

1 pound-of-butter, back-scatter, nuclear devices. And for  
2 that they've had a four-hour course on the radiation  
3 effects. And with all these isotope sources, we are now  
4 putting in a five-day course, which is 40 hours, basically  
5 not touching equipment but learning about radiation. And we  
6 expect by the end of three to five years from now every  
7 Customs officer who goes near this equipment will have had  
8 that course.

9 MS. KAUFMAN: And when do you expect that course  
10 to start being provided?

11 MR. LINDQUIST: We are doing it right now because  
12 we are operating and fielding the equipment. We are  
13 currently training people. Before the equipment can be  
14 operated at the port, we have to have all certified  
15 operators. They must know not to go in front of it.  
16 Customs officers don't generally recognize things as  
17 dangerous unless they can run them over or they go bang like  
18 a gun. And we're teaching them that radiation is bad. We  
19 don't want them standing with a little blindfold like the  
20 French radiological inspector.

21 CHAIRMAN FLETCHER: Yes?

22 MR. SZEGLIN: Do you people have film badges? Do  
23 your operators wear film badges?

24 MR. LINDQUIST: We did initially years ago with  
25 our truck X-rays, and after about five years we had it

1 surveyed and checked by FDA, and we were allowed to drop the  
2 film badges.

3           We are badging again with all the new systems as  
4 we go through our initial phase to make sure no one is  
5 receiving a dose or has inadvertently broken the rules and  
6 gone in and been dosed. Plus, we put dosimeters and film  
7 badges in various locations on the equipment, and we measure  
8 what's happening there in areas that people go into just to  
9 be sure that the total doses are within what we've measured  
10 and found at the factory and during our set-up testing.

11           So we are sensitive to dose. As I said, our  
12 people are our most valuable asset. And a traveler goes  
13 through and may only see the system once a year. Our  
14 inspectors are going to be seeing it on a daily basis.

15           An interesting thing on the truck X-ray. When we  
16 did that, I had little dosimeters for the people, and they  
17 were all worried about this big machine--because it is, it's  
18 big, it's impressive, it's scary.

19           I had one of the inspectors write his dose down as  
20 he came on and went off duty, as they all did, but I let him  
21 take it home at night. And he was in Southern California,  
22 and we discovered he was receiving four times as much dose  
23 at night, because he was only getting background radiation  
24 in the day. What was happening was he had one of those tile  
25 roofs that they have in California, and he had a pretty hot

1 roof. He was receiving quite a bit of dose at night  
2 compared to what was happening.

3 But, yes, we are doing this. We're making sure  
4 our people are in it. We have a radiation safety committee,  
5 which I'm one of the members. It's being headed up out of  
6 our headquarters in Indianapolis. We have a Ph.D. physicist  
7 in our office, and we're hiring now--I'll need your help for  
8 it, but it's one of your radiation people who go in and  
9 check medical systems and certify these things.

10 MR. KASSIDAY: Health physicist?

11 MR. LINDQUIST: Yes. Thank you, Dan. It's a  
12 health physicist. We are a very aggressively pursuing  
13 radiation safety.

14 CHAIRMAN FLETCHER: Dr. Rice?

15 DR. RICE: If you have a food container and you  
16 need over 5 MeV to penetrate the casing, what do you do? Do  
17 you always inspect that container since you can't use more  
18 than 5 MeV for food?

19 MR. LINDQUIST: That's not really a problem.  
20 Customs for years has inspected things the old-fashioned  
21 way. We have unloading docks. We have forklifts. We pull  
22 the materials out on the docks. We have the manufacturers  
23 do it, typically, or we do it, depending on what the  
24 location is and the sensitivities are. We have drug dogs.  
25 We use them. We go through the equipment by hand. We have

1 long mechanical probes. We will bust open cases, take a  
2 look at the cans. We'll open some of the cans. We'll use  
3 small X-ray pallet machines like you use on baggage. We  
4 take tin goods, we run them through on their edge because  
5 they will displace down. Drugs do not flow when they're  
6 packed in cans.

7 We have old-fashioned methods of inspection. We  
8 don't intend to violate the law. That's one of our  
9 commissioner's number one rules. You will not be a law  
10 breaker. If you do, you are dismissed from the Customs  
11 Service.

12 CHAIRMAN FLETCHER: Kathleen?

13 MS. KAUFMAN: On food microbiology, which is not  
14 my area of expertise, but I've read that one of the concerns  
15 on these relatively low types of exposures, compared to true  
16 food irradiation, as opposed to that, is that you might kill  
17 off those microbes that are not as strong, and more  
18 resilient type microbes would be those that might survive.  
19 And I'm wondering if you all have given any thought or  
20 testing to that issue.

21 MR. LINDQUIST: We are not in the realm that we  
22 will kill anything off, unfortunately, and we looked at the  
23 radiation rules that you have put in for food dosages, and  
24 we're just not approaching the operable regions or flux  
25 densities that are required to do any form of sterilization

1 or effect of that nature.

2 My major concerns are if we use the 6 MeV system,  
3 we're still below where pair production is supposed to  
4 occur, but it's a logarithmic thing, and there is the  
5 possibility of pair production modifying the structure of a  
6 medicine, and if I did that and the medicine went to a  
7 child--and we're working on infinitesimal possibilities  
8 here, but we're being very cautious. And as a result, we're  
9 following your rules to the letter on food. We do not  
10 irradiate above--at this point 2 MeV is the highest system I  
11 have to irradiate food, and the flux levels are so low that  
12 we're just not doing anything. You can't call it  
13 sterilized. You just can't claim any effect. We can't find  
14 anything.

15 CHAIRMAN FLETCHER: Let me ask one question--or  
16 two, rather. You indicate that many of these devices are  
17 right at the border or in areas where you are adjacent to  
18 probably state personnel, like port authority, water  
19 authority, et cetera.

20 MR. LINDQUIST: Yes, sir.

21 CHAIRMAN FLETCHER: Are your areas well enough  
22 marked and secured so that these people who are not informed  
23 about what's going on are protected?

24 MR. LINDQUIST: Yes, sir. We have large radiation  
25 signs. The fixed truck X-rays, you hear a speaker saying,

1 "X-ray is going on." That's a manual indication.

2           The X-rays, by the way, for those systems require  
3 a team effort. It's almost like a catapult launch crew  
4 getting this truck onto the system, getting it through, and  
5 getting it off safely. So what occurs is that the outside  
6 crew has control of the vehicle until it's in a ready  
7 position. At that point they visually ascertain there's no  
8 one in the cabinet. They know who's out there, what's in  
9 the area, the driver is where he belongs so we can see him.  
10 They hit an enable button.

11           When the enable button's pushed, there's a signal  
12 goes to the inside people, and at that point they can then  
13 activate the mechanical scan and put the X-rays. They  
14 announce, "X-ray going on." They hit the enable. The X-  
15 rays ramp up, the truck goes through the system.

16           As soon as it clears the system, the radiation  
17 stops. We have photocells that actually turn the beam on  
18 just as the truck hits, turns the beam off just as it exits.

19           Again, the truck mechanically proceeds outside of  
20 the building. We do our inspection. The results go out to  
21 the people outside. Once they stop the truck, it's gone  
22 back to outside controls so that no one can get jammed or  
23 hurt. The truck is removed. Then the outside people bring  
24 the conveyor back to the entry point, and the next truck is  
25 loaded. It's really done what I consider quite safely.

1           On the mobile systems, again, they have an outside  
2 guide because of the very tight clearances. The man is out  
3 there. He's in view of the driver. Anyone stops the  
4 progress of the truck, the beam goes off. If the truck  
5 isn't moving, the beam won't go on. We have a lot of  
6 interlocks. We have in essence kept the character of your  
7 regulations, even though we can't fall within them because  
8 we're using above a 300 KeV X-ray source. And I have worked  
9 quite closely with Pat Hansen and Dr. Tarantino and Mr.  
10 Kassiday.

11           MR. KASSIDAY: The 300 KeV limit is the food  
12 limit. It's not a limit on the cabinet standard.

13           MR. LINDQUIST: Yeah. But, I mean, that's what--  
14 there's where I start triggering everything to go in to talk  
15 to you people, show you what we're doing, showing the  
16 regulations and so on.

17           The airport types, the little machines that are  
18 used in airports, are the same equivalent level in many  
19 cases to what's happening. In fact, a lot of your airport  
20 machinery have a far higher dosage to the bag that's passing  
21 through with people's lunches, candies, things, but they're  
22 down at the 140 KeV level. But the dosage is considerably  
23 greater than we have with our systems. We're using a flying  
24 spot system in some. Some of them we're using a beam, a fan  
25 beam, which you traditionally see in an X-ray inspection

1 system, intermittent with a flying spot system. And as a  
2 result we're keeping our dosages quite low.

3 CHAIRMAN FLETCHER: I think Jill, and then John.

4 MR. LINDQUIST: We saw the levels, and when you're  
5 looking at microrem per exposure, I think that's very  
6 conservative.

7 DR. LIPOTI: The FDA has a letter that they plan  
8 to send to manufacturers, the manufacturers of the people-  
9 scanner type units, there are four things that they are  
10 recommending in that letter: that state regulators are  
11 aware of installations, that X-ray machines are registered,  
12 that operators are trained in radiation safety, and that  
13 units are labeled as X-ray-producing machines.

14 Would your Customs installations comply with all  
15 four of those?

16 MR. LINDQUIST: We do right now. They are labeled  
17 as X-ray machines. We have trained operators; they go  
18 through a two-day course on how to operate the machine, the  
19 radiation safety. We have a letter of consent that the  
20 people must sign before we will even do a search. But if  
21 they do not wish a pat-down search, we offer them this  
22 alternative. If they refuse that, we have the correct right  
23 to proceed with a pat-down search.

24 Customs officers' rights extend from the British  
25 customs rules. When you re-enter the country, you actually

1 don't get your rights until after the Customs officer  
2 releases you into the country. However, we have been  
3 sensitive to this. We don't violate it. In fact, we have  
4 self-imposed upon ourselves more and more rigorous  
5 restrictions before we proceed to cavity searches and our  
6 full X-ray. We need a very high level of port director  
7 approval nowadays, and if you're held more than an hour by a  
8 Customs officer, you have the right to make phone calls,  
9 consult with lawyers, et cetera.

10 So we are regulating ourselves, and we're  
11 sensitive to these things, and I would love to send you a  
12 copy of our consent form. Maybe that would be of interest  
13 to you.

14 DR. LIPOTI: I'm more interested in you answering  
15 the first two that I gave you about state regulators being  
16 aware of installations and X-rays machines being registered.

17 MR. LINDQUIST: We are working with that. I  
18 believe the only places we have these body scanners right  
19 now are at Miami and New York at JFK. Both state regulation  
20 authorities are aware of it. Dan was aware of it. He  
21 called me up and says, "Hey, I hear..." The word spreads  
22 very quickly through your regulation authorities, and, yes,  
23 we have been working with them and they are aware of our  
24 installations.

25 DR. LIPOTI: Do you inspect the machines that you

1 have described on a regular basis? And what would that  
2 inspection consist of?

3 MR. LINDQUIST: We have health physicists come in  
4 and check that they meet the certifications at least on an  
5 annual basis on the machines. When we have any major change  
6 or realignment or damage, because these things are around  
7 trucks and if a truck should bang into something, part of  
8 the procedure when you put it back into operation, realign  
9 it, you do a safety inspection around it again. Our Customs  
10 officers are trained to do this, and they have victorine (?)  
11 meters that they go around and make spot checks. But we  
12 actually have certified health physicists do this on at  
13 least an annual basis and any major mechanical change.

14 DR. LIPOTI: For the RAD-materials-containing  
15 devices, what is your protocol for inspection on those?

16 MR. LINDQUIST: Very similar. It meets all of the  
17 Department of Energy's requirements. One of the people who  
18 works for me is a Ph.D. physicist. He is a certified health  
19 radiologist or--I forget the exact title, but he pays a  
20 license fee every year, or we pay a license fee every year.  
21 He--

22 DR. LIPOTI: Those regulations are the Nuclear  
23 Regulatory Commission's regulations.

24 MR. LINDQUIST: Yes.

25 DR. LIPOTI: I don't think they're the Department

1 of Energy's.

2 MR. LINDQUIST: Well--I keep thinking they're part  
3 of them. I'm sorry. I'm fairly ignorant. I'm a Customs  
4 officer.

5 [Laughter.]

6 DR. LIPOTI: On your very big toys that you  
7 described to us--I think you used that term--I would  
8 certainly recommend that you use personal dosimetry and that  
9 FDA not approve any discontinuance of personal dosimetry,  
10 particularly on that CT scanner that you're considering or  
11 on the fast-pulse neutron analysis device. I'm unfamiliar  
12 with something called a pound-of-butter source. Perhaps you  
13 could enlighten me on that one.

14 MR. LINDQUIST: Okay. On the big items, they're  
15 still in R&D. We do have personal dosimeters on everyone  
16 who works in the area. We're monitoring that. Part of our  
17 agreement with the union is that we report and record all of  
18 these levels and actions, and we indeed do a study--and it  
19 will probably be three to four years before we even are able  
20 to consider if it's justified, removal of these dosimeter  
21 devices. So we're in full agreement there.

22 The pound-of-butter device is what we call a  
23 buster. It looks like a pound of butter. And it's black,  
24 it had a lead shield which is rolled out of the way of your  
25 10 microCurie cesium source, and it investigates

1 approximately 18 inches on a very light cargo. I can go  
2 over a tabletop, however, and show you where every cross  
3 beam is and so on, and it has a very sensitive detector in  
4 it which measures the reflected counts. And as I go over a  
5 denser object, more radiation is back-scattered to the  
6 detector. And when I go over something that's a void, of  
7 course, very little scatters back towards me. And by doing  
8 this, I can inspect car fenders, walls, skins of tractor-  
9 trailers, and we come upon areas of high density in tires--  
10 we know a tire normally has a 90 reading. If a truck tire  
11 suddenly has 180, we know it's full of drugs.

12           It's just another tool we have. They receive a  
13 certified course. There's a half-day course in radiation  
14 safety. There's a half-day course on how to actually  
15 operate it and find drugs with it. It's a very active tool.  
16 Our people carry it in like a pistol belt holder.

17           We had dosimetry and film badges with that for  
18 five years. We only had one positive reading, and that was  
19 caused by the person put it away with his film badge each  
20 night together. And he flicked on it a couple of times just  
21 out of curiosity to see if he would get a reading. We  
22 traced it down. We explained to him that wasn't the  
23 procedure. It was for safety. And with a small letter in  
24 his file, he no longer does that.

25           Any suggestions you have for safety I would love

1 to have. And please ask your questions. I'm delighted to  
2 take them.

3 CHAIRMAN FLETCHER: John, you were next.

4 DR. CARDELLA: I found that your presentation was  
5 fascinating, and I really was unaware of most of those  
6 activities that were going on.

7 There's something that I don't understand. In  
8 human radiography, if you want to see the colon or the  
9 kidney or some other internal part, typically you put a  
10 dense, radio-opaque material into that structure. Then you  
11 use the X-ray to penetrate through relatively easy-to-see-  
12 through skin and you try to eliminate bone and see the high-  
13 density object inside of it.

14 What I don't understand about the concept is you  
15 take these huge--I'm presuming they're metal sea containers,  
16 and let's say you had a load of engine blocks on the inside  
17 of this thing, very dense materials, and you're looking for  
18 radio-lucent marijuana stuffed in the cylinders. How does  
19 that work? Is it effective? Because, I mean, certainly all  
20 of the contraband that you're looking for is not radio-  
21 lucent, but I would think that marijuana and cocaine and  
22 condoms full of contraband would not be particularly  
23 conspicuous after you've blasted through two inches of  
24 steel.

25 MR. LINDQUIST: As you probably noticed in my

1 presentation, I did not present any images of the drug  
2 seizures and the drugs. At the break I'll be delighted to  
3 show you images I have in my briefcase, anyone here, but I  
4 will not put them on the Web.

5           How it works is that we have an average cargo  
6 density of usually less than one gram per cc, which is less  
7 than water. And when you get into things like an aircraft  
8 engine, it's big, it's bulky, but it's relatively easy to  
9 see through. And we actually see through the pistons. We  
10 see the valve stems. We see the springs. We see  
11 everything. Even in a truck engine going through these  
12 devices, we can see the pistons. When you have a solid  
13 piston, that seems strange; when we have a transmission box  
14 that is full of something opaque, rather than being able to  
15 be penetrated.

16           I told you that we work typically with a 10-degree  
17 offset. This allows us to get a little three-dimensionality  
18 so that if I clip the corner here and I can see through it,  
19 and I see through it and then finally it becomes dense, that  
20 doesn't bother me too much. But if I get to this corner and  
21 can't see through it, I begin to wonder.

22           We see the package shapes marvelously well, and  
23 I'd be glad to show anyone on the committee some images, but  
24 I will not put them on the Internet.

25           CHAIRMAN FLETCHER: Okay. Cass?

1 MS. KAUFMAN: The butter thing that you're talking  
2 about, it sounds very similar to the XRF units that people  
3 use to determine lead in paint, which uses a similar type of  
4 source.

5 MR. LINDQUIST: Same people developed it.

6 MS. KAUFMAN: The XRF, yeah. And, generally, for  
7 personnel monitoring we look more for extremity monitoring  
8 on those kinds of things, and you mentioned he was wearing  
9 it on his collar, so you're not--they don't ever use  
10 extremity monitoring?

11 MR. LINDQUIST: I would need education, I'm  
12 afraid, to understand what you're asking me.

13 MS. KAUFMAN: Okay.

14 MR. LINDQUIST: I apologize.

15 MS. KAUFMAN: Okay. Let me ask a couple questions  
16 about the people scanner. Of the 10 percent of people who  
17 selected the X-ray exposure over the pat-down, how many of  
18 those--first of all, do you know about how large a  
19 population we're talking about, how many people that is?

20 MR. LINDQUIST: I've had the data. The last data  
21 I looked at in the first few weeks, we are running about 10  
22 people a day would choose to be scanned, I believe, and I'm  
23 working from memory on this.

24 MS. KAUFMAN: And that would be at each of those  
25 two airports?

1 MR. LINDQUIST: Yes.

2 MS. KAUFMAN: Okay. And out of those, do you know  
3 how many came up with a positive scan?

4 MR. LINDQUIST: No one did.

5 MS. KAUFMAN: Do you know of those who had a  
6 positive scan how many subsequently had some further  
7 evaluation that indicated the positive scan was correct?

8 MR. LINDQUIST: Yes. We actually during the trial  
9 period do not only a scan, but we did a pat-down.

10 MS. KAUFMAN: So everybody's getting both?

11 MR. LINDQUIST: Yeah.

12 MS. KAUFMAN: So they're not really offered an  
13 option of one or the other.

14 MR. LINDQUIST: Well, we do now. And this was the  
15 initial thing to confirm that what we saw was indeed a clean  
16 body, and then we'd pat down and confirm it.

17 Now, we did test some dummies through plates and  
18 so on. I have had some quantitative results taken on these  
19 machines. The reality of it is that the people who refused  
20 to be done by this machine, however, we did get some  
21 positives with them. And, generally speaking, a smuggler  
22 will take his chances with a known technology than a new  
23 witchcraft. So they tend to refuse that. If they're given  
24 a choice, they just say, oh, no.

25 MS. KAUFMAN: Is that data available and you just

1 don't know it?

2 MR. LINDQUIST: That's correct. It is being kept  
3 by OFO, who is field operations people. We work very  
4 closely in a partnership in Customs. My customer is the  
5 field operator inspectors. We have headquarters people who  
6 have the same customer. And we keep the data. We're very  
7 sensitive to it, and, yes, it is available. I wouldn't want  
8 to make it public. I would show it to any member of this  
9 committee, again, because you have a legitimate use. But we  
10 consider it law enforcement sensitive.

11 MS. KAUFMAN: I would certainly be interested in  
12 seeing it.

13 MR. LINDQUIST: If I can meet you afterwards and  
14 get your card and I'll give you mine.

15 MS. KAUFMAN: Thank you. So you're not prepared  
16 right now to talk about how many negative scans resulted in  
17 positive pat-downs?

18 MR. LINDQUIST: Let me transfer it to our trucks.  
19 We improve the stream of vehicles that we X-ray by  
20 intelligence, by inspectors' intuition, by observation that,  
21 gee, there's a new strap put on that gas tank, that's  
22 strange, some new rivets here, something is odd in the truck  
23 or the reaction of the driver. And even doing all that, one  
24 in 2,000 trucks comes up with a load of drugs.

25 What that means is we're Ivory Soap pure; 99 and

1 44 one-hundredths percent is legitimate commerce, legitimate  
2 trade. And only a very small percentage are the bad guys.  
3 And that's why one of our goals is to effectively screen in  
4 a very short time without disrupting and damaging materials.  
5 Most people entering and leaving and most commercial  
6 shippers going across our borders are legitimate, honest  
7 people. We only have a small criminal element, and we're  
8 trying to get to them and disrupt them without making life  
9 miserable for the average person.

10 CHAIRMAN FLETCHER: On that note I'm going to say  
11 thank you very much for your presentation, and I believe we  
12 may have--if you can stick around a few minutes, when we get  
13 into our discussions, we may have some follow-up questions.  
14 Thank you.

15 What I'm going to recommend to the committee is  
16 that since the next two items are open public hearing and  
17 committee discussion, they're scheduled for after lunch.  
18 But in view of our current weather and the time, I'm going  
19 to suggest--if anyone has a problem, let me know--that we  
20 continue and finish the agenda and then adjourn.

21 MR. THOMAS: Are you anticipating those two items  
22 to take two hours, or are you anticipating them to--

23 CHAIRMAN FLETCHER: No, I don't.

24 MR. THOMAS: --take five minutes?

25 CHAIRMAN FLETCHER: That's going to be up to you.

1 MR. THOMAS: Because I've got a number of things  
2 that I want to raise in the discussion section. That may go  
3 on for at least an hour, knowing this group so far. It's  
4 your call, though, Mr. Chairman.

5 DR. CARDELLA: I would like to work through lunch,  
6 if you're trying to poll the group.

7 CHAIRMAN FLETCHER: That's what I'm trying to do.  
8 We may have to limit some of your discussion, Jerry.

9 Does anyone have, you know, a problem, they cannot  
10 work through the agenda?

11 [No response.]

12 CHAIRMAN FLETCHER: So we'll take a 10-minute  
13 break, and we'll come back and we'll recharge ourselves and  
14 go into public--we have no speakers for the public hearing,  
15 so we're really going to go right into committee discussion.

16 [Recess.]

17 CHAIRMAN FLETCHER: Will the committee please  
18 return to your seats? I know this is a very interesting  
19 presentation, but...

20 Let me first reannounce the fact that the first  
21 item of the agenda is listed as open public hearing.  
22 However, we have received no requests for presentation  
23 during that period. So I'm going immediately, therefore, to  
24 the committee discussion period, and I would request that we  
25 address our comments as much as possible to actions that we

1 want to relay to the Food and Drug Administration regarding  
2 things that we've heard and things that we're concerned  
3 about, with as much--you know, with as much information as  
4 needed but not tremendous elaboration. I guess that's the  
5 most kind way I can put it.

6 So the floor is open for discussion.

7 MR. THOMAS: May I address an issue that has--I've  
8 got a couple of quick questions that I'll ask of you.

9 Yesterday we talked about--we had a talk on re-  
10 engineering of the FDA. Over the night I thought a little  
11 bit about that, and I think that I would like to raise a  
12 concern that is also, I know, a concern of the folks that  
13 presented it, because she indicated it yesterday, but I  
14 think we need to go on record, possibly. And that is  
15 specifically if we look at the scientific qualifications of  
16 the people within the center that are currently supporting  
17 the program, these people are starting to get like me, gray  
18 around the temples, and I don't see a lot of new blood  
19 coming in.

20 My real concern--and I just want to express this  
21 concern, not necessarily a committee motion, unless others  
22 feel that way--is that we need to bring to the commis-  
23 sioner's attention the fact that the current support that  
24 CRCPD is getting from the FDA and the current technological  
25 skill sets that we're now accustomed to being behind the

1 development of the regulations isn't going to be there in  
2 five years. And I think that that's a great concern that is  
3 a concern to the nation that needs to be raised.

4 So I don't know how others feel. I've got about  
5 four or five points, some like this. I'd just like to get--  
6 does anybody think that we need to make a motion, or just  
7 the fact that I've raised the issue, is that good enough for  
8 the record?

9 CHAIRMAN FLETCHER: Jill?

10 DR. LIPOTI: I think a motion is in order. I was  
11 very concerned that the fluoroscopy regs were held up while  
12 Tom Shope worked on Y2K problems. If you've only got a  
13 depth there of a few people who know how to write these kind  
14 of regs, that's a problem from the agency. And we need to  
15 let them know that they need to replace people when they  
16 leave.

17 CHAIRMAN FLETCHER: I would ask, and hopefully  
18 when we've finished discussion, if you could, please write  
19 down the motion so that I can repeat it exactly as you  
20 intended.

21 MR. THOMAS: Well, then, since I raised the issue,  
22 unless Cass wants to make the motion, I'll make the motion.

23 MS. KAUFMAN: I'll second it.

24 MR. THOMAS: Okay. I would like to make a motion  
25 that the FDA recognize the current technological talent that

1 they have is near retirement age and that it is going to  
2 become a national concern in the X-ray regulations if they  
3 don't proactively recruit young blood at this point in time.

4 MS. KAUFMAN: I'll second that.

5 CHAIRMAN FLETCHER: Okay. I'm going to give you  
6 the essence of your motion: that the FDA proactively  
7 recruit young, qualified individuals to assist in rulemaking  
8 and other areas. Is that essentially what you're saying?

9 MR. THOMAS: That's what I'm saying.

10 MS. KAUFMAN: No age discrimination. You can't  
11 say "young" people.

12 CHAIRMAN FLETCHER: Okay. You're right. New  
13 staff. We'll just say new staff, additional staff.

14 MR. THOMAS: I guess what I'm saying is--

15 CHAIRMAN FLETCHER: You have to speak into the  
16 mike, please.

17 MR. THOMAS: I better be careful what I say.  
18 "Young," you're right. We'll remove the word "young." My  
19 concern is that we don't have additional new blood coming in  
20 to learn the regulation process. The regulation process  
21 takes a number of years to fully become competent in that  
22 process. And the technological skill sets we can't train,  
23 but we can train the regulation process.

24 CHAIRMAN FLETCHER: Okay. So I'm going to change  
25 it to "new qualified staff." Okay?

1 MR. THOMAS: Thank you, sir.

2 CHAIRMAN FLETCHER: Everyone understand the  
3 motion? Is there any further discussion?

4 [No response.]

5 CHAIRMAN FLETCHER: All in favor, raise your  
6 hands, please.

7 [A show of hands.]

8 CHAIRMAN FLETCHER: Opposed?

9 [No response.]

10 CHAIRMAN FLETCHER: Motion carries.

11 You had more, Jerry.

12 MR. THOMAS: Yeah, I've got three or four here.

13 This is an issue that has not been raised, but  
14 it's also something that we were briefed on, fluoroscopy CT  
15 and on fluoroscopy. We have a number of new emergent  
16 technologies in medical imaging and medical sciences that I  
17 have not seen any--let me rephrase that. I've seen outside  
18 of this group little proactive thought being given to  
19 specifically quality issues and dose issues associated with  
20 computed radiography, which are the phosphor plate  
21 receptors, direct radiology, which are the direct digital  
22 receptors, and also with the workstation image quality in  
23 interpretation.

24 All of those have public health-related aspects to  
25 them. All of them have implications in terms of dose to the

1 patients and the quality of the diagnostic process. And  
2 that's also, I think, part of our concern as a group, not  
3 only radiation safety but when these things go into the  
4 clinical practice that they're actually providing quality  
5 clinical information.

6 In that light, I would like to make a motion that  
7 the FDA begin more active involvement in the quality--in  
8 evaluating the needs for quality assurance in computed  
9 radiography, direct radiology, and radiology workstations,  
10 which are all associated with the new technologies of  
11 coming--pardon me, new technologies associated with X-ray-  
12 producing devices in medicine.

13 CHAIRMAN FLETCHER: Is there a second.

14 MS. KAUFMAN: I'll second it.

15 CHAIRMAN FLETCHER: Okay. Do you have this motion  
16 written down?

17 MR. THOMAS: No.

18 CHAIRMAN FLETCHER: Okay. Would you, therefore,  
19 repeat what you said so that everyone--into the mike, so  
20 that everyone knows what they're voting on?

21 MS. KAUFMAN: Could we have discussion first?

22 CHAIRMAN FLETCHER: Well, we are going to have  
23 discussion. I just want to make sure everybody heard what  
24 he said.

25 MR. THOMAS: Okay. The motion is that the FDA

1 become proactive in evaluating quality assurance  
2 requirements in computed radiography, direct radiology, and  
3 radiology diagnostic workstations.

4 CHAIRMAN FLETCHER: Okay. And the second was by  
5 Cass.

6 Discussion?

7 DR. CARDELLA: There are two additional aspects of  
8 the digitization of radiology that I think we should give  
9 some consideration to. One is the tele-radiology and by  
10 what standards will tele-radiology be permitted or by what  
11 standard is it proper for official interpretations to be  
12 rendered over tele-radiology. And the second area of  
13 interest to me is some standards initiatives in the Web  
14 browser method of transmitting images over the Internet. I  
15 would like to add those two topics to the motion.

16 MR. THOMAS: I think those are very appropriate to  
17 be added to the motion and I accept those.

18 CHAIRMAN FLETCHER: Okay. Give those to me, the  
19 two items again.

20 DR. CARDELLA: The two additional items would be  
21 standards of performance for tele-radiology systems,  
22 typically transmitted over telephone lines or cable modems,  
23 and the second area for standardized--for some standard or  
24 performance writing is in the Internet-based transmission of  
25 medical images.

1 MS. KAUFMAN: The seconder concurs.

2 CHAIRMAN FLETCHER: Okay. Further discussion?

3 MS. KAUFMAN: I was just going to mention that in  
4 facilities that have gone totally digital that we've seen in  
5 California, we have seen unnecessary exposures, and that  
6 they're not even often aware of, and they're just  
7 unnecessary. So I think that this is an area ripe for  
8 quality control testing and evaluations.

9 CHAIRMAN FLETCHER: Other discussion?

10 [No response.]

11 CHAIRMAN FLETCHER: Does anyone need the motion  
12 repeated?

13 [No response.]

14 CHAIRMAN FLETCHER: No questions. All in favor?

15 [A show of hands.]

16 CHAIRMAN FLETCHER: Opposed?

17 [No response.]

18 CHAIRMAN FLETCHER: Motion carries.

19 MR. THOMAS: Continuing down my list, I recognize  
20 that personnel qualifications is not the role of the FDA  
21 with the exception of mammography. However, FDA has  
22 indicated that they feel part of their role is education.  
23 We have a number of areas in medical imaging, specifically  
24 high dose rate fluoroscopy devices, that are becoming widely  
25 used in areas other than the diagnostic radiology department

1 who heretofore have been the principal individuals trained  
2 to use these devices. The training and qualifications of  
3 those individuals of the non-radiology community vary  
4 drastically across lines.

5 I would like to propose a motion focused in the  
6 education and information dissemination area because  
7 currently law will not allow us to do personnel  
8 qualifications. And that would be that I would like to move  
9 that the FDA again proactively become--pardon me,  
10 proactively interact with non-traditional professional  
11 organizations who are utilizing high dose rate fluoroscopy  
12 as part of their clinical practices. Specifically, earlier  
13 John had listed a number of medical subspecialties to  
14 include gastroenterology, orthopedic surgery--

15 CHAIRMAN FLETCHER: This is all a part of the  
16 motion?

17 MR. THOMAS: Yes. Well--

18 CHAIRMAN FLETCHER: We have to cut it off some  
19 place.

20 MR. THOMAS: I'll cut it off and I'll make it--let  
21 me give you the motion.

22 CHAIRMAN FLETCHER: Give me the motion.

23 MR. THOMAS: And then we'll make the motion  
24 generic, and then it can be qualified. So the motion would  
25 be that FDA proactively interact with the professional

1 organizations that are utilizing high dose rate fluoroscopy  
2 devices in their clinical practices for education of those  
3 individuals of the risks associated with those devices.

4 MS. KAUFMAN: I'll second it.

5 CHAIRMAN FLETCHER: Okay. Let me see if I got all  
6 this. You really need to write these down.

7 It has been properly moved and seconded that the  
8 FDA proactively interact with non-traditional professional  
9 organizations that are utilizing high dose rate fluoroscopy  
10 devices--and get involved in the training of individuals to  
11 use those disadvantages? I didn't get all of the last part.

12 MR. THOMAS: Why don't we say proactively interact  
13 with professional organizations whose members are utilizing  
14 high dose rate fluoroscopy devices. Leave it at that point.  
15 They can carry it from there.

16 CHAIRMAN FLETCHER: Okay. Whose members are  
17 utilizing high dose rate--

18 MS. KAUFMAN: Yeah, professional organizations, I  
19 do want to delete that word "non-traditional" because I  
20 think it needs to go out to even the traditional groups  
21 also. So I think if we just keep it at professional  
22 organizations, that--

23 CHAIRMAN FLETCHER: Okay.

24 MR. THOMAS: That's -- [nodding head up and down.]

25 CHAIRMAN FLETCHER: Okay. Questions? Comments?

1 Dr. Cardella?

2 DR. CARDELLA: It might be of some value to also  
3 delete the "high dose rate fluoroscopy" because even if it  
4 is standard dose rate fluoroscopy being used for prolonged  
5 periods of time, it poses a health hazard.

6 CHAIRMAN FLETCHER: Is that acceptable?

7 MR. THOMAS: Yeah, you're right. My initial  
8 concern was some of the newer technologies that we see in  
9 the OR where people don't know what they're really driving.  
10 But you're right. We can delete "non-traditional" and we  
11 also delete the "high dose rate." That's very fine with me.

12 CHAIRMAN FLETCHER: Okay. I'm going to restate  
13 the motion as I have it: that FDA proactively interact with  
14 professional organizations whose members are utilizing  
15 fluoroscopy disadvantages.

16 Okay. Further discussion?

17 [No response.]

18 CHAIRMAN FLETCHER: All in favor, raise your  
19 hands.

20 [A show of hands.]

21 CHAIRMAN FLETCHER: Opposed?

22 [No response.]

23 CHAIRMAN FLETCHER: Motion carries.

24 More?

25 MR. THOMAS: This will not be an issue of a

1 motion, but I do think that it's important that we recognize  
2 there is an active public debate going on on the linear non-  
3 threshold hypothesis in terms of radiation risk.

4 I heard it mentioned earlier today--when we were  
5 discussing the cargo scanners and the personnel scanners,  
6 the implication was made that we were looking at the non-  
7 linear threshold hypothesis. I want to make a general  
8 statement in that I think that we as a society have to re-  
9 evaluate the standards upon which we have established risk  
10 basis, and there is a lot of active debate, and I tend to be  
11 one of them that support the fact that I don't think the  
12 non-linear threshold hypothesis is an appropriate model for  
13 establishing risk policies. That may be a little bit  
14 radical, but that statement does then recognize that we do  
15 have such things as repair mechanisms in biological systems,  
16 which the non-linear threshold hypothesis does not  
17 recognize.

18 I just want to make a general statement. I know  
19 that there may be others that disagree with that. But I  
20 think that when we look at the cargo scanners that we're  
21 looking at, the doses and the risk to the general public is  
22 not minimal. I would say it is non-existent from the doses  
23 that they are giving.

24 CHAIRMAN FLETCHER: Okay. I'm going to have to--

25 MR. THOMAS: Enough of that.

1 CHAIRMAN FLETCHER: Okay. Because we need to  
2 focus on those things that we want to, as a committee, refer  
3 to the FDA. And I think you're going to have many opinions  
4 about the non-linear threshold, and I don't want to make  
5 that--

6 MR. THOMAS: Yes, but my concern for raising that  
7 is specifically that current regulations are being based  
8 upon that, current philosophy is being based upon that. And  
9 I don't think it's our--I agree with you, we should not  
10 debate the issue. But we should look, I think, critically  
11 at some of the basic underlying assumptions, and that was my  
12 point.

13 CHAIRMAN FLETCHER: Okay. Are there any more  
14 motions or consideration of recommendations to be presented  
15 here? Dr. Lipoti?

16 DR. LIPOTI: Well, given that that was on the  
17 record, I think I just want to put on the record that I  
18 believe we can all support the BR7 Committee looking into  
19 this issue and that as a regulatory body we can't take any  
20 other positions until we have conclusions of BR7 before us.

21 CHAIRMAN FLETCHER: Okay. Point well taken.

22 MR. THOMAS: I also agree with that.

23 CHAIRMAN FLETCHER: Once again, other items for  
24 additional discussion? This is your last chance.

25 DR. CARDELLA: This is not a motion item, but I

1 would like to make the recommendation that the computerized  
2 tomography fluoroscopy issue, if it is to be analyzed and  
3 considered for a performance standard writing, I would  
4 recommend that it be done with the CT scan standard and not  
5 with the high-dose fluoroscopy standard for interventional  
6 radiology. I would not like to see that standard deferred  
7 or slowed down because of the CT fluoroscopy issue. And the  
8 measurements and the issues, the interventional reference  
9 point that we have spent a tremendous amount of time  
10 defining do not fit well with CT. Some additional  
11 parameters and measurement methodology is necessary to study  
12 that. So I am encouraging it to be studied or to be  
13 incorporated in performance standards, but with the CT  
14 documents, not with the interventional fluoroscopy  
15 documents.

16 CHAIRMAN FLETCHER: Okay. Let me respond to that  
17 this way: I'm told that the best way we can influence, if  
18 you will, further action is to put things in the form of a  
19 motion.

20 DR. CARDELLA: Okay. I move that the FDA consider  
21 performance standards for CT fluoroscopy under the aegis of  
22 the CT performance standard as opposed to being in the  
23 interventional fluoroscopy standard.

24 MR. THOMAS: I second that.

25 CHAIRMAN FLETCHER: Okay. Discussion?

1 MS. KAUFMAN: I guess I'm not clear what  
2 interventional fluoro standard you're referring to because  
3 there really isn't one. So--

4 DR. CARDELLA: It's the one that was discussed  
5 earlier this morning, the fluoroscopy standard. It's been  
6 through the advanced notice of rulemaking, Tom Shope's  
7 presentation.

8 MS. KAUFMAN: Yeah, but that's not specific to  
9 interventional. That would apply to all fluoro equipment.  
10 It really doesn't have anything--

11 CHAIRMAN FLETCHER: Tom, do you want to clarify?

12 MR. THOMAS: I think that's what he's referring  
13 to, Cass, is that CT that's used in the fluoroscopy mode  
14 shouldn't be tied to the fluoroscopy standards.

15 DR. SHOPE: I think we're--just a little semantic  
16 problem. There is one standard for diagnostic X-ray  
17 equipment. It has four sections: a general, a  
18 radiographic, a fluoroscopic, and a CT section. So we're  
19 all talking about one standard. It has requirements in that  
20 standard for different aspects of diagnostic X-ray  
21 equipment.

22 I think what I was hearing is the amendments  
23 currently addressing fluoroscopic X-ray systems under the  
24 X-ray standard should not hold up for further considerations  
25 of interventional fluoroscopy CT-type--excuse me, I didn't

1 say it--computed tomography fluoroscopy applications should  
2 not interfere with the forward motion on the sections  
3 dealing with fluoroscopic equipment.

4 CHAIRMAN FLETCHER: Was that your intent?

5 DR. CARDELLA: Yes. The reason I referred to it  
6 as interventional fluoroscopy is my familiarity is with the  
7 IEC side of that initiative, and, you know, the IEC  
8 documents are being generated for fluoroscopic safety  
9 standards for equipment used for interventional purposes.  
10 And I was just unaware that--I thought the FDA's fluoroscopy  
11 standard was also for interventional, but if it's just for  
12 fluoroscopy in general, then I would encourage the CT  
13 fluoroscopy to be different than that standard.

14 CHAIRMAN FLETCHER: You're amending your motion?

15 DR. CARDELLA: No. I'm clarifying it. I'm  
16 clarifying my misunderstanding.

17 MS. KAUFMAN: I guess I'm still a little confused  
18 because the motion that you made was actually somewhat  
19 different, so I need clarification. Is the motion simply  
20 that we want FDA to proceed with the fluoro standards that  
21 have been previously discussed and not at this point  
22 consider fluoroscopic CT? Is that the motion?

23 DR. CARDELLA: Yes, that's part of that, and then  
24 a further recommendation is that the CT fluoroscopy be  
25 considered for a standard of performance, but under the CT

1 documents, not under fluoroscopy documents.

2 MS. KAUFMAN: Okay. If I could suggest an  
3 amendment, that we just stop at the part where we would like  
4 them to consider the CT fluoro issue in the future, and not  
5 describe that it needs to be under either the CT or the  
6 fluoro portion, because it may be that it needs a whole  
7 separate section in and of itself. I prefer to leave it up  
8 to FDA as to where those regulations would most  
9 appropriately go, either under CT or under fluoro or under a  
10 whole new section.

11 CHAIRMAN FLETCHER: We need a decision.

12 DR. CARDELLA: That's complicated because what I  
13 was trying to do, Cassie, was not slow down the publication  
14 of the fluoro one to wait for the CT, and because of the  
15 measurement methodology, it will be substantially different  
16 measurements that will be necessary under CT. I happen to  
17 believe strongly that it should be in CT and not in fluoro.  
18 I was trying to get that as a secondary recommendation--if  
19 they're seeking recommendations, because in the presentation  
20 they were raising the issue of whether it should be under a  
21 CT document or a fluoroscopy document. I think it should be  
22 under a CT document.

23 CHAIRMAN FLETCHER: Can we just some clarification  
24 here from Orhan?

25 DR. SULEIMAN: Let me throw my three cents in. I

1 think what you want is for the existing work that has been  
2 proposed on the fluoro amendments not to be jeopardized by  
3 any other activities at this point. I think we hear that,  
4 or at least I hear that.

5 I think the committee has expressed concern about  
6 CT fluoro and what should we do about it, maybe similar to  
7 what's been doing with the preceding fluoroscopy amendments.  
8 I think we're going to take that into consideration and  
9 discuss it.

10 I don't think we're going to try to slow down  
11 Tom's work at this point in time, and I don't think anybody  
12 else has that intention. I think that's your intent. Am I  
13 clear?

14 CHAIRMAN FLETCHER: Are you saying we don't need a  
15 motion?

16 DR. SULEIMAN: You could make a motion, but I  
17 think we got a message.

18 MR. THOMAS: John really had two motions. Could I  
19 ask you possibly to take them and break them into two? The  
20 first one would be specifically for the fluoroscopy  
21 standard, and then for CT fluoroscopy.

22 DR. CARDELLA: Yes, I will retract the original  
23 motion.

24 CHAIRMAN FLETCHER: And you'll retract the second.  
25 Right, Cass?

1 MS. KAUFMAN: I think Marlene--

2 CHAIRMAN FLETCHER: Marlene. Okay. Go ahead.

3 DR. CARDELLA: I move that the--

4 CHAIRMAN FLETCHER: That's why it's good to write  
5 them down.

6 DR. CARDELLA: Yeah. I move that the fluoroscopy  
7 performance standard move forward without delay for the CT  
8 fluoroscopy standard.

9 CHAIRMAN FLETCHER: Okay. Is there a second?

10 MR. THOMAS: Second.

11 CHAIRMAN FLETCHER: Is there any more discussion?

12 [No response.]

13 CHAIRMAN FLETCHER: All right. I think we  
14 understood it. Yes?

15 DR. LIPOTI: I remain concerned that there's no  
16 measurement of dose for the operator of the CT fluoro unit,  
17 and to the extent that these particular units are just now  
18 being invented by the manufacturer, I want to send a very  
19 strong message to the manufacturer that this is a feature  
20 that would be of use to an operator. And so while I may  
21 support this motion of not holding up the fluoro regs, which  
22 are almost in final written form, I feel very strongly that  
23 this body needs to express to the manufacturers the  
24 importance of having what has been called in previous  
25 meetings a speedometer and a trip gauge, but is really a

1 dose measurement that is available at the operator's  
2 position.

3 CHAIRMAN FLETCHER: Okay. Cass?

4 MS. KAUFMAN: I agree with John. I think that  
5 that dose rate measurement visible to the operator is going  
6 to probably be the most effective tool in terms of perhaps  
7 reducing patient exposures. And I don't know, though, how--  
8 I don't even have a clue as to how difficult it would be for  
9 CT manufacturers to incorporate that into their systems. So  
10 I wouldn't want the regulations to be held up for that one  
11 thing, but I would like for us to encourage FDA to look at  
12 that issue and work with the manufacturers on it and find  
13 out how feasible it is, and if it's at all doable, that when  
14 they do write regulations, that they incorporate that into  
15 their regulations, and in the interim that they encourage  
16 the CT manufacturers to include that.

17 CHAIRMAN FLETCHER: Are there any other comments  
18 on this motion?

19 [No response.]

20 CHAIRMAN FLETCHER: All in favor, raise your  
21 hands.

22 [A show of hands.]

23 CHAIRMAN FLETCHER: Opposed?

24 [No response.]

25 CHAIRMAN FLETCHER: Motion carries.

1 Now, you had a second motion.

2 DR. CARDELLA: The second half of what I was  
3 trying to achieve is stated as follows: I move that a  
4 recommendation be made to FDA from TEPRSSC that a CT  
5 fluoroscopy performance standard be written, or at least be  
6 developed, with the corollary suggestion that it be placed  
7 with the CT standard and not with conventional fluoroscopy  
8 standard, and to include indicators of radiation dose rate  
9 and cumulative dose.

10 CHAIRMAN FLETCHER: Is there a second?

11 MR. THOMAS: I'll second that. The last part's  
12 going to be tough, though, John.

13 CHAIRMAN FLETCHER: It's been moved and properly  
14 seconded that we recommend that the FDA develop CT  
15 fluoroscopy standards and that these be placed with the CT  
16 standards, and they should include dose and dose rate  
17 measurement considerations.

18 DR. CARDELLA: That's perfect.

19 MS. KAUFMAN: I'm with you right up to the point  
20 about them having--about our recommending that they be in  
21 the CT performance standard, because I'm not--I don't  
22 understand why we would care which section of the  
23 regulations they were incorporated into. We care what they  
24 say, what they require, but I'm not clear on why we care  
25 that they be in the CT section versus the fluoro section.

1 DR. CARDELLA: My thought on that is that the  
2 manner in which CT dosimetry is measured is different than  
3 for conventional fluoroscopy. So if you're already talking  
4 about rotating tube and image receptor units going around to  
5 make one slice, I think it is a smaller step to talk about  
6 that gantry rotating in one fixed slice multiple times, or  
7 over a volume of tissue if you're doing a spiral scan, than  
8 it is to force it into a conventional fluoroscopy where you  
9 just have a stationary source and a stationary detector. I  
10 think it makes more sense, basically, because you're already  
11 talking about rotational measurements of dose rate and those  
12 sorts of things. I don't think it makes any sense to put it  
13 with conventional fluoroscopy.

14 CHAIRMAN FLETCHER: Tom, you want to add  
15 something?

16 DR. SHOPE: I'd just make a brief comment. I  
17 think this is something that we'll eventually sort out, and  
18 if we need a requirement and if there's a need shown for a  
19 requirement, we can certainly find the appropriate place to  
20 put it in the standard.

21 I would mention now that the standard--the  
22 section's 1020.30 is for equipment for radiography; 1020.31  
23 is equipment for fluoroscopy. And we're defining  
24 fluoroscopy very specifically in these new amendments to  
25 talk about what we really mean by fluoroscopy a little

1 better than we have in the past. And the CT section,  
2 1020.33, is for computed tomography and the definition of  
3 computed tomography involves images from reconstruction. So  
4 it would be hard right now for me to think about  
5 requirements for these systems that make their images using  
6 computer reconstruction to be anywhere but in the CT  
7 section.

8 Now, if we need a new section because it's real-  
9 time images from reconstruction on a real fast basis and we  
10 need a new section to deal with that, then we would have to  
11 put one in. But right now--I haven't looked it up quickly,  
12 but I think even in the definition of fluoroscopy--or the  
13 applicability of that section, it says "except CT," and  
14 we've defined CT to be reconstruction. So I think we could-  
15 -maybe I'm presumptuous. I don't think we need this  
16 amendment. We'll deal with it.

17 MS. KAUFMAN: I don't care where it goes. I just  
18 would like--

19 CHAIRMAN FLETCHER: Okay. Let's take a vote, if  
20 there are no more comments. All those in favor, just raise  
21 your hands.

22 [A show of hands.]

23 CHAIRMAN FLETCHER: Those opposed?

24 [A show of hands.]

25 CHAIRMAN FLETCHER: Okay. We have one in

1 opposition. The motion does carry.

2 Are there any other matters to be discussed in the  
3 committee? Yes, Dennis?

4 MR. WILSON: There was a comment about the motion  
5 yesterday on the laser standard that we thought we'd try to-  
6 -I've tried to rewrite it here. I'm not sure if--I think  
7 I've covered it, to make sure that we cover all of the areas  
8 that we want to be clear on. So there's really, I think,  
9 about two or three things to this. One is--and I'll  
10 verbalize this and then kind of make a motion--was to wait  
11 until after the IEC amendment had completed the voting and  
12 the comment period for the amendment that's going through  
13 right now, the CDV, and to determine if there's any major  
14 impact that would affect the current standard that was being  
15 put forth, the changes. The second is then the alignment  
16 with that IEC standard, and the third piece would be the  
17 exceptions.

18 The alignment would include two areas that I think  
19 we noted which was very important. One is the hazard  
20 classification and the second was the warning labels. I  
21 think they were discussed specifically. The exceptions, or  
22 I've used the word "exclusions," were noted in their  
23 overview, and the two in particular are the light-emitting  
24 diodes and the difference in the collecting aperture for the  
25 highly divergent laser beams. And if it's appropriate, I

1 can give you--

2 CHAIRMAN FLETCHER: You want to move to replace  
3 yesterday's amendment and then you can proceed?

4 MR. WILSON: Yes.

5 CHAIRMAN FLETCHER: Okay. So I'd like to make a  
6 motion to replace that with this wording: After voting on  
7 the current IEC 76/196 CDV amendment is completed and  
8 comments are reviewed, if there are no major technical  
9 changes, we request the FDA to proceed forward with the  
10 revised laser standard, aligning it with the IEC standards--  
11 I have them spelled out here--including hazard  
12 classification and warning labels, with the exceptions noted  
13 in their overview such as exclusion of light-emitting diodes  
14 and collecting aperture for highly divergent laser beams.

15 CHAIRMAN FLETCHER: Okay. Is there a second?

16 DR. LIPOTI: Second.

17 CHAIRMAN FLETCHER: Okay. Does anyone need the  
18 motion read again because Dennis--okay. Discussion?

19 MS. KAUFMAN: The motion that we did yesterday--I  
20 guess--do you have any idea how long the comment period is  
21 going to be? Because I think the difference, one difference  
22 in what you're saying today compared to what we voted on  
23 yesterday was I think we had wanted to wait until the  
24 November voting, but now you're throwing in something about  
25 waiting until another comment period. I'm confused on that.

1 MR. WILSON: No. It's one and the same. When  
2 they put the vote in, they also can supply comments to that.  
3 And those then are reviewed at the meeting, so it should be  
4 at this November meeting that they'll have all the comments  
5 collated and discussion on those comments, and a decision  
6 can be made at that point.

7 MS. KAUFMAN: Okay. So we're still not extending  
8 it beyond that November meeting. Okay.

9 CHAIRMAN FLETCHER: Other discussion?

10 [No response.]

11 CHAIRMAN FLETCHER: All in favor, raise your  
12 hands.

13 [A show of hands.]

14 CHAIRMAN FLETCHER: Opposed?

15 [A show of hands.]

16 CHAIRMAN FLETCHER: Okay. One is opposition.  
17 Motion carries.

18 Are there any other motions to be discussed?

19 DR. LIPOTI: This is not in the form of a motion.  
20 We never had a chance to ask questions on the Y2K  
21 presentation this morning, and I did have one.

22 In any of the non-compliant reports from  
23 manufacturers, is there any possibility of a radioactive  
24 materials release or a radiation exposure?

25 DR. SHOPE: None that I'm aware of in the sense

1 that there is a--I mean, the product that first came to our  
2 minds in internal CDRH discussions way back in 1996, when we  
3 said what are the kind of products that are computerized  
4 that a computer failure due to a date problem could lead to  
5 a potential health risk, and immediately to those of us  
6 thinking about it, it was one of the few things we came up  
7 with, radiation treatment planning systems used for  
8 brachytherapy or teletherapy where the software was  
9 developed, say, in the '70s and it used two digits to  
10 represent the date, and you've got source strength  
11 calibration dates compared to today's date for delivering  
12 the therapy to calculate the dose delivered or the radiation  
13 delivered. And there are, in fact, products that have been  
14 sold that were in use that had that problem.

15 The manufacturers have identified those problems.  
16 They have in many cases said the software needs an upgrade,  
17 here it is, this is how you get it, this is what you do.

18 There were a few of those systems declared as  
19 obsolete, and the manufacturer said, look, radiation therapy  
20 planning has moved a long way since we developed this  
21 system, and we're not going to patch a new patch into this.  
22 We think you should get something new and this product's  
23 obsolete.

24 The Department of Veterans Affairs I know had  
25 seven systems that they had to replace that were not

1 inexpensive items in that situation.

2           But that's the only case that I'm aware of where  
3 there is an immediate radiation potential. When you think  
4 about where are the other problems, there have been a lot of  
5 problems identified, mostly minor in nature, with computed  
6 tomography systems, and that has to do primarily with the  
7 date associated with the image and any sorting of images in  
8 presentation to the viewer in chronological order, potential  
9 for problems along those lines. And there have been a  
10 number of approaches taken by the companies depending on the  
11 vintage of the CT system, or the MRI system even in this  
12 case, as to how they deal with those issues.

13           But I'm not aware of any potential for radiation  
14 release. I mean, the only radiation involved in medical  
15 devices I'm aware of are implants, isotopic implants, and  
16 I'm sure that if you did a plan incorrectly, you could end  
17 up putting in too much or too little, but I don't see that  
18 as a release in the sense I think you were mentioning it.

19           DR. LIPOTI: Yeah, I'm one of those people who's  
20 going to be in the bunker with the state police December  
21 31st. So that's why I'm concerned.

22           You know, you mentioned that some of these  
23 radiation treatment planning systems will be declared  
24 obsolete by the manufacturer and that the rest have largely  
25 divested itself of these. But where do they go? Don't they

1 go to other countries?

2 DR. SHOPE: The radiation treatment planning  
3 systems?

4 DR. LIPOTI: Mm-hmm. I mean, our old X-ray  
5 machines all go to Third World nations who use them for  
6 years and years. And what I'm concerned about is an  
7 inappropriate treatment in another country.

8 DR. SHOPE: Well, the radiation treatment planning  
9 systems I think are basically software or--I mean, you buy  
10 the computer and you run the software on it. Some of them  
11 come in a workstation kind of situation.

12 I don't know what the extent of the resale market  
13 is for radiation treatment planning systems. It's not one  
14 of the items that I would have expected to be big in the  
15 resale market. But there are some active discussions  
16 underway in FDA right now dealing with what we are going to  
17 say about non-compliant products in the resale market. It  
18 gets into the refurbishing, remanufacturing issue.

19 There is also some discussions underway with the  
20 General Services Administration with regard to the Federal  
21 Government policy on making surplus government-owned  
22 property and equipment available to outside parties through  
23 the surplus channel. And there have been some very strong  
24 opinions expressed about making sure that products that  
25 could present a hazard don't get into the used equipment

1 channel via the Federal Government. And there's been quite  
2 a bit of concern expressed about this. And GSA, in fact,  
3 has published a policy that's going to get redone, I  
4 believe. We had a meeting last week with them on it. I  
5 think the policy needs some work, and it's going to get  
6 revised.

7           But the idea there is to say if the product is of  
8 a type that could present a serious risk, then it can't go  
9 into the government surplus channels. It has to be  
10 destroyed. I think there are a lot of people who had a lot  
11 of concern about the fact that non-compliant doesn't mean it  
12 presents a real risk, and this approach to things was about  
13 to dry up a very useful supply of very useful equipment.  
14 Even though it may not be Y2K compliant, the receiving  
15 hospital or the receiving health care facility may be  
16 perfectly able to develop the work-around that writes on the  
17 paper record the right date as opposed to trusting the  
18 incorrectly printed date, those kinds of things. And the  
19 policy needs a little fine-tuning to take some of those  
20 things into account.

21           But the issue of the used equipment market, I  
22 voiced personally--this is not an FDA position--that this is  
23 like buying a used car. You know, the person who gets that  
24 equipment and uses it has got to be ultimately responsible  
25 of what they're doing with patients. And if people by now

1 don't realize that you can get products that have problems  
2 due to date problems and they continue to ignore that issue  
3 and buy used equipment, I'm not sure there's anything we can  
4 do to really economically, in a sensible economic way,  
5 control that. Perhaps truth in labeling or some kind of  
6 certification process might be appropriate.

7           We're considering an approach to imports coming  
8 into the country and what occur there to make sure that the  
9 items coming in we have some assurance are Y2K compliant.  
10 And, of course, anything manufactured in this country and  
11 sold we would expect to be Y2K compliant or it's misbranded  
12 or adulterated. So that controls the stuff coming from  
13 manufacturers. Then as the people who are just buying and  
14 selling, one hospital to another, one doctor's office to  
15 another, that sort of thing, that's pretty much of a stretch  
16 for us to figure out a way to effectively deal with that.

17           CHAIRMAN FLETCHER: Dr. Kaczmarek, did you want to  
18 make a comment?

19           DR. KACZMAREK: I was just going to say something  
20 about the resale for therapy planning systems. I used to  
21 work with therapy planning systems. There really was no  
22 resale market for them.

23           My opinion would be that you'd be subject to the  
24 same problems, potentially, in other countries with these  
25 systems that you would with the people that buy Cobol

1 systems or cesium systems that don't really do the dosimetry  
2 accurately. If they were to get one of these things, you  
3 probably would have the same kind of problems.

4 Countries that do, in other words, say in Europe,  
5 for example, where they're as much on top of the issue as we  
6 are, won't have a problem because they have the same  
7 approach we are to the Y2K problem. But other countries,  
8 yeah, you may potentially. But I don't really expect it  
9 with planning systems. Like Tom says, it's really a  
10 software product.

11 CHAIRMAN FLETCHER: Thank you.

12 Cass?

13 MS. KAUFMAN: Tom, the only two units that I can  
14 think of off the top of my head where release might be a  
15 cause of concern that FDA has oversight over would be the  
16 high dose rate afterloaders and the gamma knives. I can't  
17 imagine how Y2K would do that. But have you taken a look at  
18 those two units?

19 DR. SHOPE: I personally haven't looked at those  
20 two specifically, but, again, you do treatment planning for  
21 a gamma knife. You do treatment planning for afterloaders.

22 Now, the actual device themselves, it's hard for  
23 me to see how a date's relevant, but it's a possibility.

24 Let me say that we are going systematically  
25 through our list of 90 generic types of medical devices and

1 determining what each manufacturer of each of those products  
2 has said about all their products as to their Y2K status or  
3 not, whether a solution is currently available; if they  
4 promised a solution and it's not there yet, those are the  
5 ones we're going to focus on and work with.

6           So we will be taking a look at those types of  
7 products. Radiation treatment planning systems are high on  
8 that list. Because we don't have a separate classification,  
9 we end up looking at treatment delivery systems. Those are  
10 the classified products that we look at. So we'll have a  
11 comprehensive list of all those manufacturers and what  
12 they've said about all their products. So we are paying  
13 attention to that.

14           MS. KAUFMAN: And I wasn't thinking in terms of  
15 treatment delivery as much as just unintentional, you know,  
16 exposure of the sources. As I said, I can't imagine how Y2K  
17 would do that, but that might be something to take a look  
18 at.

19           CHAIRMAN FLETCHER: I have one question that's  
20 been bugging me. Supposedly, a preview of Y2K should have  
21 occurred on September 9, 1999. Now, in your oversight, did  
22 you see any anomaly that you're concerned about?

23           DR. SHOPE: I'm not aware of any reports with  
24 regard to medical devices, but I haven't spent a lot of time  
25 reading my Internet mail in the last day and a half. But we

1 did know--or note two reports about 9/9/99 problems. One  
2 was--you know, a little levity here--somebody reported a fax  
3 machine in New Zealand they thought had problems, and I  
4 think people thought that probably wasn't due to 9/9/99.

5           And there was another report for some heating/air-  
6 conditioning systems in Ireland in a health care facility  
7 that they thought the control mechanism, the thermostat  
8 controls had a problem. And apparently it was something  
9 that the vendor of this particular item--people at least in  
10 that community in England and Ireland had had some  
11 discussions about, would this thing have a problem or not?  
12 The report was that it did. But, again, these aren't  
13 medical devices, but there were associated with health care  
14 delivery in the sense that apparently you could go in with a  
15 laptop computer. If you took that over to the device and  
16 reprogrammed it, you could--you'd be all right. Or you  
17 could just wait until the next day and it was all right. So  
18 it didn't seem to be a real problem.

19           CHAIRMAN FLETCHER: You may not be able to answer  
20 this, but the oversight that you're engaged in, would you be  
21 able to detect the intentional use by a firm to maybe  
22 control the product by indicating they had Y2K problems and  
23 controlling the availability for a later time when they  
24 could raise the price?

25           DR. SHOPE: I'm not--I think what you're saying is

1 are we able to note that firms are using Y2K as an economic  
2 advantage, and I think certainly there have been some firms  
3 that made the decision: Well, we could develop a fix for  
4 this product, but we don't have a lot of them. It would be  
5 expensive, and we'd rather sell our new product, so we've  
6 declared this one obsolete. That's happened certainly in  
7 some circumstances.

8 I don't know anything about a product being held  
9 back or that sort of thing, but certainly Y2K, like any  
10 other opportunity for making a buck or two, is being used  
11 for that purpose.

12 CHAIRMAN FLETCHER: I guess my question is: Would  
13 you be able to know, be able to recognize someone actually  
14 doing that?

15 DR. SHOPE: I mean, if they've declared their  
16 product obsolete, we'll have that in our database. I'm not  
17 sure I quite grasp what you're looking for.

18 Our oversight in terms of what are we having the  
19 manufacturers do, again, we rely in our regulatory scheme in  
20 the U.S. greatly on manufacturers' endeavors. We don't test  
21 these products before they come to market. We rely on the  
22 manufacturer to develop them, to design them, to test them,  
23 to validate them. But we oversee what the manufacturer says  
24 they've done with our factory inspections, and we expect  
25 that their corrections for Y2K problems that they've

1 discovered will be done under the same quality system with  
2 the same kind of thoroughness and that they're investigation  
3 of potential problems would be done in the same manner as  
4 they would if they had a complaint about a potential problem  
5 or a real problem. And we're doing a little further effort  
6 with our auditing of the firms. We're checking a sample to  
7 see how that's going, and so far the 35 or so that we've  
8 done, it's very gratifying to see that our quality system  
9 approach seems to be working and we aren't finding any  
10 problems or concerns.

11 CHAIRMAN FLETCHER: Dennis?

12 MR. WILSON: I had a couple of questions on Y2K.  
13 In your presentation, you talked about, in your database,  
14 total manufacturers reporting were 4,268. How complete is  
15 that list compared to what's out there?

16 DR. SHOPE: Well, I can give you some numbers. I  
17 know these very well.

18 There are registered with FDA as of the last time  
19 we counted about 13,500 manufacturers. Our database  
20 includes more than just regulated medical devices, though.  
21 It also includes biomedical equipment, scientific research  
22 instruments, and when we made our initial request to the  
23 industry, we used two of the associations that represent  
24 those manufacturers, and we never got their mailing list.  
25 They mailed the letter for us. There's a proprietary

1 mailing list. But we think there is something on the order  
2 of perhaps 2,000 more firms. Some overlap between the  
3 medical device manufacturer and the instrument manufacturer.  
4 Companies make both and they would have been on both lists.

5           So we've used round figures. About 16,000  
6 manufacturers were approached to provide information to this  
7 database. But we were particularly concerned about 2,000 or  
8 so manufacturers who were the manufacturers of products that  
9 we at FDA on our own have said these have a potential to be  
10 computerized. So we think there are really only about 2,000  
11 products that--manufacturers that make products that are  
12 computerized, maybe a little bit more than that. And we  
13 initially had a list of those that we concentrated on.  
14 We've tracked exactly how many of those manufacturers have  
15 we heard from, and we've heard from the vast majority of the  
16 2,000. There are less than 100 that we can't find, but they  
17 probably never were in the business, they went out of  
18 business years ago, et cetera.

19           We have the Health Industry Manufacturers  
20 Association, which is the major manufacturers association,  
21 represents 90 percent of sales by dollar volume, and all of  
22 their members who make these kind of products have reported  
23 to the database. So I think we are--of the products that  
24 we're concerned about as being computerized and might be  
25 vulnerable, I think we have practically all the

1 manufacturers represented.

2           There are a few companies that I know of--I can  
3 name a few--that we would still like to get their  
4 information. We don't have it. I'm not sure economically  
5 they're viable and will ever have the right information for  
6 us.

7           MR. WILSON: Well, and then just--you may have  
8 answered the question earlier, but are these just U.S.  
9 manufacturers or--

10           DR. SHOPE: No.

11           MR. WILSON: There are foreign manufacturers as  
12 well?

13           DR. SHOPE: Of that 13,000, about 7,000 of them  
14 are foreign manufacturers.

15           CHAIRMAN FLETCHER: Are there any other questions  
16 or discussions by the committee?

17           Tom, thank you--oh, do you want to question Tom?

18           DR. LIPOTI: No, not for Tom. This is on the  
19 update on personnel security screening systems and the  
20 information brought to us by U.S. Customs. I really want to  
21 thank FDA for this update because it was a lot of new  
22 information that, really, I didn't know.

23           I am somewhat concerned about U.S. Customs in the  
24 fact that they are self-inspecting. In other words, the  
25 states don't have any oversight except that they're

1 voluntarily letting us know when these items are placed in  
2 our state. And so the only oversight on the use of this  
3 equipment is through FDA's choice on whether they follow up  
4 on any of these systems once they're manufactured.

5 I know that the Department of Energy doesn't have  
6 a particularly good track record with their self-inspection  
7 program, and I am somewhat concerned with any federal agency  
8 having its own oversight.

9 Now, TEPRSSC has absolutely no jurisdiction in  
10 this area, so I'm not going to make a motion on this. But I  
11 just want it to be on the record that we are concerned over  
12 continued oversight on the use of these very big toys and  
13 systems containing radioactive materials.

14 CHAIRMAN FLETCHER: As a fellow state regulator, I  
15 understand exactly what you're saying. I believe that this  
16 matter has already been surfaced at the CRCPD, and I think  
17 that's probably where more action will be forthcoming. But  
18 we do not have a good history of agencies of any kind that  
19 are self-regulating, and some of those who do a very good  
20 job still overlook some things in the operation of  
21 sophisticated equipment that, if they had independent  
22 oversight, they would find. And that's one of our big  
23 concerns.

24 Go ahead.

25 MR. LINDQUIST: For Customs, I agree with you. We

1 are not super-knowledgeable in the area. We have been using  
2 independent consultants. We are working with the state  
3 agencies when we bring equipment in. Texas, New York, and  
4 Florida have been in and looked at our stuff. When we went  
5 to California initially with the large truck X-ray, a team  
6 from CDRH arrived and made radiological measurements to  
7 confirm that it was indeed a cabinet system, although a very  
8 large one.

9 We are very concerned that we do meet the intent  
10 of your laws and regulations. Our commissioner has insisted  
11 that we follow these laws and regulations, and any--I want  
12 to call it--industrial X-ray systems will meet and be  
13 certified and licensed according to each state's  
14 requirements.

15 Now, this is a problem for us because there are a  
16 large number of states with varying requirements, but there  
17 are certain key states that seem to lead, and that is useful  
18 for us.

19 We would like to work with you. We're very  
20 delighted to do that, and it's our intent, showing you this,  
21 that indeed we do work together. In addition, many  
22 manufacturers will show us things and say it meets the World  
23 Health Organization rules. And we look at them and say, But  
24 we're a U.S. Government agency and must follow the rules of  
25 the other agencies.

1           We are by nature enforcing the rules of 400  
2 government agencies. We do not intend to violate any  
3 agency's rules in the health physics area.

4           CHAIRMAN FLETCHER: Thank you.

5           Any other questions, comments, concerns? Dr.  
6 Lipoti?

7           DR. LIPOTI: I want to thank you, Roland, for your  
8 leadership on TEPRSSC. I wrote down three words that I  
9 think describe your leadership, and they are: punctuality,  
10 equanimity, and sensitivity. Thank you very much for your  
11 leadership.

12           CHAIRMAN FLETCHER: I appreciate that. Thank you.

13           [Applause.]

14           CHAIRMAN FLETCHER: It's been my pleasure.

15           MS. KAUFMAN: I think I'd add another "p"--  
16 patient.

17           DR. LIPOTI: I also want to thank FDA, and I wrote  
18 down three words for FDA, and Orhan's the recipient of these  
19 words, being our Exec. Sec.:

20           Openness. You shared with us things that you're  
21 even thinking about and got our opinions, and that was  
22 wonderful. And we can be tough sometimes.

23           Resourcefulness. I don't know how you do all the  
24 things you do given the limited resources you have.

25           And wisdom.

1           So thank you very much.

2           [Applause.]

3           CHAIRMAN FLETCHER: Well, once again, it has been  
4 my distinct pleasure to have chaired this organization.  
5 I've seen growth. I've seen, you know, tremendous  
6 dedication. And I've learned a great deal from each one of  
7 you. So it is with that that I bid you all godspeed.  
8 Please arrive at your destination safely. I will be  
9 reviewing the Web page to ensure that TEPRSSC keeps moving  
10 along and to see what some of the other projects that FDA is  
11 pursuing will do.

12           I know that I'll be here, there, and everywhere as  
13 I continue in the position at Maryland. So, once again,  
14 thank you, FDA, thank you, committee.

15           This meeting is adjourned.

16           [Whereupon, at 1:01 p.m., the meeting was  
17 adjourned.]

**C E R T I F I C A T E**

I, **THOMAS C. BITSKO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script, appearing to read 'T.C. Bitsko', written in black ink on a white background.

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**THOMAS C. BITSKO**