

1 you have this map of the skin. So, this is the
2 back shaded, and this area is the front surface.

3 During a fluoro system, this display is
4 presented to the radiologist although I think in
5 the Siemen system it wasn't out where the
6 radiologist was, it was back at the control
7 console, but you got an idea of the hot spots on
8 the skin being developed from this cumulative
9 exposure.

10 This is really I think for interventional
11 procedures would be a real nice thing to have.
12 Apparently, there wasn't a lot of demand, and the
13 manufacturer that provided this feature didn't on
14 its last iteration of this system as I understand
15 it.

16 Anyway, that is the kind of dose display
17 that some of the radiologists said would be
18 beneficial to have. I might mention that FDA is
19 supporting through a small business innovative
20 research grant the development of a similar kind of
21 approach that might be an add-on to a system, and
22 we will have to see how that plays out in the
23 future.

24 Another comment we got was it would be
25 useful if we could see where the collimators are

1 adjusted or, in other words, how large is the X-ray
2 field without having to step on the pedal and make
3 irradiation, in other words, have the computer
4 display on the image display where the collimator
5 blades are located.

6 There are some systems that have such a
7 feature. I think the radiologists were telling us
8 this would be really nice to have, too. It would
9 allow a collimation adjustment deciding on how big
10 to make the X-ray image without actually exposing
11 or you could make a quick exposure and while
12 viewing that last image hold image, adjust the
13 collimators to the size you really need to see and
14 then begin your irradiation lab time.

15 Again, something like this would be a step
16 up for a lot of X-ray equipment and would I think
17 require a proposal in order to get there with
18 comment from the public.

19 Another question that came up was
20 something we didn't propose, and that is, you know,
21 in radiographic systems, the exposure comes on, you
22 see the needles jump or the lights flash, and you
23 know exposure is terminated when you hear the
24 little ding that goes ding.

25 But in fluoro, I think the assumption--and

1 we have no requirement in our standard that there
2 has to be a display of when the fluoro is on,
3 because previously, you looked up at the monitor or
4 you looked at the II output and you could tell the
5 X-ray was on, but nowadays, with the last image
6 hold and multiple monitors, there is a concern on
7 the parts of some of the commenters that we really
8 can't tell in this busy room exactly when there is
9 X-rays being made and when there aren't.

10 We didn't propose a requirement like this,
11 and this is one that I think we need to look at
12 perhaps. In the IEC standard, there is a
13 requirement that there be an indicator on the
14 console out in the control room when fluoro is on,
15 but there is not an indication of a requirement
16 that there be a clearly visible and unmistakable
17 indication that the X-rays are being made out in
18 the procedure room.

19 There is a requirement in the IEC standard
20 that they provide a means whereby somebody could
21 hook up a light or an alarm that does provide a
22 signal when the beam is on, but it doesn't require
23 that that signal be fed to some display out in the
24 operator's room. So, that is a comment that we
25 got, as well.

1 The last one is a little bit complicated
2 to try to explain, but I will give it a shot here,
3 and that is the idea that in this day of digital
4 imaging, a concern was raised that it is hard to
5 tell if the technologist is really doing a good job
6 of limiting the X-ray field when there might be the
7 capability of adjusting what you display after the
8 fact, in other words, what we refer to maybe as
9 image cropping or electronic cropping of the final
10 image.

11 This is probably more of an issue in
12 digital radiography rather than in fluoroscopy, and
13 I think it is something that we will have to think
14 about. I haven't heard a lot of discussion of this
15 in the community, and I am really not clear as to
16 how many systems this is a capability on currently.

17 It involves the marriage of the digital
18 image capture and some ability to manipulate that
19 image prior to storing it or prior to storing it
20 and then bringing it back later to look at it, and
21 we haven't really done a clear investigation of
22 what is out there, but let me sort of show you what
23 I was trying to get at here.

24 The idea being that in a digital image
25 receptor, let's think of it with a flat panel

1 perhaps, here is the image receptor, and good
2 radiology practice would limit the X-ray field to
3 smaller than that, so you don't waste X-rays, but
4 perhaps you are only interested in this portion of
5 the image.

6 This is where the real information is. It
7 would be possible following the exposure, made what
8 we would say with good collimation conditions, that
9 if you are worried about storage of lots of data,
10 you might only want to store this much. Then, when
11 you bring that image back later, you see the stored
12 image, but you really don't have any idea of a way
13 to tell how big the X-ray field was.

14 On film currently, you can see the edge of
15 where the film blackening was and know the
16 technologist used good collimation. This is a
17 concern if the equipment would provide a feature
18 like this where here is your image receptor, the
19 solid-state device is only so big, but in order to
20 make sure I don't miss anything, I open up the
21 X-ray field a good bit larger.

22 This is possible probably, especially when
23 you have an old conventional X-ray system that has
24 been retrofit with a digital image receptor and the
25 collimator is manually adjusted. Again, you are

1 interested in this portion of the image, and
2 following the work, somehow this is all that is
3 stored because you can electronically crop the
4 image and save storing all this unwanted
5 information in your PAC system or use all that
6 memory that would be required, but you can't tell
7 that the X-ray field was much larger than
8 necessary, even larger than the image receptor.

9 This is not an issue that we have pursued
10 a lot here at the Center up until now, but I think
11 it is one that we will need to look a little bit
12 at. I just wanted to mention this as sort of one
13 of the things that I think has appeared on our
14 plate as a result of some of some of these
15 comments.

16 This would be an issue perhaps in computed
17 radiography or digital radiography. It's I don't
18 think really an issue in fluoroscopy.

19 So, there are questions here that we have
20 about this electronic cropping. Do we need to
21 address this issue somehow, particularly for
22 digital systems, and is it an issue only for
23 systems that store these images afterwards?

24 Suppose the technologists, in their
25 pre-review of the image, can do this cropping, and

1 not give the radiologists the full picture to begin
2 with. That is one of the questions we have, so is
3 this something that is a concern to the community.
4 I think we will have to be looking at this with
5 value input from the committee.

6 We also had a few things that we didn't
7 quite get right in the Notice of Proposed
8 Rulemaking. We had a discussion in there of unique
9 modes of operation. This was something that should
10 have been taken out because this had bearing when
11 we were proposing to require manufacturers to
12 describe in the user information both modes of
13 operation and the doses associated with those
14 modes, and we were making the point that any dose
15 that was more than 88 milligray per minute was a
16 unique mode and we wanted to get that dose
17 information.

18 We, in fact, decided not to propose that.
19 We are only proposing a dose display, so there was
20 a little bit of confusion in the preamble about
21 this, so the point is that doesn't apply anymore.

22 We left off an effective date on our issue
23 describing the addition of filtration for half-hour
24 X-ray tubes, the idea of having the ability to add
25 additional filtration above the minimum when that

1 is required, say, for a large patient.

2 We also need to clarify how there is an
3 indication of what filtration is being used. We
4 didn't specifically lay that out in the standard,
5 and I think we realized that users need to know if
6 additional filtration has been added and how much
7 it is or what it is that has been added, so we are
8 working on this requirement to refine it.

9 It was pointed out that in our attempt to
10 improve that half-value layer of the X-ray beam, we
11 proposed, of course, an amendment to increase the
12 minimum half-value layer. That has an impact on
13 the requirements for attenuation requirements on
14 material that is between the patient and the image
15 receptor.

16 We have a requirement that says if you are
17 putting material between the patient and the image
18 receptor--this is things like a cradle to support
19 an infant--you don't want that to be very
20 attenuating and require extra dose, and it turns
21 out that by changing the half-value layer of the
22 minimum required filtration, we effect this.

23 So, the numbers here need to be adjusted
24 slightly in the table that presents these values in
25 the standard, and we would be adjusting these to

1 match the IEC standard, which has already taken
2 this into account.

3 There is a question about the tolerance, a
4 I mentioned, on the dose display, and, in fact, we
5 proposed two different ways of doing this in the
6 preamble that we shouldn't have. We proposed (a)
7 that the manufacturers state what the tolerance is,
8 and then later, over in 1020.32(k), we told them it
9 had to be plus or minus 25 percent. So, this
10 requirement shouldn't have been there, we didn't
11 mean to propose that.

12 There was also a typo in this section that
13 just garbled a sentence having to do with the
14 alternate location that a manufacturer can specify
15 for this reference point, so if you reading this
16 section and it's confusing, you are right. We will
17 clear that up.

18 So, those are the kind of comments we got,
19 some of the things that we have got on our plate to
20 deal with. How long is it going to take to finish
21 this? We think we will finalize regulatory wording
22 decisions here in the very near future and be
23 drafting a Federal Register Notice.

24 We didn't get a lot of comments on the
25 cost/benefit or the impact assessment, so I don't

1 think we are going to have to do a lot there. We
2 did get a couple of comments that said we had way
3 underestimated the benefit, that there was
4 tremendous risk from X-rays and therefore we were
5 going to do a lot more good than we had estimated.

6 That may be true, but I don't think it
7 will hold us up from going forward with the
8 proposal. We will, of course, have to have the
9 usual review process in line to deal with what we
10 have done and we are hopeful that we can have the
11 thing out of here by the end of the year I guess,
12 but as I have always said when I mention dates like
13 this, don't hold me to it.

14 One thing I wanted to mention just briefly
15 is this issue of the IEC standards, and you heard a
16 little bit about this from Lillian Gill this
17 morning, which was the relationship between our
18 performance standard and the IEC standards.

19 I really said that I wanted to sort of put
20 on the table and out in front of the public some of
21 the things that we are talking about internally to
22 sort of put this into context a little bit. I
23 don't think we have reached any decisions, but I
24 did think it would be useful to hear from the
25 committee opinions of views on this issue.

1 Just sort of to recap, there were no IEC
2 standards early on when we developed our standard.
3 This was done in the late '60s, early '70s. The
4 process for developing an IEC standard is a little
5 bit different. Their standard is based on the
6 consensus of national committees voting.

7 They are maintained by maintenance teams,
8 working groups, who are members of these national
9 committees, are appointed with the blessing of the
10 national committees. The structure particularly
11 of the teams that are doing the X-ray standards
12 currently are kind of being revised a little bit,
13 but there is active looking at the diagnostic X-ray
14 standards under the IEC process, sort of on a
15 continuing basis.

16 The IEC standards, there is a question
17 about how enforced they are. Clearly, to get the
18 EC mark for marketing in Europe, you have to deal
19 with a notified body who wants to know that you are
20 compliant with these standards. Often that is done
21 by type-testing of a model or factory visits.

22 We are not clear, though, how detailed
23 this is in all the various countries, and one of
24 the things that we have always prided ourselves on
25 I guess to the FDA, that if we are going to have a

1 standard that is worth enforcing, we want to make
2 sure that people comply with it.

3 Another issue is our FDA standards only
4 address radiation safety performance, very limited
5 field of view, whereas, the IEC standards cover the
6 gamut of both radiation safety, all other kinds of
7 safety, and even process, measurement, methodology,
8 a lot of different things, and sometimes they all
9 get mixed into one standard.

10 So, adopting an IEC standard is a little
11 complicated if we are trying to only pull out of
12 that the things that address radiation safety. So,
13 one of the questions is could we use these somehow
14 to lighten our load of standards development, in
15 particular perhaps for medical equipment, where we
16 have the other regulatory program for medical
17 devices, we might see some synergy that could be
18 adopted here.

19 I am not sure how far we can go with the
20 other non-medical products, but those are kind of
21 the things that we are discussing here. We would
22 like, I think, comments and views of people on
23 this.

24 One of the questions, of course, is if you
25 adopt an IEC standard or use it, how do you enforce

1 it, what is the impact of doing this on the State
2 Radiation Control Programs. Most of the state
3 programs have regulations modeled after the U.S.
4 Standard. They inspect for us, they check
5 compliance just to the same standard that we are
6 using, not that that couldn't be done and developed
7 for an IEC standard, but there would be
8 considerable work and perhaps disturbance in
9 getting there.

10 What is the impact of adopting an IEC
11 standard if it's not a formal regulation on what is
12 currently now there in terms of the federal
13 pre-emption of state regs when we have a federal
14 reg in place?

15 So, those are some of the issues that
16 don't come to mind immediately, but they are
17 underlying this issue of how can we consider using
18 IEC standards or would that be appropriate.

19 Could we use somehow the medical device
20 authorities that we currently have in combination
21 with voluntary standards, to somehow at least
22 assure medical devices provide adequate level of
23 safety?

24 Some other questions one could ask, could
25 we do this without legislative change? It is not

1 clear to me that we could, but we are just at the
2 beginning of these kinds of discussions, and I
3 don't think we could reach any conclusions
4 currently.

5 Would public health be adequately
6 protected if we placed a lot of reliance on the IEC
7 standards? Could the FDA or the U.S. National
8 Committee play a more effective role in making sure
9 that the IEC standards do what we think are needed?

10 Often, in the IEC process, if you are not
11 there at the table, actively involved in it, you
12 don't have a whole lot of influence, and we have
13 not been as active in some of the X-ray standard
14 work as we might have liked to have been in the
15 past, however, we did play an active role in the
16 development of the IEC standard for the X-ray
17 Equipment Interventional Radiology Safety Standard.
18 Bob Gagne [ph] on our staff was a member of that
19 working group.

20 Much of what we are talking about doing in
21 these amendments will get us in line with what they
22 did in the IEC standard, but there are a few
23 national deviations that we are thinking about.

24 Another question one could pose is do the
25 current problems with X-ray systems warrant

1 continued mandatory standards, are we in the mode
2 of operation where this is still the best way to
3 spend our dollars, enforcing a mandatory standard
4 and dealing with that. I think valid discussions
5 could be had on both sides of that issue.

6 Would we get a bigger public health impact
7 if FDA were doing other things like education or
8 data collection or training activities rather than
9 some enforcement type activity?

10 So, there are a lot of questions on our
11 plate here as part of this, looking at what our rad
12 health future will be, but I think, in summary, we
13 got a lot of comments, they were generally
14 supportive of our proposed amendment, so we have
15 got a few final decisions to make on some of the
16 questions that I outlined, and we would welcome the
17 committee's comments or questions if you have any.

18 DR. ROTHENBERG: Thank you, Tom.

19 Any comments?

20 DR. LIPOTI: I really like the alternative
21 display of dose information that you described
22 where you would have both the display of air kerma
23 and the cumulative display. I don't know why
24 didn't think of that before, but that really is the
25 way to go.

1 When I do my exercise equipment, it gives
2 me one or the other, and it is really annoying.

3 DR. SHOPE: Apparently, some of the
4 radiologists thought that way, that is where we got
5 the suggestion.

6 DR. LIPOTI: I met them in the exercise
7 room.

8 In terms of the future role of the IEC
9 standards, I see a difficult problem because our
10 authority is somewhat limited, and the IEC standard
11 goes beyond what we would have the authority to
12 enforce. So, it is also not clear to me, in a
13 state program, we may need legislative change
14 before we could do that.

15 Of course, states look to the FDA's
16 leadership role in a lot of these kinds of
17 standards, so the way that you are going has a
18 great deal of influence on what we should be doing.
19 That is a significant sticking point. I also
20 wanted to emphasize where would we have the best
21 public health impact.

22 It may not be with enforcement of the
23 standard, but it may be with the education, the
24 data collection, and making that available. I
25 think the next studies are a real example of

1 something which is non-regulatory, but that has a
2 great impact on public health.

3 DR. ROTHENBERG: Yes.

4 CDR LOSCOCCO: Were there any concerns
5 about when you--I also like the air kerma rate and
6 the cumulative rate, but were there any concerns
7 about indicating what that was versus the skin dose
8 mapping? Obviously, it is going to be a little
9 misleading, that is the entrance dose, but you
10 could have panned around quite a bit.

11 DR. SHOPE: Well, the proposal that we
12 made in the Federal Register was, of course, for
13 dose display of air kerma rate and then cumulative
14 air kerma at the conclusion of irradiation. That
15 was our proposal.

16 A couple of comments came back that we
17 like that, that is good, that is an improvement,
18 but what we would really like, a dose skin mapping
19 requirement, why don't you guys think about that.
20 I think my point here in bringing that up is we
21 have had that suggestion, but it is not something
22 that we could impose without another notice and
23 comment process, and understanding, you know, is
24 that feasible, can manufacturers do that.

25 Well, at least one of them has, but how

1 much did it cost and why didn't they keep it, you
2 know. There are a lot of those kinds of issues
3 that are still out there, but we think it is
4 probably a useful feature, and we put some FDA
5 money to look at that a little bit in terms of our
6 small business innovative research grant that we
7 have made.

8 CDR LOSCOCCO: And the new CT systems that
9 have CT fluoroscopy, is that also covered?

10 DR. SHOPE: CT systems, they are not
11 covered by the fluoro.

12 DR. ROTHENBERG: Tom, on the cumulative
13 display, there is still nothing here about storing
14 that information, is that correct?

15 DR. SHOPE: That is correct. We didn't
16 propose that. Surprisingly, we didn't get any
17 comments that can come to mind that it ought to be
18 stored anywhere. Clearly, manufacturers in many
19 cases would store this information in their
20 voluminous computer capability and would have it
21 there to know what has been happening with the
22 X-ray system.

23 I think if the vendors in the community
24 are interested in providing that feature, it
25 wouldn't be difficult for a manufacturer, if they

1 are displaying it, also to save it and print it out
2 or do whatever they want to do with it, put it in a
3 DICOM header if these images are stored, but that
4 was not part of our proposal and we really didn't
5 get comments advocating that.

6 DR. ROTHENBERG: I think certainly for
7 both this and the CT, it would be excellent to do
8 that. Maybe that has to come in the next round,
9 but I would like to see at least the committee
10 recommend that you look into that, even though it
11 is not part of this already issued.

12 DR. SHOPE: There is always a possibility
13 of a slight question, well, I can make the
14 immediate connection that display to the user,
15 which allows them to change a procedure and save
16 dose as radiation safety protection. The
17 recording, the requirement to record that, is that
18 also radiation protection? I think we would have
19 to develop a good argument for why that is a
20 radiation safety feature as opposed to a
21 convenience or a recordkeeping or helping do
22 quality assurance feature.

23 But we could probably make that argument,
24 but I am just saying I am not sure I know how to
25 make that argument right now.

1 DR. ROTHENBERG: Certainly, if somebody
2 comes down with these big skin burns sometime
3 later, it would be nice to know for sure that was
4 the reason.

5 I would also like to comment just on the
6 25 percent versus the 50 percent. I think 25
7 percent is doable if this is going to be applied in
8 conjunction with other studies done at other times.
9 I think we would want the smaller, more accurate
10 measurement.

11 DR. BENSON: I definitely agree with that.
12 Something that varies by 50 percent is not really
13 useful in terms of recordkeeping because you
14 wouldn't be able to compare from time to time. You
15 would have no idea what was going on.

16 DR. SHOPE: I think most of the times I
17 wouldn't expect that a system between the first
18 measurement and the second measurement on the same
19 system you would see that kind of variability. It
20 is just it would be somewhere in that range
21 constantly and not jumping all around would be my
22 expectation.

23 So, you would, I think on a particular
24 system know that the display is pretty well
25 constant and you are getting a constant relative

1 kind of number, but system to system, or facility
2 to facility, it raises a lot of issues.

3 I think the other thing you have to keep
4 in mind in thinking about this requirement is what
5 does it take to present this number. This is not
6 something that the meter tells you, but it is going
7 to have to be a number that is inferred either from
8 calibration of the technique factors in the X-ray
9 machine and some computation about where is the
10 source in the patient, so there are a number of
11 factors, and you start combining those errors, I
12 think that is the reason at least for the IEC
13 standard, that those numbers got to be probably
14 bigger than 30 percent, and they used a limit of
15 50.

16 But there may be some ways to look at that
17 and tighten that up, but there are a lot of factors
18 that could go in. If you have a direct monitoring
19 system that actually has a meter in the beam, and
20 is somehow measuring this, and then using that to
21 infer the dose at the reference point, there may
22 not be as many factors, so we will have to look at
23 how that can be played out.

24 DR. BENSON: Yes, that was the other part
25 of my question. The air kerma rate, how is that

1 modified, by collimator distance shielding?

2 DR. SHOPE: Well, I mean the rate if 1
3 over R-squared in distance from the source.
4 Collimator really, the number we are talking about
5 is the free in air, so it's independent of
6 scatters, so if you have at the patient's skin, a
7 certain amount of radiation, and you enlarge the
8 field, you will get backscatter from the patient,
9 that will probably make that number on the skin go
10 up, but the air kerma rate, which is free of
11 backscatter, would not change as a function of
12 collimation. This is meant to be the dose to the
13 skin, not how much skin is getting the dose.

14 DR. BENSON: Okay.

15 DR. ROTHENBERG: One thing with regard to
16 that accuracy, we have systems that just do dose
17 area product, not based on a measurement, and they
18 are very close. I mean they are really accurate,
19 surprisingly accurate.

20 So, I think if they can do that in
21 conjunction with collimation information--

22 DR. SHOPE: There is an IEC standard for
23 dose area product meters, and it has a 50 percent
24 spec in it.

25 DR. ROTHENBERG: But I mean the actual

1 units where we measure, they are much better than
2 that, they are not even close to having a 50
3 percent or even 25 percent.

4 DR. SHOPE: That is the kind of experience
5 I think we need to have to support this kind of
6 requirement.

7 DR. CARDARELLI: I wanted to concur on the
8 plus or minus 25 percent. I think
9 technologically-wise, we can do a lot better, so I
10 would definitely concur with that.

11 The other thing is without a question of a
12 doubt, we could develop a strong enough public
13 health argument to record the cumulative dose. I
14 don't think that that is going to be very
15 difficult. In addition to recording the dose, I
16 would also go so far as to address the cropping
17 issue of the digital image.

18 We could simply record, if it's possible,
19 the field dimension of the X-ray, as well as the
20 cropping image dimensions, and those two pieces of
21 information will be able to capture that field size
22 without increasing memory.

23 DR. SHOPE: I raised that issue just to
24 point out that we got some comments on some things
25 that we really hadn't been considering and would

1 probably take a little work to work out, so if we
2 go forward on that, you will be hearing from us
3 again I guess in the future on that kind of an
4 amendment.

5 DR. PLATNER: I wanted to step ahead a
6 little bit off the accuracy, which I agree we need
7 more accurate measurement, but one of your other
8 points was that you suggested that ultimate
9 responsibility for modifications should be able to
10 be shifted to contractors that might design the
11 modification or make the modification.

12 I guess I would oppose that sort of
13 change. I think that the owner or user has to at
14 least share responsibility, because I know in
15 construction, that is the normal practice. You
16 shift all the responsibility of contractors and
17 subcontractors and sub-subcontractors until the guy
18 that is responsible in court is incapable of doing
19 the work.

20 I would hate to see that happen here.

21 DR. SHOPE: I think our approach would be
22 that FDA says the user, the owner is responsible
23 for this. My comment was in response to the user
24 saying, hey, we are not technically competent to
25 know if it's in compliance or not, and our answer

1 is, well, then don't make the modification unless
2 you are sure that the person who is doing it for
3 you had that competence and you have worked out
4 some kind of arrangement, so that you hold him
5 responsible if you don't want to be responsible,
6 but ultimately, FDA is going to look at the owner
7 as the responsible person.

8 Now, whether that gets to the liability
9 issue is a different story.

10 DR. ROTHENBERG: Any other comments?

11 DR. SHOPE: It was a status report, as I
12 said, we are not going to tell you what we are
13 about to do because we are constrained from doing
14 that.

15 DR. LIPOTI: Larry, did you want us to
16 memorialize some sort of motion that we support the
17 recording of dose?

18 DR. ROTHENBERG: Okay. Do you want to
19 make that proposal?

20 DR. LIPOTI: Yes. I propose that.

21 CDR LOSCOCCO: Can I make one more comment
22 before you do that?

23 DR. ROTHENBERG: Sure.

24 CDR LOSCOCCO: I would think some people
25 might have a problem if you are only recording the

1 maximum dose. We have the program that Dr. Shope
2 was talking about, and your dose, your peak dose
3 can be as much as 60 to 70 percent different than
4 the dose--

5 DR. ROTHENBERG: Yes, because of the
6 angles.

7 CDR LOSCOCCO: So, recording of what?

8 DR. ROTHENBERG: Well, as long as it is
9 understood. I mean for the moment, that is what
10 the meter is going to give you. I think it is
11 better than not recording anything with the
12 understanding that it could vary, and you might
13 know from the type of procedure that was done that
14 yes, this is going to be pretty close, or, no, this
15 is because the beam is going to move around a lot,
16 this could be low by a factor of 2 or 3, but you
17 still have the number, and then you could have
18 something to work with, I would think.

19 All those who would be in favor of
20 recommending that this number be recorded?

21 Opposed? One.

22 Abstain? Two.

23 It was two, one, and everybody else. You
24 might want to record just the numbers themselves.

25 MR. KACZMAREK: This is not going to

1 appear in the final rule. This will be a future
2 consideration.

3 DR. ROTHENBERG: Right. Given the
4 discussion, I think you would want to look into is
5 this the best thing to record, but at least we
6 would like something recorded, if this is there,
7 and that is all that is there, yes, if it can be
8 more specific to the procedure.

9 MR. MYRICK: In conjunction with any
10 requirement you might come up with to record this
11 information, you would have to establish some type
12 of retention policy. How long are you going to
13 keep that?

14 DR. ROTHENBERG: I would think if it's
15 something that could be added to the digital image
16 data file, then, it would just stay with that image
17 forever as long as the image were there, and there
18 are certain legal requirements on the images.

19 DR. SHOPE: I think FDA might want to just
20 say the equipment must provide the mechanism for
21 recording without getting into the medical practice
22 of how long that is part of the patient's medical
23 record. We could require the equipment, give this
24 capability. We couldn't direct the user what to do
25 with it, I don't think, in terms of an equipment

1 performance standard.

2 DR. CYR: But there are other requirements
3 on how long the images have to be stored.

4 MR. KACZMAREK: My hope would be that once
5 this rule publishes that we are working on now,
6 that the manufacturers would go ahead on their own
7 and record the cumulative dose, make it part of the
8 patient file just because it might be a nice thing
9 to do.

10 DR. CARDARELLI: I guess I would disagree
11 with that. If you make it voluntary on any
12 manufacturer, they will not do it largely for legal
13 purposes probably. For public health purposes, it
14 is critical even though the dose itself may not be
15 the true dose the body absorbs.

16 If one had to reconstruct, say, with the
17 dose to the bone marrow or some organs or whatnot,
18 we would then have a starting point to go from.
19 Right now we have nothing to start from except
20 perhaps a guess what the machine settings were, and
21 then we would have to reconstruct.

22 At least we have a measurement now, and
23 that is why I would be a strong advocate for
24 recording some level of cumulative exposure or dose
25 with the image, and not necessarily making it

1 voluntary for the manufacturers.

2 MR. KACZMAREK: What I was saying was that
3 in the interim, in near term, until we got around
4 to making it a requirement.

5 DR. ROTHENBERG: You can't add it to this.

6 DR. CARDARELLI: I understand.

7 DR. ROTHENBERG: Thanks a lot, Tom.

8 DR. SHOPE: Thank you.

9 DR. ROTHENBERG: Now we are ready for a
10 presentation by Frank Cerra and Dan Kassiday of the
11 Security Screening Systems.

12 **Security Screening Systems**

13 MR. KASSIDAY: Hi. I am Dan Kassiday. I
14 am with the Office of Compliance. Again, here we
15 are talking about ionizing radiation security
16 systems. Hopefully, this year we will see a few
17 different things.

18 The goals for today are to update you all
19 on emerging issues and new products especially
20 since 9/11, familiarize the new committee members
21 with the other, somewhat in the past, controversial
22 items that we have dealt with, and discuss progress
23 on the previous recommendations and new projects
24 that are ongoing, and hopefully, hear committee
25 discussion to support and guide these efforts.

1 Just a quick overview of what I will be
2 talking about. The good old cabinet X-ray systems
3 have come into some contention with airport workers
4 recently. Vehicle and cargo scanners are being
5 bought and installed in many, many ports around the
6 nation, and could present a significant risk if
7 misused.

8 There are some new products that people
9 are talking about, a couple of things that are
10 getting near to release, and, of course, Personnel
11 Security Screening Systems. Then, I will talk
12 about what FDA has been doing with these things and
13 leave you with a few relevant web links. Then,
14 Frank will go over some of the studies and reports
15 on personnel scanners that have come out in the
16 last year, as well as go over a history of what we
17 have done with those products.

18 These are cabinet X-ray systems. You
19 probably recognize the one on the left as something
20 you have put your carry-on luggage through. The
21 one on the right is probably used for some sort of
22 quality control on soft foods.

23 They appear everywhere. The industrial
24 ones are still pretty quiet. The ones at the
25 airports aren't any more dangerous, but there is a

1 perception of risk with them.

2 These two are explosive detection systems.
3 They are also considered cabinet X-ray systems.
4 You will note that they are rather large. The one
5 on the left is a spiral CT system. The one on the
6 right I believe is a straight slices [ph]. They
7 are intended for checked baggage, and tend to be
8 the center of the controversy in most airports, as
9 I understand it.

10 Airport X-ray systems went under TSA
11 jurisdiction when the screeners went under TSJ
12 jurisdiction, which caused some issues with states
13 formally regulating these, and now they are not
14 regulating these, and generally, people being
15 concerned about who is regulating these for the
16 use.

17 We have been assisting TSA in developing
18 their own internal policy for how these systems
19 should be used. There have been a number of worker
20 complaints and concerns especially near the EDS
21 systems. Apparently, Customs workers that work
22 near those EDS systems have little geiger, you
23 know, crystal pagers for radiation detection, and
24 they are very sensitive, and occasionally, you will
25 get some scatter and they will go off.

1 We have done surveys in response to that
2 and found nothing unusual in compliance systems, to
3 the best of our knowledge.

4 TSA has contracted for NIOSH to do a study
5 on basically worker exposure, and Dr. Cardarelli is
6 primary investigator on that.

7 We also periodically get questions about
8 what happens if I run my food, drug, computer
9 through these systems, and we put out a Frequently
10 Asked Questions document that addresses this, and
11 our response is pretty much the same - as far as we
12 know, there should be no effect. The dose range
13 for one of those carry-on screening systems is 1
14 millirem or probably much less to any object that
15 goes through.

16 The EDS systems only in worst case can get
17 up to 120 mrem. None of these are excessive dose.
18 That is to products going through them. Of course,
19 film can be an exception, and the EDS systems are
20 the ones most likely to affect film.

21 Again, in our Frequently Asked Questions
22 document we publish, we point people to the
23 manufacturer web site for the film, you know, how
24 should I take care of my film when I am flying,
25 that sort of thing.

1 These are the emerging issues. We have
2 got cargo and vehicle systems. They are large
3 systems, they, in general, will either move past
4 the system they are screening, like the truck on
5 the right, or a truck or a part of the container is
6 pulled through it, like the system on the left.

7 Down below we have what looks like a
8 backscatter image for a vehicle. Some of these
9 systems do both a backscatter and a transmission
10 image to give various contrast for the people
11 looking at the images. Backscatter just means it's
12 resolving the image from bouncing the X-rays off
13 the system or a product being scanned, and
14 transmission, of course, is image receptor on the
15 opposite side, much like a normal medical X-ray.

16 This is an example of a truck that was
17 crossing the border down in Mexico, and you will
18 see that there are some inadvertent exposures
19 periodically along with the bananas.

20 This is a relatively new system. It is
21 basically ISO containers like you would put in
22 cargo ships, and they can be relocated in a matter
23 of a few days to put where they are needed. You
24 see a tractor on the right side pulling a truck
25 through.

1 This is a concept for an accelerator-based
2 system. Again, it is going to have a tractor system
3 to pull the vehicles through it. It appears that
4 it is here, a picture here in a port. We can
5 imagine that it might be on borders or on bridge
6 crossings, et cetera, as well.

7 All these systems at present are intended
8 to X-ray these vehicles without any passengers,
9 without any drivers.

10 This is a backscatter-only system. What
11 it is, is a panel truck, and they have got a
12 similar, but lower powered X-ray system in there,
13 and they can use that for doing cargo containers,
14 as well as perhaps personnel or security along
15 parade routes.

16 As far as I know, they have not
17 distributed that in the U.S. yet. It is clearly
18 not a cabinet X-ray system and it really doesn't
19 fall under any of our standards.

20 As I understand it, the company is
21 designing it to meet the personnel screening
22 standard for that mode, but, of course, in this
23 case, it depends on whether the people or the
24 vehicle are moving at an adequate speed to test
25 what the dose will be.

1 A couple more examples. This one drags
2 the system around, then, drags the vehicles through
3 it. Another fixed site I believe in Hong Kong, and
4 that is a transmission image as opposed to a
5 backscatter image.

6 The one on the left is a isotope-based
7 system probably cesium or cobalt 60. The one on
8 the right is the first accelerator mobile system
9 that has gone to the shipyards. As I understand
10 it, more of those are being built and are fairly
11 successful.

12 Of course, the one on the left is mainly
13 an NRC issue, however, when we get to, in our
14 participation in an ANSI Committee that we are
15 trying to start to consider these products, we are
16 going to go ahead and consider isotope systems, as
17 well as X-ray.

18 Anyway, things that are coming along. We
19 have got the backscatter X-ray van, which has a
20 relatively low output as long as it is moving
21 along. Many manufacturers have discussed portals,
22 which you can drive through, which would be
23 intended to not only screen your car, but you, or
24 trucks, or et cetera, maybe parking garages.

25 There have been any number of places these

1 things have been considered - Andrews Air Force
2 Base, like when the President is going to fly out
3 of Air Force One, et cetera, and, of course,
4 various things to do, people and pedestrians.

5 There could be some high energy
6 accelerators used for certain cargo containers.
7 The current ones only extend to 6, maybe one was 8
8 megaelectron volts. Right now the high energy ones
9 aren't out there, but there are some uses for them,
10 as I understand it.

11 Machine-produced neutron systems, there is
12 one in development that has been funded by
13 Congress, and other unpredicted technology which we
14 are going to do our best to try and stay on top of.

15 Here is the concept for the Pulsed Fast
16 Neutron. It is similar to the X-ray systems, they
17 pull the vehicle through. Several reports have
18 been done by the National Council of Radiation
19 Protection on measurements as part of the
20 Environmental Impact Statement for this product, as
21 well as things going through it, activation of
22 possible cargo and all that sort of thing.

23 According to the NTRP and the
24 manufacturer, there shouldn't be a real problem
25 with the items coming out of it, although I

1 understand they are also building a concrete bunker
2 to put it in to shield the neutrons adequately.

3 The one on the right is off the same
4 company's web site. It is apparently a mine
5 detection system. They are shooting neutrons into
6 the ground. I don't know of that being sold in the
7 U.S. yet, but who knows what is out there.

8 As a follow-on to our Personnel Security
9 Screening System's success in getting a standard
10 out in two and a half years, we are working with
11 Customs, NIOSH, OSHA, and some other agencies, TSA,
12 to try and begin the development of a consensus
13 standard that will adequately address these systems
14 that are now being rapidly deployed, that the
15 cabinet X-ray system is not necessarily appropriate
16 for, and that cause considerable worker anxiety
17 among the dock workers, et cetera, and in this
18 case, when they are accelerated, possibly for good
19 reason, if they are misused, and try and predict
20 what could be coming up and control exposures from
21 things, so that we don't get so safe that we hurt
22 ourselves.

23 This is the typical question we get asked
24 about the personnel systems, "Is their use
25 justified?" Only if the risk results in a societal

1 benefit from the increased security.

2 This was the first backscatter X-ray
3 system. As you see, it looks through your clothes,
4 detects the plastic, the gun, et cetera. This was
5 the second. Those are the only two that have been
6 reported for sale in the U.S. at this time.

7 Additionally, this system has now been
8 reported. It is an transmission X-ray system. To
9 the best of my knowledge, none have been sold yet.
10 You can see that it looks through you for
11 contraband concealed within you. We are still
12 discussing things with the manufacturer's
13 representative, and as a result of basically this
14 system coming along, we have decided that we need
15 to take our consensus standard and convert it to a
16 mandatory performance standard, as we discussed
17 last year.

18 So, what are we doing? We published
19 basically a Consumer-Operator Frequently Asked
20 Questions document about cabinet X-ray on the web.
21 We have participated in the development of a
22 consensus standard for radiation standards for the
23 cargo and vehicle systems. We had a pre-meeting in
24 August. We are hoping to resume in I believe
25 November with the N43, which is the Health Physics

1 Society's Radiation Safety Committee before ANSI
2 blessing.

3 We have drafted internal guidance, which
4 is moving its way through review about who to
5 contact about what systems, so at least when a law
6 enforcement agency comes to us, we can get them to
7 the right people quickly.

8 There is a draft guidance for
9 manufacturers. There is going to be one for users,
10 as well, eventually. We have begun drafting a
11 proposed mandatory standard for the Personnel
12 Security Screening Systems, and we have hired NCRP
13 to do a report about personnel security screening
14 systems, that is now available on the web, and
15 Frank will be discussing that in detail.

16 So, what did we cover? In the cabinet
17 X-ray consumer document, let's call it, what these
18 things are called, security screening, cabinet
19 X-ray. They come to the FDA site for more
20 information about what kind of dose am I getting,
21 it's awfully hard to find it unless there are other
22 terms for them to search on.

23 Who regulates them? Is it safe to be near
24 them? Personnel monitoring, is it necessary? Food
25 and other products being safe after they travel

1 through these.

2 On the question of personnel monitoring,
3 as far as we understand OSHA's regulations, if the
4 cabinet X-ray system is the only radiation source
5 in an area, it is not a restricted area, and
6 therefore, there is no personnel monitoring
7 required at the federal level. Of course, some
8 states have different regulations.

9 For the cargo systems, don't have
10 appropriate standards, we are beginning work on
11 that. ANSI N43.3 was last updated in 1993 and
12 covers general radiation safety for basically
13 anything that is not a closed system, like a
14 cabinet.

15 We didn't feel that that really adequately
16 addressed the safety needs of large moving
17 accelerators, and also the fact that there a lot
18 of them becoming widely distributed.

19 The internal directory, as I said, is
20 drafted and in management review. Manufacturer
21 guidance which covers product evaluation, you know,
22 how we evaluate each one independently because they
23 all seem to be very different, the basis for our
24 regulatory decisions, basically supports the use of
25 the N43.17 Radiation Safety for Personnel Security

1 Screening Systems, that we published last year.

2 History of the regulation of these
3 products, applicable FDA regs because there are
4 some reporting and recordkeeping requirements, and
5 an announcement that we are in the process of
6 drafting a proposed mandatory standard.

7 That has been drafted and is incorporating
8 various comments from within the Agency, hopefully,
9 will be moving along for management review in the
10 next week or so, which translates into maybe in a
11 few months it will see the light of day.

12 We will be drafting a guidance for the
13 users. We will essentially take the concerns
14 raised in N43 standards as a basis for this, how
15 users should record-keep to assure they don't go
16 over individual limits, user training that is
17 appropriate, those sorts of things.

18 That will be coming after we get a draft
19 of a new performance standard, and we will be
20 taking the highlights of the performance aspects
21 again of N43.17, such as the effective dose limit
22 of 10 microsievert for a front dose, labeling
23 requirements, leakage, test methods, those sorts of
24 things.

25 FDA and TSA contracted NCRP to evaluate

1 the radiation risk for these sort of systems just
2 to confirm that we are going in the right
3 direction. That report again has been completed.
4 Frank will be talking about the details shortly.

5 This is where you can find all these good
6 things.

7 It is probably easier to let Frank go
8 ahead and talk and then ask questions at the end.

9 MR. CERRA: Thank you. I am Frank Cerra.
10 I will be presenting yet another update on the
11 Personnel Security Screening Systems, actually,
12 just a continuation of Dan's talk.

13 Before I do that, let me give you some of
14 the history for the benefit of those new members of
15 the committee and also as a review.

16 The Personnel Screening Systems were
17 discussed in the September of '98 meeting of
18 TEPRSSC. At that meeting, the discussion revolved
19 mostly around the backscatter systems because those
20 were the ones that were being used in this country.

21 At the end of the discussion, it was
22 recommended that a mandatory standard be drafted by
23 FDA.

24 FDA, instead of the mandatory standard,
25 felt that we could go ahead with a consensus

1 standard, get that in the books sooner, and at the
2 same time, get a lot of input from the industry and
3 get them to buy into it and maybe that would
4 suffice.

5 So, we led that effort and in April of
6 2002, we actually had the standard, the Radiation
7 Safety for Personnel Screening Systems Using
8 X-rays. In June of last year, we discussed
9 transmission systems which began to show up in this
10 country, not being sold, but just knocking at the
11 door basically. Again, the need for a mandatory
12 standard was reaffirmed.

13 The recommendations of this committee were
14 that the mandatory standard should be based on the
15 requirements of ANSI N43.17, but the committee also
16 recognized that there may be a limited number of
17 uses where it would be desirable to have a
18 transmission system, for example, where you could
19 use them in lieu of doing a medical X-ray exam when
20 a suspect had been suspected of swallowing
21 contraband. In that case, it would actually save
22 dose to the subject.

23 So, it was proposed that the mandatory
24 standard also allow for exceptions to provide for
25 those uses, and it would provide for the

1 appropriate manufacturer's instructions on how the
2 equipment or how and when the equipment should be
3 used.

4 That is where we felt, "we," FDA, we
5 needed some help from other organizations and
6 institutions because this is really a societal
7 question on how to use or when is the use justified
8 when it is non-medical.

9 To review the limits, I think Dan has
10 already shown these, the ANSI standard. It is 0.1
11 microsievert per scan, that's 10 micrograms, and
12 250 microsievert of effective dose per year to any
13 one individual.

14 Since last year, there have been two new
15 documents from two of the leading organizations in
16 radiation safety. In February of this year, the
17 Health Physics Society published a position
18 statement on these products, and also, as Dan
19 mentioned, we have contracted with NCRP to provide
20 us with guidance, and presidential report format
21 was chosen for this effort because again it was
22 felt that it would be completed sooner although
23 there is a strong review process for presidential
24 reports, it is not as rigorous as the regular NCRP
25 report.

1 Now, there has been a lot of confusion
2 about this, I want to reassure you right now. This
3 does not come from the White House. Presidential
4 Report refers to the President of NCRP.

5 The principal requirements or
6 recommendations, I should say, of the Physics
7 Society statement are given here in their entirety.
8 The practice should be limited to those
9 applications that result in an overall net benefit
10 to society. When the practice is used to screen
11 members of the general public, screening systems
12 and their use should conform to the requirements of
13 ANSI/HPS Standard N43.17, and the subjects should
14 be informed of the radiation exposure.

15 Now, this is a good endorsement of the
16 voluntary standard, and it also leaves the door
17 open somewhat for the transmission systems, which
18 is consistent with the recommendation from this
19 committee.

20 In addition to that, the position
21 statement also has this sentence. "Appropriate
22 organizations should develop criteria for
23 determining when the societal benefits of public
24 screening outweigh the risks associated with
25 ionizing radiation exposure." The criteria should

1 be basically a consensus of all the interested
2 parties.

3 Again, this is where we also felt we
4 needed some guidance. So, in keeping with that
5 statement, FDA with co-sponsorship from the
6 Transportation Security Administration requested
7 guidance from the National Council on Radiation
8 Protection and Measurements.

9 Although the Presidential Report has now
10 been published, it is also being published as a
11 Commentary No. 16.

12 The FDA's request to NCRP included these
13 points. We asked for a review of risk assessment
14 for this type of radiation exposure. Again, we
15 asked for guidance on what constitutes appropriate
16 use conditions, any considerations that should be
17 given to targeted and susceptible populations, and
18 what the dose limits should be, and should there be
19 informed consent.

20 We also asked for guidance on how to
21 determine when an operator is deemed qualified to
22 run these systems, guidance on how to determine a
23 net benefit, again, you know, how do you weigh what
24 is the benefit versus the risk, and guidance on
25 what kinds of records should be kept by the user

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21 determine when an operator is deemed qualified to
22 run these systems, guidance on how to determine a
23 net benefit, again, you know, how do you weigh what
24 is the benefit versus the risk, and guidance on
25 what kinds of records should be kept by the user

1 facilities, and should we discriminate between
2 general screening and follow-up evaluations or a
3 more limited type of screening situations.

4 The task of writing the report was given
5 to the Scientific Committee 1-12, which was formed
6 for that purpose, and, hence, the report's
7 designation SC 1-12.

8 The committee responded to those requests
9 in the following manner. The scope of the document
10 is compatible with present NCRP system of radiation
11 protection. The committee was not going to rewrite
12 the books and reinvent the wheel, so anything that
13 came out would have to be compatible.

14 The report does include a brief review of
15 risks. It considers potentially screened
16 populations and susceptible subgroups, such as
17 infants and pregnant women.

18 It does make recommendations for dose
19 limits based on radiation safety and usefulness of
20 the images.

21 The report addresses the need for
22 communication of the radiation exposure and its
23 effects, operator training requirements,
24 recordkeeping, and testing of the equipment
25 including surveys.

1 What it does not address is how to
2 determine a net benefit. The committee felt that
3 this is a societal question and it is outside of
4 the scope of NCRP.

5 So, one of our main concerns was not
6 addressed, however, the report does provide some
7 real guidance that will be very useful and
8 something that we can use. It is being repetitive,
9 useful, and something that we can use.

10 I will jump to the bottom line. The gist
11 of the report is that the radiation dose from the
12 systems must conform with the recommendations in
13 NCRP Report 116 for frequent exposures for the
14 general public, and that is from all man-made
15 non-medical sources, the dose should not exceed 1
16 millisievert per year. That is 100 millirem per
17 year.

18 So, everything in the report is basically
19 in support of this.

20 We also realized that that would be an
21 impossible task to determine where an individual
22 has been for the past 11 months or 12 months, so
23 that they would not be given a dose in excess of
24 the annual limit. So, therefore, we felt that the
25 administrative control of a quarter of that 0.25

1 millisieverts would be a better alternative to
2 impose on a facility, and that is an alternative
3 that is also in NCRP 116.

4 Also, the committee felt that the
5 administrative control would adequately protect all
6 members of the population including the most
7 susceptible ones.

8 The report divided the screening systems
9 into two categories. The General-Use Systems,
10 basically those are the ones that conform with the
11 ANSI Standard, 0.1 microsieverts per scan. That is
12 effective dose again. Basically, it includes all
13 the backscatter systems. For these systems, it
14 would take 2,500 scans in a year to reach the 0.25
15 microsieverts administrative control, so there
16 really isn't a whole lot of need for recordkeeping.

17 The other category would be everything
18 above that, but we also have an upper limit of 10
19 microsieverts per scan, and that would include the
20 transmission systems.

21 Again, the General-Use Systems would be
22 acceptable for screening general public. That is
23 consistent with the Health Physics Society
24 statement also. But the Limited-Use Systems should
25 be used with discretion, only when following up on

1 someone who has already been suspected from another
2 screening method of carrying contraband or weapons.

3 Before using the Limited-Use Systems, the
4 report recommends that other non-ionizing
5 alternatives be considered. Again, the
6 administrative control of 0.25 millisieverts in a
7 year from one site should not be exceeded.

8 To stress that point, users of Limited-Use
9 Systems must assume responsibility of providing
10 reasonable assurance that the annual administrative
11 control is not exceeded. This can be done through
12 written protocols and rigorous recordkeeping.

13 The committee recognized that this is
14 still difficult to do, especially when you are
15 screening travelers through an airport, who you
16 have never seen before, but I felt that if any user
17 agency didn't feel that they could adequately
18 provide this assurance, then, they shouldn't be
19 using these systems at all.

20 To summarize the rest of the
21 recommendations in the report, the dose to
22 bystanders was considered, and it was felt that
23 they should be subject to the same level of
24 protection as an individual being screened, which
25 is the level for the general public.

1 Again, rather than using the 1
2 millisievert per year, we are using the 0.25 from
3 one site.

4 Operators, it was felt that it is
5 certainly doable that they be protected at the same
6 level, and so they should be.

7 There are some standard requirements for
8 equipment testing initially and after any
9 maintenance or repair, which is consistent with all
10 the other standards.

11 We addressed operator training and we
12 referred to other NCRP reports which deal with
13 training in detail. There is a list of 25 topics
14 to be covered by the training as a minimum
15 requirement, and also a requirement that annual
16 refresher courses be given followed by testing to
17 ensure continued proficiency.

18 The report recommends that information be
19 given to the people being screened on the risk,
20 benefit, and comparative examples from the exposure
21 they are going through. The information should be
22 provided in terms that are easy to understand prior
23 to the screening, and the information should also
24 be disseminated and be readily available.

25 The examples of leaflets or posters at

1 DR. CARDARELLI: Just a quick comment and
2 a question, the question first. As far as I know,
3 there are no other international standards out
4 there, so what we are doing is leading the world
5 with regard to this technology.

6 The comment that I would like to make is
7 that that's good that we are doing this, but again,
8 this is not a consensus that we might have to deal
9 with, with the IEC or other countries.

10 Another question would be since we have
11 done this for personal screening, and there is
12 nothing out there for the large cargo screening
13 technology, which uses completely different
14 energies, isotopes, is it something that you want
15 this committee to recommend in a similar fashion
16 that was done two years ago to get some standard
17 for that?

18 MR. CERRA: Dan has talked about some
19 efforts that are going on in that area, and
20 certainly you are welcome to comment on whether we
21 are going in the right direction, or whether there
22 is something that we are missing on that.

23 CDR LOSCOCCO: I just have a quick
24 question on how a facility will determine that the
25 individual can't get more than the 0.25

1 millisieverts in a year.

2 MR. CERRA: Well, that is a very good
3 question. In some cases, they can't do it, and,
4 hence, they shouldn't use it. In other cases, they
5 may be screening a familiar group of people, for
6 example, prisoners or employees in a certain
7 building who come in repeatedly.

8 They could have a system which could be
9 automated where someone isn't exposed every single
10 time. They may know it or not know it whether they
11 are being exposed or not. This is a system that is
12 being used in the diamond mines in South Africa.
13 So, that is one way. If they can show that any one
14 individual is not going to be exposed more than 25
15 times, if the system is at the limit, then, they
16 have complied with that requirement.

17 Now, when you are dealing with passengers,
18 that becomes more difficult. One way that you
19 could show it is if the number of inspections was
20 so low in a year that it would be unthinkable that
21 someone would be exposed that many times, or if the
22 risk was really high, in which case it would be
23 justifiable to be close to the limit.

24 For the risk to be high, like I said,
25 someone would have to have been suspected through

1 other means of screening.

2 DR. ROTHENBERG: Dr. Benson.

3 DR. BENSON: Would you clarify for me,
4 please, in the limited use systems, are they also
5 backscatter systems, but just employing a higher
6 energy beam?

7 MR. CERRA: No. The limited use systems
8 are defined only as being systems that deliver more
9 than 0.1 microsieverts per scan. At this point,
10 that only includes transmission systems. All the
11 backscatter systems can do much better than that.

12 DR. BENSON: For the backscatter systems
13 on page 9 of our Presidential Report, it says, "An
14 effective dose of 0.1 microsieverts per scan would
15 allow 2,500 scans of an individual," and they say
16 that that is an average of 10 scans a day, a
17 frequency that is unlikely to be encountered,
18 however, on page 16, it describes backscatter
19 systems as saying that each person is scanned twice
20 for an examination, and sometimes up to four times
21 if they do lateral scans.

22 MR. CERRA: Right.

23 DR. BENSON: So, that cuts into the number
24 of times that you can examine a person.

25 MR. CERRA: That's true. Let me clarify.

1 The 10 microsievert is the upper limit, and it
2 refers to effective dose. The ANSI standard has
3 some charts on how to calculate the effective dose
4 based on an exposure measurement.

5 The backscatter systems that are being
6 used are delivering about half of that or less,
7 maybe 0.03 to 0.05 microsieverts.

8 One thing I didn't mention is that the
9 limit refers to a frontal scan, you are being
10 exposed from the front. When you are exposed from
11 the back from the same machine, depending on the
12 energy, the effective dose is going to be lower
13 because most of the vital organs, which are
14 susceptible to radiation, are in the front of the
15 body, and from the sides, even lower.

16 So, even if you have a system that is
17 close to the limit, it doesn't really double the
18 dose. You may get maybe one and a half times the
19 dose. So, it is true, it may not be 2,500 scans,
20 maybe 2,000 scans before you reach the limit.

21 DR. ROTHENBERG: Kim.

22 MS. KANTNER: I was looking through and it
23 wasn't apparent to me about any like quality
24 assurance in terms of verification of the operating
25 status of the system. Where is that going to be

1 clarified or can you elaborate more on that?

2 MR. KASSIDAY: Right now there isn't a
3 mandatory standard for what the machines have to
4 do, so there is not a lot we can evaluate their
5 quality control based on. Even if we found a
6 machine that was a little bit out of sync, there is
7 maybe not a lot we could do because it would be
8 hard to show a health risk.

9 The point of the mandatory standard is
10 once that's in place, they then have to report to
11 us how they are certifying that they meet our
12 standard, and in doing that, we will be looking at
13 their quality control and testing systems, and that
14 will allow us to go out and start doing field tests
15 hopefully with new instruments with some luck to
16 actually have some oversight over these.

17 At present, the personnel scanners aren't
18 really exploding into use per se. It is more the
19 cargo systems and the other large systems that
20 actually have fairly high energy which are of
21 greater concern, which is what we are trying to
22 concentrate on right now.

23 Does that answer the question?

24 MS. KANTNER: Yes, I guess I was getting
25 confused on the back here about the status of the

1 mandatory standard. So, that is under development
2 still?

3 MR. KASSIDAY: Very much so.

4 MS. KANTNER: Thank you.

5 DR. ROTHENBERG: Yes, David.

6 DR. LAMBETH: It seems to me that to set
7 the standard based upon the long-term exposure may
8 be missing the point in that we don't really
9 understand some of those things, at least I don't,
10 and the rest of the committee can correct me, but
11 if the standards are set, so that you got the
12 entire full year exposure in one day, which is the
13 way it is written now, it is quite viable for that
14 to happen by accident or by whatever, no one would
15 want that to happen.

16 If I were setting a time period of
17 integration, I think I would do it more on the time
18 scale of the body renewing, the cells renewing, and
19 whatnot. So, on that basis, you would think you
20 would have an upper limit on a per day or a per few
21 days or a week sort of time scale rather than only
22 per exposure and then per year.

23 Is there any way to address that, or
24 should it be addressed? I will ask my learned
25 colleagues, as well.

1 MR. CERRA: It seems to me that if you had
2 one limit per day, it would be very similar to the
3 per scan, because in most cases, you are not being
4 screened more than once in one day.

5 Also, like I said, we didn't want to
6 invent anything new. We only went with existing
7 recommendations from NCRP. Your point about
8 reaching the limit in one exposure, that was
9 discussed, and that's why we now have an upper
10 limit for the transmission systems, which would
11 required 25 exposures to reach the limit, not just
12 one.

13 So, if you did one or two where you didn't
14 keep any records, you are still off by over 20.

15 Does that help at all?

16 DR. PLATNER: If you look at some
17 subgroups where people are working behind security
18 barriers, like flight attendants, machinists in an
19 airport, construction workers working on nuclear
20 plants or defense contractor sites, I mean they may
21 easily go through security a half dozen times,
22 maybe even more per day, and so just because they
23 are going in and out as part of their job, so it
24 seems like there is a concern that they could get
25 close to that 25 especially if they are doing

1 multiple scans.

2 MR. CERRA: Again, if they were going in
3 and out several times in one day, then, those would
4 have to be the general use systems where the limit
5 is much lower.

6 DR. LIPOTI: I was interested in the
7 Health Physics Society position statement where
8 they say that, "Appropriate organizations should
9 develop criteria for determining when the societal
10 benefits for public screening outweigh the risks
11 associated with ionizing radiation exposure," and
12 they go on to say that, "The criteria should
13 represent the consensus of professional, consumer
14 advocacy, labor, and business organizations,
15 academic institutions, government agencies, and the
16 general public."

17 I think that should be done. My question
18 is, what is the appropriate organization for
19 pulling all these people together to determine the
20 societal benefit? Apparently, it is not the NCRP,
21 because they say that is outside their role as
22 defined by the congressional charter.

23 Is it the FDA?

24 MR. KASSIDAY: In our opinion, it is the
25 people that would be using these systems to detect

1 threats since they are the ones qualified to
2 evaluate what the threat is, and since the threats
3 are sometimes classified, we don't want to know
4 what the threat is, we are happier that they do and
5 that they are doing what they--but we are trying to
6 work with those agencies to make them aware of what
7 the risk is, so that when they make their decision
8 to use the system or not use the system, they are
9 making an informed decision and doing it for a
10 rational reason.

11 DR. LIPOTI: But are they involving this
12 consensus of all these organizations? I would say
13 they are probably not. They are just buying the
14 thing and installing it.

15 MR. KASSIDAY: Well, fortunately, they are
16 not buying them or installing them at the moment.
17 I mean the only agency I know of using personnel
18 scanners is Customs. They are using a general use
19 system screening people coming into the country who
20 have already been selected for a patdown search,
21 which means they are not using it even generally
22 screening.

23 So, at the present, while I would love to
24 have that dialogue occur, so I would find out where
25 we really should be, that may not be necessary

1 since these things just aren't proliferating yet.
2 We are trying to be proactive in establishing a
3 mandatory standard before that happens and to get
4 some guidance out there and lay out things like the
5 NCRP report, which tells people this is what you
6 are doing when you do this. Do you really want to
7 do this?

8 For example, if you go from a backscatter
9 image to a transmission image, which could be a
10 factor of 50 or 100, are you getting 50 or 100
11 times more information that is of necessary use?
12 That is sort of balancing, but we can't, again, we
13 don't know what the threat is.

14 DR. LIPOTI: I guess I have a follow-up
15 and that has to do with the backscatter X-ray van
16 that you showed us, that you said could possibly be
17 used to scan people who are lined up for a parade.
18 I guess I am not clear on how you might use this,
19 you are driving past people and backscattering
20 them?

21 MR. KASSIDAY: The way it was described to
22 us, one, they can use it in a shipyard doing
23 multiple layers of cargo containers, and that is
24 fine, they are shooting into a cargo container.

25 DR. LIPOTI: But if it's a backscatter

1 unit, you are only getting the surface.

2 MR. KASSIDAY: Well, as you saw in the car
3 image that was earlier, you can really see pretty
4 deep with backscatter. I would assume they would
5 have to do both sides.

6 As far as the parade route comment, the
7 way it was described to me is they would go, say,
8 before a presidential parade or a VIP and screen
9 the cars along that route to look for car bombs and
10 whatnot. The personnel thing only has come up with
11 reference to applications at present overseas, as I
12 understand it, where the van would be stationary
13 and probably covert, to determine if anyone is
14 walking around with a bomb on them.

15 DR. LIPOTI: Well, that certainly defeats
16 any informed consent.

17 MR. KASSIDAY: Yes, it does. We are
18 working with them to make sure that whatever method
19 they have of assuring that no one stands in the
20 beam works because that is the primary thing, that
21 if the van is stationary, people better be moving.
22 Most of the other moving systems have interlocks
23 where if they stop or go slow or something, it cuts
24 off the beam, which is sensible.

25 Right now I don't know where that stands.

1 As far as I know, it hasn't been reported yet
2 because it is not quite out there yet, but I think
3 it falls clearly in the cargo scanner side of
4 things with some applicability of the people
5 scanner side of things.

6 We need a standards group to work on this.

7 DR. CARDARELLI: I wanted to point that
8 out, the issue that we are talking about. The van
9 is not necessarily covered by all of the work that
10 the ANSI and Health Physics Society has addressed.
11 The vans and the cargo, it's a whole separate unit,
12 and there is nothing for us to evaluate what to do
13 about that, and that is one of the challenges that
14 we are facing.

15 So, the question is, that I would pose
16 this to my committee members, as TEPRSSC, to give
17 guidance to FDA, do we feel it is necessary that we
18 go down a similar track to address these portable
19 cargo vans and other devices that use isotopes,
20 accelerators, perhaps neutrons, to scan equipment,
21 and if it ever gets to the point where they
22 mobilize it, that is what they are doing now where
23 they can use it for purposes other than scanning
24 stationary equipment, and the public could be
25 involved.

1 What standard do we compare that against?
2 Right now, there is none.

3 DR. PLATNER: I just want to say I think
4 it's appalling personally that you might have a van
5 coming down spraying you with x-rays without having
6 any idea it's there. I mean in the airport or in a
7 port facility or in a sensitive defense
8 installation, I can certainly understand it and you
9 can get informed consent, but I guess I disagree
10 when you said the position was that informed
11 consent shouldn't be specifically required.

12 I think it should be. I mean it can be
13 incorporated into signing your airline ticket, but
14 I think that informed consent is an ideal mechanism
15 for educating people about what the potential risks
16 are, and I think any Institutional Review Board for
17 human subjects and research would certainly want
18 informed consent even with these relatively low
19 X-ray doses if you were in a research setting.

20 I don't like the idea of dropping the
21 informed consent for just education.

22 MR. CERRA: I am not taking sides on this
23 issue, but just explain where that came from. It
24 is really based on other situations where people
25 are exposed from other sources without knowing it,

1 and they never have to be told.

2 In this case, the committee has said that
3 they should be told because this is an intentional
4 exposure, however, because the doses are the same
5 as what is allowed to expose the general population
6 from other types of source like if you live next to
7 a nuclear power plant, and so on, and so forth,
8 then, it would be inconsistent to require informed
9 consent for that type.

10 It also might scare the subjects unduly
11 because if they are asked to sign, then, they will
12 think twice about it, and they, you know, maybe we
13 should read this a little more carefully, and then
14 it would make the whole process kind of meaningless
15 because nobody would let themselves be scanned.

16 DR. PLATNER: I guess I wasn't proposing
17 that the screening be optional for anybody that
18 refuses. In certain settings, that is not
19 reasonable, but they ought to be able to turn
20 around and go out, quit the job or ride a bus or,
21 you know, do whatever they choose to do rather than
22 enter through that security port.

23 MR. CERRA: I think they always have that
24 option. Of course, there are consequences that you
25 are not going to get on the plane or whatever you

1 are trying to get into.

2 DR. PLATNER: Just another question that
3 is sort of along these same lines. Are these
4 images that are generated considered medical
5 records or private?

6 MR. CERRA: No.

7 DR. PLATNER: It seems like before you
8 take a medical X-ray, you would have to have
9 consent of the patient. Is that true here and what
10 happens with the data, is it covered by HIPAA?

11 MR. CERRA: In all instances, at least in
12 this country, the images are not stored. If
13 someone passes the inspection, everything is erased
14 right then and there. The only time that Customs
15 may store an image is if they are needed, when they
16 have found something for a court case or something
17 like that.

18 DR. PLATNER: Is that inherent in the
19 machine? It seems to me that in a future
20 regulation, there should be a requirement that that
21 data be blanked unless it is to be used for certain
22 processes. Right now it is my understanding that
23 when someone comes through Customs and they think
24 they have swallowed drugs in balloons or something,
25 if they refuse to give permission for an X-ray,

1 then, they are set in a hospital room and monitored
2 until they know it has come through, so that they
3 come up with alternatives that don't require
4 consent.

5 MR. CERRA: Customs, in fact, does that.
6 Anytime they use even the backscatter systems, they
7 will ask the subject whether they would rather do
8 that or a patdown search that is voluntary from
9 Customs part.

10 DR. ROTHENBERG: I think we have had a lot
11 of discussion. I would like to thank you for
12 participating in the committee that drafted this
13 report for the NCRP, I think it's an excellent
14 report and it has also got lots of additional
15 worthwhile educational material in there beyond the
16 specifics of these devices.

17 I get the sense that maybe our committee
18 would like to encourage the CDRH to certainly
19 continue to be involved in any of these units which
20 fall within their purview and report to this
21 committee updates on an ongoing basis.

22 Would anyone like to add anything to that
23 or say anything further?

24 DR. CARDARELLI: Just perhaps some
25 emphasis on the lack of anything associated with

1 the mobile cargo scanning type of technology that
2 is now being used, specifically, the non-person
3 screening technology. This uses 450 keV, the
4 accelerators, isotopes. It has been beam
5 mobilized. It is exposing a variety of different
6 environments.

7 DR. ROTHENBERG: I am sorry?

8 DR. CARDARELLI: There is no standard, not
9 even on exposure limits or leakage or anything like
10 that per se for building these devices to be used,
11 but they are building them and they are selling
12 them and using them, and I think Dan had mentioned
13 that that is what is being sold in America right
14 now, not necessarily these personnel screeners that
15 we spent all the time on.

16 So, one of them we have now in place, a
17 mechanism to identify the standards that we are
18 going to compare them against, but now we have a
19 whole new technology, that there is no such
20 standard that applies to it, because it's
21 brand-new, and that would be the one concern that I
22 am raising at this point.

23 MR. CERRA: May I say something about
24 that? I think that in view of the work, there
25 certainly is a lot of interest in voluntary

1 standard and we have a pretty large group who have
2 shown that they are willing to work hard at this
3 issue, and as this group goes on with their work,
4 it may uncover some real concerns or not concerns,
5 and at that point, maybe it will be appropriate for
6 this committee or for us, FDA, to present to this
7 committee about what has been discovered and where
8 we think the problems lie, and maybe at that point,
9 you can make a recommendation.

10 DR. CARDARELLI: Let the record show that
11 there is an ANSI Committee or something that is
12 starting to form to address that issue.

13 MR. CERRA: Right. It's not an ANSI
14 Committee yet, it's a group who will be proposing a
15 new standard to an ANSI-accredited committee.

16 DR. CARDARELLI: So, it is being
17 addressed. Thank you.

18 DR. ROTHENBERG: Thank you very much.

19 MR. CERRA: Thank you.

20 MR. KACZMAREK: We were scheduled for an
21 open public comment session, but I don't think
22 there is anyone from the public who wants to make
23 any comments. Is that true? If so, raise your
24 hand. If not, then, we will just skip that. We
25 can take a short break or go right into the

1 committee deliberations.

2 DR. ROTHENBERG: It is already 4 o'clock
3 and there may be some people with travel
4 restrictions, so I would recommend, unless there is
5 a strong sense of urgency to have a break, that we
6 continue with the committee discussion, which I
7 gather will not be terribly long.

8 MR. KACZMAREK: We already sort of started
9 the committee discussion with the questions that
10 Frank and Dan had. My feeling is that if the
11 committee feels that they have explored the
12 security screening systems enough, maybe we should
13 revisit the medical X-ray discussion that Tom had
14 and see if there is anybody that wants to bring up
15 anything about that. I know we asked him some
16 questions at the end of the talk, but maybe
17 somebody wants to bring up some more.

18 DR. ROTHENBERG: I thought we had covered
19 everybody's concerns. Does anyone have any other
20 information or comments or questions for Tom?

21 Okay. I have one item I think you would
22 be interested in which doesn't concern the
23 committee, but there is a new fluoro regulation
24 that has just been published by New York State for
25 its health code and if you haven't seen that, I

1 brought a copy for you to look at. It is addressed
2 more at the user and measurement.

3 MS. KANTNER: I know there were some
4 proposals or some recommendations for direction on
5 I guess IEC standards. I was just wondering what is
6 the committee's role. It seems like there have
7 been questions relating to lack of completely
8 versus there seems to be in one case here there
9 seems to be acceptance of it, but yet there is
10 still some uncertainty and the points were raised
11 very clearly in Tom's presentation.

12 In kind of looking or considering forward,
13 what would be next steps on the committee level? I
14 would like to get a sense of what we would be
15 involved in in trying to address these.

16 There seem to be different layers and it
17 doesn't seem like it is necessarily a blanket, but,
18 you know, we have X-ray activities going on here
19 that started many years ago, and I think in the
20 circumstance here, there was no IEC at the time, so
21 there seems to be some questioning of enforcement,
22 you know, items that I think need to be looked at.

23 I don't know if it is a very simple
24 solution or what the options of looking into that
25 are.

1 DR. ROTHENBERG: It sounds like it is very
2 complex in the sense that in some areas, it seems
3 like it would be appropriate to proceed along the
4 international path and in others it may not work
5 very well.

6 MS. KANTNER: That's true. I am not
7 getting a strong sense of what the issues are or
8 how to even, as a member, pursue those.

9 DR. ROTHENBERG: Where shall we start?

10 MR. MYRICK: It seems to me that the FDA
11 is somewhat isolated on this issue. There are
12 other organizations like Underwriter's Laboratories
13 and the FCC that have adopted at various levels,
14 whether it be just a reference to an IEC standard,
15 pulling some of the wording from the standard, or
16 adopting the whole standard in full. UL uses the
17 full wording of the standard and then adds national
18 deviations, so they must have already dealt with
19 the copyright issues and enforcement issues. FCC
20 has dealt with the enforcement issues. So, I would
21 hope that the FDA would be at least trying to
22 inquire of those organizations how they have
23 handled it and what they have done.

24 DR. ROTHENBERG: It sounds like a good
25 suggestion. What would be the appropriate group to

1 follow up on that?

2 DR. SHOPE: Maybe I could add just a bit
3 of clarification. Actually, FDA is quite active in
4 the IEC activities, have discussions underway
5 currently about how to approach some of these
6 issues, so I think we have a long history, in fact,
7 in the medical device arena, the recent--I lose
8 track of which amendment it was to the Food, Drug,
9 and Cosmetic Act--but encourages the use of
10 voluntary standards, and FDA actually looks at all
11 the available voluntary standards, not just from
12 IEC, but from other sources as the National
13 Committee for Clinical Laboratories or ANSI or
14 others, and adopts those officially by publishing a
15 Notice in the Federal Register, and you can go to
16 our web site and see which standards have been
17 adopted, but these are adopted, not as mandatory
18 performance standards, but as standards that can be
19 used by manufacturers submitting premarket
20 submissions with regard to medical devices and what
21 this allows the manufacturer to do is rather than
22 submit comprehensive test data in their premarket
23 applications to the FDA to support a marketing
24 application for a medical device, they can just say
25 they conform to the following standards that we

1 have recognized and obviate any additional
2 submissions to us.

3 We then verify that during our factory
4 inspections or our visits to them, so it cuts down
5 quite a bit on the submission paperwork because we
6 have looked at these standards, we know what they
7 contain, and we say if you cite conformance to
8 that, that's enough to know about biocompatibility
9 or that's enough to know about what you have done
10 with regard to electromagnetic or whatever, but
11 those are different than mandatory standards that
12 are enforced and checked to make sure there is
13 exact compliance with the requirements in a
14 mandatory standard because many of these standards
15 are test method kinds of things or other kinds of
16 issues that are not the kind of things that we
17 enforce, but we do use the international standards
18 quite a bit in our medical device program.

19 I think the thing that the Center is now
20 looking at is trying to balance the competing
21 issues of demand, public health issues, resources,
22 and the fact that there now exists a whole body of
23 international standards that weren't there in the
24 1960s when we started in this business, and the
25 question keeps coming up, well, how do we best use

1 what the rest of the world has worked together to
2 do and do we really need, in our standpoint, to do
3 it all ourselves or can we make advantage of this
4 collaborative consensus work that has gone on.

5 I think we are very early in this process
6 at the Center in terms of thinking through these
7 things. There are a number of legal issues, a lot
8 of questions that remain that we internally haven't
9 sorted through, and you sort of got an early
10 preview of some of the discussions that are going
11 on internally, and I think that we wanted to do
12 this in order to let people know that these
13 discussions are occurring to give people a chance
14 to think about them, to give us your views and your
15 comments and problems that you may see in that
16 area.

17 So, it is very early in the process for
18 us, I think, to determine what we are going to be
19 doing exactly for any particular product, but it is
20 clearly something that we are looking at to try to
21 determine what makes sense from a public health
22 standpoint balanced against the resources that we
23 have.

24 I don't know if that helps any or not.

25 DR. ROTHENBERG: I guess your intent is to

1 keep us informed.

2 DR. SHOPE: Of course.

3 MR. MYRICK: Like you said, it is early in
4 the process for you, but I believe that other
5 organizations have gone through at least some of
6 this already, so to contact them and find out what
7 the issues were and how they resolved them, I think
8 would be helpful.

9 DR. PLATNER: I think it's great to look
10 at all these voluntary consensus standards, you
11 know, it saves a lot of work and writing
12 regulations, but I think there is a real place for
13 actual regulations that are mandatory and I think
14 it is important that FDA continue to work in that
15 arena, as well as working with the consensus
16 committees.

17 IN my experience, the consensus standards
18 only really work in work sites where you have got
19 professionals or folks that are informed enough to
20 know they exist.

21 I think in a lot of smaller workplaces,
22 which is the majority of workplaces, there isn't
23 anybody like that on staff.

24 DR. LIPOTI: I would just make one final
25 comment on this, that the standards which are

1 consensus standards frequently do not involve all
2 of the stakeholders, and one of the things that it
3 really helps is when you promulgate regs, it is a
4 proposal and everybody can comment on it, give
5 input, and you respond to those comments.

6 I go back to that Health Physics Society
7 position statement that says you should have some
8 sort of consensus of professional, consumer
9 advocacy, labor, business organizations, academic
10 institution, government agencies, and the general
11 public. You can't get all those people together
12 when you have a small group working through the
13 issues.

14 DR. ROTHENBERG: Comments?

15 MR. CERRA: For what it is worth, to
16 comment on the last comment, that is very true.
17 The ANSI N43 committee, though, in their charter
18 have makeup of what the committee should be, and
19 all those groups are represented, however, the
20 purpose of the committee is for radiation safety,
21 and they don't make value society judgments, so it
22 is hard to find a group when you asking to consider
23 justification of non-medical versus medical.

24 MR. KASSIDAY: One other thing that we are
25 trying to do, in fact, later this month, is present

1 some of these issues to a group called ISCORES,
2 which is an interagency federal meeting on
3 radiation safety, and try to get them to at least
4 be aware of the issues and be a player in this, so
5 that it is uniform throughout all the agencies.
6 So, we have some hope of giving them the right
7 information, so they can make informed decisions.

8 MR. KACZMAREK: I just want to reinforce
9 what Tom was saying. I don't think the committee
10 should get the impression that the FDA is going to
11 go away and wipe out everything that is in Part
12 1000 immediately, because as a matter of fact, Dan
13 and Frank were talking about writing new
14 regulations where none existed, so, in fact, you
15 have got kind of a mixed bag there.

16 As Tom was saying, we are just beginning
17 to discuss these things ourselves, and we have the
18 same concerns that, for example, Jill raised about
19 the regulations making from consensus standards
20 bodies. We are going to be discussing these in the
21 months ahead and there will be more opportunity to
22 discuss them I think.

23 DR. ROTHENBERG: Does anyone have other
24 items of concern or future recommendations for the
25 committee?

1 MS. BARR: This is just a minor comment on
2 Tom's presentation before we leave that topic,
3 which I said to him, and it's just food for thought
4 for the committee, since you seemed to
5 enthusiastically endorse the idea of having a dual
6 dose display with cumulative dose, I just wanted to
7 point out as a radiologist who has done thousands
8 of fluoroscopic procedures that the way the
9 proposal is written now, all you would have to do
10 to get the cumulative dose display is take your
11 foot off the pedal and every time you did that you
12 would have a cumulative dose display.

13 It might be a disincentive to have the
14 cumulative dose display all the time because you
15 don't have to take your foot off the pedal, you can
16 just merrily, fluoroscopically go along. That is
17 just food for thought when that comes around again.

18 MR. KACZMAREK: At this time what I am
19 going to do is mention that we have some committee
20 members that are going to be leaving us this year,
21 so this is probably going to be their last meeting
22 since I don't think there are going to be any
23 TEPRSSC meetings for the rest of the year.

24 Three of those people are here. I have a
25 suitable recognition of their achievements or their

1 efforts.

2 Dave Lambeth, this is his last year on the
3 committee, Michele Loscocco, and Larry Rothenberg.
4 I am going to be giving them these plaques and
5 letters, which are letters of appreciation.

6 The other people that are leaving are
7 Maureen Murdoch Nelson and Bob Pleasure.

8 Typically, normally, we discuss when we
9 might want to have the next meeting. I don't know
10 whether FDA will be ready to have a meeting in the
11 spring, for instance, of 04. Probably the earliest
12 time would be the fall of 04.

13 But are there any time, does the committee
14 prefer the spring or the fall, for instance, or
15 July? Washington in July? No.

16 What I am going to do then is just assume
17 that this time frame was probably good and if we do
18 meet in 04, probably pick around this time. Of
19 course, I will be in touch with everybody on the
20 committee. Also, some of the slides that were
21 shown were not available until just the time the
22 person was showing them, so I am going to collect
23 them from the speakers and e-mail them to the
24 committee members after the meeting. I am also
25 going to see that they get included in the postings

1 on the web site from the materials from the
2 meeting.

3 I guess we can close the meeting unless
4 somebody wants to bring something else up.

5 DR. ROTHENBERG: I would personally just
6 like to thank Rick and staff and all of our
7 presenters for their excellent presentations and
8 thank you all for the opportunity to be involved in
9 this. I have always learned new things when I have
10 come to this meeting and enjoyed interacting with
11 some people that I don't see in my normal rounds in
12 the medical physics AAPM RNSA rounds of meetings.

13 Personally, I am very pleased to have been
14 part of all this.

15 DR. LAMBETH: I will second what was very
16 eloquently said and I agree. Thank you very much.

17 CDR LOSCOCCO: I will third that I guess.

18 DR. ROTHENBERG: Thanks to all the
19 committee members for taking time out of your busy
20 schedules to participate in this activity.

21 MR. KACZMAREK: I want to second that and
22 thank everybody for coming and giving us the
23 benefit of their opinions and expertise which we
24 really value.

25 With that, I am going to close the

1 meeting. Consider the meeting adjourned.

2 [Whereupon, at 4:20 p.m., the meeting was

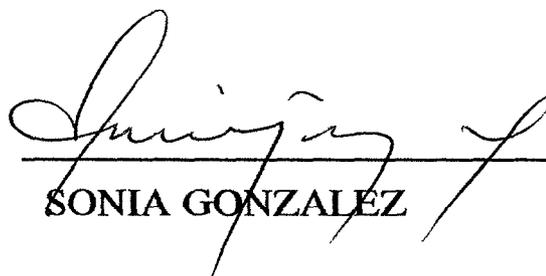
3 adjourned.]

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C E R T I F I C A T E

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



SONIA GONZALEZ