any other questions?

21 Is there any -- I'm sorry. Yes.

22 MR. PLEASURE: Just one question. Thank

1 you.

2 Is there a part of your process where you  
3 work with other federal agencies where there is  
4 overlapping responsibility like with EPA and NIOSH on  
5 collaborative research surveillance, intervention?

6 MS. BARRON: We do have some working  
7 relationships with federal agencies. Some of them  
8 work well. Some of them don't work as well. We  
9 definitely would like to improve that.

10 MR. PLEASURE: Let me just commend from my  
11 experience NIOSH's efforts through their national  
12 occupational research agenda, NORA, to try to engage  
13 other federal agencies on overlap, and certainly where  
14 you're attempting to affect exposures of operators,  
15 workers who are working with devices, it would seem to  
16 me from NIOSH's standpoint, which is moving toward an  
17 intervention strategy and trying to move up the chain  
18 to the engineering level, and actually is seeming to  
19 expand some of its capacity in engineering; that there  
20 are some real opportunities for synergy.

21 Some of these <sup>\*\*</sup> issues we've been dealing  
22 with for the last two days that deal with worker

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 exposures would benefit greatly from cooperation  
2 there. NIOSH particularly, I think, would benefit  
3 from working with you.

4 MS. BARRON: All right. We'll have to  
5 pursue that a little further.

6 CHAIRMAN ROTHENBERG: Any other comments?  
7 Is there anything additional that TEPRSSC can do at  
8 this time?

9 MS. BARRON: The only thing I would ask is  
10 that you consider a little bit further, as Jerry  
11 mentioned, about the mandatory versus voluntary  
12 standards, in particular, after you hear the other  
13 morning talk.

14 CHAIRMAN ROTHENBERG: Okay. Thank you  
15 very much.

16 MS. BARRON: Thank you.

17 CHAIRMAN ROTHENBERG: Our next item is  
18 review of medical devices' approval process. Dr.  
19 Kimber Richter.

20 DR. RICHTER: Good morning. My name is  
21 Kimber Richter, and I'm a Deputy in the Office of  
22 Device Evaluation.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And many radiation emitting products are  
2 also regulated as medical devices. So I wanted to  
3 talk a little bit this morning about how that process  
4 works, and I have a handout, but I'm going to save it  
5 until the end because it's not organized in quite the  
6 same way as my talk, and if you have a question later  
7 and want to go back and reference it, you'll have  
8 something in writing, but I'm afraid it might be  
9 confusing to be jumping back and forth right now.

10           Medical devices are regulated by the Food  
11 and Drug Administration under laws going back to 1976,  
12 the Medical Device Amendments. In 1990, Congress  
13 updated that with the Safe Medical Devices Act.

14           In 1992, there were additional amendments,  
15 and in 1997, there was a fairly substantial change in  
16 the law with what we call FDAMA, of the Food and Drug  
17 Administration Modernization Act. And that has  
18 changed a little bit the scope of our regulation and  
19 the focus of our work.

20           Products are considered medical devices if  
21 they diagnose, cure, mitigate, treat or prevent a  
22 disease or condition, and in addition, if they affect

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the function or structure of the body if they do not  
2 achieve intended uses through chemical action. So  
3 they're not drugs, and if they're not metabolized.

4 Obviously that covers a very wide range of  
5 products from tongue depressors and gloves all the way  
6 to X-ray equipment and even therapeutic radiation  
7 products.

8 Devices are classified into three classes.  
9 Class I would usually be your lowest risk devices, and  
10 those are usually regulated through general controls.  
11 About 30 percent of devices fall in to Class I.

12 Class II is about 60 percent of devices.  
13 Those are products that need more specific regulation  
14 and oversight by FDA, but we understand enough about  
15 the product to know where the risks fall, and those  
16 are managed under special controls.

17 Class III are very new or very high risk  
18 devices. They require a full premarket approval, and  
19 we see about 50 of those submissions a year.

20 Altogether our office receives about  
21 20,000 submissions a year\*\* for either new clearances  
22 and approvals for new devices or for changes to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 devices that are significant.

2           There are about 1,750 device categories  
3 that the devices are grouped into, and we have 18  
4 advisory panels somewhat similar to TEPRSSC to advise  
5 us on how to regulate these products.

6           General controls that all devices are  
7 required to follow or to be regulated under include  
8 things like we have authorities to act if product is  
9 adulterated or misbranded, if a company lies about  
10 their claims, or if they produce a product in a way  
11 that's dangerous.

12           We have registration and list of devices.  
13 Companies have to tell us what devices they make. I  
14 think the other one of significant note is the quality  
15 systems regulation. Companies are required to have a  
16 process in place to control the way the device is  
17 manufactured.

18           And a little bit more about that. This  
19 covers both the design and manufacture of medical  
20 devices sold in the U.S. It's consistent with the  
21 European and Japanese and other countries' quality  
22 regulations, and it gives us the basis for authority

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

[www.nealrgross.com](http://www.nealrgross.com)

1 to audit device establishments. So we can do in and  
2 inspect that they are, in fact, meeting their own  
3 procedures.

4 Class II devices, which is many of the  
5 devices, require special controls. We might require  
6 that a standard be followed, that post market  
7 surveillance be conducted on a device, that patient  
8 registry be maintained for the use of a new device.  
9 We might provide guidelines or recommendations, and we  
10 have the latitude to require other things. Sometimes  
11 we have labeling requirements.

12 Most Class II devices also require  
13 clearance before they go to market, and we call this  
14 clearance process the 510(k) submission process, and  
15 510(k) submission is required when a new Class II  
16 device and some Class I's even are introduced to the  
17 market for the first time.

18 If there's a major change to the intended  
19 use of the marketed product or if the company is  
20 making a major modification that could affect the  
21 safety or the effectiveness of the product, we want to  
22 see it.

1                   And the 510(k) process is very unusual  
2                   because it's based on demonstrating substantial  
3                   equivalence to a previous product. Congress said in  
4                   1976 that we're going to take the baseline as what's  
5                   already on the market for good or for bad, and all new  
6                   products have to do is be the same, at least as good.

7                   So in some cases people say to us, "Well,  
8                   how could you let that awful product on the market.  
9                   You know, you know it doesn't work." Well, if it  
10                  didn't work in 1976, it doesn't have to work now. It  
11                  only has to be as good, as equivalent, and then we  
12                  provide the clearance to market. So this is not  
13                  drugs, a very different system.

14                 And a device would be considered  
15                 equivalent if, when we compare it to an already  
16                 marketed device, it has the same intended use and the  
17                 same technological characteristics. So we do not see  
18                 clinical data on most Class II devices.

19                 If, however, it has different  
20                 technological characteristics and an engineering  
21                 assessment doesn't assure us that it's the same, then  
22                 we would look to see if there are new questions of

1 safety in our minds or new questions of how it works,  
2 and we could ask for a demonstration that it is, in  
3 fact, as safe and effective as the earlier product.  
4 So then we might ask for clinical data or analytical  
5 data.

6 We have a couple of new reengineered  
7 processes for 510(k)'s. We have a special 510(k)  
8 process. When the company is changing their own  
9 device, they can come in with a special 510(k) which  
10 says that they already know how to do the  
11 manufacturing, and instead of giving us all the data,  
12 they simply follow their own procedures and give us an  
13 assurance, which we then can go out and audit, and if  
14 they lie to us, then we take their 510(k) away.

15 But it can't be a major modification that  
16 affects the fundamental technology or intended use of  
17 the device, but this allows these products, these new,  
18 modified, improved products to get to market quickly.

19 There's also an abbreviated 510(k) process  
20 where if a manufacturer is intending to do a new  
21 product of Class I or Class II<sup>\*\*</sup> that requires a 510(k),  
22 they can point to one of our guidance documents or

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 they can point to standards that we've recognized and  
2 simply reference that they meet those.

3 So instead of us reviewing all of the  
4 data, they simply say, "We met the conditions of the  
5 standard." And, again, we can audit to make sure that  
6 they did that, and the idea is that these new types of  
7 510(k)'s will require less data. It will be less  
8 burdensome for the company, which is one of the things  
9 that FDAMA required us to do, was to be less  
10 burdensome, and it also lets us save our resources for  
11 the new products that are concerning to us.

12 Class III products come under a full  
13 premarket review, and they have to be approved by us.  
14 This is a little bit different process because in this  
15 case we're looking at the safety and the effectiveness  
16 of the device. We aren't interested in previous  
17 products. They have to meet a new standard. They  
18 have to use valid scientific evidence, and when we  
19 decide to approve a product, we would weigh the risk  
20 and the benefit of this particular device.

21 So you might have a product that's not  
22 equivalent to previous products, but it might add

1 value. For example, some of the new glucose level  
2 monitors, they're not equivalent to the blood sticks,  
3 but they do add extra value in letting the doctor  
4 follow the trends of blood sugar within the body. So  
5 it's a new product, but it adds value in its own  
6 right. So we would approve it.

7 We consider valid scientific evidence to  
8 be well controlled clinical investigations, partially  
9 controlled studies, studies and objective trials that  
10 don't have a matched control. Sometimes we will  
11 accept well documented case histories that are done by  
12 experts or even reports of significant human  
13 experience. Sometimes we'll get reports from Europe.  
14 You know, there will be broad European experience, and  
15 we will take that into account.

16 What we don't accept is we're not  
17 interested in individual case reports and anecdotes.  
18 An awful lot of device manufacturers or doctors that  
19 have a good idea are convinced just inherently that  
20 their product must work, and so we really like to see  
21 some kind of evidence rather than an isolated case  
22 report or random experience or unsubstantiated

1 opinions.

2 And we don't accept reports that lack  
3 enough detail for us to validate them.

4 We've also been offering companies the  
5 option of a modular PMA review, which means that as  
6 each part of their data is done, they can send it in,  
7 and we'll review it in pieces, and we'll lay out a  
8 specific outline with the company for which pieces  
9 should be reviewed as a module. So you can customize  
10 it to the device, and the nice thing about that is if  
11 you're going to need additional data.

12 We've had cases, for example, where  
13 materials raise concerns and they need to do extra  
14 cancer testing or something. You can identify that  
15 well ahead and they can get that done before you're  
16 ready to approve the rest of the product. That's  
17 another reengineering success that's come out of that.

18 In addition to traditional PMA approvals  
19 where the company does all of the research and then  
20 sends in their result and asks for approval, we have  
21 a new process we're offering where the company comes  
22 to us before they've tested their product, and they

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

[www.nealrgross.com](http://www.nealrgross.com)

1 and the FDA would agree on what success criteria they  
2 have to meet to be marketed.

3 And so you decide up front. The company  
4 says, "Well, I think my product will perform in 90  
5 percent of cases," and you agree to that, and they put  
6 that in writing, and if they meet that we don't  
7 review. We don't do a final review of everything. We  
8 simply go ahead and approve the product because we've  
9 already agreed to the success endpoints.

10 But, of course, the risk with that is that  
11 a lot of these newer products, the companies don't  
12 guess very well about how they're going to perform,  
13 and that can create a certain risk for the  
14 manufacturer.

15 We also have a fairly new program that is  
16 called an HDE or humanitarian device exemption, and  
17 this is offered for diseases or conditions that only  
18 affect a small number of people, maybe 4,000 patients  
19 per year or less. If there's no alternative on the  
20 market, it's difficult for these products to be tested  
21 and to prove that they work. So as long as there's a  
22 reasonable likelihood that they're effective and we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 don't have safety concerns, we can now approve these  
2 products through an HDE process so that patients can  
3 have access to them, and we do that on a 75-day clock,  
4 which is very good considering the volume of  
5 submissions we receive.

6 Just a last couple of words about some  
7 related regulatory things. We're very, very pressured  
8 right now because of the new changes in the law to  
9 find the least burdensome way to get products to  
10 market. That means if we can eliminate the need for  
11 clinical data or if we can collect clinical data post  
12 market or if there's any other ways that we can find  
13 to help manufacturers quickly get products to market,  
14 Congress has made that a high priority for us.

15 And so we're dealing with these issues  
16 right now of being least burdensome, involving the  
17 smallest investment of time, effort and money on the  
18 part of the submitter and FDA.

19 I also just want to mention that we have  
20 some authority for medical device labeling. Any label  
21 or written material on the device or material that  
22 accompanies the device, promotional materials with the

1 device is considered labeling. Labeling has to  
2 provide adequate directions for use, and it may not be  
3 false or misleading.

4 And, you know, we're watching the Internet  
5 very closely right now with all of the claims and so  
6 forth that are flying around there.

7 We also have some guidance on the general  
8 versus specific intended use. Frequently medical  
9 devices like surgical lasers will come in with general  
10 claims that they cut tissue, and then later the  
11 company will want to claim that they can be used to  
12 effectively treat cancer, and so we have developed  
13 some clear guidance on when you can find it  
14 substantially equivalent to something that has a  
15 general indication and when does the specific  
16 indication for use become a new intended use?

17 And this is going to ultimately be of  
18 interest to this committee because we have the same  
19 thing with diagnostic products. You know, when does  
20 an X-ray machine have a general imaging claim versus  
21 I can, you know, identify breast lumps or I can  
22 identify this or that?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

[www.nealrgross.com](http://www.nealrgross.com)

1                   So we deal a lot with the issue of when is  
2 the claim new and when does it require specific new  
3 data.

4                   Another big issue for devices is off label  
5 use. We have a practice of medicine policy which says  
6 that it's the physician's job to decide when the  
7 device should be used. We can require clear labeling.  
8 Doctors need to be well informed. They should be  
9 using firm, scientific rationale and sound medical  
10 evidence, and they need to be maintaining records on  
11 the use and effects of these products.

12                   But, in fact, we try not to step into the  
13 arena of what's appropriate for particular patients,  
14 and we try not to cross into practice of medicine.

15                   And then we have a division that is  
16 intended to help small manufacturers, and they provide  
17 a lot of information and details about all these  
18 programs and guidelines on how to submit and so forth  
19 are all on our Web site, and we have an E-mail  
20 address, a fax and a phone, which is in the handout  
21 also if you have any questions. We provide that for  
22 either consumers. The manufacturers can get to that.

1 And do you have questions? Can I field  
2 questions for anyone?

3 CHAIRMAN ROTHENBERG: Yes, Cass.

4 MS. KAUFMAN: A couple of things. One is  
5 the criteria that you showed early on that shows what  
6 a medical device is, and there were, I think, four  
7 different criteria for that.

8 DR. RICHTER: Un-huh.

9 MS. KAUFMAN: Do they have to meet just  
10 any one of those or all of them?

11 DR. RICHTER: Oh, goodness. Let me pull  
12 that slide out again.

13 MS. KAUFMAN: I think it was early on.

14 DR. RICHTER: Yes, it was right at the  
15 beginning. It's like Slide No. 1 here. Slide No. 2  
16 actually. Phil, can you help me with that?

17 I think it has to meet all of them because  
18 if it diagnoses or cures, but it does it through a  
19 chemical action, then we would consider that a drug,  
20 right?

21 MR. FRAPPAOLO: Yeah. You'd have to go  
22 through all of those to make the case for a medical

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 device.

2 DR. RICHTER: Yeah. So it would be a  
3 device if it treats through something that's a  
4 mechanical treatment or a replacement. You know, if  
5 it's an artificial sinew or something like that that  
6 you're using or an artificial joint. That's a  
7 function or a structure of the body that's treating  
8 something, and it's not chemical and it's not  
9 metabolized.

10 DR. LOTZ: Okay. I was going to follow up  
11 on that only in the sense, oh, for example, Joanne,  
12 you had commented about RF heat sealers. They can  
13 produce enough exposure to affect the function of the  
14 body, but they wouldn't be intended for any of those  
15 other things.

16 DR. RICHTER: Which products are you  
17 talking about?

18 DR. LOTZ: I just mentioned RF heat  
19 sealers as an example. But that clarifies it if it  
20 has to do all of those. Then --

21 DR. RICHTER: Right. I mean a product  
22 might have harmful side effects, but if it doesn't do

1 these other things, we wouldn't consider it a device,  
2 but through the RAD health program, we might regulate  
3 it if it produces radiation. Any other questions?  
4 Other questions?

5 MS. KAUFMAN: I have another question.  
6 You mentioned that as long as the -- was it the 1974  
7 date where --

8 DR. RICHTER: Six, 1976.

9 MS. KAUFMAN: 1976 date. Did that also  
10 mean that -- let's say that FDA approved a product in  
11 1979 that turned out not to be very effective. In  
12 other words, is that holding firm on that date or is  
13 anything before that date and anything approved after  
14 that date they also just have to meet that '79  
15 criteria?

16 DR. RICHTER: That's exactly right. Once  
17 they grandfathered in everything to 1976 and anything  
18 that came along and was found equivalent to that later  
19 could then become a predicate also

20 MS. KAUFMAN: Okay.

21 DR. RICHTER: So we have people who will  
22 pick and choose which of several devices they want to

1 be found equivalent to, and the company is given the  
2 choice. They can offer a predicate that they've  
3 compared themselves to, and as long as it's a  
4 legitimate predicate it's their choice because the  
5 technologies will vary, and so one might be more  
6 comparable, you know, to a specific device. So that  
7 they're asked to recommend a predicate.

8 But you're right. If you get one that  
9 doesn't perform particularly well and you cleared it  
10 in 1986 without looking at much data, then we deal  
11 with that, and it's not usual that we would be able to  
12 go back and eliminate that clearance. That's a very,  
13 very major effort.

14 MS. KAUFMAN: That's what I was afraid of.

15 DR. RICHTER: Again, devices are very  
16 different from drugs. The standards that we use are  
17 different. They're so diverse amongst themselves that  
18 the way to -- you need very broad rules to regulate  
19 it, and we use different standards of what's  
20 acceptable.

21 There's a feeling that different things  
22 are appropriate for different patients depending on a

1 person's side perhaps, their age, many other things.  
2 So we give doctors -- the intent is to give doctors a  
3 range of options, and if we try to require clear  
4 labeling of how the product does perform and in what  
5 population it can be successfully used, then the  
6 doctor has quite a bit of autonomy, and that seems to  
7 be -- does that seem fair? -- that seems to be  
8 Congress' intent.

9 CHAIRMAN ROTHENBERG: Yes.

10 DR. BALZANO: How recent is your reading  
11 of the 1,750-plus categories that you showed before?  
12 Is that a recent categorization or is it something you  
13 can probably collapse if you want to speed up your  
14 process?

15 Sometimes integration with a little  
16 differentiation can really help you out. I was  
17 wondering how long is your categorization if you plan  
18 to --

19 DR. RICHTER: I think the categorization  
20 goes back to grouping even in the regs., right? I  
21 mean these are spelled out these are the different  
22 groupings because that was done when they first were

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 classifying devices, and it doesn't really affect the  
2 amount of time we invest in reviewing devices. It's  
3 simply a way of us to track them and, I guess, to  
4 label them.

5 We code them in certain ways so that if we  
6 need, for example, all of the orthopedic  
7 manufacturers, maybe we have an issue and we want to  
8 tell them something about labeling. We could go in  
9 and say, "All the products of this type" -- pull out  
10 all of the manufacturers so that we could send them  
11 all a letter, or if we're writing, maybe we want to  
12 down classify a product. We would do it by that  
13 group.

14 So from time to time we look at this, and  
15 we might put something in the regulations changing the  
16 number or defining them differently, but it's mostly  
17 used to classify, and most of that work has already  
18 been done.

19 Again, Phil, Joanne, does that sound  
20 right?

21 MR. FRAPPAOLO: Phil Frappaolo, Office of  
22 Compliance.

1 Right now internally there's a group  
2 working on the fact that we have categorizations like  
3 this. One of the complaints internally among some of  
4 the staff is we don't have enough categories. You  
5 know, so many more devices have come along over the  
6 years since the initiation of the law in '76. They  
7 think that we're kind of being held to just a very few  
8 codes. So we're trying to look at that.

9 Also, the basis of the databases that we  
10 created back when this process began pretty much is  
11 integrated throughout all of the databases in the  
12 center, and that's one of the biggest problems we  
13 have. If we start expanding codes, then that's that  
14 many more things that you have to do in terms of going  
15 back and correcting all of the databases and all of  
16 that sort of thing.

17 So we're struggling with that process.  
18 The other thing we're doing is that there is an  
19 international nomenclature group. We're sitting on  
20 some committees overseas that are looking at some  
21 different ways to categorize devices, and I'm not  
22 quite sure yet how heavily invested we are in that

1 process or whether we plan on going with some kind of  
2 an international way of looking at device categories  
3 and classifications. So that yet remains to be seen.  
4 So that will be many more months, I'm sure, before we  
5 know.

6 CHAIRMAN ROTHENBERG: Okay. Anymore  
7 questions or comments?

8 Thank you, Dr. Richter.

9 DR. RICHTER: Let me pass out my handout.

10 CHAIRMAN ROTHENBERG: Oh, yes. We're  
11 right about on schedule. So we'll take a short break  
12 until ten o'clock.

13 (Whereupon, the foregoing matter went off  
14 the record at 9:36 a.m. and went back on  
15 the record at 10:09 a.m.)

16 CHAIRMAN ROTHENBERG: Okay. The next item  
17 on our agenda and the final information item is  
18 ultrasound diathermy, and we'll have Ms. Joanne Barron  
19 and Dr. Bruce Herman presenting, with visual aids this  
20 time.

21 MS. BARRON: Yeah, we'll see if the --

22 CHAIRMAN ROTHENBERG: We hope.

1 MS. BARRON: -- Power Point works this  
2 time.

3 What we're going to talk to you about is  
4 a proposal for shifting from one of our mandatory  
5 radiation performance standards to a voluntary  
6 standard by utilizing our medical device authorities.  
7 The concept is that we'd like to use consensus  
8 standards on a more regular basis. We think it will  
9 reduce some of the resources that we have to put into  
10 mandatory standards, give us an opportunity to  
11 harmonize between the FDA and the IEC standards, and  
12 make use of the dual authorities that the center has  
13 for those medical devices that emit electronic product  
14 radiation.

15 What we're going to speak to you about  
16 today is specifically therapy ultrasound products.  
17 These are deep muscle heating using ultrasound for  
18 physical therapy purposes. The mandatory standard is  
19 20 years old, and we have an IEC standard that's out  
20 for final vote now.

21 These products are subject to the medical  
22 device authorities as a Class II device. They submit

1 510(k) reports prior to market. They are subject to  
2 the quality systems regulations, and if we go to some  
3 of the activities we're talking about, they may be  
4 able to claim conformance to the IEC standard, which  
5 means that they might be able to submit one of the  
6 reduced 510(k) reports.

7 This is a mature industry. They've been  
8 around for a number of years. It's a small industry  
9 so it would be a small group of manufacturers that  
10 we'd be working with initially.

11 They're primarily in the United States and  
12 in Europe and most of the European companies are very  
13 familiar with the IEC standard. The U.S. industry is  
14 not quite as familiar with this, and there may be some  
15 training efforts needed in this particular case.

16 Next slide. Here we go.

17 What I'd like to first talk to you about  
18 is the differences between the two standards because  
19 it makes a little bit of difference in how we try to  
20 apply it in this particular case.

21 For a regulatory standard, a mandatory  
22 standard that goes through the government process, the

1 administrative procedures for rulemaking, FDA actually  
2 develops the standard, and it actually requires us to  
3 do some of it as closed session. We can't release it  
4 in certain phases of the development process. We have  
5 to follow the process very specifically.

6 It is published in the Federal Register.  
7 It allows anybody to comment because it's open in the  
8 Federal Register. When it's complete, it's published  
9 in the Code of Federal Regulations and available to  
10 anybody who wants to pick up a copy of the code.

11 However, we have no review time or  
12 amendment time that's mandated. These standards can  
13 sit on the books forever and never be amended, and  
14 there's nothing that makes us do anything.

15 We have had retrospective reviews on  
16 occasion for most of our standards, but there's  
17 nothing that makes us do it unless Congress starts  
18 asking questions, for example.

19 They are enforceable by FDA and by the  
20 states in some instances if they adopted in toto.  
21 There is a preemption clause in our law that the  
22 states cannot have anything that's more restrictive

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 than the standard that we publish. So basically if  
2 they're going to adopt the standard as a state  
3 requirement, they would adopt it as the same thing.

4 Consensus standards, on the other hand,  
5 are developed by groups of people, primarily by the  
6 industry because they have the biggest stake, but  
7 others, such as laboratories and professional  
8 societies often get involved.

9 We become a participant rather than a  
10 leader usually in most of the standards. We influence  
11 safety requirements, but because we're part of a  
12 group, we don't always get everything we want in the  
13 safety arena.

14 Members of the groups are the people who  
15 comments. It's not quite as the Federal Register in  
16 terms of who can comment, but more and more of the  
17 committees are trying to make that a more open process  
18 for commenting. So that's improving over the years.

19 These standards are for sale. So there's  
20 some limitation for some small businesses, we think.

21 They are mandated to review their  
22 standards about every two to five years, I think. So

1 they have a regular process for updating them.

2 We have a process within the center under  
3 FDAMA to recognize voluntary standards, and we can  
4 recognize them as they are or recognize them with  
5 expectations. In other words, we can put some  
6 additional criteria on what we will accept.

7 There is some question about the  
8 enforcement of voluntary standards, particularly if  
9 it's outside the purview of the medical device  
10 amendments. For non-medical products there's not been  
11 a good legal interpretation of what we could do, but  
12 in this particular case, we're trying to work under  
13 the medical device authorities. So we would look at  
14 that enforcement process.

15 We've not looked real carefully at how  
16 that would impact on enforceability by the states. So  
17 that might be something that needs to be considered in  
18 this case.

19 We're not proposing that we adopt the IEC  
20 standard, but we are looking at a number of options.  
21 We started out and we said, "Well, what if we leave  
22 the FDA standard alone and don't harmonize? We'll

1 just leave our 30 year old standard and leave it as  
2 is."

3 The U.S. industry would probably like  
4 that. The difficulty, I think, would be for the  
5 European and the imports, and the imports would  
6 probably cause us more time answering people's  
7 questions and figuring out what to do with detailed  
8 products than it would solve any particular issues.

9 Another is to amend our standard to  
10 harmonize. Again, a regulatory process would cost us  
11 an amount, a fair amount in resources to do that.

12 Another option was to adopt the IEC  
13 standard, which we think is not appropriate at this  
14 point.

15 We considered asking TEPRSSC to just  
16 repeal the FDA mandatory standard and just leave the  
17 voluntary standard as the only option for this  
18 industry.

19 And the last option was to leave the FDA  
20 standard on the books, but grant an exemption if they  
21 meet the IEC standard, and that's the direction that  
22 we'd like to talk to you about today.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Next slide.

2 What we would like to recommend as a  
3 pilot, and we truly mean this to be a pilot, is to  
4 recognize the IEC standard with exceptions. So we  
5 would pose guidance on how they could conform to the  
6 standard, what would be acceptable as a predicate  
7 device for their 510(k), and so forth, and we have a  
8 mechanism where that's put up on our Web site so that  
9 everybody has a chance to see the criteria and utilize  
10 it for their device submissions.

11 Then what we would like to do is exempt  
12 the industry from the FDA standard and from the  
13 radiological health reports if they will claim  
14 conformance to the IEC standard as we have recognized  
15 it with the exceptions.

16 This gives the industry an option. They  
17 do not have to follow the IEC standard. They may  
18 continue to follow the FDA standard.

19 As you'll hear in a moment, there are a  
20 couple of areas where our standard is a little bit  
21 more comprehensive. So we don't want to take the  
22 standard off the books yet. We'd like to see if this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 works, if the industry will adopt it, if it works with  
2 enforcement and so forth before we do anything with  
3 the mandatory standard. We would do all of this  
4 administratively.

5 In the future what we'd like to do is  
6 revise, make some recommendations for revisions to the  
7 IEC standard to fix a couple of the things that are  
8 not quite the same, and then if the pilot is  
9 effective, consider repealing the standard, and that  
10 will depend a little bit on how well it works and what  
11 other options we think we have for dealing with this  
12 industry.

13 So at this point I'd like to let Bruce  
14 Herman go through and give you an explanation of what  
15 the various differences are between the two standards.

16 MR. HERMAN: Please excuse my voice. I  
17 have a fairly bad sore throat.

18 This may be more than you want to know,  
19 but I'll be discussing some, we feel, important  
20 differences and similarities are between the FDA and  
21 IEC standards from a technical as well as  
22 applicability viewpoint.

1                   Could you first -- next one, please.

2                   The FDA standard is just titled the  
3 "ultrasonic therapy and surgery product performance  
4 standard." Ten, fifty, point, one is a CFR citation,  
5 and as Joanne mentioned, it was promulgated in 1978.

6                   The IEC standard is a particular  
7 requirement for the safety of ultrasound physiotherapy  
8 equipment. That's 60601-2-5. Again, if you went back  
9 now to what's currently in process, it was developed  
10 under Subcommittee 62 of the IEC, which is the  
11 electronic equipment and medical practice  
12 subcommittee.

13                   This standard references the last  
14 standard, physiotherapy system's performance  
15 requirements, et cetera, et cetera, which deals more  
16 with the specifics of the irradiated field, and that  
17 was developed under Technical Committee 87, which is  
18 ultrasonics.

19                   Next, please.

20                   The FDA standard applies to any  
21 applicator, transducer shape, and applicators have  
22 multiple crystal applicators. The reason we did this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 is that when we developed this standard, there were  
2 actually a few rectal/vaginal probes on the market, as  
3 well as we say multiple crystal applicators.

4 I recently called up a company who  
5 produced these, and they still produce a multiple  
6 crystal applicator and are just about to reintroduce  
7 a vaginal and rectal probe, and the shapes are that as  
8 you might imagine.

9 The IEC standard is valid only to a single  
10 crystal, plain, circular transducer. Of course, the  
11 IEC standard also talks about flammability, electrical  
12 leakage, mechanical hazard, et cetera, which are  
13 covered in more general FDA standards for the  
14 ultrasound and the therapy equipment.

15 The next one, please. I'm sorry. Oh,  
16 well.

17 The FDA differentiates -- actually I see  
18 what's going on. Could you -- we changed overheads.  
19 Could you go to a different overhead, the next one,  
20 please? Okay. My slides are changed so much from  
21 yours.

22 The FDA defines the beam area, which is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the important factor for the therapist to know, as the  
2 area in any plane, some of the points where the  
3 intensity is greater than five percent of the peak  
4 intensity. It's usually measured using a small  
5 hydrophone, usually less than a wavelength of the  
6 ultrasound, and typically these machines do operate at  
7 about a megahertz, about a million cycles per second.

8 All of these measurements, both the FDA  
9 and IEC, are done in degassed, distilled water.

10 The IEC defines the area as the minimum  
11 area encompassing 75 percent of the total energy in  
12 the plane. So a can we've done using a hydrophone, a  
13 series of areas would be developed, and the smallest  
14 area would be the beam area.

15 Next one, please. I'm sorry.

16 The effective radiating area is just the  
17 beam area at the applicator face. With the FDA it's  
18 measured five millimeters from the face, and one of  
19 the difficulties with the FDA standard is that when  
20 you're this close to a transducer, you have fine  
21 structure. You're in the near field of the  
22 transducer. So it's a little hard to find the peak.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And since the area is defined as, you  
2 know, those points where the intensity is a percentage  
3 greater than five percent of the peak; if you don't  
4 find the actual peak, then the area from one  
5 measurement to another can be fairly variable.

6           But by the same token, this does  
7 accommodate strangely shaped applicators because you  
8 can scan right across the face five millimeters away  
9 from any weirdly shaped applicable.

10           The IEC, again, is only for plain  
11 applicators, determines the beam areas by measuring  
12 the effective radiating area, by measuring the beam  
13 areas at four distant planes and then extrapolating  
14 back. You can see why this will not accommodate  
15 strangely shaped transducers. You know, the beam  
16 areas are defined in the plane. If you don't have a  
17 single plane transducer, you can't use your  
18 definition.

19           The next one, please. Actually go back to  
20 the beam shape now, I think. Go back two. Right.

21           The FDA differentiates into a diverging,  
22 collimating, and focusing beam depending upon the beam

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 area 12 centimeters away from the transducer. If it's  
2 diverging, then the area is twice the effective  
3 radiating area, 12 centimeters. For a focusing beam,  
4 it has to be less than one half the effective  
5 radiating area.

6 Any beam that's non-diverging or focusing  
7 is by definition collimating.

8 The IEC divides the beam shape into  
9 diverging, collimating and convergent with reasonably  
10 similar definitions, but not highly focused beams are  
11 allowed. We'll come back to that a little later.

12 Next one, please.

13 This would be modulation in the time  
14 domain, temporal modulation. To the FDA a beam is  
15 considered modulated; a device is considered modulated  
16 when the peak pressure amplitude of the modulating  
17 wave is greater than five percent of the root mean  
18 square pressure amplitude.

19 This doesn't necessarily imply a  
20 deliberately pulsed beam, at least on the machines  
21 that we surveyed 20 years ago. Often this occurred  
22 because of poor filtering, and the AC line voltage was

1 just causing this modulation, although some devices  
2 then and now are deliberately pulsed.

3 We'll see again later on the FDA handles  
4 pulse regimes a little better than the IEC.

5 The IEC has the same definition for  
6 modulated, but again as we'll see later, they stress  
7 mainly thermal effects, and when we developed the FDA  
8 standard, and there still is some contention as to  
9 whether therapy is only useful due to temperature rise  
10 or there are direct effects on tissue in which case,  
11 you know, a pulse regime might be effective.

12 Next one, please.

13 Effective intensity. Again this is a very  
14 important parameter. The therapists use it to  
15 determine, you know, what setting of the machine  
16 they'll use for a particular therapy session, and  
17 that's just the average intensity at the transducer  
18 surface, which is the total power divided by the  
19 effective radiating area. The FDA has no limit.

20 Also, for a focused beam, the FDA allows  
21 focus beams. The effective intensity is defined at  
22 the focal surface, meaning that instead of the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 effective radiating area, you use the beam area at the  
2 focus, which would be a lot smaller, obviously, which  
3 mean the effective intensity would be a lot higher.

4 The IEC does have a maximum allowed value  
5 for this, and it's three watts per square centimeter.

6 Now, I should mention that because the way  
7 the effective radiating area is measured using the IEC  
8 standard, the ERA tends to be smaller using the IEC  
9 definition than the FDA definition, and because the  
10 ERA is smaller, that means the intensity, which is the  
11 power over the ERA, tends to be larger using the IEC  
12 definitions of effective intensity.

13 Next, please.

14 This is the BNR, the beam nonuniformity  
15 ratio. This just defines the ratio of the spatial  
16 peak to effective intensity. It tells the therapist  
17 whether there are any hot spots in the field.

18 The FDA has no limits to the BNR, although  
19 it requires the manufacturer to specify what is, as  
20 we'll see later. The IEC has a maximum specification,  
21 a maximum allowed of eight for the BNR. So obviously  
22 this limits. This is why it allows no focus beam

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 because for a focus beam we've got a very high  
2 concentration of ultrasound. You have a beam  
3 nonuniformity ratio much greater than eight.

4 As a side note, if you have a plane wave  
5 circular source, the typical BNR would be about four.

6 I should also note that if you take the  
7 maximal out power under the IEC standard of three  
8 watts of intensity, of three watts per square  
9 centimeter, and then utilize the maximum out BNR of  
10 eight, the IEC allows the maximum spatial peak  
11 temporal average intensity, the maximum hot spots, of  
12 24 watts per square centimeter.

13 Some of you may have see this as regards  
14 to diagnostic devices.

15 Next, please.

16 The FDA doesn't even mention the  
17 applicator temperature at all. The IEC limits the  
18 maximum temperature rise of the applicator itself to  
19 16 degrees Kelvin, and this is measured in water.

20 The temperature rise of the applicator  
21 tends to be more important with the higher frequency  
22 ultrasound devices because high frequency ultrasound

1 is absorbed more in tissue, which means that the  
2 temperature rise due to the ultrasound occurs closer  
3 to the surface. If the rise due to the ultrasound  
4 occurs close to the surface, the addition of the  
5 temperature rise due to the applicator heating up  
6 tends to be more important.

7 Next please.

8 Leakage. This would be the intonation of  
9 the therapist, you know, what ultrasound exposure they  
10 might get while they are holding the applicator by the  
11 handle. The FDA doesn't mention it at all. The IEC  
12 limits the leakage to 100 milliwatts per square  
13 centimeter.

14 This is not really a problem, and the  
15 intensity is virtually nil, but the IEC does have it  
16 in there.

17 Next please.

18 Both have timer specs. The FDA spec.  
19 actually specifies the timer which must have an  
20 automatic shutoff to 30 seconds if the therapy session  
21 is less than five minutes; ten percent if the therapy  
22 session is between five and ten minutes; and to within

1 a minute it has to be accurate if the therapy session  
2 is greater than ten minutes.

3 The IEC is the same, but allows a maximum  
4 therapeutic session of 30 minutes.

5 Next please.

6 The FDA requires a meter calibrated  
7 control or visual indicator for the following  
8 quantities: for continuous wave ultrasound, the  
9 average power has to be specified. This is probably  
10 the single most important indication typically in  
11 meters that the therapist would utilize, and also the  
12 effect of intensity, which is the power divided by the  
13 effective radiating area, has to be shown.

14 The reason I don't have an accuracy spec.  
15 on that is because the FDA allows the manufacturer to  
16 specify the accuracy with which he gives the effective  
17 radiating area, and since the effective intensity is  
18 the average power over the effective radiating area,  
19 we don't know what the accuracy of the intensity is  
20 until we find out what the manufacturer specifies the  
21 ERA to be.

22 For a modulates beam, a meter or

1 calibrated control or visual indicator, it has to show  
2 the temporal maximum power to within 20 percent  
3 accuracy, and the temporal maximum effect of  
4 intensity, again, unknown because the effective  
5 radiating area specs. are unknown.

6 If pulsed, the pulse duration and  
7 repetition rate, if variable, has to be shown. If not  
8 variable, then they can just be given in the  
9 accompanying literature.

10 And there also has to be a visual  
11 indication when and only when power is applied to the  
12 transducer. This came about because, again, in I  
13 think 1974 when we did a survey of machines that were  
14 in use, we found that even though the meter may be  
15 showing, that there is actually ultrasound intonating  
16 the patient.

17 Typically -- well, not typically -- but in  
18 a fairly high number of machines, there was no power  
19 out there at all, and basically patients were getting  
20 and paying for sessions which had no ultrasound coming  
21 out of the therapy applicator at all.

22 We decided that the therapist utilized a

1 back-up indicator such that if there was no voltage  
2 supplied to the crystal, there'd be some light that  
3 would go on or go off.

4 The IEC, again, either meter or calibrated  
5 control, for a continuous wave machine requires the  
6 average power to 20 percent and the effective  
7 intensity to 40 percent. That's because they required  
8 the effective radiating area to be given to an  
9 accuracy no worse than plus or minus 20 percent. So  
10 you add the two 20 percents and you get 40 percent for  
11 the intensity.

12 For modulated beam, it requires a temporal  
13 maximum power, 20 percent, and the temporal maximum  
14 intensity to 40 percent similarly. The pulse  
15 characteristics are given in the literature for each  
16 modulation study. This is why I said that the FDA  
17 handles pulse regimes better than the IEC because  
18 obviously if you have a continuously variable pulse  
19 regime, as some machines actually do, to give the  
20 specs. in the literature as a function of machine  
21 settings when it's continuously variable is not  
22 particularly relevant. At the very least it would

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

[www.nealrgross.com](http://www.nealrgross.com)

1 require pages and pages and pages, you know, to the  
2 accuracy of the dial.

3 And it does not require any visual  
4 indication when the transducers are energized. Again,  
5 machines today tend to be a lot better and a lot more  
6 reliable than they were when we, you know, promulgated  
7 the FDA standard in the '70s.

8 Both the FDA and IEC require specification  
9 on the applicator generator or in literature. The FDA  
10 actually requires some of these parameters to be given  
11 both on the applicator and in the literature. As  
12 we'll see, the IEC requires it only in one or the  
13 other, on one or the other.

14 The FDA requires the frequency to be  
15 given; the applicator type -- we'll go down the left-  
16 hand column -- description of the beam, whether it's  
17 modulated, pulsed, continuous; the maximum beam  
18 nonuniformity ratio; the effective rate of any area;  
19 the focal length and focal areas; pulse duration and  
20 repetition rates; and the temporal maximum effective  
21 intensity to the effective intensity.

22 This allows you to go back and forth

1 between average and temporal maximum powers and  
2 intensities depending upon whether the machine is in  
3 pulse or continuous mode, and again, the manufacturer  
4 is allowed to specify the error, but he does have to  
5 give an error for all of these quantities.

6 Next, please.

7 The IEC spec., again, requires all the  
8 same with two additional, the two bottom quantities.  
9 It requires the maximum power and the spatial peak  
10 temporal average intensity, and this does require at  
11 least for certain of the parameters limits on the  
12 actual errors.

13 You can see the BNR has to be given to  
14 plus or minus 30 percent. The effective radiating  
15 area has to be given to plus or minus 20 percent, and  
16 the ratio of the temporal max. effective area to the  
17 effective intensity has to be given to five percent  
18 even though it's not shown on that particular  
19 overhead.

20 That, I think, sums up what we considered,  
21 you know, the important, you know, similarities and  
22 differences. It will give you a general feel for, you

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 know, how easy or difficult or, you know, how  
2 disparate the numbers would be, you know, if a  
3 manufacturer came in under IEC or the FDA standards.

4 That's it.

5 MS. BARRON: So we'd like to go back to  
6 the pilot suggestion and request your comments and  
7 suggestions, whether or not you would like us to  
8 proceed with the pilot, if you have any concerns about  
9 how we would do it, or, as I mentioned this morning,  
10 the general concept of how we would utilize voluntary  
11 standards in place of mandatory standards.

12 CHAIRMAN ROTHENBERG: Comments? Yes,  
13 Greg.

14 DR. LOTZ: Joanne, would you comment a  
15 little more on how would you actually go about moving  
16 to the IEC standard? Would this be something where  
17 you would now publish an NPRM that that was what you  
18 were intending to do?

19 It's not clear to me how you would  
20 actually adopt the IEC standard for your action.

21 MS. BARRON: Okay. Under the medical  
22 device authorities, we have a list on the Internet of

1 standards that we have recognized. That term  
2 "recognized" means that there are some reductions in  
3 requirements for a manufacturer if they claim  
4 conformance to that standard. That Internet site puts  
5 up what the standard is, what it covers, what is  
6 acceptable to us, and under what conditions.

7 And then the manufacturer, if they claim  
8 conformance to that standard, can then be exempted  
9 from the full reporting, for example, for medical  
10 devices.

11 But they would also be held in their  
12 quality systems to the criteria that they had claimed  
13 conformance to so that the quality system, their  
14 design process, and their production testing  
15 verification/validation processes would all have to  
16 refer back to that standard.

17 DR. LOTZ: So this is a considerably  
18 simpler process than what we were talking about, some  
19 of the things yesterday.

20 MS. BARRON: Yes. This is purely  
21 administrative.

22 DR. LOTZ: Okay.

1 MS. BARRON: Yes.

2 MS. LOSCOCCO: You said you were going to  
3 recognize the IEC with some exemptions. What would  
4 those be?

5 MS. BARRON: Those would be all the  
6 differences that Bruce pointed out that we feel are  
7 still important.

8 MR. HERMAN: One obvious major exemption  
9 is if an applicator does not contain a single plane  
10 wave transducer, and if it's, you know, vaginal,  
11 rectal, or multiple crystals, it would have to be done  
12 under the FDA standard. It could not be done under  
13 the IEC.

14 CHAIRMAN ROTHENBERG: Yes, Jerry.

15 MR. THOMAS: Kind of a general, but very  
16 naive question about the IEC. Yesterday we talked  
17 about laser standards, and FDA has a member that's  
18 very active in that process. Is the IEC something the  
19 United States is able to vote on those standards?

20 And if so, who is the representative or is  
21 the FDA the group that provides the representation to  
22 the IEC or how is the United States represented on the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 various IEC committees?

2 MR. HERMAN: Well, the FDA typically does  
3 send individual experts to the various committees to  
4 develop technically. When it comes to a vote, I  
5 believe ANSI is the U.S. representative as the country  
6 representative to IEC.

7 So if a standard is developed or any  
8 voting has to be done, even though I and other people  
9 from FDA would be on the technical committees and have  
10 a great deal of input, you know, to direct the  
11 development of standards, the actual voting country by  
12 country, you know, is done one vote per country, and  
13 the vote within the U.S. is done by ANSI.

14 MR. THOMAS: Okay. So ANSI then is the  
15 body that casts the vote for the United States --

16 MR. HERMAN: That's correct.

17 MR. THOMAS: -- on any one of the IEC  
18 votes; is that correct?

19 MR. HERMAN: Yes. Often, of course, they  
20 seek our input, the FDA input, and the input of the  
21 people who are actually on the -- you know, sitting  
22 there developing the standards does and historically

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 has been quite important in determining the actual  
2 vote.

3 MS. BARRON: As Jerry Dennis mentioned  
4 yesterday, within the United States there's a  
5 technical advisory group for each one of these groups  
6 of standards, and they are under the auspices of ANSI.  
7 So the technical advisory group within the United  
8 States has a single advisor who works through ANSI to  
9 vote on the IEC standards.

10 CHAIRMAN ROTHENBERG: John.

11 DR. SANDRIK: Yeah, I guess I would tend  
12 to say I see a lot of merit in offering this from the  
13 manufacturer's point of view. I think from the point  
14 of having to generate global products, at least having  
15 some alternative and in many cases when the products  
16 may have been developed in another market meeting IEC  
17 standards, the ability to bring them into the U.S.  
18 market may be greatly simplified, providing it  
19 doesn't, you know, bring any new risk or anything.

20 You know, certainly FDA maintains that  
21 oversight, but I think also from the point of view as  
22 you mentioned, you know, FDA is participating in the

1 IEC committees. So you have your effort that way to  
2 work both ways.

3 I think also the benefit from the point of  
4 view that the IEC standards do get regular reviews; in  
5 fact, you could probably work out harmonization of IEC  
6 with FDA in some cases instead of you having to  
7 harmonize with all of the IEC, you know, if it really  
8 turns out that the FDA's way is better, the fact that  
9 IEC is on regular schedule to revise the standards  
10 gives a better opportunity to incorporate things than  
11 I think we have through FDA where you aren't required  
12 to review these on any particular schedule.

13 And I think, you know, that's sort of the  
14 thing we often fear, is when you get some very  
15 detailed method for doing things or certain levels of  
16 requirement, whatever, that have become an FDA  
17 regulation, the help with changing those seems to  
18 diminish rather rapidly. We have that forever.

19 So I think in general I see merit with it,  
20 and I would certainly encourage going forward with  
21 this idea.

22 MR. HERMAN: Yes. I'd like also in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE. N.W.  
WASHINGTON, D.C. 20005-3701

1 general -- the FDA, because of the huge United States  
2 market, in terms of developing these standards is very  
3 often the 600 pound gorilla in the room. You know, we  
4 do hold -- the U.S. does hold a lot of sway both  
5 because of U.S. manufacturers and the FDA. That's  
6 just the way it is. It's a very practical  
7 consideration for other countries' manufacturers.

8 CHAIRMAN ROTHENBERG: Cass?

9 MS. KAUFMAN: Well, and it may be you're  
10 the gorilla because you have legal authority, which  
11 under this you potentially might lose, which might  
12 make you become a little spider monkey.

13 A couple of questions. One is it's still  
14 a little unclear to me. If a manufacturer chooses to  
15 use the IEC standards instead of FDA standards, would  
16 they have to notify you of that prior to introducing  
17 that ultrasound device into market?

18 MS. BARRON: Yes. That would become part  
19 of their 510(k) submission, which is a premarket  
20 submission.

21 MS. KAUFMAN: Okay.

22 MS. BARRON: They have to wait for 90 days

1 for clearance.

2 MS. KAUFMAN: And then if you approve them  
3 coming in under the IEC standard, it's still real --  
4 this is a question. Is it still real unclear as to  
5 how much, if any, of that enforcement authority you  
6 might have if when it was finally introduced it didn't  
7 comply with the IEC standard?

8 MS. BARRON: We would take enforcement  
9 action under the medical device requirements of  
10 adulteration.

11 MS. KAUFMAN: So you would still have  
12 legal authority over them?

13 MS. BARRON: Yes.

14 MS. KAUFMAN: To enforce IEC standards?

15 MS. BARRON: Yes. If they claim  
16 conformance to that standard, they will be held to it.

17 MS. KAUFMAN: So it's not really voluntary  
18 on their part. It's simply giving them a choice of  
19 using IEC standards or FDA standards.

20 MS. BARRON: Yes.

21 MS. KAUFMAN: But it's not voluntary in  
22 terms of their compliance.

1 MS. BARRON: It's voluntary in terms of  
2 whether or not they choose to go to the IEC standard  
3 rather than the FDA, but, yes, in essence, it makes  
4 them both mandatory.

5 MS. KAUFMAN: Okay. The second thing is  
6 if they went to the IEC standards and if they didn't  
7 comply with the IEC standards and if it turned out  
8 that your enforcement was a lot shakier because it was  
9 IEC standards instead of our own, what potential harm  
10 might there be to patients, if any?

11 MS. BARRON: In severe cases, we've had  
12 skin burns, not as severe as the fluoroscopy burns we  
13 were talking about yesterday, but significant burns.

14 MS. KAUFMAN: And under the IEC standards  
15 is it more or less or equivalently likely that that  
16 harm could occur?

17 MR. HERMAN: It's about the same, yeah.

18 MS. KAUFMAN: Equivalent? Okay.

19 MR. HERMAN: It would be hard to say that  
20 one would produce any more machines, you know, that  
21 would or any higher likelihood of burns.

22 MS. KAUFMAN: Okay.

1 MR. HERMAN: And similarly, in terms of  
2 effectiveness they'd both be similar in terms of  
3 having a machine that, you know, just basically wasn't  
4 very effective as opposed to the safety aspects.

5 MS. KAUFMAN: Oh. Say that again.

6 MR. HERMAN: Well, these standards also  
7 help to insure that not only are the machines safe,  
8 but they are effective. In other words, they are  
9 producing what they say they're producing.

10 So both in terms of safety and  
11 effectiveness, it would be hard to distinguish one  
12 standard from the other in terms of a greater  
13 likelihood of getting, you know, more machines that  
14 were not safe or not effective.

15 MS. KAUFMAN: So you're saying that in  
16 your view, the IEC standard would result in equivalent  
17 safety --

18 MR. HERMAN: Yes.

19 MS. KAUFMAN: -- and efficacy.

20 MR. HERMAN: Yes.

21 MS. KAUFMAN: Okay. Thank you.

22 CHAIRMAN ROTHENBERG: Yes?

1 DR. BALZANO: Yes. My concern was  
2 analogous to one of the other members. To the effect  
3 of therapeutic benefit since the American, the FDA  
4 standards seems to be superior with regards to the  
5 variety of sources to be brought to bear in the case,  
6 while the European and the IEC system seems to be just  
7 using one source, and on that basis I don't see the  
8 need for the rush to do anything different other than  
9 what you're doing right now.

10 MR. HERMAN: Well, again, of course, under  
11 the plan that Joanne mentioned, a manufacturer would  
12 have the option, you know, of going either under FDA  
13 or IEC if they use a multiple crystal source or a  
14 strangely shaped applicator or even if they had a  
15 continuously variable pulse regime. You know, if they  
16 didn't want to go to the trouble of, you know, putting  
17 down, you know, or having a dial with unknown  
18 resolution putting down, you know, the specs. for each  
19 particular setting of the dial.

20 They have the option of going to the FDA.  
21 This just allows -- and of course, most machines, by  
22 far 90 percent and greater of the machines would be

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 applicable under the IEC standard. So as a practical  
2 matter, the small number of machines that were not  
3 relevant to the IEC could come in under the FDA.

4 Now, again, I think part of the plan is,  
5 you know, to see what happens over a few years. How  
6 many devices come in under which? And then we can  
7 decide whether or not, you know, to phase out the FDA  
8 or induce IEC to change their standards.

9 There will be give and take on both sides,  
10 and it would be nice to have one standard eventually,  
11 and that is not precluded by the plan that Joanne  
12 mentioned.

13 CHAIRMAN ROTHENBERG: At the current time  
14 is the IEC looking into these other sources or is it  
15 felt there's too few for them to put that effort?

16 MR. HERMAN: Well, they felt it was too  
17 few, but again, they understand the FDA's position and  
18 that we'd see what happens the next few years. Again,  
19 because of the review process in IEC, it's actually a  
20 little earlier to change an IEC standard probably than  
21 it is an FDA standard often.

22 So I think depending upon the practical

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 situation, I'm on the committees that develop these  
2 standards. So I know the people who are doing it. If  
3 it turns out that the standard was irrelevant, you  
4 know, for a number of devices, I think they'd be very  
5 amenable to altering it.

6 CHAIRMAN ROTHENBERG: Maureen.

7 DR. MURDOCH NELSON: I just want to  
8 clarify Michele's question. It sounds to me what  
9 you're saying is if they adopt the IEC standards, they  
10 adopt them wholesale. So, for example, when you're  
11 talking about there's a standard for metered  
12 calibrated control or visual indicators, you're not  
13 saying if they adopt the IEC, they adopt IEC except  
14 for that little piece where they --

15 MR. HERMAN: No, it should not be done  
16 piecemeal.

17 DR. MURDOCH NELSON: Okay.

18 MR. HERMAN: It would have to be done one  
19 or the other. That's correct.

20 DR. MURDOCH NELSON: Okay.

21 MS. BARRON: Yes, with the exceptions that  
22 we would note in the recognition of the IEC standard.

1 DR. MURDOCH NELSON: Okay, and those  
2 exceptions are actually when they have a transducer  
3 that's not amenable to the IEC standards?

4 MS. BARRON: We were thinking more in  
5 terms of a product, for example, that might not have  
6 a visual indicator that the voltage was getting to the  
7 ultrasound crystal. If we required that as an  
8 additional item besides what was already in the IEC  
9 standard, their claim of conformance would have to be  
10 a claim that they meet the IEC standard plus whatever  
11 we say also needs to be there.

12 DR. MURDOCH NELSON: So you're going to do  
13 this on a case-by-case basis then?

14 MS. BARRON: No, this would be in the  
15 general guidance to the entire industry. So they  
16 would either accept the IEC plus our exceptions or  
17 they'd be expected to meet the entire FDA standard.

18 DR. MURDOCH NELSON: Okay. Got it.

19 CHAIRMAN ROTHENBERG: Jerry.

20 MR. THOMAS: With the reengineering of the  
21 center and the forecasted retirement of about 50  
22 percent of the technical experts that you have, does

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 it look like we're going to be able to continue to  
2 have the expertise needed to participate actively in  
3 the development of the IEC standards in the future?

4 MR. HERMAN: Well -- I'm sorry. Go on.

5 MR. THOMAS: If so, then we're in good  
6 shape. If not, we may be setting ourselves up to  
7 adopt a standard that we no longer have the technical  
8 expertise in two to four to five years to participate  
9 in the reengineering or redevelopment of new standards  
10 coming out, and that's a concern that I have.

11 What does your crystal ball say?

12 MR. HERMAN: Well, I think that is a valid  
13 point, I being one of the people who would come under  
14 that category probably.

15 Another problem is that there is fewer and  
16 fewer dollars to actually attend these meetings at  
17 which most of the stem developments are done. IEC  
18 tends to be in Europe, Australia sometimes, although  
19 I've seen a number of times it's in the States, too,  
20 and you know, as the years go by, it seems that we can  
21 attend, you know, fewer and fewer of these meetings  
22 because of the economic situation, the money, the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 budget situation.

2 MR. THOMAS: So are you telling me that if  
3 we don't attend the meetings, then we're stuck with  
4 the collective decisions if we decide to go this way?

5 MR. HERMAN: Well, we do review the  
6 documents, and we, you know, have our technical inputs  
7 into the ANSI groups which could actually vote, and  
8 you know, in most of the drafts a country can vote  
9 with suggested changes and alterations. We can do  
10 that.

11 But I can tell you as a practical matter  
12 that most of the development of these standards is  
13 done at the meetings. You know, you are sitting down  
14 and you are either screaming at each other or, you  
15 know, collegially working out, you know, equations and  
16 concepts, and that's -- you know, if you want to have  
17 a lot of input into the standard, you pretty much have  
18 to be at these meetings.

19 CHAIRMAN ROTHENBERG: Yes?

20 DR. BALZANO: Again, to follow up, the  
21 description you give us right now for the future  
22 doesn't seem to be very encouraging. So, again, I see

1 with a certain amount of alarm the fact that we may be  
2 abandoning a better standard for a more restrictive  
3 standard, and again, whatever we can do as an  
4 accommodation to continue to participate very actively  
5 to these meetings because I personally have  
6 experienced exactly as you've described.

7 You've got to go there, and you have to  
8 have a discussion, local, in order to come up with the  
9 write-up that you finally want. So I think that the  
10 FDA should continue down the path of being active  
11 participant of the technical session of the IEC so  
12 that we don't end up with a standard that would be  
13 inferior to a standard that's 20 years old.

14 CHAIRMAN ROTHENBERG: Yes, Michele.

15 MS. LOSCOCCO: I have two questions. One  
16 gets back to my original question that we've been  
17 talking about, is basically what you're telling us is  
18 that there are some positions that the IEC that have  
19 better. You have no limits; they do have some limits.

20 So you're going to -- it's easier -- I  
21 guess what you're proposing is to recognize their  
22 standard with a few caveats that you're going to take

1 back from yours where they don't have any requirements  
2 than it is to try and go back and redo your standard.

3 MS. BARRON: That's correct.

4 MS. LOSCOCCO: Okay, and then the second  
5 question is actually just a question with regards to  
6 is there a reporting requirement if the machine does  
7 produce a skin burn.

8 MS. BARRON: Yes. They are actually  
9 subject to both the medical device reporting that we  
10 were talking about yesterday, and the electronic  
11 reporting that's called accidental radiation  
12 occurrences, but those are required only from  
13 manufacturers.

14 We do occasionally get them from others  
15 than the manufacturers as well, and we put those in  
16 the very small database that we have.

17 MS. LOSCOCCO: So during use if a hospital  
18 notices a patient has a small thermal burn, then  
19 they're supposed to report that, and it would be  
20 required under either of the two?

21 MS. BARRON: Yes. That would be the same  
22 as what we talked about yesterday with fluoro.

1 MS. LOSCOCCO: Right.

2 MS. KAUFMAN: Wait a minute, wait a  
3 minute. The reporting requirements -- and, Tom,  
4 please jump in if I've got this wrong -- are for  
5 serious adverse effects, right? In other words, it,  
6 I think, would be left up to the facility to determine  
7 if the burn fell into that category; is that correct,  
8 Tom?

9 They have a fair amount of leeway in terms  
10 of determining if it's reportable or not.

11 MS. LOSCOCCO: I can tell you personally  
12 I've had a thermal burn from one of these, and it  
13 wasn't reported, but it was only the size of probably  
14 your fingernail tip. So I think it gets back to the  
15 what are the actual hazards. Did they feel that it  
16 was over what they might have expected?

17 It's a little gray area.

18 DR. SHOPE: Yeah. I mean we go back to  
19 our definition of serious injury, which has to do with  
20 permanent impairment or looking at the definition on  
21 that page that we referred to yesterday. So something  
22 that is an injury maybe is painful but doesn't result

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 in permanent impairment, probably doesn't meet our  
2 definition of a serious injury.

3 MS. KAUFMAN: Well, and then the other  
4 issue was that it would never be required to be  
5 reported, am I correct, if it occurred in a private  
6 single doctor's office?

7 PARTICIPANT: No reporting is required.

8 MS. KAUFMAN: No reporting is required.  
9 Do we know what percentage of these therapeutic  
10 procedures are performed in a sole practitioner's  
11 office?

12 MR. HERMAN: It used to be quite a few.  
13 I really have no idea what the current situation is.  
14 Do you, Joanne?

15 MS. BARRON: I have no idea.

16 CHAIRMAN ROTHENBERG: But just to clarify  
17 with regard to your discussion, the reporting would  
18 take place no matter which standard was being  
19 followed, right?

20 MS. BARRON: If it met the criteria for  
21 serious injury, yes.

22 CHAIRMAN ROTHENBERG: But I mean the fact

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 that they would choose to use the IEC standard as  
2 opposed to the FDA wouldn't affect --

3 MS. BARRON: No.

4 CHAIRMAN ROTHENBERG: -- reporting  
5 requirements, and we're --

6 MS. BARRON: That's correct.

7 CHAIRMAN ROTHENBERG: -- discussing  
8 reporting requirements. I think we don't want to get  
9 into too much of --

10 MS. KAUFMAN: Well, I have a question  
11 because one of your slides says that they are exempt  
12 from reporting. What exactly were they exempt from?

13 MS. BARRON: That reporting was the  
14 manufacturer reports on the product description, its  
15 compliance, and the radiation quality control testing  
16 program that is required under the Radiation Control  
17 Act. Instead, what they would be doing is claiming  
18 conformance, filing the 510(k), which is kind of the  
19 abbreviated 510(k), and then incorporating it in their  
20 quality systems' management within the device purview.

21 So basically what we're doing is just  
22 saying that we don't want to duplicate the reporting

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 on the product and the compliance which goes  
2 completely with the device process.

3 MR. HERMAN: This is reporting to us  
4 during the initial submission, not adverse events  
5 reporting.

6 MS. BARRON: Right.

7 MS. KAUFMAN: Because then you had  
8 mentioned something about one of the things you would  
9 be interested in would be how many units come in under  
10 IEC versus FDA. How would you know that?

11 MR. HERMAN: I'd ask Joanne.

12 MS. KAUFMAN: I mean how would you know  
13 how many units came in? Once they file the initial  
14 501, they wouldn't be required to report how many  
15 they're selling, right?

16 MS. BARRON: We'd have to figure out how  
17 to do that, whether it would be something we could  
18 count based on the reports and the 510(k)'s we do get,  
19 or if that's not sufficient, maybe we'd have to go out  
20 with a questionnaire or something.

21 MS. KAUFMAN: Okay. Tom?

22 DR. SHOPE: I'd just make the point, I

1 think, that in neither case, our FDA standard nor the  
2 use of the IEC requires sales information to be given  
3 to us on product sales or the number of products  
4 introduced into the market. Both of these premarket  
5 processes are for a model of a specific kind of --

6 MS. KAUFMAN: They don't have to do  
7 reports like they did for X-ray equipment?

8 DR. SHOPE: No.

9 MS. KAUFMAN: Okay.

10 MR. HERMAN: But I think the point, and  
11 it's a valid point, if we're using the number of  
12 particular units, you know, one or the other, to  
13 determine how we're going to handle the standards in  
14 the future, I think it is a relevant question as to  
15 exactly how many of these machines are actually being  
16 used.

17 MS. KAUFMAN: Yeah.

18 MR. HERMAN: I think it's a valid question  
19 in terms of how we deal with the two standards in the  
20 future.

21 MS. KAUFMAN: Okay. So could you briefly  
22 summarize the advantages to going to the IEC standard?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701