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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TWENTY-SIXTH MEETING
TECHNICAL ELECTRONIC PRODUCT RADIATION
SAFETY STANDARDS COMMITTEE

Volume II

Thursday, September 16, 1999

8:36 a.m.

2451 3 3722 0177

Lincoln Ballroom
Holiday Inn
Silver Spring, Maryland

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
Washington, D.C. 20002
(202) 546-6666

P A R T I C I P A N T S

Roland Fletcher, Chairperson
Orhan H. Suleiman, Ph.D., Executive Secretary

MEMBERS, GENERAL PUBLIC

John F. Cardella, M.D.
Marlene H. McKetty, Ph.D.
William A. Rice, M.D.

MEMBERS, GOVERNMENT

Kathleen A. Kaufman, B.S.
Jill A. Lipoti, Ph.D.
Gregory Lotz, Ph.D.
Jerry Thomas, M.S.

MEMBERS, INDUSTRY

John M. Sandrik, Ph.D.
Steve Szeglin, M.S.
Dennis Wilson

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1 P R O C E E D I N G S

2 CHAIRMAN FLETCHER: Good morning, everyone. As
3 far as we know, there are no announcements to be made this
4 morning that differ from anything we said yesterday.

5 I think all of us have been following the weather
6 pretty closely. It looks like we're dodging the brunt of
7 the storm, but there's still going to be heavy winds and
8 rain about the time we're due to adjourn. So keep that in
9 mind. I don't have all the details on flights, et cetera,
10 but I know there's a scheduled closing of National at 9
11 o'clock. I don't know whether that will continue or not.
12 That's what the weatherman said this morning. How long that
13 will last, I don't know.

14 As far as opening remarks, yesterday I held off
15 because I realized that today would be our last meeting, so
16 I decided to wait until today. One of the things I want to
17 say at the outset is that I feel very honored and I
18 certainly appreciate being selected as Chairman and
19 something of a re-establishment, if you will, or
20 resurrection, re-emphasis, re-energizing of this committee
21 after a six-year absence. And to be placed in that role to
22 me was a great honor, and I sincerely hope that I've
23 fulfilled whatever FDA had in mind when that occurred.

24 But I didn't do that in any way on my own. I want
25 to thank all of the members of the committee--old, new, and

1 returning--for everything that you've done to support this
2 meeting and in all the meetings in the past.

3 And I want to be very specific about that. The
4 new members who are here for the first time, I think you've
5 seen a little bit of what goes on here, and I certainly
6 encourage and, you know, just wish you well and hope that
7 you can have the kind of success and enthusiasm and interest
8 and influence on the future of radiation safety of new
9 devices that we feel that we've had.

10 I'm just going to mention the new members: Dr.
11 Rice, Dr. Lotz--I only have last names here--Balzano--

12 DR. SULEIMAN: Balzano was stuck in Florida
13 because of the storm.

14 CHAIRMAN FLETCHER: Okay. Dr. Sandrik, and Alice.
15 Alice had to leave, I guess because of the weather, I'm not
16 sure, but she's already made a contribution, and I'm sure
17 that her contribution will continue. For those returning,
18 Jerry Thomas, Dr. Marks, Dr. Cardella, Cass Kaufman, Steve
19 Szeglin.

20 Once again, you've already had a flavor of this
21 committee, and I am confident that, you know, everything
22 will continue. What I'm hoping is that this committee never
23 has the kind of absence that it's had, because I think it's
24 very important to the community, and I just want to
25 encourage all of you to keep it going.

1 And now for the people I know best, those people
2 who came in at the same time I did: Jill Lipoti, Marlene
3 McKetty, Dennis Wilson, and--who am I forgetting?--David
4 LaGrande, who is not here. I thank you particularly because
5 we have had some sessions that were very, very enthusiastic,
6 and we've had, I think, a great deal of influence on the
7 direction of regulations and amendments. We've had very
8 intense discussions on the various advisory committees from
9 the onset, and I really appreciate your help and support,
10 and I wish you godspeed. And I know I'll be in touch with
11 Jill and perhaps Marlene, but all of you, please keep in
12 touch the best you can, and I'm sure we'll run into each
13 other at other times.

14 So, once again, thank you for selecting me for
15 this position, and I want to particularly thank Orhan
16 Suleiman and Rick Kaczmarek, who have done tremendous work.
17 They've done a whole lot more than they take credit for in
18 ensuring the success of this committee, and I'm sure they
19 will continue to be involved, and I will continue to be
20 involved with them. But a very heartfelt thank-you and to
21 the FDA overall for everything you've done to support this
22 committee.

23 Enough said.

24 [Applause.]

25 CHAIRMAN FLETCHER: Our first presenter will be

1 Dr. Tom Shope, who will give us a presentation on proposed
2 fluoroscopy amendments.

3 DR. SHOPE: Now we are warming up. Good morning.

4 The purpose of my presentation today is just to
5 give you a brief update on where we are with regard to the
6 work on the amendments to the diagnostic X-ray standard for
7 fluoroscopic X-ray systems. I wish I could stand here and
8 tell you that we've made tremendous progress since last year
9 when we presented in detail the proposals that we were
10 developing to amend the diagnostic performance standard to
11 address some of the concerns about fluoroscope X-ray
12 systems.

13 We have been at work on this all year, somewhat
14 delayed by, I think, diversion of efforts on a number of
15 other pressing issues. So we haven't made quite the
16 progress we would like, but I do want to report that we are
17 still at work. I expect that we will have a Federal
18 Register notice ready to go out of the center to FDA for
19 processing certainly within a month, probably shorter than
20 that, if we're lucky. We do have the draft document almost
21 completed, and so we're making some progress.

22 We've had a lot of discussions in the group about
23 fine-tuning of the requirements since we talked last year,
24 and we've incorporated quite a number of the suggestions
25 that we received from the committee last year.

1 Just let me remind you what we've done on this set
2 of amendments to date, and this really began I think even
3 before 1994 with our concern about the reports of skin
4 injuries from fluoroscopy. And as part of our efforts to
5 address that, back in 1990 we talked with the committee at
6 the meeting in 1990 about some changes to the X-ray standard
7 that would add a maximum exposure rate limit to fluoroscopic
8 systems during the "high-level control mode." That mode of
9 operation up until 1994 had no limits on the amount of
10 system output, and we were concerned about that, along with
11 the increasing output capabilities of systems that were
12 coming into the market, sort of utilizing the tube
13 technology developed from CT for very high outputs.

14 In 1994, we published that final rule, but it
15 wasn't a complete story because it left unaddressed some of
16 the high-level control mode operation issues with regard to
17 pulsed operation.

18 In April of '96, we came to the committee and
19 discussed our concerns about the interventional procedures
20 and the injuries that were resulting from those procedures.
21 In April of '97, two meetings back, we discussed the
22 concepts for the proposed amendments that we were developing
23 and the proposal to publish an advanced notice of proposed
24 rulemaking to gather further input on the concepts for
25 amendments that we were discussing.

1 We discussed that with the committee. The
2 advanced notice was published in December of '97, followed
3 by then, last year at the meeting, a discussion of our
4 proposal in detail. The committee last year supported our
5 going forward with a proposed rule and a notice of proposed
6 rulemaking, and that's the effort that we currently have
7 underway.

8 We continue to have concerns, primarily due to the
9 changes in technology that have occurred. Not only are we
10 seeing the increased tube output capabilities, the
11 capabilities of these systems to deliver long exposures at
12 high currents, but also the very evolving technology in
13 fluoroscopy involving solid state X-ray image receptors and
14 the changes that that technology really demands that we put
15 into the standard in order to accommodate those. Our
16 standard is currently based on the image intensifier tube
17 technology, and in many places, we're finding that word has
18 got to go out of the standard, and we've got to put in a
19 more generic term in order to address these changes. And so
20 we've incorporated those kinds of changes.

21 One of the concerns that we had was the increasing
22 complexity of fluoroscopic systems, the various modes of
23 operation that they were coming out with in terms of digital
24 imaging, digital storage, various modes of operation,
25 labeled various ways by manufacturers, not altogether

1 completely clear as to what the dose impacts of those modes
2 may be. And so one of the things that we talked about in
3 the amendments was to provide some additional information
4 about how these systems operate, what the dose implications
5 are of selecting some of these modes, and the feeling that
6 the users needed right at hand more information of this
7 type.

8 We continue to see increased uses of fluoroscopy
9 in interventional procedures, which was part of the driving
10 concern here that resulted in some of these injuries that
11 we've heard about.

12 We have not heard the last of injuries. We
13 continue to get a few reports through our MDR system or
14 other ways. I don't have an exact scorecard for you, but we
15 do have reports of injuries that have occurred from
16 exposures that happened after our public health advisory in
17 1994 and '95. So we know the word is not totally out, or if
18 people got the word, they didn't pay attention to it, or
19 they may not have thought they were in that situation. So
20 we still think there's a continuing need for this kind of
21 information that we're talking about incorporating into the
22 standard.

23 I think our last comment here about our concerns
24 is this is really not primarily an equipment problem,
25 although making some changes to the standard to provide some

1 features that will enhance the use of the equipment will be
2 beneficial. This is not the complete answer. We do need to
3 continue to work on educating the users about these modes,
4 and we have participated in some efforts along those lines
5 over the last year.

6 Since last year, as I mentioned, we've been
7 working on the requirements, refining our approaches,
8 incorporating some of the suggestions that we got from the
9 committee last year. I wasn't going to take time to go down
10 through a list of those, but if people are really
11 interested, we can get into which ones did we take, which
12 ones did we not take, and why. But I didn't think that
13 would be productive right now since we're not doing a
14 detailed discussion of the standard. It will be shared with
15 the committee as soon as it's ready to go to the Federal
16 Register, I'm sure.

17 Our amendments are basically final, and we're
18 putting the final touches on the Federal Register notice.
19 We still have a couple of editorial issues that we need to
20 work out. And the prime piece remaining for us is basically
21 the economic analysis or the types of analyses that we need
22 to complete to assess the economic impact or the
23 cost/benefit impact or the impact on small businesses. All
24 those things have to be wrapped up into a consideration
25 that's part of the Federal Register notice, and that's the

1 activity that's currently underway.

2 In addition to working on the amendments over the
3 year, we have continued our participation in the Working
4 Group 24 activities of the IEC 62B committee that's
5 developing an international standard for safety aspects of
6 equipment intended for interventional procedures. Bob Gagne
7 has been out representative on that, and I think, Dr.
8 Cardella has been involved in that group as well.

9 The group met again in June and basically finished
10 their work on this standard and sent it off to the IEC for
11 final promulgation and approval, is our understanding of the
12 current status. So we've been paying very close attention
13 to the changes that were occurring in this draft in order to
14 make sure what we're doing in our regulations or our
15 proposed regulations will be harmonized with that, and we
16 think we've managed to continue to do that. And so we're
17 looking forward to the IEC standard coming out and then our
18 regulatory standard being in agreement with that. Some of
19 the similar things that they're doing, we're doing in our
20 standard.

21 Another small effort has been--and I participated
22 in it--drafting of a ICRP report, which is aimed at
23 physicians, and the topic of this is the avoidance of
24 radiation injuries from interventional fluoroscopy, or
25 something resembling that. I think the working title is

1 evolving here. And this is intended to be just an
2 information-type report that gives background techniques,
3 what you should do, and how to avoid some of these types of
4 injuries.

5 Our contribution has been primarily the
6 description of the numbers of injuries that have occurred
7 and what led up to them. So we've been continuing to try to
8 do some educational work along this line as well.

9 Just a brief review of some of the changes that
10 we've incorporated since the last meeting. This may be the
11 most controversial thing left in the standard, and that is,
12 do we use mGy or cGy? We can take a vote on that and
13 probably get a change of opinion the next day on this.

14 Our current thinking is that we will go with the
15 standard approach of using mGy. Although cGy is the thing
16 that mentally converts quickly to the old unit of rad, we
17 think it's time that we assisted people in learning that
18 mGy, 10 of those is the same as one rad, and let's see if we
19 can't make that conversion and use the accepted protocols
20 with the use of the SI units.

21 We have done a good bit of discussion, lots of
22 hours spent hashing this issue out, which is: What do we
23 put in the revised information to user section? Our
24 proposal to you last year was that we were going to propose
25 requiring manufacturers to give a lot of detailed

1 information about the doses resulting from the various modes
2 of operation, incorporating that information as generated
3 from a standard phantom of some sort, and we had some
4 discussions about what kind of phantoms should be used and
5 could we require a standard phantom. Our approach last year
6 had been to let the manufacturer choose the appropriate
7 phantom and describe it in detail.

8 We've backed away from that approach at this
9 point, and I think in our proposal we're going to rely on
10 the display of dose rate and cumulative dose information,
11 which the radiologist or the user of the system will see
12 real time to tell them what the doses are during a typical
13 procedure or during a given procedure, during a given mode
14 of operation. And the reason, I think, for this, although
15 we'd like the users to get some advance notice of what the
16 typical doses would be for the various modes, it looked like
17 it was going to be very difficult to write a requirement
18 that would accomplish what we wanted to do, but would also
19 not end up being a great burden on the manufacturers to try
20 to decide which modes do I have to give information for and
21 how much detailed information.

22 With our proposed display of real-time exposure
23 rate, the user will have right there what's happening at the
24 moment, and so hopefully we will be able to educate the
25 users about what that information means and how to use that

1 and not have to put a lot of effort into trying to hash out
2 what should be in user information for the various modes of
3 operation. And, again, there has always been the question
4 of how useful is this if it gets put on a shelf somewhere
5 and do users really see it ever once the installation is
6 complete.

7 So that's our current thinking, and that's what we
8 are planning to put in the proposal, that we will change
9 some aspect of the user information to give an explanation
10 of what is this user image display of exposure rate for,
11 what's the accuracy of that, that sort of information to
12 explain the new feature, but not to give a lot of detailed
13 information on the various exposures that occur. So that's
14 where we are on that particular requirement.

15 We've taken your suggestion that we ought to
16 mention appropriate service schedules and the warning label
17 that's currently there on the system, on the control
18 console, and so we will incorporate that this thing could be
19 hazardous if proper precautions and service is not
20 maintained.

21 We've continued to talk about the beam filtration,
22 and our current proposal now is a requirement that would
23 require means to add additional filtration at the user's
24 option, basically, a way to select additional filtration if
25 the user wants to apply it, and this feature would have to

1 be available on systems that have the high tube load
2 capability, the kinds of systems that could have the output
3 that could accommodate the additional filtration. So the
4 criteria for whether a fluoro system has to have this
5 ability to add additional filtration at the user's option or
6 selection will be based on a heat-load capacity criteria for
7 the X-ray tube.

8 So those systems that are using interventional
9 procedures where it may be appropriate to add some
10 filtration and they have the tube capability to handle that
11 additional filtration, this would be a required option.

12 We're continuing to look at our maximum exposure
13 rate limit requirements. We're going to revise the current
14 wording in the standard significantly, I think, to make it
15 simpler. And one of the things as an additional requirement
16 that we discussed last year which will address sort of the
17 current loophole, if you will, on the addition of analogue
18 tape recorders to systems and calling that recording and
19 having unlimited exposure rate allowed. The exposure rate
20 limits of 20 R per minute--forgive me for lapsing, but I
21 think it's 88 mGy per minute--will allow that concern to be
22 addressed by implementing a requirement that it imposes the
23 exposure rate limits on any type of analogue recording.

24 The digital recording is still--we haven't
25 developed criteria for the image performance required which

1 would allow one to set maximum exposure rate or maximum air
2 kerma rate requirements in that situation. So it's not
3 totally as one might like, but we are continuing to address
4 that concern. And we feel that having the real-time display
5 of exposure rate will moderate somewhat the tendency to use
6 these systems with very high exposure rates when the user is
7 not aware of that.

8 We also want to make clear that for the existing
9 installed base, we're adding some requirements in the
10 standard that change the performance characteristics of the
11 newly manufactured equipment. And the question always comes
12 up, well, can we retrofit the old equipment? And we want to
13 make it very clear that that's acceptable to FDA, to upgrade
14 the older equipment if that's technically feasible and the
15 user can find a manufacturer who will do that for him.
16 We're adding clarification that users may apply Section
17 1020.30(Q), which is the current section that says users can
18 modify equipment as long as it doesn't result in a conflict
19 with the standard and the equipment has to be so labeled or
20 records indicated of what change has been made to the
21 equipment. So we're explicitly putting that in with regard
22 to the exposure rate limit requirements and for the exposure
23 real-time display and the new timer requirements that we're
24 proposing on the fluoroscopic timer.

25 So if manufacturers can develop retrofit kits or

1 if a user can develop a means to retrofit equipment, as long
2 as that retrofit complies with the existing standard, that
3 will be something that a user would be able to do and
4 implement and not be in conflict with our federal standard.
5 So we think that's going to be a useful feature.

6 We've done a lot of fine-tuning to make sure the
7 intent of a number of the requirements are a little clearer
8 than they were last time, so we've done a lot of editorial
9 work, and in the process realized that we probably need a
10 few more definitions, and we're adding some additional
11 definitions to clarify the intent in several places.

12 So that's my quick status report. I'm hopeful
13 that we will have a Federal Register notice cleared out of
14 the center within a matter of weeks. Don't pin me down as
15 to how many weeks at this point, but we're working hard on
16 getting that done.

17 I'd be glad to answer any questions if people have
18 them.

19 CHAIRMAN FLETCHER: We'll go ahead and entertain
20 questions now because I know the next presentation is
21 somewhat different than yours.

22 Cass Kaufman?

23 MS. KAUFMAN: Kathleen Kaufman. A couple of
24 questions.

25 On the real-time exposure rate that's going to be

1 shown, displayed, will that include--will it compensate for--
2 -for example, if they go into a magnification mode where the
3 exposure rate increases, it will show that and--okay.

4 DR. SHOPE: Yes. There are two requirements. One
5 is that when the foot pedal is depressed, basically, the
6 instantaneous exposure rate is displayed real time. So if
7 you've gone to mag mode and the exposure rate goes up, the
8 display would go up to reflect that.

9 When the exposure is disengaged, either the
10 display will revert or a second display will show, and we
11 don't care how they do it--the cumulative exposure,
12 including any recording that might have been done, spot
13 films or whatever, since the beginning of the fluoro. So it
14 will give you a cumulative count total of where you are at
15 that point in the procedure as well as a real-time display
16 anytime during a fluoro operation.

17 MS. KAUFMAN: So the cumulative is going to show--
18 spot film exposures will be included in there also?
19 Interesting.

20 DR. SHOPE: If they're made with a fluoro tube.

21 MS. KAUFMAN: Okay. Great.

22 My other question was, you were talking about the
23 Group 24 of the IEC. I'm not familiar with those standards.
24 Do those include use-type recommendations or are they
25 strictly equipment performance?

1 DR. SHOPE: There, again, the requirement is meant
2 to be for the manufacturer to make equipment. That's not to
3 say that there are some things in there that we may not be
4 able to reach in our regulatory radiation safety performance
5 standard, but they're typically more performance-oriented
6 than how to use the equipment.

7 MS. KAUFMAN: Okay, because where I'm going on
8 this is I think that a considerable number of the problems
9 that we've seen do have to do with operator training or lack
10 of information. And I'm wondering if FDA has developed any
11 kind of a real plan to distribute that kind of guidance to
12 actual users.

13 I know, for example, the informational notice that
14 went out a couple of years ago on fluoro I think went to
15 hospitals, but is there any thought on actually trying to
16 target those physicians most likely to use fluoro?

17 DR. SHOPE: There have been some discussions about
18 some additional educational efforts. I think the IEC RP
19 report will be useful, and perhaps we can bring that to
20 people's attention once it's available. Orhan's group has
21 also been in some discussions recently about some additional
22 material that might be made available on this issue.

23 So we've been focusing more on getting the
24 standards amended rather than some additional outreach
25 efforts, frankly. But I think that's something that we

1 ought to always keep our goal to further work with the user
2 community to get the message out.

3 MS. KAUFMAN: And I think that might be an area
4 where CRCPD might be able to be helpful because if you all
5 came up with some real informational booklets or whatever,
6 during inspections inspectors could distribute those to
7 actual users. That might be a good resource to get the
8 information to the user.

9 CHAIRMAN FLETCHER: Dr. McKetty? And then Dr.
10 Sandrik.

11 DR. MCKETTY: Marlene McKetty. I had a question.
12 Once the rule is established, then how much time
13 would people have to comply?

14 DR. SHOPE: Our normal process and the way it
15 would apply to this one, I'm fairly sure, is one-year
16 effective date. So we are at the proposed rule stage now.
17 So if we publish our proposed rule, probably with a comment
18 period of 120 days, the public has a chance to comment on
19 that. We have to take those comments, review them, make
20 determinations on how we should change the proposal to
21 become the final rule, publish that final rule with an
22 effective date typically one year in the future.

23 So we're really talking about 2001, probably, for
24 a final rule, optimistically.

25 CHAIRMAN FLETCHER: Dr. Sandrik?

1 DR. SANDRIK: John Sandrik. I'd just like to
2 clarify or get a clarification on the acceptability to
3 modify existing equipment. My understanding of most of
4 these rules is that they would apply to systems manufactured
5 after some date. But are you saying that if somebody should
6 choose on their own to update equipment because they think
7 it's a good thing to do, that would be allowed, but none of
8 these would require that old equipment be updated for some
9 of these rules?

10 DR. SHOPE: That's right. Existing equipment is
11 not touched by this rule, but our existing standard in
12 1020.30(Q) says a user may cause equipment to be modified as
13 long as it doesn't result in a non-compliance with the
14 standard. And what we're interpreting that is with the
15 existing standard that's written today. So you can take an
16 old piece of equipment and have it modified to meet the
17 current requirements.

18 The purpose here is to allow systems that have
19 this limit on entrance exposure rate maximum at 5 R
20 currently to be able to go from 44 mGy to 88 mGy per second,
21 as well as to allow the new type of timers to be installed
22 as opposed to the "rings in five minute" type timers that we
23 currently have.

24 CHAIRMAN FLETCHER: Jerry Thomas?

25 MR. THOMAS: Tom, user education I think is very

1 important. In another part of the FDA world, specifically
2 mammography, we have very prescriptive training requirements
3 for the operators, interpreters of procedures. And I
4 realize that's not part of what's coming out.

5 What thought process has been going on within your
6 group looking specifically at making specific requirements
7 for the use and operation of these pieces of equipment,
8 specifically very high dose--the higher-dose fluoroscopy
9 systems?

10 DR. SHOPE: Well, frankly, we haven't been
11 considering that because that's not within FDA's authority
12 to make requirements of that sort. Mammography is courtesy
13 of a very special legislative act of Congress that gave us
14 that authority.

15 For X-ray equipment, we only have the authority to
16 regulate the manufacturer. We can continue, of course, to
17 make public health recommendations or recommendations to the
18 user community, but other than mammography and a little bit
19 on user reporting for medical devices and a little bit on
20 the clinical evaluation, clinical trial-type regs, we don't
21 at FDA have the authority to tell users what to do.

22 CHAIRMAN FLETCHER: Dr. Suleiman wants to add to
23 that.

24 DR. SULEIMAN: Let me throw in a couple of things.
25 Let me clarify with mammography, that's a completely

1 different statutory responsibility and came with actually
2 some funding.

3 CHAIRMAN FLETCHER: That always helps.

4 DR. SULEIMAN: That's helped, and our proximity to
5 some of that has helped as well.

6 The center has committed some funding this year,
7 actually, for some outreach activities related to
8 fluoroscopy, and education is education. We're targeting
9 the states to help target, you know--I think at this point
10 we're thinking of the cardiology community is probably the
11 one that probably needs the most focus. But this is still
12 in a very, very embryonic phase in terms of how we're going
13 to conduct this activity.

14 And I also think that as these regs move forward
15 and they get attention and publicity, it would only seem
16 natural--not just FDA but probably other organizations as
17 well would take this opportunity to mount some of these
18 educational opportunities because, clearly, there is an
19 educational component of this problem.

20 CHAIRMAN FLETCHER: Dr. Cardella, then Dr. Rice.

21 DR. CARDELLA: John Cardella. More a comment than
22 anything, Tom. You mentioned that the equipment regulations
23 do not represent the entirety of the problem, and although
24 the equipment is becoming very sophisticated and very
25 capable of creating deterministic effects, skin burns and

1 that sort of thing, the big problem in my mind is the
2 extension of the user community outside of individuals
3 formally trained in the use of such equipment.

4 I guess I would echo Cass' comment and Jerry's
5 comment as well that even if the FDA is not the correct body
6 to do so, the equivalent of a fluoroscopy driver's license
7 ought to be considered at some level. In our deliberations
8 in the IEC committee, there are European countries--and I
9 think the European Community in general is moving toward
10 licensure and certification of operators of fluoroscopy.

11 In this country, that would involve getting to the
12 cardiology community, the orthopedic surgery community,
13 neurosurgical community, gastroenterologists, pulmonolo-
14 gists. It's a large group that's using fluoroscopy with,
15 you know, less than complete training. And although the
16 equipment is very sophisticated and provides a lot of
17 information about the instantaneous dose rate and the
18 cumulative dose rate, many of the users of that equipment
19 won't know a Gray from a grocery bag. And I think somebody-
20 -maybe not the FDA--ought to be looking toward that, . beyond
21 an educational effort, frankly, a regulatory or licensing
22 effort.

23 DR. SHOPE: I just might comment that, of course,
24 in the U.S. under our system that's a state prerogative or a
25 state responsibility with the practice-of-medicine-type

1 activities. And so I think there is a chance here to work
2 cooperatively with the CRCPD to encourage that kind of
3 activity or consideration on the part of the state
4 governments.

5 CHAIRMAN FLETCHER: Dr. Rice?

6 DR. RICE: I think that the retrofit proposal is
7 very noble from the FDA. I'm wondering how cooperative,
8 though, the manufacturers and X-ray companies will be with
9 this proposal.

10 On a personal note, when I tried to retrofit my
11 mammogram unit, I was told it would cost so much that I
12 might as well get a new unit. And I'm wondering whether or
13 not that would be a driving force. I mean, salespersons are
14 salespersons first, and they don't always--they're not as
15 helpful about, you know, upgrading your systems, at least in
16 my experience.

17 DR. SHOPE: Well, I think that's a good question.
18 We haven't really entertained a discussion with the
19 manufacturers on how likely they would be to offer such
20 equipment or such modifications to existing equipment. But
21 I think there is a strong potential that if the user
22 community desires that and that becomes well-known, these
23 are not complex, complicated retrofits. They generally
24 don't involve the mechanical aspects of the system. You're
25 not going in and changing its mechanical operation or

1 anything like that. These are typically electronic
2 circuitry add-ons or modifications. I think in general in
3 our discussions, we think these kind of add-ons are not that
4 complex or complicated to do.

5 At this point, we wouldn't be surprised to see
6 some entrepreneurial effort either on third parties or with
7 regard to the OEMs to do this kind of thing, provided that
8 they can provide the user the assurance that it continues to
9 meet the current requirements in the standard. Because once
10 these modifications have been made, it's the user that
11 becomes responsible for the equipment and its performance at
12 that time. He sort of takes on some of the role of a
13 manufacturer in having these modifications done. So if
14 there's a problem with the equipment, FDA would come back or
15 the state would come back to the user and say: You had
16 something done to your equipment, it's not meeting
17 standards, you need to get it fixed. We wouldn't turn to
18 the manufacturer. I think that would be a contractual
19 relationship between the user and whoever he had modify the
20 equipment for him.

21 CHAIRMAN FLETCHER: Dr. Lipoti, and then Cass.

22 DR. LIPOTI: I'm a little concerned because the
23 rule proposal will come out a time when this group won't be
24 together to think about it collectively. We seem to be much
25 better at providing comments on regs when we're all together

1 than when we're all separate in our offices and have piles
2 of paper on our desks and we don't always get to it.

3 So I was wondering if you might organize some sort
4 of stakeholder group, a kind of focus group for you, once
5 the regs are in the Federal Register to be able to obtain
6 comments from people thinking about it collectively. And I
7 like the list of individuals that Dr. Cardella mentioned who
8 are all parts of the user community and who might
9 synergistically come up with even better comments than they
10 would have on their own. So I'd just like to throw that out
11 as an opportunity.

12 That would also be an opportunity to begin to
13 plant in people's minds the idea of a fluoroscopic driver's
14 license. You talked about how the states are really the
15 ones who would be able to effect that change. But I will
16 tell you that the state radiation control programs, while
17 they may desire it very much, simply don't have the
18 political clout to get that through a legislature. The ones
19 that can get it through the legislature are the people who
20 are being regulated. And it may sound strange that they
21 would like to be regulated, but, in fact, those that are
22 more highly trained would like to exclude the others from
23 that field.

24 And so it may be an opportunity to bring together
25 some sort of groundswell of support to make it possible for

1 our efforts in the state to be successful.

2 CHAIRMAN FLETCHER: Cass?

3 MS. KAUFMAN: I just wanted to have the record
4 show that California is, I believe, the only state that
5 currently does have a fluoroscopic permit required for any
6 physician who uses or supervises a fluoroscope. While
7 there's certainly lots of room for improvement in our
8 program, at least I think it is a start.

9 I guess what concerns me is when--wasn't it in the
10 '70s or something, when FDA recommended certification for
11 radiographers, and that didn't seem to have any impact on
12 states, you know, requiring certification. So I'd like to
13 encourage FDA to come out with something similar for
14 physicians using fluoroscopes, but I'm not sure how
15 effective it would be.

16 I have a question about the SI units. Some years
17 ago, when FDA went to the SI units, there had originally
18 been a proposal that would have resulted in a reduction of--
19 I mean an increase in permissible exposure rates. And I
20 just would like you to clarify that with these changes that
21 still will not occur, they will still have to comply with
22 the original exposure rates in R per minute.

23 DR. SHOPE: That's right. We'll be dealing with
24 88 mGy per minute as opposed to 100.

25 MS. KAUFMAN: Good.

1 DR. SHOPE: Forty-four instead of 50.

2 CHAIRMAN FLETCHER: Thank you, Tom. Or do you
3 have more?

4 DR. SHOPE: I'm finished. I'm responding to
5 questions.

6 CHAIRMAN FLETCHER: Thank you, Tom.

7 Our next presenter will be Dr. Gagne, who will
8 give us a presentation on computed tomography fluoroscopy.

t1B 9 DR. GAGNE: Just a second here.

10 Well, I guess continuing along the same vein, to a
11 certain extent, what I'm going to be talking to you about
12 today is fluoroscopy, but fluoroscopy in a different--is
13 there a problem?

14 CHAIRMAN FLETCHER: I think you need to stay close
15 to the mike.

16 DR. GAGNE: What I'm going to be talking to you
17 about today is fluoroscopy, but fluoroscopy in a different
18 manner. And it's not really associated with any amendments
19 or rulemaking decision at this point. I've been working
20 with a particular focus group at the center on this
21 particular topic for the last year or so, and Rick Kaczmarek
22 suggested that maybe this might be a good time to give you
23 at least a status report of what's happening here with
24 respect to this particular type of equipment.

25 In fact, I think to a certain extent it's sort of

1 an interesting problem, if you want to call it a problem--
2 I'm not sure it's a problem--because of the following thing:
3 It's a situation where you have a piece of equipment that's
4 been around for a long time, computed tomography, and you
5 find a new way to use the equipment. And so you have
6 radiation protection and control aspects associated now with
7 a new application for existing equipment. And so when you
8 think about it, then, you start to think, well, how do the
9 regulations and so on apply to this new application of this
10 existing equipment? Does it fit? Doesn't it fit, et
11 cetera, et cetera? And are there concerns of things that
12 come up with the new use of this equipment that are
13 different than what were present with respect to the
14 existing equipment? I'll explain that as I go along here.

15 And so my intend today is to just give you a
16 description of this new application for existing technology
17 and give you a little bit of a flavor in terms of what kind
18 of dose levels we're talking about and what sorts of things
19 we're doing to try to incorporate some radiation protection
20 and control with respect to this new application.

21 Now, we've had a special interest particularly on
22 what I'm calling CTF, which is computed tomography
23 fluoroscopy, because it is a new application for this.
24 There are about, I believe, seven different manufacturers
25 that provide this feature, so we're not talking a lot of

1 manufacturers here.

2 Also, the implementation of it, I don't know what
3 the numbers are with respect to the number of installations
4 that have this feature of their systems, but I'm sure that
5 it's a fairly small number.

6 Clinically, you use CT fluoroscopy usually in a
7 situation where you're talking about seriously ill patients,
8 and it's used in an interventional sort of screening. For
9 example, you might be doing biopsies with a needle using CT
10 fluoroscopy, or you might be draining an abscess or
11 something like that.

12 In fact, Barry Daly--I have a reference there--has
13 a very good reference article on the use of this particular
14 modality with respect to the clinical aspects of it. But
15 the point I'm trying to make is the patient population
16 demographics and the kinds of procedures that are being used
17 and how many of these systems are out there available.
18 We're not talking about--if there is a public health
19 concern, it's a small public health concern at this point.

20 Now, you've heard Tom talk about amendments we
21 proposed with respect to traditional fluoroscopy, and,
22 really, we've had an interest in fluoroscopy for a long time
23 as Tom has pointed out. And pieces of that interest
24 included changes in equipment performance, but, of course,
25 there were also pieces that were associated with the user.

1 And that piece associated with the user was to try to get--
2 to sensitive the users to the exposure levels and the
3 possibility of radiation injuries, particularly in terms of
4 interventional fluoroscopy.

5 When we did a pre-market review of this new
6 device, CTF--this was about four or five years, ago,
7 actually, when the first one came in--we saw aspects of the
8 use of this equipment that were similar to the sort of
9 things that we had seen in terms of interventional
10 fluoroscopy. And so, of course, it piqued our interest to
11 be sure that we kept up to speed here in terms of what was
12 happening.

13 Just to give you a general description, for those
14 of you that aren't aware of or know what this particular
15 device--how it operates, what you have is a computed
16 tomography system, and what you're doing is you're taking a
17 continuous scan of a section of the patient.

18 For example, if you were to do 50 seconds of CTF
19 and the X-ray tube has a rotation time of one second, that
20 would correspond to the X-ray tube going around the patient
21 50 times. All right? And the way you get fluoroscopy is
22 that you get cross-sectional images, of course, in CT, but
23 the fact that you're going around the same place many, many
24 times then means that you can start updating after the first
25 scan is done at a rate of about six to nine images per

1 second. So basically you're getting, if you want--and I put
2 "real time" in quotes because it's not a frame rate that's
3 the same as fluoroscopy. It's not 30 frames per second.
4 It's only on the order of six or nine. And so there's going
5 to be some movement that you're not going to be able to see
6 with this. But basically what you're seeing is real-time,
7 cross-sectional images of the patient.

8 Now, if the patient doesn't move--this is also a
9 problem, of course, in interventional if you have the beam
10 only in one position. One strip of skin is going to get the
11 full brunt of the radiation exposure during the procedure.

12 So the first thing that comes to mind, then, is:
13 What kind of dose descriptor should you use in order to
14 describe the dose for this particular new application of CT?

15 When you think about fluoroscopy, one usually
16 thinks about entrance dose because what we're concerned
17 about--if there is a concern here, we are concerned about
18 the radiation levels, of course. But if we're thinking
19 about skin injury, then we're thinking about the dose at
20 entrance to the patient. And you usually think about the
21 dose in terms of a rate, so you think about entrance
22 exposure and you think about rate.

23 Now, there are some problems when you try to
24 describe the dose that's present to the patient when you do
25 CT fluoroscopy, because people are used to using CTDI, which

1 is computed tomography dose index. But that dose descriptor
2 is a procedure-dose descriptor. It corresponds to doses
3 that you would get if you took a scan, stepped by the slice
4 thickness, took another scan, stepped by the slice
5 thickness, and had 14 slices and then looked in the middle
6 for the average dose.

7 That's not the situation here because we're not
8 stepping between the slices. So CTDI is not necessarily the
9 right thing to measure here. In fact, it overestimates the
10 exposure.

11 So what is the appropriate dose descriptor? My
12 feeling is that it's the estimate of the dose at the center
13 of the dose profile.

14 Rick, do we have a pointer or anything around
15 available?

16 [Pause.]

17 DR. GAGNE: Use a computer. Good idea.

18 This is a cartoon caricature, then, of the CT
19 system. This is my patient here, the yellow cylinder, and
20 what you have is you have an X-ray tube going around that
21 patient, third-generation scanner, and you have a strip of
22 skin denoted by the white which is being irradiated during
23 the fluoroscopy part of this procedure. And if I was to
24 look at the dose profile from Position A to Position B here,
25 what I would find is that it would be slowly, gradually

1 going out, but then it would be most intense at the center
2 of the beam, at the center of the strip, and then down.

3 What I'm saying is that in this particular case
4 the thing that you might want to use to describe dose would
5 be the average value probably around the peak here. That
6 would be the best descriptor of this at the surface because
7 we're trying to do descriptor fluoroscopy.

8 Now, if you wanted to do that, it's a little
9 difficult to do that because the beam sizes in fluoro, in CT
10 are on the order of 10 millimeters, and so you have to have
11 devices that are going to sense the exposure or the dose at
12 the center of that profile within a 10-millimeter area. So
13 you have to have something that is looking down in here.

14 And if you do the CTDI, then what you're doing is
15 you're bringing in dose from the outside of these tails into
16 the measurement, and that could actually effectively
17 overestimate the dose.

18 So there are things that make this measurement a
19 little bit complicated, including the beam profile. Also,
20 there are things associated with technique factors on the
21 system, like the tube current. You can have a low tube
22 current, a high tube current, or whatever. So when you
23 express the dose, you have to be sure that you express it
24 with respect to what the conditions were in the machine.

25 Now, the other thing is that since the beam--this

1 thing is sticking. Just a second here.

2 Since the beam is going around the patient, if I
3 want to get the exposure at a point, it's really going to be
4 the exposure in one minute, for example, not per, because
5 the exposure will be changing continuously as the beam goes
6 around the patient. These are really all kinds of technical
7 things. What I'm trying to say is that to get an
8 appreciation for dose, you have to be a little bit careful
9 on how you do the measurement.

10 Now, what I'd like to share with you now is dose
11 values which are close to being under the conditions that I
12 just said, which is it's the value of exposure expressed in
13 Roentgens in one minute for a 50 mA tube current for the
14 seven different manufacturers. And what we're talking about
15 then is that the Roentgens in one minute is anywhere on the
16 order of from 26 to 43 R per minute.

17 Now, I have two references here. In three of
18 these, the information came from pre-markets and middles,
19 and the other was from a paper at a AAPM annual meeting.
20 And we don't have the information--at least I don't--
21 associated with the other three manufacturers. But, at any
22 rate, this gives you an appreciation of the levels that
23 we're talking about here with respect to rate.

24 These measurements were made in a phantom.
25 They're close--you read it at the surface or one centimeter

1 in, and there is some scatter that has been included,
2 probably not appropriately, so they may be a little bit of
3 overestimate. But I think the conclusion you can make with
4 this is that if you are talking about a situation where you
5 spend a lot of time doing CT fluoroscopy, just like
6 interventional fluoroscopy, there may be circumstances where
7 there's a potential for a high exposure to a particular
8 strip of skin.

9 So what are the skin dose implications? I have
10 the good news on your left and the bad news, if you want to
11 call it that, on the right.

12 We haven't had any reports of injuries associated
13 with this particular modality, this new use of CT. And, in
14 fact, if you move the patient during the interventional
15 procedure, of course, then you have a lot of skin sparing
16 just by doing that. And, in fact, Barry Daly at the
17 University of Maryland Hospital has indicated that in some
18 of the clinical procedures there is some of that going on.
19 And so the 20 or 30 or 40 R in one minute is not occurring,
20 in fact, to one strip of skin.

21 And just like regular fluoroscopy, if you have
22 discontinuous intermittent use of this technique so that you
23 go on, you place the needle further in or do some
24 positioning without fluoroscopy, then you cut down on the
25 total exposure.

1 On the other side is the extrapolation of patient
2 dose. Now, this is patient dose using a phantom,
3 measurements by Nawfel (ph) in that AAPM paper, where he
4 quoted that the mean value was 74 cGy, and for the purpose
5 of this particular talk, you can make a one-to-one
6 correspondence between Roentgens and cGy, with a mean of 74
7 cGy for the procedures that he monitored during his CT
8 fluoroscopy application, with a range of 4 to 490 cGy.

9 And as I said, there was scatter. This was not
10 really the dose descriptor that I would prefer to use, and
11 so there may be a little bit of an overestimate here--well,
12 it's more than a little, with respect to what those values
13 of dose are.

14 So regulatory-wise, how does CT fluoroscopy, how
15 are they subject to the regulation? Well, they're a medical
16 device and so there are pre- and post-market reviews,
17 510(k), product reports, the performance standard, et
18 cetera. You know, and the diagnostic performance standard
19 has some particular requirements for X-ray fluoroscopy and
20 has particular requirements for X-ray computed tomography.

21 But the problem is: Is this X-ray fluoroscopy or
22 is this X-ray CT? It's a combination of the two of them.
23 And it really isn't the only device that's similar to this.
24 There are other devices very similar to this where it's not
25 really one or the other; it's a combination of two of them.

1 And so when you look at the requirements in the
2 performance standard for CT or fluoroscopy, it's difficult,
3 if not impossible, to fit it to CT fluoroscopy. So it's not
4 clear exactly how the regulate appropriately with respect to
5 the performance standard. We still have that under
6 discussion.

7 We have a small working group within the center
8 with a specific focus on this particular application, and we
9 have some short-term actions that we've taken associated
10 with labeling and guidance and so on, and long-term actions,
11 we don't know what that will be, and I'm going to describe a
12 little bit to you what we've been doing in that focus group.

13 Really, our main concern--the focus group right,
14 the main concern that we have is that there may very well
15 be, just like at the beginning of the interventional
16 fluoroscopy stage, a real lack of knowledge of the dose
17 implications of this mode of operation. It's very, very
18 similar to interventional fluoroscopy. If you put all the
19 radiation in one port, if you put all the radiation in one
20 strip of skin, you have to know what you're doing.

21 So our approach right now is really to try to
22 sensitize the user to this potential high patient dose
23 through the use of operator information, and at this point
24 we're really in the information-gathering stage. We're
25 keeping our eyes and ears open. As I said, we don't have

1 any reports of injuries at this time associated with this
2 device.

3 So one of the conclusions of the actions that the
4 focus group wanted to do is we wanted to make sure--we
5 thought there was a need for appropriate and consistent dose
6 information to the user. And whether we can get that to the
7 user through pre-market decisions, like 510(k), or product
8 report reviews with respect to the performance standard,
9 we'll pick one of those avenues, whichever is the most
10 productive. We've actually done this in 510(k) review, but
11 now some of them--we haven't been consistent in implementing
12 that, and so we have to look at other alternatives to try to
13 get this information to the users.

14 In fact, as far as testing is concerned, there are
15 going to be aspects of CTF that will be incorporated into
16 the next NEXT procedure, and in this particular case, it
17 will either be demographic information--and I think there
18 will actually be some test data being taken.

19 Long-term-wise, as I said, we're really in an
20 information-gathering stage. We're just trying to talk to
21 people about it, get people sensitive about it, and keeping
22 our eyes and ears open. We're interacting with
23 professional, technical, and state organizations on this
24 particular aspect. And we're not sure at this point what
25 new regulatory constraints should be put on this particular

1 device. We really need to wait until we get more
2 information here about how this all comes out.

3 But it's a really rapidly changing field,
4 particularly when you think about the fact that multi-slice
5 CT is also very much on the horizon and being used right
6 now, and there may be an application for CT fluoroscopy
7 using multi-slice CT systems.

8 So, in summary, I wanted to give you a little bit
9 of a flavor about some of the things that we run into where
10 we have a new application for an existing technology.
11 Sometimes it's difficult to regulate this type of equipment
12 appropriately. And in this particular case, I hope I've
13 given you some of the reasons why we think we have a special
14 interest here, and our short-term course of action is really
15 more to gather information and try to sensitize the user
16 with respect to the use of this particular equipment.

17 Thanks. Any questions? I'd be glad to answer
18 any.

19 CHAIRMAN FLETCHER: We'll entertain questions at
20 this time. Cass Kaufman?

21 MS. KAUFMAN: Kathleen Kaufman. Several
22 questions. One is you were talking about patient motion,
23 but if we're talking about a 10-millimeter thickness slice,
24 and if they're looking for--if they're obtaining a biopsy,
25 it would seem to me that there would still be a fairly--some

1 portion of that 10-millimeter slice that's always going to
2 be within the beam, as I say, particularly if you're
3 looking--if they're doing biopsies with it.

4 DR. GAGNE: Yes, I think it would depend on the
5 clinical circumstance and whether the patient is moved or
6 not.

7 This particular technique is effectively to look
8 at a biopsy needle as it moves towards a site that's in the
9 field of view, and so you wouldn't necessarily be changing
10 the field of view very much. You'd be changing the needle.
11 And so, yes, I think--but Dr. Daly has expressed the view
12 that there are some clinical circumstances where you may, in
13 fact, have to reposition the patient. And if you do that,
14 then you pick up the skin sparing pretty quickly because the
15 beams are so small, if you move just a little bit, then
16 you're off of that one piece of skin that's been getting all
17 of the radiation.

18 But I think in the normal circumstance you would
19 probably find that there would not be a lot of patient
20 motion going on.

21 MS. KAUFMAN: Usually that's not a goal when
22 you're doing a biopsy, to have a lot of patient motion.

23 DR. GAGNE: Right.

24 MS. KAUFMAN: And I'm presuming that when they do
25 the actual insertion of the needle, for example, for a

1 biopsy, they're doing it under real time. So I'm wondering,
2 Have you looked at operator exposure to extremities and that
3 kind of thing?

4 DR. GAGNE: Yes. I didn't spend a lot of time
5 talking about that, but obviously that is a concern because,
6 like any interventional procedure--and I'm sure John can
7 comment on this, also--there are circumstances where you
8 might have to use some tools in order to get your hand out
9 of the beam. And there has been quite a few papers that
10 have been written with respect to tools that can be used for
11 this particular procedure to get the operator's hand out of
12 the beam.

13 Interestingly enough, the first submittal from--
14 the first manufacturer of this device sent a videotape where
15 you could clearly see the operator's hand in the beam, in
16 the cross-sectional images.

17 MS. KAUFMAN: Yes. And on the next NEXT survey,
18 normally when we do those, we're looking at multiple scan
19 average dose, the MSAD. Will it be the same procedure for
20 this? Will there be a calculation difference? And normally
21 we have the probe in the middle of the phantom.

22 DR. GAGNE: Well, I don't know if we want to get
23 into those details here, but we have the experts with
24 respect to NEXT in the audience here. If they want to
25 comment, they may do that. Stan and Rick Kaczmarek are

1 here.

2 MS. KAUFMAN: I guess the main reason why I'm
3 asking is because in case we encounter this in the near
4 future, I would like to have some idea as to what kind of
5 testing we might do in order to provide you all with
6 information.

7 DR. GAGNE: I think the main thing to be a little
8 bit cognizant about is that when you take the CTDI
9 measurement, that is not the dose descriptor that's
10 represented here. In my experience, I've taken a look, in
11 fact, at some data, since I have a lot of CT dosimetry that
12 I've taken many years ago. If you take the CTDI at one
13 centimeter inside the phantom, you can expect that the
14 estimate from the CTDI compared to what you get at the
15 exposure at the surface is probably off by a factor of two.
16 It overestimates by a factor of two, close to that. So you
17 have to be a little bit careful on how you do that.

18 Stan, I don't know if you want to make a comment
19 or not.

20 DR. STERN: I'm Stanley Stern. We've just drafted
21 a new protocol for doing the CT NEXT survey in the year
22 2000, and we submitted it to the NEXT Committee of CRCPD,
23 and they'll be meeting here in Rockville next week. So it's
24 in draft form.

25 We are changing the measurement procedure a bit to

1 get a reasonable estimate of skin exposure, and it's to be
2 decided. But it's in the works.

3 MS. KAUFMAN: To measure this, you would still use
4 the pencil probe, just like we do for--

5 DR. STERN: Yes. We're going to use a pencil
6 probe, but we have--different aspects of that measurement
7 we're changing.

8 CHAIRMAN FLETCHER: Dennis, and then John.

9 MR. WILSON: Dennis Wilson. I found an article in
10 yesterday's USAToday, a report I guess that came out,
11 according to this, yesterday from the doctors at the Harvard
12 Medical School and Children's Hospital in Boston where they
13 are using computed tomography to look at appendicitis in
14 children. Is that another use for this? It looks like they
15 looked at 108 patients and found it was 94 percent effective
16 in diagnosing appendicitis versus using standard X-rays.

17 DR. GAGNE: No. I think in this particular
18 application you're using this particular application for
19 situations where you're trying to get some dynamic
20 information. And so you're really looking for things like
21 you're placing needles or objects in a particular position
22 within the patient, and you want to see what happens when
23 that thing is moving. And so you have information in the
24 temporal domain, in the time domain. And so, no, I wouldn't
25 think that would be the case.

1 Now, in this particular case, I think you might be
2 talking about a situation where you're doing either spiral
3 CT or regular CT. I don't know which. But it wouldn't be,
4 I don't think, germane to this particular application.

5 That's not to say that pediatrics aren't
6 necessarily subject to some of these procedures if they're
7 pretty ill or have something that needs to be taken care of,
8 if that was your concern on the pediatric side.

9 CHAIRMAN FLETCHER: Dr. Cardella?

10 DR. CARDELLA: John Cardella. Dennis, the article
11 that you refer to is purely diagnostic CT. They're using
12 that as a modality to diagnose appendicitis, not treat it.
13 So it's done in the conventional--either helical-slice or
14 single-slice mode, depending upon the machine. It's not
15 fluoroscopically determined.

16 Bob, I had a question. I wanted to sort of
17 compliment you on taking a very tough topic and making it
18 clear. In Slide 6, line segment AB, is that on the
19 patient's surface, or is that a central axis line?

20 DR. GAGNE: It can be anywhere, but I'm really
21 intending it to be on the surface.

22 DR. CARDELLA: On the surface, okay. And all I'm
23 trying to show there is that you get scatter on the outside
24 wings of that particular profile.

25 Then on the seventh slide, the 120 KVp at 50 mA,

1 if I remember my CT details, that's pretty much of a chest
2 technique. And when they do CT scans through the abdomen,
3 the mA is a little higher, if I'm not mistaken. That would
4 then make these self-reported Roentgen in one minute numbers
5 higher, would it not?

6 DR. GAGNE: Well, that's why I was trying--let me
7 reinforce what I was saying with respect to the technique
8 factors. The data that I presented in this particular slide
9 is really for 50 mA. It turns out that when they implement
10 this on a CT system, they use, let's hope, relatively low
11 tube current because you don't--for one thing, you don't
12 want to blow the tube out. I mean, you can't pick 300 mA
13 and run it for 3 minutes, for example. I don't know what
14 the tube housing capability is, but I think they're running-
15 -most of the systems that I've seen in terms of the
16 available mAs with this particular technique, I think the
17 highest mA I saw available was 100. They're either 25, 50,
18 75, or 100.

19 But the thing to remember is that this set of data
20 that I'm giving here in this particular table is really only
21 for the 50 mA position. If you used 100 mA, then you would
22 have to double all these numbers by two, obviously. And if
23 you used 25 mA, you would then halve all the numbers by two.

24 So you have to be a little bit careful here in
25 terms of when you make the dose measurement to specify

1 particularly the tube current that was associated with it,
2 because if you run at a higher or lower tube current, you
3 have different values.

4 That's a little bit different than fluoroscopy,
5 but you also have the possibility of having different tube
6 currents in fluoroscopy, although it's not as obvious. It's
7 usually an R position 1 or position 2 or something like
8 that.

9 CHAIRMAN FLETCHER: Dr. Sandrik?

10 DR. SANDRIK: John Sandrik. I understand you
11 haven't been followed this in a detailed way, but even are
12 there trends maybe apparent at some sites that you've been
13 working with that maybe doses are coming down as familiarity
14 is gained? Or it's determined that, you know, it's not a
15 diagnostic image you're looking at, and particularly if
16 you're trying to image a needle, it's not a difficult
17 contrast problem. You know where your target is.

18 Is there any indication that considerably lower
19 than typical CT doses would be used as you might be familiar
20 under the CTDI or something?

21 DR. GAGNE: I really don't know the comparison
22 with normal CT, but you're right, obviously, that in this
23 sort of a circumstance where you're talking about such a
24 high contrast object, it would seem that instructions for
25 use--it would be nice to have instructions for use with

1 these systems that indicated those sorts of things and
2 recommended low tube currents for doing these procedures.
3 And if that happened, it may actually end up that the dose
4 may be lower than normal CT, but I don't think so because
5 not if you don't have the patient moving. If the patient is
6 not moving, you're getting that one strip of skin getting
7 the full brunt, whereas--unless you're talking about normal
8 CT biopsy. If you're doing biopsies with normal CT, then it
9 may be comparable.

10 DR. SANDRIK: Thank you.

11 DR. GAGNE: I confused the issue.

12 CHAIRMAN FLETCHER: Dr. Lipoti?

13 DR. LIPOTI: In Slide 10, you talk about what
14 regulations are going to be applied, and you say that it's
15 difficult to apply the CT standards to this thing which is
16 half-fluoro, half-CT, and it's difficult to apply the fluoro
17 standards to this thing. And this morning, just before you,
18 we heard about the new fluoro standards that you're going to
19 propose.

20 Will it be possible for you to get real-time dose
21 information to the physician who's using this piece of
22 equipment with the new regulations? Will that piece of the
23 new fluoro proposal be able to be used here?

24 DR. GAGNE: We had not intended it to change or
25 delay the other amendments, the other proposals to handle

1 this particular case, for a couple of reasons. One, this is
2 something brand new that's really in the steep part of the
3 learning curve and just starting up, so we're not absolutely
4 sure how much it's going to take off, exactly what kind of
5 ways it will actually be used, et cetera. So it may be a
6 little premature to try to stick it in.

7 But I guess in the other cases, it's just more of
8 a practical matter in that trying to put it into the current
9 proposed amendments and fit it in there may delay the entire
10 process with respect to that. So our hope is that we can
11 address a lot of the concerns simply through--and the CT
12 regs, by the way, unlike the fluoroscopy regs, are really
13 labeling regs, anyway. So we're trying to do the labeling
14 part of the CT regs either through those regs or through
15 other aspects or other ways. And hopefully we'll be able to
16 accomplish it that way.

17 DR. LIPOTI: But you have mentioned that the
18 single most important thing that you really need to do is to
19 sensitize the users to the dose that they are giving their
20 patients. There's one way to do that, and that is to
21 measure the dose as they're getting the dose. That would
22 seem to me the single most important piece of information
23 you could supply to the physician so that they could modify
24 their techniques and get better with practice if they have
25 that piece of information.

1 I think you should think very carefully about
2 exempting this piece of equipment from those proposed fluoro
3 regs. I think that would--I think it will make the practice
4 better if you give the doctors the tools they need.

5 DR. GAGNE: Thank you.

6 CHAIRMAN FLETCHER: Dr. Suleiman?

7 DR. SULEIMAN: Yes, I'm going to exercise my
8 prerogative here and hope to clarify a couple of things.

9 There was mention earlier about the NEXT survey,
10 the Nationwide Evaluation of X-Ray Trends. Dr. Stanley
11 Stern actually was given the opportunity to direct the CT
12 survey because that's what it's going to be in the year
13 2000, not because of his value in terms of doing the NEXT
14 survey, but separate from that, and his primary task was to
15 develop a handbook to calculate tissue doses from computed
16 tomography, because one of the problems with calculating
17 dose is to assess risk. You really need to know what the
18 doses are to all the various organs and tissues. And Stan
19 has undertaken that task and hopefully will get it finished
20 within the next year or two. And we didn't want to miss the
21 opportunity of the 2000 survey to collect some demographic
22 information and any other technical information that we
23 could conceivably collect in a very short period of time as
24 part of the survey. So, hopefully, we will have a tool, a
25 handbook, from which you could come up with effective dose

1 and a more definitive measure of risk.

2 Separate from that activity and effort, obviously
3 the issue that I've been very concerned about over the years
4 is what's common about the fluoroscopy amendments and the CT
5 fluoro is we're talking about filmless imaging. And
6 contrary to, I think, what John Sandrik mentioned, I don't
7 think personally, professionally, that as these
8 technologies--as the computerization of medicine takes over,
9 people are not going to think dose. They're going to think
10 this is easy. You're going to see more utilization, more
11 use, more procedures, and I'm concerned that people are
12 going to be getting a lot more dose than may be necessary to
13 conduct the exam.

14 So I think the fluoro amendments are a step in
15 that direction. It's not trivial. It's very, very complex
16 to calculate dose from CT let alone give real-time feedback.
17 So I think making that leap, you know, it won't take another
18 millennium, but I don't think it's going to be done in a
19 year or two. But I think you're making a valid point as
20 well.

21 But there are various parts that the center is
22 doing, and I'm not going to go into any detail right now,
23 but the use aspects, the American College of Radiology,
24 SCIVR, Society of Cardiovascular Interventional Radiologists
25 that Dr. Cardella is on, the IEC activities--you've got

1 everybody doing a patchwork, doing a part of the puzzle to
2 put together a solution. But it's really a very, very
3 complex issue. And I'm concerned about the doses that
4 patients, you know, are receiving and will receive.

5 CHAIRMAN FLETCHER: Any further comments?

6 [No response.]

7 CHAIRMAN FLETCHER: Thank you, Dr. Gagne.

8 DR. GAGNE: Thank you.

9 CHAIRMAN FLETCHER: At this point I'm in kind of
10 puzzle. We are a little less than 10 minutes before our
11 break time. I think what I will do is go ahead and take the
12 break and have everyone back here by 10:10. That way we'll
13 start 5 minutes early for Dr. Shope.

14 [Recess.]

15 CHAIRMAN FLETCHER: Our next presenter will again
16 be Tom Shope, who will give us a presentation on year 2000
17 conversion.

xx 18 DR. SHOPE: Well, this presentation is more an
19 informational type presentation than something we're seeking
20 advice on. Of course, we're always open to suggestions or
21 ideas from the committee.

22 What I wanted to do today is give you a little bit
23 of an update and an overview of the activities that CDRH and
24 actually all of FDA have been involved with with regard to
25 our friend, the year 2000 date problem or the millennium bug

1 or the computer glitch, or however you want to describe it.

2 Some couple years ago, in my role as a division
3 director of the Division of Electronics and Computer
4 Sciences--I emphasize the word "computer" there in our
5 organization's name--we raised the issue of the impact of
6 Y2K on medical devices, and somehow as a result of that were
7 unable to duck getting more deeply involved in this issue.
8 And I think that is part of my alibi for some of the
9 slowness with the fluoro regs in the past year. This has
10 been an all-consuming activity, almost. But with that
11 little bit of introduction, the purpose here is just to give
12 you an overview of some of the things as background
13 information.

14 First of all, we have been exerting a lot of
15 effort in FDA, as we have in any of the executive
16 departments of the Federal Government, to get our
17 hardware/software mission-critical applications ready, and I
18 think I can say with great assurance that FDA's mission-
19 critical systems are ready. We've had independent outside
20 verification and validation activities, and that's sort of
21 the end of the story there as far as we're concerned. We
22 will be ready. We don't expect to have any computer
23 problems that would interfere with FDA's conducting our
24 mission.

25 Our other activity, however, has been on looking

1 at our regulated industry programs and the progress that the
2 regulated industry is making in preparing to deal with
3 issue. And there are for FDA, and particularly for the
4 center, two aspects of this issue. For the other components
5 of FDA, it's probably only one of these issues, but for us
6 it's two, and that is, many of the products that we regulate
7 are computerized and are potentially vulnerable to having
8 problems due to using only two digits to represent a year
9 and the confusion that that could bring on; and, second,
10 we're concerned all across FDA of the impact of this problem
11 on the continued availability of our regulated industry's
12 products, that is, the continued supply of pharmaceuticals,
13 biological products, even the food supply, as well as
14 consumable medical supplies, which are also medical devices.

15 There are a lot of products that the hospitals to
16 deliver health care need on a daily basis and a continuing
17 supply. And as I'm sure you're aware, there's been lots of
18 speculation, lots of concern about the potential impact on
19 the supply of just about everything, from our water to our
20 power to all the other products that we use on a daily
21 basis. So this has been the focus of FDA's activity.

22 I know this committee is not heavily involved into
23 our device regulatory scheme, but I did want to just remind
24 you of our role here for devices and how that sort of
25 impacts what we're doing with regard to Y2K.

1 Again, we regulate the manufacturers of medical
2 devices. I guess I should stop a minute and say we passed
3 out a handout of some information material that we recently
4 put together and are making available to people who ask us
5 what's happening with regard to devices in FDA. This
6 concerns our activities in the center with regard to Y2K.
7 Most of the material in this handout is available on our
8 Internet website, so we've done a lot of work to make what
9 we're doing and how we're doing it available to the public,
10 for those that are interested.

11 Again, for health care facilities, which is where
12 the majority of the work with regard to medical devices has
13 to be done to prepare for the year 2000, we have limited
14 regulatory authority there at FDA to influence hospitals'
15 preparations for the year 2000. But we do have some
16 requirements that require health care facilities, medical
17 device user facilities, to report to us about adverse
18 events. And if there's an adverse event that's due to a Y2K
19 problem, we certainly want to hear about that as rapidly as
20 possible.

21 We, of course, have the Mammography Act which
22 influences health care facilities and our clinical
23 investigation oversight.

24 So a very limited role here to require health care
25 to do things, but some strong interest there.

1 With regard to medical devices, our role is
2 primarily the pre-market review. That's where probably the
3 majority of our activities go. We do have oversight of the
4 manufacturers' quality system. That is the way in which the
5 medical devices are produced to assure they're meeting the
6 specifications and that the product produced and put on the
7 market is as desired or designed. We're also involved, as I
8 mentioned, in our post-market surveillance follow-up of
9 products once they're on the market in our normal public
10 health kind of activities where we may not have a regulatory
11 role but an information delivery role.

12 A medical device, the breadth of our interest in
13 Y2K, this is the definition. I don't expect you to read it,
14 but it's everything involved in health care that has an
15 impact on the delivery or the treatment of care to an
16 individual patient. A quite broad responsibility.

17 As I mentioned, there are two concerns. One is
18 product availability and then the impact on computerized
19 products. We've had quite a bit of interaction with firms
20 and the industry associations to try to assess the readiness
21 and the status of the pharmaceutical industry, the
22 biological products industry, and the medical device supply
23 industry to assure that these industries are taking the
24 necessary steps to prepare, to get their internal
25 manufacturing control systems that may be computerized,

1 their internal ordering and recordkeeping--all the things
2 that an industry or a company has to do in order to stay in
3 business, that they're taking those kinds of steps.

4 Our prime activity here has been through some
5 survey work that FDA has initiated in addition to some of
6 the surveys that the individual manufacturing associations
7 have undertaken. The pharmaceutical industry has done a
8 number of services. The Health Industry Manufacturers
9 Association has surveyed the medical device manufacturers.
10 And all indications are that this industry or these
11 industries are taking this issue quite seriously, are taking
12 a lot of steps to prepare for being able to continue to stay
13 in business after the turn of the new year.

14 FDA has done surveys of the industry and devices.
15 It was really a survey not of the durable equipment
16 manufacturers, but of the manufacturers who make what we
17 call consumable essential medical supplies. And the varying
18 numbers of firms on the pharmaceutical side, it's something
19 like 4,000 firms, but this includes a lot of gas
20 manufacturers, people who just supply medical gases. There
21 are a large number of those kinds of facilities.

22 On the device side, we identified about 3,000
23 manufacturers who make consumable supplies, and we sent a
24 survey to them asking about their abilities to stay in
25 business. Do they have a plan to deal with Y2K? Are they

1 executing it? What's their schedule? Are they worrying
2 about their suppliers, especially foreign suppliers? Do
3 they have the capability to increase production if demands
4 are there?

5 That survey information is now currently coming
6 in. This survey effort started back in April for
7 pharmaceuticals and in June for devices and biologics, and
8 we're probably at the greater than 75 percent return rate
9 now from the manufacturers. And we're following up. We
10 didn't just send a survey to manufacturers, but we're
11 actually doing some efforts to validate these surveys by
12 having a contractor who has an experienced computer
13 software, computer engineering type staff that have been
14 involved with the Y2K remediation activities and other
15 industries, actually call and do telephone interviews with
16 the people in the firms that are responsible for the Y2K
17 activities there.

18 This is a couple of hours phone interview, usually
19 with several people from the firm on the other end of the
20 line, to gauge through this interaction the validity and the
21 comprehensiveness of the company's efforts and does that
22 jibe with the written survey response we got. And in those
23 cases where it maybe raises some doubts, we may actually
24 then have the contractor go do an on-site visit to the firm
25 to confirm or to further investigate the issues that the

1 firm may be having.

2 Our focus here has been on, in the pharmaceutical
3 side, certain types of manufacturers, the people who market
4 only--the only source of a pharmaceutical, a particular drug
5 only comes from one firm, or they're the firms who make the
6 200 most prescribed pharmaceuticals. There are some other
7 criteria as well.

8 On the biologics side, the focus is on some of the
9 vaccine type products and the blood bank issues and the
10 blood supply issues.

11 In devices, we've focused on those manufacturers
12 who make a product from which there are only three or less
13 producers of that particular item, and we know there are
14 about 225 firms in that category, and then we know there are
15 about 55 firms are the only source of a particular medical
16 supply that's consumed, and we are focusing our attention on
17 those.

18 So hopefully this will give us a strong level of
19 confidence of what the industry is doing to be prepared to
20 continue to stay in business. I think the message at this
21 point is good. We expect the Federal Government will be
22 making some outreach activities to tell the public the
23 results of these survey activities, basically confirm what
24 the industry associations have said earlier in the year, and
25 continue to focus on this.

1 So I think right now my view is that we're getting
2 very good response from the industry in terms of responding
3 to us. The audits so far have not really uncovered any
4 major concerns with the firms that we've done the audits
5 with. Their survey result seems to be appropriate, and
6 they're giving us the straight scoop, so to speak.

7 I think we're getting very comfortable with the
8 preparations that the industry is taking to deal with this
9 problem. But we also have--for those situations where there
10 is a concern, we have a manufacturer who's the only source
11 of a product, or we have the manufacturer of a
12 pharmaceutical that's thought to be a very necessary
13 pharmaceutical, and we're not hearing from them the way we
14 think we ought to, we certainly have the option for FDA to
15 do further inspectional type follow-up of those firms, and
16 we will do that if necessary.

17 On the medical device side, that is, the
18 computerized products, the products that use microprocessors
19 in their operation and maybe use dates in that operation, I
20 think the news is also good here. I'll talk a little bit
21 more about our efforts to understand the situation. But for
22 medical devices, the problems are rather minor, typically
23 involving either a date printing on a record of what the
24 device did but not involving how the device actually did
25 that operation.

1 There are some significant risks for some few
2 products that we need to pay attention to, and the hospital
3 or the user community that has these products in hand need
4 to make sure they take the appropriate steps to make sure
5 that these products are remediated.

6 We've done most of our information dissemination
7 through our website, and back in 1998 we established
8 something that has become known as, later in the year, the
9 Federal Y2K Biomedical Equipment Clearinghouse. This was a
10 central source of information, information provided by the
11 manufacturers of the devices, about the Y2K status of their
12 products.

13 What we did hear, a couple of things. We
14 initially asked for information about products that had
15 problems, and we've later come along and asked additional
16 information on certain types of products so that we could
17 get some information for the health care community, an
18 affirmative statement that the product is okay, it doesn't
19 have a Y2K problem.

20 In part of this activity, we've identified a
21 series of types of products. These are not individual makes
22 and models, but they're generic types of products. An
23 example would be hemodialysis systems or infusion pumps as a
24 generic category of products. And what we did is we said:
25 What products are there that have a role in health care

1 delivery that's either life-sustaining or life-supporting or
2 it's a monitoring function that monitors a vital bodily
3 process or function that you need to know that status all
4 the time? Or something that's critical and diagnostic
5 information provision, but not necessarily all diagnostic
6 products. There are many diagnostic products that aren't
7 that critical to the utility. An example here of the kind
8 of diagnostic product that we're paying some close attention
9 to are ultrasound diagnostic imaging systems that also have
10 the capability to predict fetal age and delivery dates, and
11 those become of a concern. If you do that calculation
12 wrong, you'd have some bad information that could have some
13 adverse impact.

14 So we didn't include diagnostic X-ray systems in
15 our high critical type products because those are somewhat
16 removed from an immediate impact on the patient.

17 We're doing further work here with another
18 contractor to actually go out to the firms that we
19 identified that make these types of products, and this list
20 of types of products has been put on the website and
21 published in the Federal Register so people know the kind of
22 products we're focusing on. But we have a contractor
23 reviewing what the manufacturers of these products have done
24 on a sample basis. We're looking at basically our
25 contractors for 80 firms to be audited by an on-site visit

1 to see what the firms have done to assess the Y2K status of
2 their products and, when they have found they have a product
3 with a problem, what they did to remediate that problem.
4 How did they test their fix? How did they validate that the
5 solution they've developed for their Y2K non-compliant
6 product is going to be appropriate?

7 Further, internal in CDRH and along with our
8 contractor, we're taking a look at what each and every
9 manufacturer of each and every of these potentially high-
10 risk products has had to say about their products, what the
11 status is, and what kind of solutions they're providing. So
12 we're taking sort of a focused look at these 90 or so types
13 of products.

14 With regard to products that have a problem, we're
15 a bit limited in what we might like to do. When we first
16 got into this with the other federal agencies who basically
17 are the purchasers in the Federal Government of these
18 biomedical products that have problems--the Department of
19 Defense and the Department of Veterans Affairs--we're very
20 interested in learning the Y2K status of the products they
21 have in their inventory and that they use on a daily basis.
22 And they turned to FDA for all the answers, and we didn't
23 have all the answers for them. And so we've done some
24 educational work there to explain what we can do and can't
25 do.

1 Immediately, the assumption was that FDA will make
2 the manufacturers give us Y2K-compliant products to replace
3 all these that have a problem of one sort or another, and
4 that's not quite what our authorities are.

5 We do have the authority, however, to take action
6 on a product that presents a substantial risk of harm to the
7 public health or an unreasonable risk of substantial harm.
8 I'll say it right here in a minute. And that's a fairly
9 high threshold for FDA to require a recall, a mandatory
10 recall, a provision of repair, replace, or refund. There
11 are some other criteria that apply before we can actually
12 even do that.

13 So our role here to make whole, as you might
14 consider, the purchasers who bought a non-compliant product
15 is somewhat limited. But we can encourage manufacturers to
16 deal with the issue, to make the information that users need
17 to have available to make sure that the users don't use a
18 product in an inappropriate way. So just making the point
19 here that our authorities here for actually mandatory
20 forcing manufacturers to do something is somewhat limited,
21 although we certainly can take action in those situations
22 where it's warranted to prevent a serious concern.

23 With regard to our database that I mentioned
24 earlier, this is information we collected from the
25 manufacturers, and information from each manufacturer is

1 available on this Internet website, either directly on the
2 website or through a link to the manufacturer's information.
3 And providing information to the FDA in this list was a
4 certiifaction to the government that this is the complete
5 and true story for all my products, and we only wanted
6 information to be provided from manufacturers when they had
7 done their complete assessment of all their inventory, both
8 their current products and the products that had been
9 introduced into the market in the past but still might be in
10 use. So this was much broader than just what they're
11 currently making.

12 The manufacturers have the ability to update this
13 if they need to change some information or for those
14 manufacturers who are coming late to the game to continually
15 add information.

16 The database, you can go to it and search by
17 manufacturer name, by model, or by generic type of product.
18 So we initially did this activity to provide information
19 that the Federal Government purchasers of medical devices
20 needed, but we quickly realized in our discussions that this
21 is something that every health care facility would need.
22 And so our decision was to make this available publicly.
23 And, in fact, you can download the entire database, put it
24 in your spread sheet in a hospital and compare it to your
25 inventory.

1 So we're hearing that this has been a quite useful
2 feature for many of the health care facilities trying to
3 deal with their own internal inventory of medical devices.

4 We also in response to requests from the health
5 care industry in March of this year requested the
6 manufacturers of these types of products that are
7 particularly vulnerable to Y2K problems, the kind of things
8 people might think could have a problem because they're
9 computerized or they're electronic in nature, they plug into
10 the wall, whatever their criteria is, that we get from
11 manufacturers also a list of all their products they've
12 determined to be compliant. This was partly due, I think,
13 to some of the urging that some of the health care
14 facilities had from their legal advisers to do what's called
15 due diligence and to show they've covered all their bases.
16 They needed affirmative statements from manufacturers that
17 products were okay, which was not the original intent of our
18 database. Our original intent was list the products that
19 have problems. That's what people really needed to know
20 about.

21 So we expanded the database capability in the
22 spring of this year, and we continue to get information from
23 manufacturers on both compliant and non-compliant products.

24 Just briefly summarizing what I've said, the
25 manufacturer originally could list products that were

1 impacted. They could tell us all their products are okay.
2 They could tell us all their products don't use dates, give
3 us a list of the products that had problems, or give us a
4 link to their own website where they've provided this kind
5 of information.

6 Our current status, just as a bit of information,
7 we have information now in the database from over 4,200
8 manufacturers, some numbers here that just illustrate the
9 kinds of responses we've gotten. You'll see a lot of the
10 manufacturers that reported their products don't use a date,
11 and that's because our mailing list, when we solicited this
12 information, is not fine-tuned enough in FDA to know who
13 makes a computerized product and who doesn't. So we
14 captured in this mailing some of the sunglass manufacturers
15 and some of the bandage manufacturers and the suture
16 manufacturers, who obviously don't have a product that uses
17 a date.

18 But we do have information from a number of
19 manufacturers that have reported non-compliant products; 345
20 of those have data in our database, and another 340-
21 something have it in their own website database where we
22 have a link to that manufacturer's information.

23 Currently, we have in our database about 1,000
24 products that are listed as having a Y2K problem of one sort
25 or another. We also know that out in the manufacturers'

1 websites there's probably five times as many products listed
2 with problems. We haven't actually done that count, but the
3 General Accounting Office back in the spring attempted to do
4 that count and came up with a number something more than
5 5,000. So we know there are a lot of products that have Y2K
6 problems, but the vast majority of them have a minor
7 problem. It displays a date wrong; it prints a date wrong.
8 It doesn't affect the functionality of the product.

9 What we mean by Y2K compliant basically is that
10 the product will work appropriately as designed and as
11 intended and as the user expects regardless of what the date
12 is, before or after the turn of the year. It knows that
13 next year is a leap year and accounts for February 29th. It
14 doesn't have days where it doesn't work right because of
15 some kind of date problem. Basically, the problem arises
16 when the year is represented using only two digits, and we
17 go to the year 2000, those systems that were done that way
18 would think 00 for the year and they don't know if it's
19 1500, 1900, or 2000.

20 If the only function that the date is used is a
21 date-recording function and it prints on a piece of paper
22 for the physician or the health practitioner to read 00 for
23 the year, that's not much of a problem because we know there
24 weren't any computers printing records in 1900. The human
25 can interpret 00 as the year 2000, and that doesn't really

1 put a manufacturer in a non-compliant status under our
2 definition.

3 However, if that information is used in some kind
4 of calculation, algorithm, sorting routine, sequencing
5 operation, then there's a potential for a problem, and we
6 would consider those non-compliant.

7 CHAIRMAN FLETCHER: Tom, could you start to
8 summarize in the next couple of minutes?

9 DR. SHOPE: Okay. I got a little too wound up
10 here.

11 This is our definition of compliance. There's
12 much in this handout that I'm not planning to touch on,
13 actually, so I wasn't going to go through all these slides,
14 but give it to you as background information. I've covered
15 most of this.

16 There are PCs that control medical devices. They
17 have the same kind of problems that your non-compliant PCs
18 on your desktop have. They mess up the file dates and those
19 kinds of things.

20 Manufacturers are giving quite a number of
21 solutions, many of them free, many of them at some charge to
22 upgrade a medical device. They've also declared many
23 devices obsolete. The thing is 15 years old, we haven't
24 made it in 10 years, we're not even going to investigate it,
25 we're washing our hands of it. And the user then is put on

1 notice that they need to either decide they can continue to
2 use it safely or they need to replace it. So there's quite
3 a variety of solutions that have been provided.

4 I'm going to skip by some of this manufacturers'
5 roles and the recall discussion that I put in just sort of
6 as background.

7 I've covered some of our activities with the
8 industry in terms of gathering information so that we can
9 provide the public with some status report. Early in
10 October, probably, is when we'll begin to see all these
11 messages coming out as a result of our survey activities.

12 We'll continue to monitor what the industry is
13 doing and deal with any industry firms that seem to be
14 having problems, seem to be coming around slowly that we're
15 anticipating as having problems. And FDA deals with
16 shortages on a daily basis, almost. There's always some
17 pharmaceutical in short supply, and so the interruption of
18 production capability by a manufacturer is always something
19 that we have procedures in place to deal with and the
20 industry has procedures in place to deal with these. So
21 we're fairly confident that the Y2K problem is not going to
22 present a big impact to health care due to either devices
23 malfunctioning or lack of supplies. And that has to be with
24 the proviso that the health care facility has done the
25 appropriate thing to deal with the products they have in

1 their inventory. And the last couple of slides just list
2 some issues of concern, what the health care facilities can
3 do to deal with the problems in-house, what they need to do.

4 Basically, they need to look at their system,
5 anything that's been interconnected from different
6 manufacturers, where there's no one responsible for it, and
7 we encourage the facilities, of course, to report to us any
8 problems that they may have.

9 I will indicate here that the year 2000 problem is
10 not going to occur just on January 1, but there will be
11 problems distributed throughout the year. People have
12 already had Y2K problems, and they'll continue long after
13 the 1st of January.

14 We'll continue to develop our outreach. We have a
15 hotline where the public can call in with questions about
16 Y2K and FDA. We're developing our messages on supply, and
17 this is our website where all this information is available.
18 And we're hopeful--I guess I'm at the end of things here.
19 There it comes--that the year 2000 problems we have are the
20 bugs that come in through the screen door, not the ones that
21 exist in our medical devices after the turn of the year.

22 Thank you.

23 CHAIRMAN FLETCHER: Thank you, Tom. We're going
24 to reserve questions until the open discussion, I mean the
25 committee discussion. We have two more presentations, so we

1 need to move on.

2 Our next presenter is Mr. Kassiday, who is going
3 to provide us with current information dealing with non-
4 medical security systems which produce ionizing radiation,
5 and he will be followed by another presenter.

6 MR. KASSIDAY: Hello. I'm Dan Kassiday. I'm with
7 the CDRH Office of Compliance, and there are two parts to
8 today's presentation. First I'm going to briefly update you
9 on activities on personnel security screening systems, and
10 then we've invited Mr. Roy Lindquist from the U.S. Customs
11 Service--he is the acting branch chief for the Research,
12 Development, and Evaluation Branch in the Applied Technology
13 Division--to give an overview of new non-invasive products
14 that Customs is using to examine income cargo and trucks and
15 all sorts of things. A lot of these products are new
16 applications of old technologies or new technologies, and we
17 just sort of wanted to get them out there so that you're
18 aware of them in case there's any kind of guidance you'd
19 like to offer on them.

20 I'm going to begin with a brief review of what a
21 personnel security screening system is. Pictured is one of
22 the two products on the market. These systems work by
23 receiving back-scattered X-rays. They look through your
24 clothes for non-metallic items and contraband.

25 The X-ray is a small cursor, moves back and forth

1 from top to bottom, and presents you with an image. And, in
2 general, you'll have to rotate, do it again back and forth,
3 to get the back image. It's not a transmission image. It's
4 a reflection. The exposure for this is approximately 5
5 microRoentgen.

6 Specs for one of the systems: The beam size,
7 again, is very small. It's about a centimeter square. The
8 two potentials, around 50 kV with 5 mA tube current. The
9 source to subject distance is approximately 81 centimeters.
10 Some of that is within the machine; some of that is outside
11 of it.

12 The whole thing takes about three seconds, which
13 results in the dwell time in any one place being
14 approximately 72 microseconds, which is how you arrive at
15 the 5 microRoentgen exposure.

16 The reason we're still talking about this is that
17 the use of non-medical exposure to ionizing radiation is
18 still somewhat controversial. The linear no threshold model
19 is based, of course, on high dose rates giving you high
20 risk. This is a very small exposure which would presumably
21 under that model result in a very small risk, although a
22 small risk is not equivalent to no risk. Of course, the
23 other side of the controversy is the benefit achieved from
24 the security gain from the screening procedures.

25 Last year, the committee discussed these products

1 at some length and came up with several recommendations to
2 the Food and Drug Administration: that we work
3 cooperatively with the manufacturers to ensure that state
4 regulators are informed of the products when they're used in
5 their state; that they encourage their users to properly
6 register their products; that the operators of these
7 products are trained properly in the basics of radiation
8 safety and radiation safety procedures; and that the units
9 are appropriately labeled as producing X radiation so that
10 the subjects are aware they're being exposed. The committee
11 also recommended that FDA begin work on a federal
12 performance standard for these types of systems.

13 These are the FDA activities to date. A lot of
14 them are ongoing. We plan to issue a letter to the
15 industry, both manufacturers, which will address the points
16 raised--the first four points raised by the committee last
17 year: that they're going to notify states that the systems
18 are in use in their states, that they're going to encourage
19 their users to register properly where there's a
20 registration requirement, that there's proper training in
21 radiation safety for the operators so they know what they're
22 dealing with, and we're also going to request that they
23 appropriately label them so that people know they're being
24 exposed to X-ray.

25 I was hoping to have the letter out, but as Dr.

1 Feigal said, we have a new Deputies Committee and a
2 Radiation Council, and they thought this was a great place
3 to get involved, so they're going to review it before it
4 goes any further.

5 Additionally, and possibly more importantly, Frank
6 Cerra of our Office of Science and Technology has put
7 together a scope of work and gotten a work group approved
8 from the American National Standards Institute under their,
9 I guess, N43 Technical Committee, and that committee will
10 involve FDA, manufacturers, state regulators, and users of
11 these products, trying to develop a consensus standard which
12 will address the radiation safety of the subjects, the
13 operators, and also bystanders.

14 Additionally, we're going to revise our reporting
15 requirements so that full product reporting is again
16 required for these products so that if new entrants into the
17 field appear, we can get full details on their dosimetry,
18 their safety systems, and that sort of detail. And in the
19 event that we do end up going with a mandatory standard,
20 we'll have the information in-house should it be necessary.

21 Now I'd like to turn this over to Mr. Lindquist,
22 who will tell you all about the new non-intrusion devices
23 Customs has, as soon as we can switch off to the older
24 technology here.

25 MR. LINDQUIST: As I approach this committee, I'm

1 afraid Customs feels somewhat like these Customs officer
2 from France who, in the late 1900s, were using X-ray for
3 inspection. It was state-of-the-art then. As you can see,
4 there is a source. The inspector holding the bag had a
5 blindfold to protect his eyes, and then, of course, there's
6 the person looking through the bag with his detector.

7 This looks funny until you realize that--and when
8 I was a child, I would stop by the Buster Brown store and
9 look at my toes and see if they still fit in my shoes. It
10 was my key when I would get a new pair of sneakers or shoes.

11 We've advanced a long way. We're very concerned
12 about our people. We're very concerned about radiating
13 people. And we have major concerns about what some of this
14 energy can do to products that we are examining,
15 particularly medicines, where ionizing radiation or particle
16 production could change the characteristics of it and have
17 an adverse impact on a drug that perhaps you had tested and
18 cleared which had not been ionized beforehand and then we
19 had changed the characteristics. Customs treats this very
20 seriously. We do consider our people safety paramount.

21 With that in mind, I'm going to give you our non-
22 intrusive inspection program. It's going to be somewhat of
23 a high-speed reading. I've been asked to keep this to half
24 an hour, and I will. And here goes.

25 To put this in context, we have--is there a...

1 [Pause.]

2 MR. LINDQUIST: I apologize. That's better.
3 Customs officers are fairly mobile people.

4 [Laughter.]

5 MR. LINDQUIST: We are trying to help shield
6 America's frontiers against drugs by increasing the risk of
7 drug smuggling, particularly along the southern tier of the
8 United States from Southern California through Puerto Rico.
9 We have a tremendous drug threat there, and it impacts our
10 society.

11 Our counter-drug responsibilities are broad. They
12 include inspection of inbound and outbound conveyances, and
13 outbound, we look for the money. Drug smugglers have to
14 ship three pounds of money out for every two pounds of drugs
15 they ship in. This is as big of a problem to them as
16 shipping the drugs in.

17 We also are trying to disrupt the smuggling and
18 money-laundering operations. Many of these are electronic
19 means of detection and have nothing to do with X-ray
20 technology or ionizing radiation.

21 We are interdicting aircraft and boats. There was
22 a rather dramatic film on the news the other night of shots
23 being fired at go-fast boats. We are collecting, analyzing,
24 and disseminating intelligence. One-third of the Customs
25 Service are investigations officers. They don't open

1 suitcases. They don't check cargo. They are essentially
2 investigators. And we bribe and get informants and
3 everything else. And, finally, we provide protected
4 communications to various people in various modes when
5 necessary.

6 Of those, we're going into our area. Technology
7 is vital. We're using it as a force multiplier. We're
8 getting new capabilities. We want to be more effective, and
9 we need quick responses to new threats. The smugglers are
10 innovative. They adapt. They really do their thing. And
11 we're going to cope with growing workloads with less people.

12 What are we doing about it? Well, one, we have a
13 lot of experience and success in developing technology for
14 use in the field. We've used X-ray very broadly for over
15 ten years. We're adding technologies which we think have a
16 high probability of success, and we're trying to put them in
17 the areas where the drug threats are biggest.

18 What we plan to do is disrupt smugglers. We're
19 going to force them to operate in different ways. When they
20 do, they contact new people. They have people they don't
21 always know, and we hear about it through our intelligence,
22 and we get them. And we do want to broaden the technologies
23 we use.

24 All of this going on the Internet is throwing me.
25 Most of this data has been seen in various places,

1 so it is open. As you can see, we have a well-defined group
2 of cartels. The Mexican cartels are brilliant. They are
3 vertically integrated. They go from growing poppy,
4 marijuana, and coca leaves in South America and bringing
5 them up through their distribution systems in Mexico. They
6 refine in Colombia. Really a well-run, modern business
7 organization.

8 They were contracted by the Colombian cartels
9 because the Colombian cartels were having trouble getting in
10 through South Florida. Now we have threats in Puerto Rico,
11 Florida, and all along our very long border.

12 I'll give you a rough idea of our seizures. There
13 are three-quarters of a million pounds of marijuana, cocaine
14 is 150,000 pounds a year, and heroin about 1,500 pounds a
15 year. That's a lot of problems socially.

16 We have miles of borders. We have 810,000 air
17 flights that we screen each year, 240,000 ship arrivals, and
18 these are container ships, some of them, with huge amounts
19 of cargo onboard, 10,000 truck and sea containers--that
20 number is wrong. One hundred sixteen million cars cross our
21 border along the Texas and California frontier, through that
22 area. We have 430 million people cross our border, and we
23 have 400-plus agency rules and regulations to do in our
24 spare time also.

25 Just to add to that workload, again, we're showing

1 by sector. We have 3.5 million trucks, 2.7 million sea
2 containers, 320,000 railroad cars. As if we didn't have
3 enough trouble with the other items, we have eight major
4 train rails coming into the United States through Mexico.
5 And we have 79 million POVs. The numbers vary slightly
6 depending what year the slide was made from.

7 Our goal is to make the risk high for the
8 smuggler, and what we're doing is we're implementing
9 technology. We're now at the T1-2 level. We've put in a
10 lot of technology. We're adding more. And my hope here is
11 to show you what we're doing.

12 I'm going to skip some of these. Right now we're
13 currently using over 800 items of non-intrusive inspection
14 technology. They range from busters, which are a small
15 radioisotope, back-scatter, hand-held device like a pound of
16 butter, very effective, ten microCuries of cesium in them,
17 up through a six MeV X-ray machine which I am now testing in
18 southern Arizona.

19 We have a lot of new big equipment. I'm going to
20 show it to you, and it's 50 percent of our new technology
21 investment. We need to force multiply. We have to make the
22 Customs inspectors' jobs more effective and faster.

23 What are we buying? Just so you get a rough idea,
24 we have eight fixed truck X-rays. I'll show those to you.
25 We have 25 mobile systems in our plans. We have 27 gamma

1 systems, which has now been brought up to 50. We have 22
2 cargo pallet-type inspectors. These are big pallet
3 machines. We have eight railroad car inspectors, six
4 tractor-trailers, and I'm not sure what the bottom one is.
5 But since we're getting none of them, it's fine.

6 [Laughter.]

7 MR. LINDQUIST: Perhaps that's other inventions
8 that have come to our attention.

9 The money investment is huge, \$631 million. We
10 have recurring costs of \$160 million a year, and we're going
11 to need 2,200 people to operate this stuff.

12 X-ray. It's over 100 years old. It's non-
13 intrusive, it's fast, and we don't have to unpack the
14 pallets. We don't break the materials, and we have happier
15 shippers who do not like their shipments being held up while
16 Customs says, well, we'll open that up tomorrow. It has to
17 be done then, now, and cleared.

18 Problems with radiographic inspection, sometimes
19 indeterminable. I'm sure the medical people have the same
20 problems. We have limited penetration because we are using
21 minimal doses, and quite often we're using lower resolution
22 screening. We try to use as low as possible to keep the
23 dose down, and we rely heavily on operator skill.

24 Reflective energy imaging systems. This is what
25 Dan just showed you. These are ultra-low exposures.

1 Compared to your flight in an airplane, they're negligible.
2 We get the same information as a pat-down search. People
3 object to a Customs officer taking them behind this screen
4 and a man inspecting a man, a lady officer inspecting a
5 lady. We do segregate by sex. It's proper and it's
6 required. And it's slow because we have a lot of legal
7 forms, and, Dan, I will send you our legal forms that we're
8 using. We declare to people what we're going to do. It's
9 offered as an alternative to a pat-down. And it's accepted
10 about 10 percent of the time because people are very
11 frightened of radiation.

12 The same machine Dan showed. And Dan and I have a
13 slightly different number. The reason is that's a measured
14 number, and we did it over repeated times. Their
15 specification is actually less than 5 microrem. It is a
16 cabinet safe system for the operator. It is cabinet safe
17 for the recipient of the X-ray image.

18 I have a low-resolution picture here. In the
19 original, you can see the buttons on his 501 jeans.
20 Basically, only in the forward shin area do you see any
21 reflection of the bone. It's basically a skin and surface
22 thing. We do not see items concealed behind folds of flesh,
23 and that isn't how we use it. That's a manufacturer's
24 picture. When Customs has someone do it, you assume the
25 pat-down position. It stretches your clothes tight over

1 your body, and we can see the carried concealments quite
2 readily. And we do use two views, and should we suspect
3 something, we will take two side views, for a total of less
4 than 20 microrem exposure. After that, we have no
5 compunction about going to the next stage.

6 Truck X-ray. We're going to have eight of these
7 along the border. We actually have eight of these along the
8 border. It consists of a large car-wash-type installation.
9 The front wheels of the truck are put onto it. We remove
10 the driver from his cab for several reasons, one of them
11 that he's in charge of an 80,000-pound weapon. Two, he can
12 have a gun in there. We take him out of his world and put
13 him in ours.

14 Once that occurs, there's an announcement, X-ray
15 is going on, the truck is automatically transported through,
16 scanned, and we look at the images. It's very good. We
17 have seized tons and tons and tons of drugs with it,
18 typically over 20,000 pounds a year with this machine.

19 What is it good at? We designed it for empty
20 trucks, and that sounds stupid, but empty trucks are not
21 always empty. It's a great "wrapper" inspection. It does
22 the outer vehicle beautifully.

23 The cargo inspection, if it's very heavy and very
24 dense, we don't have a lot of energy here, so we don't
25 penetrate it. However, we do see anomalies. If we have a

1 very dense area in the cargo and the rest of it we're
2 penetrating, like pinatas or picture frames, we kind of
3 wonder what that dark lump is in the middle.

4 False compartments show up very well, and the
5 device is film-safe, which puts it under the 1 millirem per
6 exposure.

7 We have the same machine mounted in a truck. Here
8 we have the X-ray source on board the truck. We have back-
9 scatter detectors here. We have our transmission detector
10 hung out on a boom. We have created a cabinet, and it will
11 probably show better here, from this point to the far
12 corner, from this point to the forward corner. When you put
13 a truck in there like that sea container on a carrier, no
14 one is going to try and walk in between those areas. It's
15 mechanically hazardous and very apparent to anyone that
16 they're not going to fit there and they're not going to like
17 the results.

18 The results of the inspections are tremendous. We
19 took over two tons of cocaine down in Laredo in a very nice
20 hit last year. They ran it through the port just at closing
21 time. The container was supposedly an empty tanker. You
22 opened the hatch and looked in, and there was two inches of
23 animal fat that was rancid. The man just about fell off the
24 top of the truck, sent it over to the X-ray, and we saw
25 false compartments.

1 Again, it's designated for empties, but it does
2 loaded trucks. It's a great wrapper inspector. Again, what
3 we find on the border is that most of the smuggling is done
4 in the truck, not in the cargo. We have a lot of
5 manufacturers working over the border. They're very
6 interested in being good manufacturers. Their business is
7 not to make money on drugs. Theirs is on their product.
8 And they cooperate with us. If we get a delivery of drugs
9 through their plant, we're the first people they call and
10 say you might want to look at this load of television sets,
11 it's full of cocaine. and they help us trace it back. So we
12 have found great cooperation with the manufacturers.

13 Again, selective cargo inspection. There are some
14 things we can't do. But, again, the drugs are usually in
15 the wrapper. They're in a false nose compartment. They're
16 in the roofs. They're in the sidewall. They're in the
17 tires. They're in the gas tanks.

18 False compartments show up very well. Film-safe,
19 rapidly deployable.

20 Since this is a technical committee, what levels
21 am I really talking about? I have a 450,000-volt X-ray
22 source. It's operated at 6.6 milliamps. And the fixed
23 truck X-ray, I have the same X-ray source; however, it's 10
24 milliamps. And I have two of them, and it comes from
25 underneath.

1 Dose, 110 microrems, and that's to an object in
2 there. It's conceivable we would have a person. We have
3 found 19 illegal, undocumented people in a vehicle--in
4 vehicles in the five years we've been operating, one of whom
5 we saved their lives. There were 17 people in the back of a
6 travel trailer. When we took them out, they all required
7 medical attention before they could even be moved from the
8 port. They had been jammed in there, lack of air, heat. We
9 were just about to proceed to drill when one of the guys
10 says, hey, let's send it through that new machine. They put
11 it in the machine, saw the people, took them out, and the
12 guy who was about to drill was very pleased that he hadn't.

13 We have a second machine being built by a
14 competitive manufacturer. It runs at a slightly higher
15 milliamperage rate. It also has some other features. And as
16 you can see, the dose to the object is now one half-
17 millirem. However, the operators are all under the half-
18 millirem per hour--in an hour, sorry, dosage rate, and the
19 system footprint is very similar to that I showed you in the
20 other truck.

21 We have a system called VACIS. This is an
22 isotopic system. The source is in here, the detector tower
23 is there. We pull the truck up, we park it, we move the
24 driver out, we scan it, we make our decision, put the driver
25 in and allow him to leave--sometimes with Customs officers

1 following him.

2 Dosages. Just to give you a comparison, since we
3 don't really regulate this part of it, but, again, showing
4 our sensitivity to dose. We have an exclusion area of 85 by
5 110 feet. This puts them down into dosage levels that are
6 appropriate for people working around equipment. The object
7 receives a 5 microRAD dose, very low. Again, it's purely
8 listed to show you that we are concerned about the amount of
9 dosage and what energies we're using.

10 By the way, cesium-137 is an energy level of, I
11 think, 668 or thereabouts.

12 Mobile VACIS. We take the same source, except
13 bigger. We hang it from the end of this boom. The
14 detectors are over here, and if we have a smooth parking
15 lot, we get a very good image, and we are able to, again,
16 rapidly deploy, move into a location, scan something, put it
17 away and go somewhere else and disrupt the smugglers,
18 because we can show up, be operating in 20 minutes. They've
19 been in line with their trucks for two hours. And then we
20 can disappear again and go somewhere else and disrupt
21 another flow.

22 Customs has tried not to invest in large fixed
23 systems where we build a Maginot Line that can be easily
24 circumvented.

25 This is a 1.6 Curie source, again, cesium-137,

1 and, again, about 5 microRADS. It scans faster.

2 We get to another isotopic system. Now we're
3 going for some power here. We're doing railroad cars. We
4 cannot figure out how to do this with X-ray at a reasonable
5 cost, so, again, we have our isotopic source. We have a
6 detector tower. We have an exclusion zone. We are going
7 down, signing an agreement at the end of this month with the
8 railroad, and we are opening up a car inspection.

9 Here we do fear that we will be occasionally
10 subjecting people coming across the border to radiation, but
11 the dose, again, is very, very minor. We scan the cars
12 traveling through at 2 to 5 miles per hour. We have it so
13 that if the car should stop, we shut off the source
14 immediately. If they get in below 2 miles an hour, we shut
15 off the source, and we have made it so that basically we're
16 not going to sit and expose somebody to a line source while
17 they've been parked in a railroad yard. Safety zone, 20 by
18 50 feet.

19 This system I should be accepting next month.
20 It's a heavy pallet X-ray system. It's designed to do air
21 cargo containers. It will do eight-by-ten pallets.
22 Particularly flowers coming up from South America are prone
23 to having packages put in them with drugs. The reasoning is
24 that the packages must be moved very quickly. Flowers are
25 highly perishable, and our method of inspecting them to this

1 time has been long steel probes pushed through the flowers,
2 which the flower merchants really don't appreciate.

3 This is a true pallet system. A lot of
4 manufacturers sell a pallet system that will do something
5 about the size of a suitcase, and they are actually suitcase
6 machines with a large belt on the outside of them. We have
7 high penetration, great flux, high energy. We're up at 1
8 MeV now. Some of them will be 2 MeV that I'm considering,
9 and transmission imaging is the key to success. The loads
10 in pallets are buried in the cargo. They're sometimes very
11 sophisticated concealments. Again, I talked about the
12 vertical integration of the smuggling operations. We have
13 had molded cashews placed in tin cans, put in boxes, and
14 then put among other boxes of actually legitimate product,
15 all matching, but there are 20 boxes of them aside that are
16 different. And, again, finding those requires intelligence,
17 luck, and work.

18 Again, breakdown of the pallet, it's very labor-
19 intensive. We get charged for breaking things. And the
20 levels we're using, our nested high-voltage generator--and
21 that machine you saw is very innovative. It's taken a long
22 time. It's neither a LINAC nor an X-ray tube technology.
23 We use a scanning electron beam. It goes into a vacuuated
24 chamber where it hits targets, creates X-ray just below the
25 object, and then it goes up to the right comb. And by

1 scanning the beam along this target, we're able to actually
2 scan an X-ray. And it's very clever. It's not quite proven
3 technology, but we are seeing images with it now. Dose less
4 than a tenth of millirem, again. We are very conscious of
5 this, and that system was shown with doors, but it doesn't
6 require doors to be cabinet safe--or cabinet-like safe, as
7 Dan has taught me, because as soon as I get above a 300 KeV
8 source, I truly don't meet the bounds of the regulation.
9 But we are meeting the radiation intent of the regulations.

10 We have a larger pallet X-ray that's been proposed
11 to us. Whether I fund it or not is going to be dependent on
12 budget and also probably the success or failure of the last
13 machine. We're looking at fairly large dosages here, 9 to
14 36 millirem per scan. However, the chance of scanning a
15 person in this is zero to none. We will see someone hiding
16 on a pallet.

17 And we have gamma ray systems that we're looking
18 at for pallets, and, again, we're using cesium and cobalt.
19 Cobalt comes in at about 1.3 MeV, and the operator will have
20 a background level. The operator will have a background
21 level. The object gets 5 microrem or 20 microrem, depending
22 on which source we're using. This is on the drawing board.
23 We are funding it, and we will see how it goes.

24 Now we're getting into some of our very big toys.
25 We had a meeting on this. U.S. Customs is considering

1 procuring large numbers of these for the seaports. Again,
2 we are not building a Maginot Line. This has a 2 or a 6 MeV
3 switchable LINAC. The interesting thing is around this
4 thing we are at cabinet safe radiation levels of less than a
5 half millirem per hour. There is substantial lead in this
6 structure. The thing weighs 70 tons. We have the operator
7 room up above in that white box you see the gentleman
8 standing in. We have two driver's cabs, one at each end.
9 The driver gets out and goes around to the other one to
10 drive back the other way.

11 We do have ground personnel. Ground personnel
12 guide them over the fairly tight fitting on cargo
13 containers. Their maximum dose is about 15 microrem, and I
14 did that by walking with someone holding my shoulder to pull
15 me aside if I started to fall, right in front of that big
16 wheel. In other words, I walked right there. And what I
17 was most afraid of was that I would trip and be run over by
18 the machine. And I was right on the edge of the cabinet,
19 took very careful readings. We really were not receiving a
20 lot of scattered radiation out the end, and we expected to.
21 The cargo itself becomes an absorber and shields the person
22 at the end very rapidly.

23 Just to give you more indication of the size of
24 the beast, the lead shields are actually two tunnels
25 attached at each end. I have a sub-R&D project to get rid

1 of those lead shields and just hang it on the direct object.
2 We have a source low on the operator's side, which is this
3 side you're looking at, and the detectors are a vertical
4 string on the other side. We also use a 10-degree offset,
5 and the reason for that is we get a small amount of three-
6 dimensionality in our image, and we find it helps the
7 inspector relate where he is in the cargo.

8 What are we looking for in sea cargo inspection?
9 Dense materials are common. It's not your Rolex watches
10 that are being shipped by sea cargo containers. Bulk loads
11 are common. Penetration requires power, as you're very
12 aware, and there's a 5 MeV limit for food products that we
13 recognize. We are at 6 MeV available. We're still below
14 the ionizing radiation. I have spoken to some of the FDA
15 people. We keep hoping that some variations in the
16 radiation levels can be worked out. If not, for food
17 products we'll operate at 2 MeV.

18 The nice piece of this is we had a water tanker in
19 that earlier slide. We did full penetration. We could see
20 the concealments hidden in the water. And water is a pretty
21 tough item when you're using X-ray energy to see through.

22 There are other systems out there. There are
23 fixed 4 1/2 and 9 MeV systems being operated--offered by
24 Hyman, EG&G, and many other manufacturers. And, of course,
25 there's pulsed fast neutron analysis, and Congress has

1 funded us to do a test program. We will do it in El Paso.
2 All parties there are extremely cautious at the amount of
3 radiation that's being used and put on cargos and so on.

4 Probably one of the funny things related to the
5 fixed systems is that there is a system in Xianjin(?) with
6 British Aerospace built. EG&G claims it is theirs,
7 RapidScan claims it is theirs, and one other manufacturer
8 claims it is theirs. And they've all maintained it at
9 different times, and we've had people take four delegations-
10 -or our delegation out to the same piece of equipment, and
11 they all claim it.

12 What has the Eagle for dosage rates? Because I
13 have a LINAC, I have to present this a slightly different
14 way. It depends on the pulse rate we're using. Since we
15 have not even completed our final acceptance test--we had a
16 preliminary one--we've been operating at 30 and 60 pulses
17 per second; 2 MeV, I have 25 or 50, depending on the pulse
18 rate, and at 6 MeV I have 50 or 100 RADs per minute at one
19 meter. However, you're never at one meter in the device.

20 We put dosimeters in in several locations, and
21 after several scans, we averaged out what we received, and
22 it's about 6 millirems per scan that is being given to an
23 object or a person in the container or cargo. And these
24 were empty containers, steel containers, so they weren't
25 doing a lot of absorption, and we were just getting what was

1 happening. Some of them we had light cargo in it. We had
2 scattering materials. And it's beginning to what I call a
3 significant dose, but compared to medical dosages, it's way
4 down.

5 This is what we hope to do. We plan to have sea
6 containers be able to--as they come off the ship, actually
7 they'll be sitting on their tractor-trailers. We'll just
8 signal the drivers over into a line. We'll run past them.
9 And here you can see the leaded container or tunnel that we
10 have, and we have the skirts up for maneuverability because
11 once we drop the skirts for radiation protection, we cannot
12 move more than a four-degree turn in our wheels.

13 However, we think we're going to be able to
14 operate in a cabinet-like environment. We won't have to
15 have a large safety area. We will have a safety area around
16 it, but not for radiation but for the mechanical hazard of
17 this item.

18 We had a kickoff meeting yesterday. We're using
19 CT scan technology. We have one of the major manufacturers
20 putting one of the CT machines in a truck for us. It's
21 going to be suitcase-sized examinations. In other words,
22 we're using a medical CT scanner. The object will receive
23 100 millirem, but, again, being a package suitcase size,
24 we're not worried about people. We are looking at cargos,
25 though, however, which could be food, frozen shrimp, frozen

1 fish. Those are favorites by smugglers to bring drugs in.
2 They've gone to the level of doing shrimp by taking condoms,
3 filling them with cocaine, actually curling them to look
4 like little shrimp and stacking them along just like the
5 shrimp would be in the package and freezing them into the
6 thing. So that when you look at it, it looks very like
7 shrimp until you really look at it.

8 What is Customs' task? We're going to screen for
9 drugs. We want a minimal disruption to you, the traveler,
10 and trade. That's important.

11 Finally, we're trying to make the smuggler's job
12 tough, make them go elsewhere.

13 We're increasing the quality of our examination.
14 Instead of being a spot-check, we're actually getting to
15 look for major anomalies. We're able to do a greater amount
16 and volume of materials. The intensity of our examination
17 process is really being increased, and we're making the risk
18 to the drug smugglers significant. When you lose over two
19 tons of cocaine while smuggling it, you still pay for it.
20 And they better be able to pay for it. These people do not
21 hand out pink slips.

22 The increased detection, seizure, we've seen it.
23 We have forced smugglers to do things they normally wouldn't
24 do, and we believe we're making them divert how they
25 smuggle. We have had tunnels being built. We have a lot of

1 very desperate measures.

2 Customs' plans? One, get the job done. We're
3 very performance-oriented. Our people work hard. I'm proud
4 to be associated with them. People are the key to our
5 success. No matter how good a machine, if someone doesn't
6 use it or apply it properly, it will not work. And the
7 mobility is critical so that we are not fixed in a Maginot
8 Line.

9 Our commissioner, he's running special operations,
10 very innovative, telling the inspectors: You figure out
11 what you want to do, let us know, and we'll okay it.

12 We're being innovative because the smugglers are.
13 Some of the things they do absolutely astounds me.

14 And, finally, we're having a coordinated use of
15 assets. We sometimes bring in special focus on an area,
16 really crush them.

17 Thank you.

18 CHAIRMAN FLETCHER: Thank you very much.

19 We will now open for questions from members of the
20 committee.

21 MS. KAUFMAN: Could you describe the kind of
22 training that you're giving the operators and other
23 personnel adjacent to these units? How many hours and what
24 does it consist of?

25 MR. LINDQUIST: Depending on the system, typically

1 the truck X-rays, we have had a three-day training program.
2 The first day we give them four hours of walking around the
3 equipment, showing them what it is, showing them where the
4 cabinet is.

5 I will not walk through a cabinet area. I lead by
6 example. None of our supervisors will walk through a
7 cabinet area. They understand that if we want people to
8 believe in these areas, we have to respect them.

9 We explain to them the difficulties and dangers.
10 This is on the X-ray type equipment. On the radiological,
11 we actually have to have a certification for our operators.

12 But then on the second day, they man the positions
13 of the equipment on a rotating basis. We have four people
14 operate, for instance, the truck X-ray system. And what we
15 do is we put them in on the screens, we put them in on the
16 people guidance.

17 Our major danger, by the way, when handling truck
18 drivers are the drivers themselves. They can come out with
19 a gun. They can come out with a club. They usually submit
20 very quietly or hope they're going to get by. We've had
21 some of them go off to the men's room and never return for
22 their truck in the line. But our major danger is the truck
23 driver.

24 In the equipment, even in the operating cabinet,
25 there are only two areas that are really hot. But because

1 of the mechanical danger and the way we do this, we just put
2 the whole building out of bounds. It has all the door
3 locks, interlocks, and so on. And we have emergency buttons
4 in several places. They're taught how to use them. And we
5 rotate them through all the positions so that they can work
6 the screens, they work the data entry, which is very
7 important for us to keep records of who's coming in and what
8 we're finding, and at the end of three days, they're
9 confident to go out and learn how to operate equipment. And
10 what I mean by that is they think they can read X-ray
11 images. X-ray images they get pretty good at over the next
12 40 to 60 hours of actually looking at the screen. Then they
13 think they're a pro and their performance sinks like a rock.
14 And then something happens and they climb back up that hill,
15 and they are superb. They're better than I'll ever be, and
16 I've put a lot of hours behind these screens, but these
17 people using it get very good.

18 MS. KAUFMAN: Could you narrow it down to, out of
19 those three days, how much of that pertains to radiation
20 safety and radiation physics and biologic effects and that
21 sort of thing? Just delete the part about how to interpret
22 the scan and mechanical safety and--

23 MR. LINDQUIST: Probably about two hours, but
24 there is another radiation course that they have already all
25 had because they carry the busters, which are these little