

1 other standards. That's important. We can't just
2 make arbitrary limits and also it's important that the
3 standard be accepted by all the parties. This is a
4 consensus standard and it would be meaningless if
5 people did not just -- decided to ignore it. Along
6 those lines we -- it is also important in developing
7 the standard we are sensitive to all the concerns
8 regarding radiation safety, no matter how small the
9 doses are. And there must be a benefit from this use.
10 Trivial use, for entertainment purposes or what not is
11 not acceptable.

12 Going to some of the specifics, like I
13 said, we want to be consistent with other standards.
14 We are looking at all the recommendations from NCRP,
15 ICRP and also existing EPA and NRC standards and the
16 25 millirem per year for one source of radiation that
17 is man-made radiation for an individual of the general
18 public is what is recommended and that is what we are
19 putting in the standard.

20 In addition to that, we are also setting
21 a limit of 10 microrem of effective dose per scan and
22 this is to insure that 25 millirem per year is never

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1 exceeded. It also insures that there is no
2 technology creep where some other devices may come
3 along where the dose is multiplied by a large factor
4 and which may deliver 25 millirem in one scan and they
5 say well, we're -- you can only do one scan per year.
6 So the 10 microrem effective dose per scan kind of
7 addresses that problem.

8 We are saying that subjects must be
9 informed of the x-ray exposure and the risks. This is
10 going that extra step because this is after all an
11 intentional exposure and it is not sufficient to just
12 be consistent with other standards, but this is a
13 special case so we are going the extra step saying
14 that we need to inform people. We need to have
15 labeling and indicators showing when the scan is in
16 progress. We also discuss some limits for leakage and
17 operator dose limits which will be similar to the
18 subject dose limits and another thing that's not on
19 this slide is requirements for safety interlocks.

20 We are currently considering requirements
21 for operator training and qualifications. We have
22 observed the training that the U.S. Customs Service is

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1 doing to their operators. We will be considering
2 requirements on records and documentations, records of
3 quality assurance and maintenance and documentation
4 needed to assure that no individual does come close to
5 25 millirem per year.

6 One of our considerations that we really
7 think is important is the measurement methodology. We
8 want to be sure that everybody measures the same
9 thing, effective dose is not easy to measure. It is
10 the quantity of interest, but we intend to have a very
11 detailed appendix on the -- on how to do the
12 measurement and the appendix will include detailed
13 conversion factors based on kilovoltage and filtration
14 of the unit.

15 And we are also discussing trying to
16 finalize the sections that we already drafted into
17 more detail.

18 Our goals are to have a final draft by the
19 end of this year. That may be a little optimistic,
20 but I think we can still do it. It is reasonable to
21 expect that there will be about 18 months period
22 before the standard will be published after the final

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1 draft so that we're shooting for a publication date of
2 June of 2002. And beyond that we will explore how to
3 best use the standard in the regulatory process. We
4 are considering working with the States and having
5 them adopt a standard and there is the possibility of
6 adopting some parts of the standard in a mandatory
7 standard in the future. A lot of this will depend on
8 whether the standard is adhered to or not.

9 This concludes my talk. This has been an
10 update of work that was stimulated by this Committee
11 and we thank you for the stimulus.

12 DR. ROTHENBERG: Thank you. Do we have
13 questions from the Committee?

14 Cass?

15 MS. KAUFMAN: A couple of things and one
16 is and maybe it's in your specific details, one of the
17 concerns is that because off of these things is so
18 difficult to measure that it may be difficult to
19 determine when or if the unit malfunctions. I don't
20 see in there any requirement for an indication of kVp
21 or mA or exposure time or accuracy of those factors or
22 anything like that.

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1 Is that in the proposal and you just
2 haven't discussed it or --

3 MR. CERRA: We have requirements insofar
4 as safety interlocks are concerned. These include --
5 one of the possible scenarios where you could have a
6 significant dose is if the beam stopped and then one
7 area of the body will be exposed too many times the
8 radiation.

9 So we have requirements for safety
10 interlocks to see that that does not happen. The 10
11 microrem is the absolute maximum that the unit could
12 deliver so I think that includes, the maximum kV that
13 the unit could put out.

14 MS. KAUFMAN: Gosh, I've seen x-ray
15 equipment all the time where the maximum was supposed
16 to be this and then you measure it and it's not that,
17 it's this and that's true for mA and all of that.

18 So why not have a requirement that there
19 be an indication of kVp and mA for every scan?

20 It seems like it would be pretty simple to
21 do. And at least it would give some idea to the
22 operator whether the unit might be malfunctioning or

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1 not.

2 MR. CERRA: Okay, well, the standard is
3 not finished yet, so I will take that under
4 consideration. Thank you.

5 DR. ROTHENBERG: John?

6 DR. CARDELLA: I had two questions. If
7 the subject dose limit is 10 microrem effective dose
8 and the allowed 25 millirem per year, is that correct?

9 MR. CERRA: Yes.

10 DR. CARDELLA: You're allowing for 2500
11 scans per year or could you increase -- I mean it
12 seems unlikely to me that somebody would be subjected
13 to that many scans. If you were to increase the 10
14 microrem, would that allow for a better scan picture
15 or if 10 microrem is all you need, why not dial down
16 the 25 millirem?

17 MR. CERRA: I'll take the last one first.
18 The 25 millirem is what is recommended and is
19 consistent with all the other international and
20 national standards so we don't want to deviate from
21 that, otherwise we'll just be setting limits that are
22 not based on any science. The 10 microrem is based on

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1 what the manufacturers can do right now and they can
2 do it well. They see no reason to increase that for
3 several reasons and one not the least of which is
4 public concern about exposure.

5 There are instances which have been not --
6 well, have been envisioned, let me say that where
7 these units will be used, could be used and so widely
8 that the same person could be scanned many times.
9 Also, the 10 microrem refers to one scan. Sometimes
10 they do a -- they usually do a front and a back and
11 sometimes they do the two sides, so that would be four
12 scans. Now the effective dose would be lower for the
13 back and the sides, so four scans does not add up to
14 40, but it would add up to something like 20 or 30,
15 depending on the energy of the beam.

16 So for those -- if -- for those uses
17 where, for instance, in a prison, it was mentioned
18 that some prisons were contemplating using it for
19 every time a prisoner went from one area to another so
20 that could happen several times a day. If they did
21 that every day of the year, it's conceivable that they
22 could reach 25 millirem. We do have a requirement in

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1 the standard that if that is a possibility that they
2 need to keep records.

3 DR. CARDELLA: I had one other question as
4 well. On your eighth slide, there was a reference
5 made to systems that can detect swallowed contraband.

6 MR. CERRA: Right.

7 DR. CARDELLA: Is that now crossing over
8 from purely reflective scattered radiation to some
9 transmitted radiation?

10 MR. CERRA: Exactly.

11 DR. CARDELLA: And if it does should that
12 one be a yes, instead of a no in terms of scope?

13 MR. CERRA: There is still many questions
14 that are unresolved, whether a unit like should be
15 considered a medical unit because it is transmission.
16 You do get an image inside your body. So rather than
17 to deal with those questions which would slow down the
18 development of the standard, we decided to leave those
19 out and leave it for the future. Hopefully, the
20 guidance that we will provide in this standard will be
21 used in making decisions in the other standards also.

22 DR. ROTHENBERG: Michele?

1 MS. LOSCOCCO: I just had a question about
2 the unit itself. Is it a fixed kV? Is it variable
3 depending on the size?

4 MR. CERRA: Yes. The ones available right
5 now are all fixed.

6 MS. LOSCOCCO: And is there a requirement
7 for the manufacturer like there is for a standard
8 x-ray piece of equipment that it be within a certain
9 percentage of the stated value?

10 MR. CERRA: Of the kV itself?

11 MS. LOSCOCCO: Right.

12 MR. CERRA: No. We have a requirement
13 that the kV should be optimum for the image that
14 they're looking for. We wanted to put a limit on the
15 kV but then the manufacturer said that in some cases,
16 depending on what they're looking for, they may want
17 to use a different kV, higher kV, so we didn't put any
18 limits on the kV.

19 We didn't feel that it was necessary to be
20 that specific. The bottom line is the dose and --

21 MS. LOSCOCCO: What's a general Kv that
22 they use?

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1 MR. CERRA: There are two manufacturers
2 and one is using 50 kV and the other is using 120.

3 MS. KAUFMAN: I know that you went out to
4 a prison in California and took some measurements on
5 the Rapiscan unit. Can you tell us what skin exposure
6 you measured from that unit?

7 MR. CERRA: Yes. Skin exposure? The
8 exposure was somewhere near 10 microrem. Converting
9 that to an effective dose which takes into account the
10 detriment to all the organs of the body, it converts
11 to about 3 microrem.

12 MS. KAUFMAN: And have you measured the
13 other unit, the 120 kV unit?

14 MR. CERRA: No, we haven't done that yet.
15 We have done some calculations of what to expect and
16 we expect them to be under 10 -- closer to 5 or 6
17 micro rem.

18 MS. KAUFMAN: You'd be surprised going
19 from 50 to 120.

20 I wanted to mention the 25 millirem
21 because I'm not sure that that's a good number to use.
22 The 25 millirem from any single source is actually

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1 based on decontamination criteria for when you have
2 the site that's contaminated, particularly from
3 radioactive materials that you clean up that site to
4 a level where no one would get more than 25 millirem
5 per year. So it's based on an issue where it costs a
6 considerable amount of money to clean up a site and at
7 what point do you say it's clean enough? I'm not sure
8 that that -- that we should be using the same criteria
9 for a situation where we are deliberately exposing
10 humans to ionizing radiation when the benefit is much
11 less known. In other words, in the decontamination
12 criteria you have a clear monetary value and issue in
13 terms of cleanup costs and compared to this -- and
14 you're not deliberately exposing humans. It's to me
15 a very different scenario than where you're
16 deliberately exposing humans and I really think that
17 the group might want to rethink the 25 millirem
18 criteria.

19 MR. CERRA: My understanding is the 25
20 millirem per year is based on not only contamination,
21 but all man made exposures. Actually, the limit is
22 500 millirem for infrequent exposures, 100 for

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1 frequent exposures and 25 for exposures from one
2 source.

3 MS. KAUFMAN: That's not correct. It's
4 500 millirem from a patient who has received a
5 therapeutic dose under certain criteria. But the
6 limit is 100 millirem to the public.

7 MR. CERRA: It's in --

8 MS. KAUFMAN: It's in part 20.

9 MR. CERRA: It's also in NCRP 116 --

10 MS. KAUFMAN: I'm going by the
11 regulations.

12 MR. CERRA: NRC and EPA have adopted those
13 limits for nuclear fuel cycle facilities and other
14 things and I think that is -- it is also a limit that
15 has been endorsed by the Health Physics Society for
16 members of the public.

17 MS. KAUFMAN: Can CFR part 20 gets a limit
18 of 100 millirem to the public and under certain
19 circumstances and those circumstances actually are a
20 therapeutic dose to a patient, you can allow an
21 individual member of the public to receive 500
22 millirem from that therapeutically treated patient,

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1 but it's not a 500 millirem limit to -- it's 100
2 millirem to a member of the public in 10 CFR part 20.

3 DR. ROTHENBERG: Jerry.

4 MR. THOMAS: I have a follow on question
5 to John's question regarding the systems to detect
6 swallowed contraband. Are those standard medical
7 fluoroscopic units or are they designed --

8 MR. CERRA: No.

9 MR. THOMAS: So there are fine spot
10 scanners similar to these, but transmission scanners?

11 MR. CERRA: Right.

12 MR. THOMAS: That isn't a medical device.
13 You implied that was a medical device in your answer
14 to him.

15 MR. CERRA: No. I'm saying that there are
16 questions. It's been suggested that they should be
17 regulated as medical devices.

18 MR. THOMAS: It's not being used as a
19 medical application so how can it be regulated as a
20 medical device?

21 MR. CERRA: I am not sure where you make
22 the distinction and maybe --

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1 MR. THOMAS: I don't know. In my mind's
2 eye I make it very clearly if it's not being used
3 under the guidance and direction of prescription of a
4 person qualified to practice medicine in this country,
5 it can't be a medical device, can it?

6 DR. SHOPE: I think the Committee may be
7 focusing on the definition of a diagnostic x-ray
8 system in our diagnostic x-ray standard where the
9 applicability statement reads something like for the
10 diagnosis or visualization of the human body. It
11 doesn't connect it to a medical treatment requirement.
12 It's just imaging or visualization of the human body
13 and so I guess the point is this could be looked at as
14 visualization of the human body, therefore, the
15 diagnostic x-ray standard in this country would be
16 applicable and I think that that's the issue that we
17 need to talk some more about.

18 MS. KAUFMAN: Does ANSI have any divulging
19 -- that's not the word I want -- criteria for members
20 of the Committee? In other words, we on this
21 Committee have to let people know what our financial
22 relationship is with these various companies. Does

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1 ANSI have that requirement?

2 MR. CERRA: I'm not aware of that kind of
3 requirement concerning conflicts of interest, but they
4 do have a requirement that all the sectors have to be
5 represented, so our main N43 Committee has
6 representatives from public groups and labor groups
7 and industry and government and so forth.

8 DR. ROTHENBERG: You did mention among the
9 -- in addition to the scanner that looks inside the
10 other two types of scanners, looking at a moving
11 vehicle, etcetera. Are any of those to the point
12 where they're in use and is some other group looking
13 at them?

14 MR. CERRA: No. Well, the cargo scanners
15 are being used. We are regulating those as cabinet
16 x-ray units.

17 DR. ROTHENBERG: Those do not involve
18 normally a person?

19 MR. CERRA: No.

20 DR. ROTHENBERG: Shouldn't.

21 MR. CERRA: No.

22 DR. ROTHENBERG: Hopefully.

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1 MR. CERRA: Although some times people are
2 hiding in the cargo like just yesterday 58 bodies were
3 found in a truck and these would find them, hopefully
4 before they die.

5 DR. ROTHENBERG: One might be the car
6 crossing the border?

7 MR. CERRA: Right. That one is only a
8 conception. I'm not aware of any units having been
9 built at this point.

10 DR. ROTHENBERG: Any other questions? Is
11 there any action we have to take at this point? It
12 seems like this action, your action was taken
13 following our recommendations. I think -- thank you
14 for your --

15 MR. CERRA: Thank you.

16 DR. ROTHENBERG: At this point I think we
17 should move ahead to the final item of today's agenda,
18 the CT NEXT Survey and CT fluoroscopy and I guess Dr.
19 Gagne will speak first.

20 DR. GAGNE: I'll be getting to the purpose
21 of my presentation in the next slide. I have the
22 title slide coming up.

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1 And I want to point out before I get to
2 stating those objectives, one thing that's -- I think
3 important and that's the following. You have to
4 change your position with respect to radiation
5 exposure when you think about what I'm going to be
6 presenting and what was just presented in the previous
7 talk because what I'm talking about, we're talking
8 about radiation exposure levels that are in the order
9 of six orders of magnitude higher. So if you're at
10 the position that we're talking about people scanners,
11 you need to move six orders of magnitude in order to
12 get to where I'm going to be talking about. So just
13 to give you a little bit of a perspective if you want
14 with respect to where we are on that exposure scale.

15 Next slide, please. Now what I'd like to
16 do and the objectives that I'm going to try to do
17 today is to update the Committee on the actions that
18 we've done over the last year pertaining to computer
19 tomography fluoroscopy. I gave you a presentation
20 last year on that topic and so about a third or a half
21 of this particular talk will be devoted to that.

22 But I thought it would also be appropriate

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1 and I'm not really looking, I'm looking for input and
2 comment, but I'm not really proposing anything today.
3 This is really more of an information sort of talk and
4 I think Dr. Stern, Dr. Stanley Stern's talk is
5 somewhat the same way. But I thought it would be
6 appropriate to maybe take a retrospective look at our
7 activities in the CT arena. And at the same time as
8 we look back, look forward because there's a lot of
9 things going on in CT right now that are kind of
10 exciting and they may, in fact, have some unique
11 radiation protection and safety aspects and
12 considerations that we need to worry about and get
13 your comment and feedback. So that's my objectives
14 today and hopefully I'll meet those objectives.

15 In 1999, I described for the Committee a
16 new real time imaging application for -- technology
17 that already existed, except it's being used in a
18 different way. It's called computer tomography
19 fluoroscopy. And that new application involved some
20 real time if you want quote unquote real time imaging
21 where you get about 6 to 9 images per second, using
22 existing technology and we sort of have a special

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1 interest and I think we still do to a certain extent
2 because it has a lot of similarities between
3 traditional interventional fluoroscopy that we've been
4 pretty heavily involved in in terms of amending the
5 standards and computer tomography fluoroscopy. So our
6 mission in this particular area and really in other
7 areas is to sensitive people, ourselves included to
8 exposure levels and the possibility of radiation
9 injuries from the use of the equipment in this manner.

10 So just to give you a little bit of a
11 review here, what we're talking about here in a
12 general description of CT fluoroscopy is that we have
13 a continuous scan of a narrow section of the patient
14 and you could have, for example, a 50 seconds of this
15 fluoroscopy going on and as I said of images of about
16 six to nine images per second that involve one
17 rotation of the x-ray tube per second about the
18 patient. And you get a series of cross sectional
19 images updated at a rate of 6 to 9 images and you get
20 not quite real time like a fluoroscopy with 30 frames
21 per second, but you can see things moving which is a
22 new application, a new way to use this.

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1 If there's no patient motion during the
2 procedure then obviously there's a strip of skin that
3 gets the full brunt of the radiation exposure and we
4 have to get into what kind of exposure are we talking
5 about.

6 Next slide, please. So on the left hand
7 side is a schematic of a situation where a system is
8 operating, if you want, in a CT fluoroscopy mode where
9 you go around the patient 50 times and the same strip
10 of skin there between A and B is getting the radiation
11 exposure because the patient is not being moved and I
12 showed you some of the data that we had last year,
13 associated with that and what we're talking about here
14 on the right hand side are exposure levels in the
15 order of 20 to 40 roentgens in one minute which is why
16 I was telling before that we're talking about here six
17 orders of magnitude with respect to radiation
18 exposure. Totally different risk benefit aspect,
19 don't get me wrong. It's real hard to quantitate the
20 benefit in either case, but with respect to the risk
21 side this is what we're talking about.

22 Now, as I said, we were a little bit

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1 concerned because these are numbers at, for example,
2 50 mA. If you double the mA or whatever, there's a
3 linear relationship and those numbers go up.

4 So going on, I explained that the
5 requirements of the standard were difficult, if not
6 impossible to fit to this particularly new application
7 of the equipment. We have regulations for computer
8 tomography equipment and we have regulations for x-ray
9 fluoroscopy equipment. It's not clear how to regulate
10 this equipment appropriately. And so I described a
11 series of short and long term actions associated with
12 this new application to the Committee last year and
13 what I'm going to do now is review a little bit about
14 what we, in fact, have been doing.

15 As far as short term actions are
16 concerned, those are in process. Dr. Stern will talk
17 a little bit about that when he talks about the NEXT
18 2000 survey. The NEXT 2000 survey is, in fact, a CT
19 survey and we're drawing lots of different
20 information, I think, this time which will help us not
21 only with CT fluoroscopy getting a picture of what's
22 happening there, but CT in general.

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1 Now as far as possible amendments to the
2 performance standard, if you go to the next slide,
3 there was a recommendation, suggestion, whatever word
4 you wanted to use to piggy back some requirements on
5 CT fluoroscopy from the Committee last year on to the
6 fluoroscopy amendments and I think one of my jobs here
7 is really to sort of explain that we really made a
8 negative decision with respect to that at this time
9 with respect to this long term action for a couple of
10 reasons.

11 We really didn't want to hold up the
12 fluoroscopy rule making procedure and there's really
13 sort of a resource argument involved with that to a
14 certain extent. The people involved with the
15 fluoroscopy amendments are going to be the same people
16 involved with these amendments and so there's a
17 resource limitation part of it. That was part of it.

18 The other part is we really haven't
19 finished a short term action program which is try to
20 gather some information about how this is used and
21 what's the situation with respect to CT fluoroscopy
22 and we didn't give that a chance to happen.

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1 Additionally, I'm not sure there's really
2 a consensus yet, exactly how to make the measurements
3 with respect to exposures from these systems and so
4 there has to be some consensus building associated
5 with that.

6 As an example, I have some data there from
7 a publication where a piece of the data says one thing
8 and the other piece says something else. What I mean
9 by that is if you're going to do a biopsy, for
10 example, using conventional CT in this particular case
11 we were talking about a mean skin dose of about 30
12 rads. For CT fluoroscopy, the mean skin dose was 43
13 rads. So that seems to be saying we're getting a
14 higher exposure, at least for this particular
15 publication for that application.

16 But then on the right hand side it's the
17 other way around. Conventional CT provides a higher
18 dose, rad CT fluoroscopy is lower. So the data
19 doesn't really point either way with respect to we're
20 talking an increase or decrease in dose.

21 So that's sort of the history of what's
22 happened with respect to CT fluoroscopy. What I'd

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1 like to do now is to take a look back then and see
2 what we've done actually in the CT area as an agency.
3 There were amendments to the performance standard.
4 They were adopted in September of 1985, but they
5 really developed in the late 1970s and there are a
6 couple of performance criteria and those requirements
7 associated with light localizers and table increment,
8 but most of the basis for the requirements was really
9 a labeling requirement. There had to be dose and
10 imaging performance information in the user manual.

11 And at the time that the amendments were
12 developed and promulgated in 1985, CT was basically
13 axial scanning, if you want. You had, for example, a
14 10 mm slice. You took continuous scans and you
15 stepped the table after you finished the scan. So if
16 we go on to the next slide, I'm trying to show that
17 particular process, actual scanning with a 10 mm slice
18 in this representation where on the top I'm showing
19 the x-ray at different 90 degree positions around the
20 patient as it circulates, makes one complete rotation
21 and then at the bottom showing you, if you want,
22 looking at the side of the patient in terms of what

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1 tissue is being imaged at each angle. So back then
2 when the amendments came out which they were basically
3 a labeling amendment, this is the way CT was
4 performed.

5 Now are these labeling requirements and/or
6 regulations relevant for the new applications of CT?
7 We've already seen the situation where in this fluoro
8 application it doesn't really fit. And we're not the
9 only ones. To a certain extent to not keep up with
10 the times because in AAPM Report No. 39, for example,
11 there is no mention of spiral scanning. But spiral
12 scanning is available. It's a fast scanning
13 technique. It brings in new imaging performance
14 considerations. It may also bring in new dose
15 implications associated with the use of it in that
16 manner and from marketing survey data we know that the
17 installed CT base, there's 62 percent of the systems
18 actually have a spiral capability. And the number of
19 procedures is also going up. So CT is not going away,
20 I think is the message that I'm going to try to give
21 over here and it's growing. It will keep growing, I
22 believe.

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1 So when you think about spiral CT I'm
2 using the same representation where I've shown the
3 tube going around the patient at 90 degrees. What
4 happens in this case is that the table is actually in
5 motion as the x-ray tube goes around the patient.
6 Here, I've tried to show a 10 mm slice in what's
7 called a 2:1 pitch and so if you look at the tissue
8 that's being imaged there as the tube is moving each
9 one underneath the corresponding angle, you're
10 actually covering twice the amount of tissue in this
11 particular case in terms of the image formation and it
12 has obviously an imaging performance aspect and a dose
13 aspect. You probably get less dose, obviously, if you
14 have this gap in between there and you have to
15 interpolate the data. So none of that was handled or
16 taken care of, certainly, in the regulations back in
17 the late 1970s.

18 Now currently I said there was 62 percent
19 of the systems that provides spiral capability. The
20 newest thing that's happening is multi-slice bio CT
21 and what you have in this particular case is wonderful
22 images that are produced as on the right hand side

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1 over here and I just want to give you a little bit of
2 appreciation as to what's involved there and I have to
3 look at my notes for just a second.

4 (Pause.)

5 What we're talking about is doing a whole
6 CT exam here for a trauma patient and that scan was
7 done in 57 seconds and the total coverage of the
8 patient is 140 centimeters at a 1.25 pitch with a 4
9 slide system. So you're capable of getting the entire
10 body, the volume of the body in 47 seconds.

11 I think that those aspects are similar to
12 what is traditional CT but that's a little bit of an
13 unknown. I think the next procedure will help to
14 answer some of those questions.

15 So in this particular case that I've shown
16 here if you had two 10 mm slices and a 1:1 pitch, you
17 can cover twice the volume in half the time as you
18 spiral down the patient, so these new techniques in
19 this revolution in CT provide new applications for
20 this modality.

21 Next slide, please. So just to give you
22 a little bit of appreciation as to how much the

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1 changes are, what we're talking about here for one
2 slice is changes from 5 seconds down to a half a
3 second for multi-slice spiral and scan times the cover
4 a 40 centimeter volume in a patient from 120 seconds
5 down to 10 seconds. Don't hold me directly to these
6 numbers. These are just approximates. And basically,
7 smallest volumes of about half a millimeter by half a
8 millimeter by half a millimeter. That's how far
9 things have progressed in CT.

10 So next slide. With respect to radiation
11 protection and safety, one thing that is known is that
12 the relative contribution of CT to national collective
13 dose is large. Yet, it's a small fraction of all
14 examinations. It's only in the order of 3 to 4
15 percent of examination and yet it contributes about 10
16 to 40 percent of the total dose contribution,
17 collected dose now and I have some examples that are
18 really hard to see, but the U.S. is not included
19 there. These are all European countries and what
20 we're talking about is the CT procedures are about 10
21 to 40 percent of the total dose.

22 So I think there are some interesting, if

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1 you want, radiation protection and safety aspects that
2 are coming to the fore here with respect to these new
3 applications of CT. There are some really exciting
4 things. There's a clinical trial that's going to
5 start very soon on patients meeting specific criteria
6 for lung cancer. It looks very, very promising in
7 terms of screening for lung cancer under certain
8 criteria. And then there are other things that are
9 happening that are sort of because it's easy to get
10 the images. That maybe in my mind are not quite as
11 exciting.

12 So next slide. So the question is what
13 can be done with respect to use, education and
14 training here. When you select operating parameters
15 on these systems, there's obviously a strong influence
16 on dose and imaging performance on what you use. And
17 so with respect to user training and education, this
18 is complicated equipment and no less complicated, if
19 you want than interventional fluoroscopy. And we need
20 to keep getting the users sensitive to these possible
21 exposure levels. There are complex clinical
22 procedures and they may require a lot of dose in order

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1 to get the benefit from it.

2 In Europe, one of the approaches that they
3 used to address some of these concerns is setting a
4 reference dose value and then providing specific
5 guidelines when you exceed that particular dose value
6 in a clinical procedure. Those kind of approaches are
7 not present in the United States. I'm not suggesting
8 they should be. I'm just saying this is the way that
9 they are approaching it in Europe.

10 So there's a lot of -- and I'm bringing
11 these things up because what I'm saying is that if
12 this is a significant contribution to the collective
13 dose then some pushing in this particular area can
14 have also a significant impact and some of that
15 pushing doesn't necessarily mean regulation, but use,
16 education and training.

17 Now with respect to equipment, equipment
18 performance, I think yeah, it could be that you can
19 make improvements in the way these systems behave, but
20 we're not talking factors of 2 or 4 here. We're
21 talking percent.

22 One thing which is sort of interesting

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1 though is that these systems don't provide, those who
2 are familiar with diagnostic x-ray equipment, they
3 usually have what is called automatic exposure control
4 that modifies the technique factors that run on the
5 machine, depending on the attenuation load that's
6 present. That sort of equipment is not present on CT.
7 It's sort of a strange thing to me. In other words,
8 if you have low attenuation, you should run a lower
9 MAS for example or a change kV or whatever. If you do
10 a pediatric versus an adult -- and some of that
11 happens automatically in traditional, general purpose
12 radiography and fluoroscopy, but it doesn't in CT. So
13 to me this is sort of an interesting side light, if
14 you want.

15 So in summary what I've tried to show is
16 I said this was really kind of an information thing in
17 terms of telling you what happened with respect to CT
18 fluoroscopy and what we're doing, but also give you a
19 little bit of a perspective of what we've done in the
20 past and what we're doing now. Stanley will describe
21 for you some of the information we're gathering in the
22 next survey, but there's a renaissance, really, in

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1 what's going on in CT, I think, because there's new
2 applications with significant events that's going on.
3 And have the user and equipment programs kept up? I'm
4 not sure. Yet, it's a significant dose to the
5 population and a fertile area for dose improvement and
6 as I said, we're open for suggestions, not necessarily
7 regulatory approaches in this area.

8 Thank you.

9 DR. ROTHENBERG: Thank you, Bob. Just one
10 comment. There are reference value -- there is an
11 AAPM Committee I think that Joel Gray has chaired,
12 working with the ACR that is going to be putting out
13 reference values including CT.

14 DR. GAGNE: I see.

15 DR. ROTHENBERG: The basic work has been
16 finished and it should be coming out at some point.

17 DR. SULEIMAN: I'm on that Committee.

18 DR. GAGNE: I know there was some mention
19 about that at the NCRP meeting last year, but I wasn't
20 aware of this particular Committee.

21 DR. SULEIMAN: So this referenced dose
22 business, the ACR also was there, going to be adopting

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1 it and using a similar approach and using some of the
2 very NEXT data, N-E-X-T data for the data for deriving
3 those values.

4 DR. GAGNE: I see.

5 MS. KAUFMAN: It was my understanding that
6 it was the next data that they were using as reference
7 values. So again, these are not optimal values.
8 These are just what are out there.

9 DR. SULEIMAN: State of the practice.

10 MS. KAUFMAN: State of the practice.

11 DR. SULEIMAN: Not state of the art.

12 MS. KAUFMAN: Not state of the art. Okay.

13 And are they going to hold off on CT reference values
14 until this next report or are they using old next
15 values or what are they doing on CT?

16 DR. SULEIMAN: I think they're using the
17 best data available, but they're plugged into us
18 through me.

19 DR. GAGNE: There's not a lot of data
20 associated with a spiral scan technique, a
21 multi-slice. Most of the data is available is still
22 back in the axial scanning days. I think things are

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1 changing so quickly and new applications are coming to
2 the forefront so quickly it's really hard to keep up
3 to a certain extent.

4 DR. ROTHENBERG: Also, with regard to the
5 automatic exposure control idea, there were a few
6 papers presented, RSNA, where they're starting to work
7 with that, plus there are some sort of two step
8 approaches including with GE with the scanned -- Scout
9 View and two Scout Views AP lateral and then adjusting
10 on the basis of that, but it's not an automatic thing.

11 DR. GAGNE: I see.

12 MS. KAUFMAN: Are we waiting until all of
13 the presentations or are we talking about this part
14 now?

15 DR. ROTHENBERG: I think we should wait
16 for the next one and then we'll continue.

17 MS. KAUFMAN: Okay.

18 DR. ROTHENBERG: Thanks. The next speaker
19 will be Dr. Stanley Stern on the NEXT survey.

20 DR. STERN: Thank you. This presentation
21 is about how CDRH is leveraging the Nationwide
22 Evaluation of X-Ray Trends, to obtain up-to-date

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1 information on clinical practice, patient workload and
2 patient dose related to computer tomographic exams and
3 procedures across the United States.

4 I will briefly describe what NEXT is,
5 outline how it works, and cite some key findings.
6 I'll identify the most significant technological
7 advances in CT since the last CT survey in 1990 and
8 describe how innovations of this past decade and their
9 promotion of related clinical applications have led us
10 to revamp the CT survey. The heart of this discussion
11 is the 2000-CT survey. I'll highlight the parts of it
12 intended to garner dose and dose-rate data associated
13 with the most recently developed modes of operation
14 for exams of the body as well as the head. A primary
15 motivation for characterizing x-ray trends is to
16 understand how they affect individual and population
17 radiation dose, and so I'll speak briefly about
18 aspects of dosimetry that are peculiar to CT and how
19 the survey is designed to facilitate inference of
20 patient and population dose. And finally, I'll
21 mention a complementary CDRH project underway to
22 develop a compendium of patient tissue doses

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1 associated with CT exams.

2 Can I have the next slide, please? NEXT
3 is a cooperative program encompassing national quality
4 assurance and radiological-health research. The
5 program is administered through the Conference of
6 Radiation Control Program Directors, which is the
7 umbrella organization of State radiation-control
8 agency directors. CRCPD's NEXT Committee coordinates
9 annual participation of over 40 States. Each year,
10 States provide personnel who recruit clinical
11 facilities, do on-site surveys, and perform x-ray
12 equipment measurements in approximately 350 locations
13 across the country including private practices,
14 hospitals, clinics. Surveyors acquire x-ray system
15 data on technique, exposure, image-quality, and
16 patient-workload associated with a particular
17 radiological exam whose selection for survey varies
18 from year to year.

19 Now CDRH underpins the program
20 scientifically and technically. We develop the survey
21 instruments and protocols for measurement. We
22 identify, design, test, procure, and calibrate

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1 equipment and materials. We select survey samples
2 from State rosters of facilities. We develop
3 curricula for training surveyors. We enter survey
4 results into databases, analyze and interpret the
5 data. And we publish NEXT findings as technical
6 reports and as papers in peer-reviewed journals.

7 Next slide, please. The NEXT program is
8 unique in the United States. It is the only mechanism
9 for obtaining medical radiology data that are
10 nationally representative of the amount of x-ray
11 exposure and numbers of people exposed, image quality,
12 and clinical practice related to patient dose.
13 Facilities that participate in the survey are
14 solicited by random sampling of State rosters. What
15 each year's survey captures for particular type of
16 examination are snapshots of the U.S. distributions of
17 the most important machine generated radiological
18 variables affecting patient dose. Examples of such
19 variables are radiation exposure at the skin entrance
20 plane, x-ray tube peak voltage, tube current, exposure
21 time, and so on. Data have been collected on the
22 quality of film processing also. In acquiring these

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1 data, surveyors employ patient-equivalent phantoms or
2 nearly equivalent, some embedded with test-image
3 objections to attenuate the radiation. They
4 standardize the measurement of exposure and assessment
5 of image quality across all facilities surveyed.

6 CDRH composes brochures of these data that
7 CRCPD provides to the States for distribution to
8 facilities when State personnel inspect them as part
9 of their routine radiation-control programs. These
10 brochures serve as a quality-assurance tool. They
11 enable comparison of the facility's radiological
12 techniques and exposures to nationwide norms.

13 For a given kind of examination, national
14 trends emerge from analysis of data collected over
15 time. Over the course of a number of years,
16 information published from NEXT surveys has proved to
17 be a seminal resource, cited in scientific journals
18 and used by researchers to identify radiological
19 health problems and to suggest solutions involving
20 changes in equipment technology, radiological
21 techniques and clinical protocols. In recognition of
22 the impact of the NEXT program in promoting

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1 radiological health, the international journal Applied
2 Radiation and Isotopes invited CDRH to review NEXT
3 findings in a special edition published last year.

4 May I have the next slide, please? This
5 slide indicates the scope and some principal findings
6 of the NEXT program since 1984, and I'd like to use it
7 to highlight several points.

8 First, please look at the two columns on
9 the left. In the past fifteen years seven different
10 types of radiographic and fluoroscopic examination
11 have been surveyed. Every few years an examination
12 category is repeated, perhaps with some kind of
13 variant introduced, for example, hospitals versus
14 private practice or 4.7 versus 4.2-cm
15 compressed-breast phantom, adult versus pediatric
16 chest radiography. These variations are introduced in
17 order to keep pace with technological and clinical
18 developments. In 1996, for example, along with the
19 survey listed here for upper gastrointestinal
20 fluoroscopy, there were pilot studies of fluoroscopy
21 in cardiac catheterization labs and on mobile C-arm
22 units. These kinds of technical pilots are useful as

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1 an "avant-garde" anticipating prospective widespread
2 incorporation of such modalities into clinical
3 practice.

4 The two columns on the right correspond to
5 measures of radiation levels, either at skin-entrance
6 or absorbed by the tissue of clinical interest. So
7 for mammography surveys, the radiosensitive tissue is
8 the glandular breast tissue, and the circled values
9 show a clear trend of increasing mean glandular-tissue
10 dose. Let me hasten to add that along with an
11 increasing dose for film/screen mammography there are
12 associated trends, which are not explicitly presented
13 in this table, of progressively better scores for
14 visualizing test-image objects, of the near
15 disappearance of Xero-mammography as a relatively
16 high-dose modality, and of the nearly universal
17 adoption of the use of grids to suppress radiation
18 scatter. For mammography, the bottom line is improved
19 image quality over this period of time.

20 For this slide, the last item I want to
21 cover is computed tomography and the CT surveys are
22 highlighted in the color shading there. There are two

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1 key ideas presented. First, the skin-entrance dose,
2 it's 41 milliGray or the internal-head dose, as it
3 were, 47 mGy, incurred on average by a patient in a
4 routine CT head examination is the largest dose among
5 those of all the radiographic examines listed,
6 fluoroscopy excluded. In fact, CT may be the single
7 modality which contributes most to the collective
8 population x-ray dose arising from diagnostic
9 radiological exams, and Bob Gagne just presented some
10 data about that. We're hoping that the year 2000
11 survey will enable estimation of just what the CT
12 contribution is to population dose.

13 For CT, the numbers in parentheses are the
14 extreme of a range that includes 50 percent of all of
15 the values of the sample distribution. In other
16 words, 50 percent of the doses fall within this range
17 and 50 percent fall outside of the range. The second
18 key idea about CT is that the ranges are relatively
19 broad, if you look at those ranges. The implication
20 is that through judicious selection of technique
21 factors, it's possible to obtain satisfactory image
22 quality and spare patient dose as well. So, these two

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1 points, large dose, broad range, represent our base
2 line for CT.

3 If that's our baseline, our starting
4 point, what are the challenges we face in mounting a
5 survey in the year 2000? What's happened since 1990
6 that we need to capture in a new survey?

7 May I have the next slide? The bulleted
8 items correspond to the principal technological
9 advances that have already been incorporated or are
10 being incorporated into most CT systems in the field.
11 They have led to profound changes in how CT is applied
12 in clinical practice. Slip rings are housed in the
13 gantries of CT systems, and they conduct electrical
14 energy between the high-voltage power supply and the
15 rotating x-ray tube or between the computer and the
16 data-acquisition array, if the x-ray detectors are
17 rotating with the tube. This technology is in common
18 use in low-cost as well as top-of-the-line scanners.
19 Here's the important point: slip rings eliminate the
20 constraint of electrical cables, and so the x-ray tube
21 or detectors can rotate continuously over many 360
22 degree rotations while the x-ray tube is energized.

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1 So the technology has fostered a new mode of scanning
2 called helical or spiral scanning where the patient
3 table moves at a constant rate while the x-ray tube is
4 rotating, and in effect the x-ray beam traces out a
5 helical pattern around a patient as the patient table
6 advances through the gantry opening. Helical scanning
7 has spawned an explosion of new clinical applications
8 of CT because of the advantages it holds over
9 conventional, slice-by-slice, axial scanning, namely,
10 speed, reduction of patient-motion artifacts and
11 facilitation of volume rendering of images. Just a
12 few examples of such applications are spiral CT
13 angiography, detection of spine fractures, evaluation
14 of laryngeal disease, cinematically displayed
15 visualization of pancreatic vascular and ductal
16 anatomy and detection and management of renal and
17 ureteral calculi and there are many other
18 applications. One of the key objectives of this
19 survey is to find out what percentage of CT systems in
20 the field of helical-scanning capability. We already
21 have some data from a recent market survey report that
22 Bob Gagne alluded to in his talk.

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1 Another significant advance in CT
2 technology has been the development of high
3 heat-capacity x-ray tubes. If we look for example at
4 the x-ray tube specs of one particular CT
5 manufacturer, from 1986 to 1998 the heat capacity of
6 their tubes increased by a factor of five, from 1.5 to
7 7.5 million heat units. And this capacity, in
8 conjunction with the ability of scanners to rotate
9 continuously has led to the growth of what's called
10 "CT fluoroscopy." Bob has talked about that in his
11 talk. I'm not going to go into detail. I think for
12 some systems it can be up to 200 revolutions of 360
13 degrees each while a patient is more or less
14 stationary.

15 This year's next survey has become to
16 obtain an accurate picture of the nationwide
17 prevalence of this mode and the dose rates and doses
18 associated with its use.

19 A third major group of technological
20 advances falls into the category of what's called
21 "ultra-fast" scanning. There are really two
22 technologies here. First "e-beam" CT refers to

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1 electron-beam computed tomography. Although it's
2 really been around since the early 1980s it wasn't
3 followed at all in the 1990 CT survey. In
4 electron-beam CT, x-rays are produced by
5 electromagnetically scanning an electron beam about a
6 large, semicircular tungsten target underneath the
7 patient. There's no mechanical motion. And because
8 of that scan times of 50 milliseconds are possible.
9 The extent to which electron-beam CT has caught on is
10 not clear, and the NEXT survey this year is trying to
11 answer that question.

12 The second technology, multi-slice helical
13 CT, is relatively more recent. It uses two to four
14 parallel arcs of detectors of produce a double or
15 quadruple helix of volumetric data. Some multi-slice
16 scanners have x-ray tubes that spin at two revolutions
17 per second so that the 4-slice units can be eight
18 times faster than most single-slice scanners.

19 May I have the next slide, please? The
20 single word that summarizes these changes is
21 "complexity." Because of these developments, there
22 has been a shift in the types of exams done. These

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1 days, there are more clinical applications of CT to
2 the body than there are to the head. In 1983, 63
3 percent of the 5 to 5.5 million CT procedures in the
4 U.S. were head scans, whereas a 1997 study of the ten
5 most frequently performed CT procedures at the
6 Cleveland Clinic Foundation indicates that head
7 procedures account for only 41 percent of the total.
8 Because of the advent of CT fluoroscopy, computed
9 tomography is used to visualize interventional
10 procedures as well as for diagnosis. The
11 proliferation of helical scanning with many different
12 kinds of models and options such as CT fluoroscopy and
13 multi-slice scanning has resulted in a variety of
14 different irradiation and scanning conditions whose
15 terminology itself is not completely standardized.
16 This complexity has led us to try some major changes
17 in conduct the Year 2000 survey compared to what was
18 done in 1990.

19 May I have the next slide? The national
20 sample size was initially set for 350 facilities
21 randomly distributed across the United States. This
22 year 42 States are actually participating in the

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1 survey and they will cover 314 facilities. I might
2 add that in our last session of training of the
3 surveyors there was some representation from Health
4 Canada as well and they are doing an independent
5 survey of the CT scanners there. Facilities are
6 picked randomly from rosters submitted by States, and
7 the sample size within each State is proportional to
8 its population. The target in each of these
9 facilities is the most frequently used CT system.

10 Because of the advances in technology and
11 clinical practice since 1990, we've had to introduce
12 several new aspects into the way the NEXT survey is
13 conducted. The major innovation is that the survey
14 for each facility is divided into two parts. One part
15 is an on-site visit that focuses on routine exams of
16 the adult head. Now even though the focus is the head
17 exam, several crucial features of the survey pertain
18 to body exams as well. A second part of the survey is
19 based on a questionnaire that the facility fills out
20 in advance of the surveyor visit. It is through this
21 questionnaire that we hope to obtain more complete
22 information about exams of the body, which, as I

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1 mentioned earlier, comprise the preponderant part of
2 the CT universe.

3 This slide summarizes the important
4 elements of the surveyor's visit on site at a
5 participating facility. The on-site visit represents
6 the traditional way a NEXT survey is done. A surveyor
7 interviews a CT technologist familiar with the system
8 and makes measurements with a standardized reference
9 phantom. But there are several new twists as well.
10 For example, we are going to determine what
11 percentages of CT systems are capable of helical
12 scanning and of CT fluoroscopy.

13 Also, we will obtain information about CT
14 fluoroscopy that will help us make informed regulatory
15 decisions. The patient-workload data and technique
16 factors sought for the CT fluoro-mode are not limited
17 to head exams. They refer to the most typically-used
18 settings for body or head scanning of all patients,
19 pediatric as well as adult. We are explicitly asking
20 for the average "beam-on" time for a CT
21 fluoroscopically-guided procedures and by making
22 measurements of the dose, duration of exposure and

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1 slice width near the surface of a head phantom, we can
2 estimate the skin-dose rate and typical values of skin
3 dose in the CT fluoroscopic mode of operation. This
4 information will give CDRH the most definitive insight
5 to date on the pervasiveness and dosimetry for an
6 increasingly popular mode of operation potentially
7 associated with skin injury.

8 For the routine head exam in particular,
9 surveyors are asking for the weekly patient workload
10 and also for a breakdown of how a facility does those
11 exams according to what clinical protocol. What
12 percentage of exams involves axial CT exclusively.
13 What percentage uses helical scanning? How many head
14 exams consist of a scanning phase without contrast
15 media followed by a scanning phase with contrast
16 media. Of course, if there are two distinct phases to
17 an examination the radiation dose would be double that
18 for a single phase.

19 We will find out the technique sets, tube
20 voltage, current, scan time, number of slices, slide
21 width, table increment, number of scan rotations and
22 so on, applied for the most frequently used

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1 axial-scanning protocol and separately for the most
2 frequently used helical-scanning protocol of the head.

3 The survey entails three sets of exposure
4 measurements, two of which are with the standard head
5 phantom developed by CDRH. The head phantom is a
6 16-cm diameter cylinder approximately 16 cm long, made
7 of polymethyl methacrylate, a material whose atomic
8 composition and density make for reasonably good
9 simulations of the radiation-scattering and
10 attenuation properties of tissue.

11 The first set of measurements will be made
12 with an ionization chamber in the center hole of the
13 phantom and will yield the multiple-scan average dose.
14 That's the MSAD which is a descriptor of the central
15 dose amongst a series of scans comprising a head exam.
16 These values can be directly compared to those
17 obtained from the 1990 survey and they will offer the
18 clearest indication of dose trend over this past
19 decade.

20 The second set of measurements will be
21 made in a phantom hole located 1 cm from the
22 phantom-entrance surface, and values from these

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1 measurements can be used to describe the average dose
2 rate and dose at the skin surface when the CT unit
3 operates in a CT fluoroscopic mode. These
4 measurements can also be related to those obtained in
5 the 1985 survey whose values were also measured in a
6 surface hole of the head phantom.

7 The third set of measurements will have
8 the ionization chamber aligned along the axis of
9 rotation free-in-air. The great advantage of this
10 last set of measurements is that because they are
11 unencumbered by the attenuation and scattering
12 introduced by the head phantom, the free-in-air values
13 are not limited to descriptors of head does.
14 Free-in-air values can be applied to make estimates of
15 internal-tissue doses to the body based on computer
16 calculations by the National Radiological Protection
17 Board of the United Kingdom. The NRPB calculations
18 simulate radiation transport in an anthropomorphically
19 modeled mathematical phantom. They offer a way for us
20 to estimate what we expect will be the largest
21 contribution to population dose from CT as it is
22 practiced today, namely, doses to tissues from exams

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1 of the body not limited exclusively to exams of the
2 head.

3 May I have the next, please? Most of this
4 slide summarizes features of the second principal
5 aspect of the year 2000 CT survey. The second part
6 consists of a detailed questionnaire addressed
7 primarily to the CT technologist but also to the
8 medical physicist most familiar with the most
9 frequently used CT unit. These questions cover exams
10 of the body as well as those of the head, and although
11 the focus is adult patients, there are some queries
12 about pediatric patient workload and techniques, too.

13 First, we try to identify the types and
14 numbers of CT units available at each facility
15 surveyed, units with only axial-scanning capability,
16 units that can do single-slice or multi-slice helical
17 scanning, units capable of doing electron-beam CT.

18 Second, we seek detailed enumeration of
19 patient workload per week, of frequency of use of
20 scanning protocols, axial versus helical, contrast
21 versus no-contrast, and of x-ray system technique
22 factors. Each data set is associated with an

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1 examination category for the most frequent types of
2 examinations, abdomen and pelvis, head, simple sinus,
3 chest, abdomen-pelvis, and so on. This information
4 represents the core of CT practice and exposure as
5 they relate to patient dose in the U.S. and its
6 acquisition would enable a detailed estimation of
7 population dose heretofore unavailable.

8 Third, the questionnaire includes a group
9 of queries about system maintenance and
10 quality-assurance tests. Quality assurance is an
11 important aspect of maintaining imaging integrity and
12 radiological protection and it simply was not covered
13 in the previous CT survey.

14 At the bottom of the slide I have
15 underlined a major initiative intended to help the
16 NEXT program transition to an era of electronic file
17 transmission. For the first time, surveyors are being
18 provided with diskettes containing pre-formatted
19 spreadsheets for their data entry. We are encouraging
20 electronic transmission of these files as a
21 time-saving efficiency and in the future we are
22 planning to work with the CRCPD to establish web-based

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1 date entry of NEXT survey results.

2 Next slide, please. Previous CT surveys
3 relied on what are quote dose descriptors to
4 characterize an amount of radiation energy
5 representative of what's absorbed per massive generic
6 tissue typical in an adult head exam.

7 The best known dose descriptors for CT are
8 the multiple-scan average dose which I mentioned
9 earlier and a related quantity called the computer
10 tomography dose index. It's abbreviated CTDI. These
11 descriptions are derived from measurements of dose
12 within a physical phantom intended to approximate the
13 radiation scattering and attenuation qualities of the
14 head. Now the year 2000 CT survey will obtain
15 measurements of MSAD using a head phantom.

16 But what we are really interested in is
17 estimating doses to the radiosensitive tissues of the
18 body. Evaluation of tissue dose is the foundation of
19 ionizing radiation risk assessment and the principal
20 risks associated with absorbed radiation are morbidity
21 and mortality of induced cancer, transmission of
22 genetic defects, fetal mental retardation and acute

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1 skin injury. This slide is meant to illustrate
2 several considerations involved in CT tissue
3 dosimetry. What's plotted is a single set of
4 calculated dose values corresponding to one particular
5 grouping of scanners, the GE 8800 and 9000 series.
6 And they've been modeled by the National Radiological
7 Protection Board in computer simulations of radiation
8 transport through an anthropomorphic mathematical
9 phantom. The ordinate here corresponds to the doses
10 to the tissues indicated so any particular color
11 indicates a dose to the whole dose, the dose averaged
12 over the entire mass of the tissue wherever it's
13 distributed. Tissue dose is plotted as a function of
14 the location of a 5-mm wide scan-slice along the
15 length of a person. On this scale, zero centimeters
16 corresponds to the base of the trunk of a person, and
17 94 centimeters corresponds to the top of the head. In
18 other words, if there were a single axial scan at 50
19 centimeters above the base of the trunk, then the
20 average dose to the breast would be about 0.015
21 relative units here and to the lungs it would be .007
22 units, and to the active bone marrow it would be 0.002

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1 units.

2 Two points I want to make with this slide,
3 the unit of measurement indicated by the ordinate is
4 not tissue dose per se. It's actually a ratio of
5 tissue dose to dose free in air. In other words,
6 internal tissue doses are represented by ratios
7 normalized to the radiation output of the CT unit so
8 that the doses themselves can be evaluated only if one
9 knows how much radiation the CT unit emits in the
10 first place. This situation reflects several
11 important facts that many people are not aware of.
12 Internal-tissue doses cannot be practicably measured.
13 They are generally not known during the actual
14 radiological exam, but they can be estimated from
15 computer simulations. The radiation output of a CT
16 unit, evaluated in terms of dose free-in-air, is
17 really just the starting point in the estimation of
18 internal-tissue doses.

19 Second, the radiosensitive tissues are
20 distributed throughout the body and in order to
21 estimate tissue doses we would need to know the
22 anatomical ranges covered by various scanning

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1 protocols. The year-2000 survey is obtaining this
2 information, as well as x-ray technique factors, dose
3 free in air, exam frequency, frequency of use of
4 contrast phrase, and patient workload, hopefully all
5 of the ingredients that we need to infer population
6 dose from CT.

7 Next slide, please. Finally, I would like
8 to briefly mention a CDRH project that is
9 complementary to the NEXT program CT survey and that
10 is the development of a handbook of tissue-dose values
11 from CT exams. The handbook will be targeted to
12 medical physicists and radiologists in a format
13 entailing look-up of dose values according to the type
14 of examination. We will try to have a generically
15 applicable set of tables, one table for each kind of
16 exam and that table should be valid for any CT model.
17 We would like to include options for estimating dose
18 for all the current and upcoming CT technologies,
19 including multi-slice helical scanning and
20 fluoroscopic CT as well as axial scanning. NEXT
21 survey results will give us insight into how to
22 accurately parameterize dose values in terms of these

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1 new scanning modalities. We also want to include ways
2 to estimate pediatric and fetal doses.

3 Our initial approach in handbook
4 development is to characterize and generalize the
5 existing set of normalized CT doses computed by the
6 National Radiological Protection Board of the United
7 Kingdom. We have already mapped anatomical scanning
8 regions to corresponding mathematical coordinates of
9 the NRPB anthropomorphic phantom for approximately 50
10 distinct CT exams. In addition to dose free-in-air,
11 we would like to normalize tissue doses to a reference
12 parameter commonly measured in the U.S., namely the
13 computed tomography dose index. Our goal is to have
14 this handbook available in approximately one year.

15 That completes this talk. It was
16 presented for your information and I would be pleased
17 to address any questions that you might have.

18 DR. ROTHENBERG: Okay, thank you. I guess
19 we can have questions for either Dr. Stern or Dr.
20 Gagne.

21 DR. SANDRIK: Thank you for those talks.
22 I guess one I think I'm curious about is I think you

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1 addressed one side of the risk-benefit issue, mainly
2 the dose side and the risk. Occasionally, you've made
3 mention of image quality, but I haven't seen any
4 explicit indication of how you would or if you intend
5 to do any assessment of image quality. Is that part
6 of the next 2000 plan or some other indicator and do
7 you have the intent to say when you talk about this
8 wide range of dose values to see if they correlate to
9 any range of image quality for these systems?

10 DR. STERN: Well, I think your remarks are
11 great. I think it would be very nice to have image
12 quality information. We don't. We don't have plans
13 for image quality. We're using a phantom that was
14 used for practical reasons. It was used -- same
15 phantom that was used in the 1990 survey and we've had
16 to sort of limit the scope of what, of all the
17 information that we can gather and we're not gathering
18 image quality. That's a short answer to your
19 question.

20 DR. ROTHENBERG: Yes, Kathleen?

21 MS. KAUFMAN: The NEXT study is measuring
22 MSAD, right?

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1 DR. STERN: That's one of the things that
2 will be inferred from the data that we measure, yes.
3 MSAD is one of the parameters that we will --

4 MS. KAUFMAN: Because the normalized
5 tissue dose is going to be in CTDI?

6 DR. STERN: Well, we can normalize tissue
7 doses -- tissue doses are -- there are tables of
8 tissue doses normalized to free-in-air values. We can
9 relate those to CTDI as well. We can infer values of
10 MSAD or CTDI from the measurements we are making in
11 the NEXT survey.

12 MS. KAUFMAN: Okay. On your pediatric
13 NEXT information, you had mentioned chest only, but I
14 thought that was also doing abdomen, no? Pediatric
15 abdomen. I thought it was the same phantom, but it
16 was looking at both.

17 DR. STERN: I'm not expert on the
18 pediatric survey.

19 DR. SULEIMAN: We're referring to what I
20 think is the chest, but the pediatric chest-abdomen is
21 approximately one and the same.

22 DR. STERN: It's one phantom covering

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1 that, yes.

2 MS. KAUFMAN: I think the rest of my
3 questions are for Bob, so I don't know, does anybody
4 else have questions for -- hi, Bob. Is there some
5 reason and actually our GE person might be best able
6 to answer, why they never used AEC on CT scanners? It
7 is a -- why don't they? Is there some reason?

8 DR. GAGNE: We'll put the hot seat to
9 John. I don't know.

10 DR. SANDRIK: I think -- well, partly
11 there is the thing like Larry had mentioned where
12 there is at least an option to try to taper the MAS as
13 you go around, if you know in advance what you are
14 facing. I think the issue gets to be with the intense
15 level of accuracy that you need in the data so that
16 you don't generate artifacts and if you're doing AEC
17 fluoroscopy you step on the pedal, you have too much
18 dose, you can turn it down. If it's too little, you
19 can turn it up. But you're not depending on that data
20 while the dose is being adjusted to do anything else
21 with. You're just sort of zeroing in. But if you're
22 doing a CT and you're going around and say that's not

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1 right, I'm going to keep adjusting and playing around
2 with the dose, I think you have the problem of wasting
3 data or not knowing exactly what the data represent
4 after you've acquired them. So I think sort of the
5 feedback mechanisms to try to adjust those on the fly
6 and then still keep track of exactly what you were
7 doing so you can get an accurate reconstruction just
8 hasn't been done.

9 MS. KAUFMAN: That's what I thought and
10 that's what I'm wondering is the technology such today
11 that they can do that now?

12 DR. SANDRIK: I guess I can't answer that.
13 I'm not that close to the engineering side of that.

14 MS. KAUFMAN: Bob, has anybody looked at
15 on these CT fluoro and maybe spiral too where they're
16 biopsy work table, next to the table top, has anyone
17 looked at operator exposure on those?

18 DR. GAGNE: Well, I think there's been a
19 lot of publications associated with the use of tools,
20 you know, when you do that, because you can -- just
21 like any interventional procedure you have to be
22 careful not to get your hands in the beam and so on,

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1 and so I know that there's been some work done and
2 some work published where people have talked about a
3 variety of different tools to use to try to keep your
4 hands out of the primary beam. I don't know that
5 there's as much work that's been involved in terms of
6 looking at the scatter contribution and so on, but
7 certainly there's been a concern there and just like
8 an interventional scene of being careful about not
9 getting your hand in the primary beam.

10 MS. KAUFMAN: Uh-huh.

11 DR. GAGNE: In fact, when they first came
12 out one of the products that came in for review to us
13 included a videotape with the hands in the beam so it
14 was sort of interesting to see that when we reviewed
15 that.

16 DR. ROTHENBERG: I know the group at
17 Harvard with Judy and Nawful have looked at this and
18 reported on it. I was a preprint of one paper but I'm
19 not sure whether it got published yet.

20 DR. GAGNE: I think Barry Daly at the
21 University of Maryland probably has some publications
22 to where he talks about the use of tools and there's

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1 a Japanese author also, but I don't remember the name
2 of --

3 MS. KAUFMAN: And what kind of exposures
4 did those studies indicate, extremity exposures?

5 DR. GAGNE: Well, if you don't have your
6 hand in the beam, it's really -- it's such a small
7 narrow beam of radiation, I don't think the scatter is
8 really probably all that significant. It's really
9 more a question of keeping your hands out of the
10 primary beam and if you have a tool which has good
11 tactile sort of sensation so that it doesn't stop you
12 from doing the job, if you have to do the job and you
13 have to put your hand in the beam you put your hand in
14 the beam is the way I would look at it, but if the
15 tool is sufficiently good to be able to do the job
16 without getting your hand in the beam and I think the
17 Japanese author talks about those kind of aspects,
18 then the exposure is pretty small, really.

19 MS. KAUFMAN: And what beam width are they
20 using?

21 DR. GAGNE: In the cases that I was
22 showing there we're talking about a situation where

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1 you might have a 10 millimeter slice and you're just
2 going around the patient, whatever, 50 times at the
3 same spot. So it's a 10 millimeter width slice.

4 MS. KAUFMAN: Because I can tell you, when
5 I've taken scatter readings on a 10 millimeter slice,
6 one rotation, not fluoro, it's not all that
7 insignificant, the scatter radiation.

8 DR. GAGNE: It certainly can't be as bad
9 as when you have a whole body -- a whole 14 by 17 or
10 something or something like that, but yeah, I'm not
11 saying this is a consideration you shouldn't take --

12 DR. ROTHENBERG: There's another thing.
13 The current is much lower when they're doing these --
14 at least on some. It may be 50 mA instead of 200 or
15 300.

16 DR. GAGNE: Yes, they do drop the mA down.

17 MS. KAUFMAN: Okay.

18 DR. ROTHENBERG: And kV sometimes.
19 They've done some at 80 kV as well.

20 DR. GAGNE: There are some manufacturers,
21 for example, that throw in extra filtration when
22 you're doing CT fluoroscopy, but you know, that brings

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1 up the point that Dr. Sandrik brought up. We focus
2 and we should on the radiation protection and safety,
3 but the part of the equation is the imaging
4 performance and you can put filtration in and knock
5 the exposure down, but if you don't see anything when
6 you put the filtration in, what's the good of it. You
7 got to what the imaging performance at the same time.

8 MS. KAUFMAN: You had mentioned that at
9 our earlier meeting we had talked about possibly tying
10 in your current fluoro standards with the CT fluoro.

11 DR. GAGNE: Yes.

12 MS. KAUFMAN: Do you know any kind of a
13 motion from this group to separate those as you've
14 done?

15 DR. GAGNE: Well, I think the problem is
16 that we really didn't have an appreciation as to how
17 prevalent this technique was and I think Dr. Stern is
18 pointing out that the next survey this year is really
19 going to provide a lot of good information, not only
20 in CT fluoroscopy, but all the CT procedure. So we're
21 going to get some data from that. He didn't mention
22 you know how many CT fluoros we've seen in this survey

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1 yet.

2 Stanley, can you?

3 MS. KAUFMAN: None, I think.

4 DR. ROTHENBERG: I don't know if you want
5 to do that.

6 DR. STERN: No. We've only received -- we
7 expect something like 314 surveys and 314 returns
8 optimally 100 percent. We've only received like 4 or
9 5 back.

10 MS. KAUFMAN: Considering there are not
11 very many units like this around it's possible that
12 your sample is going to have none of these or one.

13 DR. STERN: Well, we'll find out.

14 DR. GAGNE: It's supposed to be
15 representative sample, right?

16 DR. STERN: Yes, it's randomly selected.
17 It's representative.

18 MS. KAUFMAN: Includes private practice in
19 addition to hospitals?

20 DR. STERN: Yes. States submit rosters of
21 CT facilities from private practices, hospitals, all
22 their CT facilities and they're picked randomly.

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1 DR. SULEIMAN: I'd like to clarify
2 something. If my memory serves me right I thought
3 last year the Committee was very specific that we not
4 try to add -- do the CT amendments on to the fluoro
5 because I think they wanted the fluoro amendments to
6 proceed, but they wanted dose displaced similar to the
7 fluoro amendments, but they wanted the Center to
8 proceed on a separate track.

9 MS. KAUFMAN: That's what I thought too,
10 but his slide said that --

11 DR. GAGNE: No, I thought they were
12 specific, the recommendation to go ahead and tag it on
13 and that's why I addressed that particular topic.

14 MS. KAUFMAN: That's what I --

15 DR. GAGNE: I hope my explanation as to
16 why we didn't do it was okay.

17 MS. KAUFMAN: That's why I wondered if you
18 needed any thought from us because I certainly would
19 like the fluoro regs to proceed without being tied in
20 to this, so I didn't know if you needed a motion from
21 this group on that.

22 DR. SULEIMAN: No. I don't think so.

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1 MS. KAUFMAN: One thing, have you gotten
2 any feedback from manufacturers in terms of how many
3 CT fluoro units are out there?

4 DR. GAGNE: No. I can't say that I have
5 or we have.

6 MS. KAUFMAN: I don't think there are very
7 many and what we might want to do is go to the
8 manufacturers and ask them where they are and then
9 includes those if we really want data on them.

10 DR. GAGNE: Yes, right.

11 DR. ROTHENBERG: Michele?

12 MS. LOSCOCCO: Likewise, are you planning
13 on including that type of data in the handbook that
14 you're going to have in approximately one year or is
15 this based on the data from previous survey?

16 DR. STERN: The handbook is going to --
17 the handbook is not -- the handbook will be helped by
18 the NEXT data, but it's not tied to it and we will try
19 and make provisions to indicate what doses are from CT
20 fluoro modes, if we get those data in the handbook or
21 how to evaluate to such doses.

22 MS. LOSCOCCO: Because it's not -- you say

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1 that it will be the NRPB, but isn't that from a GE
2 8800?

3 DR. STERN: That was one table from the
4 NRPB data set and they've modeled -- these are old
5 data. These are from -- modeled from like 1989 or so.
6 They're like 27 different models of -- that was just
7 one example, from different manufacturers for 23
8 different irradiation conditions. So we are trying to
9 adopt all of those data, all of those different models
10 and doses and tables into something general,
11 basically. That's what we're trying to do.

12 DR. ROTHENBERG: John.

13 DR. SANDRIK: Question on the possible
14 dosimetry here. If you do have a scanner that does
15 helical, it's in large part say of what they do, do
16 you intend to also do dosimetry in the helical mode as
17 part of this study or would it be done in a standard
18 axial mode and I guess if you are, we'd be interested
19 in how you plan to do helical dose imagery.

20 DR. GAGNE: I'll let Stan answer that one.

21 DR. STERN: The NEXT survey, we're not
22 doing helical dosimetry per se, we're doing a standard

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1 axial dosimetry, but we're asking for the technique
2 factors used for the helical mode and we're asking for
3 the protocols they use. And we'll try to figure out
4 one from the other basically.

5 DR. GAGNE: Because obviously the pitch in
6 other characteristics will all have an effect on that
7 and will have to be input into the whole problem, the
8 whole question.

9 DR. ROTHENBERG: You have to look at that
10 carefully. my experience with the single slice
11 helical is it's pretty easy to go from one to the
12 other, but with the multi-slice, you've got to think
13 about it a lot.

14 DR. STERN: Yes, it's complicated.

15 MS. KAUFMAN: The plan on the NEXT is to
16 use the head phantom?

17 DR. STERN: Yes.

18 MS. KAUFMAN: And then try and use that
19 data to calculate what it would be for the abdomen?
20 Because these days I think your report said 60 percent
21 of the exams --

22 DR. STERN: We're using the free-in-air

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1 measurements for the bodies. We can relate the doses
2 to tissues of the body for all kinds of exams to the
3 free-in-air measurements. We don't need the phantom
4 at all.

5 MS. KAUFMAN: Okay, your free-in-air
6 measurements are going to be taken outside the phantom
7 altogether?

8 DR. STERN: Correct.

9 MS. KAUFMAN: Not in any of the holes?

10 DR. STERN: Correct.

11 MS. KAUFMAN: So you're just going to use
12 inverse square law to calculate?

13 DR. STERN: Well, we use the -- basically,
14 it's the dose in air to an ionization chamber on the
15 axis of rotation.

16 MS. KAUFMAN: Right, but I'm saying the
17 distance would be different for a body than a head,
18 just relative to the distance from the source?

19 DR. STERN: That's where the -- we're
20 using the tables of the National Radiological
21 Protection Board. See, they've modeled the body.
22 They have a phantom where they've modeled, an

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1 anthropomorphic phantom and by measuring the dose
2 free-in-air, we can relate that dose to the tissue
3 doses in their tables, without knowing the distance
4 from the source to the axis for rotation. We don't
5 need to know that.

6 MS. KAUFMAN: There is a CT body phantom
7 though.

8 DR. STERN: There is, but we don't have
9 those available for the survey. We've distributed --
10 there are some 40 phantoms being distributed to
11 surveyors or have been distributed and they have that.
12 We just don't have that available.

13 DR. ROTHENBERG: Do you know the
14 relationship between the NRPB calculations and the
15 ones that the -- there's a German group that also did
16 mathematical --

17 DR. STERN: GSF?

18 DR. ROTHENBERG: Yes. Are they similar?

19 DR. STERN: I don't specifically recall.
20 In the report by the NRPB from 1990 they discussed
21 their calculations versus those of GSF also, same era,
22 1989-1990. And they're comparable.

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1 DR. ROTHENBERG: I've used those and
2 adapted some of those as well.

3 DR. STERN: Thank you.

4 DR. ROTHENBERG: Any other comments?
5 Thank you very much. I think we're at the end of our
6 agenda for today. So unless there are other items we
7 need to look at I think we'll adjourn for today and
8 we'll see you all, for those of you who can make, for
9 tomorrow morning at 8:30 again.

10 (Whereupon, at 4:47 p.m., the meeting was
11 recessed to reconvene tomorrow, Thursday, June 22,
12 2000 at 8:30 a.m.)

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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: TECHNICAL ELECTRONIC PRODUCTS RADIATION
SAFETY STANDARDS COMMITTEE MEETING

Before: CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH

Date: JUNE 21, 2000

Place: ROCKVILLE, MARYLAND

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

Rebecca Davis

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