# TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRAITON

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TECHNICAL ELECTRONIC PRODUCT RADIATION

SAFETY STANDARDS COMMITTEE

TWENTY-FIFTH MEETING

VOLUME I

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

Pages 1 Thru 306

Gaithersburg, Maryland
September 23, 1998

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AT



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

# TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

## TWENTY-FIFTH MEETING

**Volume II**

Wednesday, September 23, 1998

8:30 a.m.

Gaithersburg Hilton
260 Perry Parkway
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
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PARTICIPANTS

Roland Fletcher, Chairman
Orham Suleiman, Ph.D., Executive Secretary

MEMBERS

John Cardella, M.D.
Joe A. Elder, M.D.
Kathleen Kaufman, B.S.
Jill Lipoti, Ph.D.
Marlene McKetty, Ph.D.
Mary V. Marx, M.D.
Stanley Savic
Stephen Szeglin, M.S.
Jerry Thomas
Robert Turocy
Dennis Wilson

FDA

Richard V. Kaczmarek

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

2 DR. FLETCHER: Good morning. At this time, the
3 25th meeting of the Technical Electronic Products Radiation
4 Safety Standards Committee will come to order.
5 I would like to turn this portion of the meeting
6 over to Dr. Orhan Suleiman, who will give some introductory
7 remarks and some instructions.

8 **Greetings and Introduction**

9 DR. SULEIMAN: Good morning. In accordance with
10 the Radiation Control for Health and Safety Act of 1968,
11 Public Law 90-602, the Secretary, Department of Health and
12 Human Services, has established the Technical Electronic
13 Product Safety Standards Committee for consultation on
14 matters relating to technical electronic product radiation
15 safety.
16 As specified by Public Law 90-602, the committee
17 consists of 15 members, including the chairman, who are
18 appointed by the Commissioner of Food and Drugs for
19 overlapping terms of four years or less.
20 Five members are selected from governmental
21 agencies, including State and Federal Governments, five
22 members from the affected industries, and five members from
23 the general public, of which at least one shall be a
24 representative for organized labor. Members must be
25 technically qualified by training and experience in one or

1 more fields of science or engineering applicable to
2 electronic product radiation and safety standards.
3 The primary function of TEPRSSC is to provide
4 advice and consultation to the Commissioner of Food and
5 Drugs on the technical feasibility and reasonableness of
6 performance standards for electronic products, to control
7 the emission of electronic product radiation from such
8 products, and to review amendments to such standards before
9 being prescribed by the Commissioner. The committee is not
10 requested to review individual applications or particular
11 products of specific firms.
12 Public Law 90-602, and its legislative history,
13 clearly indicated that the TEPRSSC members are expected to
14 represent a very wide range of interests with at least one
15 third of the committee nominated by the regulated industry
16 itself and appointed on the basis of their being able to
17 represent industry-wide concerns.
18 Section 534 of the Federal Food, Drug and Cosmetic
19 Act specifies that TEPRSSC members are not to be considered
20 officers or employees of the United States for any purpose
21 including conflict of interest determinations.
22 However, to be consistent with FDA's general
23 policies regarding advisory committees, the Agency believes
24 a public disclosure memorandum should be made a part of the
25 public record which identifies each member and provides

1 their employment affiliation.

2 Approved on March 20, 1996, and September 15 and
3 23, 1998 by the delegated authority of the Commissioner of
4 the Food and Drugs, the members of the Technical Electronic
5 Product Radiation Safety Standards Committee are:

6 From the General Public: David LeGrande, who is
7 affiliated with the Communication Workers of America;
8 Marlene McKetty, Howard University Hospital; Betty Sisken,
9 University of Kentucky; John Cardella, Hershey Medical
10 Center; and Mary Marx, University of Michigan Medical
11 Center.

12 Representing the Government: Roland Fletcher,
13 Maryland Department of the Environment; Joseph Elder, U.S.
14 Environmental Protection Agency; Jill Lipoti, New Jersey
15 Department of Environmental Protection and Energy; Kathleen
16 Kaufman, Los Angeles County, Department of Health Services;
17 Jerry Thomas, Uniformed Services of the University of the
18 Health Sciences.

19 Representing Industry: Jane Ehrgott, AT&T Bell
20 Laboratories, Lucent Technologies; Stanley Savic, Zenith
21 Electronics Corporation; Robert Turocy, Picker
22 International; Dennis Wilson, Heat and Glo, and Stephen
23 Szeglin, PTW New York Corporation.

24 **Chairperson's Opening Remarks**

25 DR. FLETCHER: Thank you very much. At this time,

1 I would like to take the opportunity to welcome all
2 committee members here, those returning and those who are
3 new to TEPRSSC.
4 I feel very privileged to have the opportunity
5 once again to chair this committee, and as you have perhaps
6 surmised, a very unique committee, and unique of course is
7 an overused word sometimes, but if you look at the
8 scheduling of this committee, this committee meets only when
9 there are subjects that need to be discussed. It just
10 doesn't meet because a date and time on the calendar rolls
11 around.
12 Our last meeting was in April of 1997, this
13 meeting is in September, and not only are we meeting at this
14 time for subjects that, as you will see from the agenda, are
15 quite important, we are also meeting in a new setting. The
16 last two meetings, of course we met at the corporate
17 headquarters of the CDRH.
18 So, I welcome you. I encourage you, although I
19 feel from reading the credentials I don't need to do a lot
20 of encouraging, I encourage you to listen to each one of the
21 proposals and presentations and to ensure that any area of
22 concern or any area of further interest and exploration,
23 that you feel very free to explore.
24 This is a very tight schedule. We have a lot to
25 do in the two days that we are scheduled to meet, and there

1 may be times when I will have to adhere very closely to the
2 times prescribed in the schedule.
3 I understand that I may be receiving some aids in
4 doing that in the form of a gavel and perhaps some kind of a
5 time piece should that become necessary, but I just want to
6 let you know ahead of time that we have a lot of material.
7 Some of the material we are going to cover is
8 perhaps somewhat controversial, and we will need to be very,
9 very close as far as the time is concerned.
10 I do want to once again encourage you to do the
11 work of the committee in the way that you have always done,
12 and that is conscientiously and to the point. Should there
13 be any need for any kind of an administrative perhaps recess
14 to just have a break in the schedule, I will try to let you
15 know that ahead of time. Otherwise, things will proceed
16 according to the way they have been laid out.
17 Once again, I thank all of you for being here. We
18 have a few seconds, so even though Orhan has read each of
19 your names, just so that there is eye-to-name contact, why
20 don't we just go around and give just a two-sentence
21 introduction of yourself starting with Dr. Cardella.
22 DR. CARDELLA: My name is John Cardella. I am the
23 Chief of Interventional Radiology at Penn State University.
24 My research interests are in radiation safety and the design
25 of safer x-ray equipment. I represent interventional

1 radiologists probably a 2,800-member organization is my
2 professional affiliation.
3 MR. WILSON: I am Dennis Wilson. I am the Vice
4 President of Engineering for Heat and Glo. My background
5 has been in the microwave oven industry. I have got about
6 20 years experience there.
7 DR. MARX: I am Victoria Marx. I, like Dr.
8 Cardella, am an interventional radiologist. I am head of
9 the Division of Interventional Radiology at University of
10 Michigan, and my interest in this area primarily arose out
11 of being a relatively young person going into an active and
12 hopefully long career in interventional radiology, and we
13 are among the highest -- the work force exposed to the
14 highest amount of radiation in the medical field, and that
15 is how I got interested in this.
16 DR. ELDER: I am Joe Elder. I am employed by the
17 United States Environmental Protection Agency. I work as a
18 special assistant out of the Office of the Director of the
19 National Health and Environmental Effect Research
20 Laboratory. I am on the committee I believe because of my
21 expertise with radiofrequency radiation.
22 MS. KAUFMAN: I am Kathleen Kaufman. I am
23 Director of Los Angeles County Radiation Management. We are
24 a regulatory compliance program having responsibility for
25 approximately 18,000 x-ray tubes and 350 radioactive

1 materials' licenses.

2 This is my second advisory committee. I am proud

3 to serve on this one. I was formerly on the NMQAAC, the

4 Mammography Advisory Committee.

5 MR. SAVIC: My name is Stanley Savic. I am the

6 Vice President of Product Safety and Compliance at Zenith

7 Electronics Corporation. This is my second term on the

8 TEPRSSC. Approximately 10 years ago I served my first term.

9 In my pre-industry employment, I was on the staff

10 of the Radiology Department at the University of Chicago

11 where I was involved in some research with radiation

12 treatment planning and for the past number of years at

13 Zenith I have been in charge of product safety especially as

14 it regards x radiation safety from television sets.

15 DR. McKETTY: I am Marlene McKetty. I am a

16 medical physicist at Howard University Hospital. My

17 training was mainly in radiation oncology physics, however,

18 through most of my career I have been worked in diagnostic

19 radiology. My main interests are in mammography and

20 cardiology in terms of x-ray equipment in cardiology.

21 I also am in charge of the radiation safety

22 program at Howard University Hospital and the University.

23 MR. TUROCY: Good morning. I am Bob Turocy. I am

24 with Picker International. We manufacture major diagnostic

25 imaging equipment, such as MR and nuclear CT, and we also

1 provide service to the industry.

2 I have been with Picker for 25 years. I am a

3 regulatory affairs and compliance manager in the corporate

4 arena, and I am also associated with NEMA, National

5 Electrical Manufacturers Association.

6 DR. FLETCHER: I am Roland Fletcher. I am the

7 chair of the TEPRSSC Committee. I am also the program

8 manager for the State of Maryland. I have formerly chaired

9 the Conference of Radiation Control Program Directors, and I

10 currently chair the Organization of Agreement States.

11 My background is I am a retired Army Lieutenant

12 Colonel. I was in the U.S. Army Chemical Corps, and I have

13 spent 12 years in the position of radiation management at

14 the State of Maryland.

15 DR. SULEIMAN: I am Orhan Suleiman, Executive

16 Secretary for the Committee, with the Center for about 21

17 years.

18 DR. LIPOTI: My name is Jill Lipoti. I am in

19 charge of the radiation protection program in the New Jersey

20 Department of Environmental Protection. We have

21 responsibility for about 23,000 x-ray tubes. We license

22 radiologic technologists. There are 17,000 in New Jersey.

23 In other regulatory programs, we deal with naturally

24 occurring and accelerated produced radioactive materials in

25 New Jersey, clean-up of contaminated sites, radon exposure,

1 and we have one of the larger non-ionizing programs in the
2 states. We have two people.
3 We also perform environmental surveillance around
4 our nuclear power plants and respond to postulated
5 accidents. I am also the past chair of the Conference of
6 Radiation Control Program Directors.
7 MR. SZEGLIN: Good morning. My name is Steve
8 Szeglin. I am President of PTW, a medical device
9 manufacturer specializing in electrometer ionization
10 chambers. My background is clinical medical physics,
11 specializing in diagnostic measurements.
12 MR. THOMAS: Good morning. My name is Jerry
13 Thomas. I am Chief of Radiological Physics at the Uniformed
14 Services University of the Health Sciences. I have been
15 involved in the area of digital imaging and radiation
16 biology for the last 25 years, and look forward to working
17 with all the people on the committee.
18 MR. KACZMAREK: I am Richard Kaczmarek. I work
19 for FDA, Office of Health and Industry Programs, Radiation
20 Programs Branch. I am a medical physicist.
21 DR. FLETCHER: Thank you all very much. From
22 another administrative perspective, this meeting is being
23 recorded, and it is very important that when you speak,
24 please speak into a microphone. It may at least initially,
25 and perhaps all the way through the meeting, be practical

1 for each person to identify themselves. Okay. That won't
2 be necessary, but make sure you are speaking into a
3 microphone.
4 At this point in time, I would like to begin our
5 agenda. Our first topic deals with Fluoroscopy Proposed
6 Amendments. Tom Shope will begin. He will be followed by
7 Mr. Gagne and Stern.

8 **Fluoroscopy Proposed Amendments**

9 **Introduction**

10 DR. SHOPE: Good morning. It is nice to be back
11 with the committee to talk about our regulatory efforts
12 related to x-ray equipment, in particular fluoroscopic x-ray
13 systems.
14 [Slide.]
15 This morning we will be presenting some proposals
16 formally to the committee in the step required prior to
17 publishing in the Federal Register.
18 The next slide sort of outlines how we are going
19 to operate this morning.
20 [Slide.]
21 I would say that the committee has been given
22 copies of the slides, and you also have a rather thick copy
23 of the proposed amendments, and I will be referring to the
24 double-spaced version line numbers as I go through the talk,
25 so I think the double space is a little easier to read, I

1 hope it is not too confusing to those of you who read
2 through the single-spaced copy you got and have notes and
3 can't relate them to the double-spaced copy, but maybe we
4 will be able to get through it.
5 The outline of our presentation is we are going to
6 sort of go through it chronologically in sequence. I am
7 going to talk about three or four of the topics that we are
8 addressing with amendments, followed by Dr. Gagne to talk
9 about three sections, followed by Dr. Stern to talk about
10 two sections.
11 We suggest perhaps that if there are specific
12 questions about each of the sections, we take a few minutes
13 at the end of each discussion to address those brief
14 questions, and then at the end of the presentations, we will
15 have an opportunity hopefully to get into a deeper
16 discussion about anything that comes to mind during the
17 discussion. We do plan to have breaks for questions after
18 each numerical item up here.
19 [Slide.]
20 Just to orient the committee and the audience as
21 to where we are in the process with regard to these
22 amendments, we are working on amendments to the Federal
23 Performance Standard for Diagnostic X-ray Equipment, which
24 is in Title 21, Code of Federal Regulations, Section 1020.30
25 through 33.

1 We talked with the committee about these proposals
2 in sort of a concept stage at the last meeting. In December
3 of '97, we published an Advanced Notice of Proposed
4 Rulemaking outlining the areas we were working on,
5 soliciting comments. We got about 15 or so written comments
6 from the public on our concepts, and have considered those
7 comments in working toward this draft.
8 We are here at the meeting today to review this
9 with the committee. Our schedule then would call, following
10 the committee, to consider the comments from the committee,
11 prepare the Federal Register Notice, which contains the
12 rationale and the other analyses that are appropriate, and
13 then publish the amendments for public comment, probably
14 around the first of the year, in '99, and 120-day comment
15 period followed by probably coming back and talk to the
16 committee about the results of those comments, followed by a
17 final publication. The idea would be that most of the
18 requirements would be effective a year following that
19 publication of the final rule.
20 [Slide.]
21 I just want to say the mechanics of this.
22 Additions to the regs are shown with underlines, deletions
23 with strike-throughs. We will use the line numbers trying
24 to locate things.
25 The first thing I want to talk about is sort of a

1 general change occurring throughout the standards. This has
2 to do with the quantities and units used in the standard.
3 When we amended the x-ray standard sometime ago, I
4 believe it was in 1990 when it was proposed and became final
5 in '93, we made some conversions in the standard, but we
6 didn't convert or change the units, quantities used to
7 describe radiation or radiation exposure or radiation
8 intensity, and it led to some awkwardness in terms of using
9 the SI units to ohms per kilogram as the units to describe
10 the quantity exposure.
11 We made those changes earlier, and we are making
12 this change because of the policy to use the metric system
13 or the International system of units or the French version,
14 which I can't pronounce and won't try.
15 We will also follow the new units with the
16 conventional or historic inch-pound type units. In this
17 case it's roentgens, the measure that we use for describing
18 x-ray exposure. The ionization of the air that occurs from
19 the x-rays measured in roentgens will be replaced by a
20 quantity that we refer to as kerma or air kerma.
21 [Slide.]
22 This proposed change, the way we are doing it is a
23 little different than we talked about in the concepts, and
24 responds partly to some of the comments we got to the
25 concepts.

1 [Slide.]

2 We will make the change in the quantity used to
3 describe the radiation, but we are doing it in such a manner
4 as the actual limits, the amount of radiation allowed by the
5 places in the standard where there are limits. It won't
6 really change any significant amount.

7 [Slide.]

8 Just brief, I don't want to dwell on this. Just
9 to remind you of the definition of this new quantity that we
10 will be using to describe radiation. It is the quantity
11 kerma. It has to do with the kinetic energy of the charged
12 particles that are liberated by uncharged ionizing
13 particles, i.e., photons, from the x-rays in a mass of
14 material.

15 The units are energy per mass, joules per
16 kilogram. It has a special name, the "gray." That
17 describes absorbed dose, as well as air kerma.

18 [Slide.]

19 Just to sort of help you see that for diagnostic
20 x-ray energies, these are basically the same quantity. Air
21 kerma is the kinetic energy to positive in the mass, and it
22 is basically equivalent to the average absorbed energy in
23 the mass when, in the case of x-rays, there is no
24 bremsstrahlung occurring and the energy basically is
25 deposited right there in the mass, and it doesn't escape,

1 radiated out somewhere else.

2 [Slide.]

3 Here is the conversion factors that one would use

4 to convert from x-ray exposure to air kerma, that is, the

5 energy deposited in the air where normally you would be

6 measuring the ionizing radiation or the amount of ionization

7 created in the air.

8 It is based on the conversion of the energy it

9 takes to ionize an air molecule divided by the charge of the

10 air molecule. That is the conversion factor in joules per

11 kilogram, 3.97. This is from the ICRU Report 47.

12 Basically, the rule of thumb you can use is the

13 does in milligray is 8.76 times the exposure in roentgen or

14 the dose in microgray is 8.76 times the dose in

15 milliroentgen.

16 [Slide.]

17 This slide illustrates the impact of the change.

18 We are changing limits. These are some of the limits that

19 exist in the standard, in fact, it may be most of the

20 radiation limits, numerically listed, so we have to learn

21 44-88-hike or something like that.

22 We tried to limit to two digits because that is

23 about as accurate as you need to be for radiation protection

24 purposes here, and so there is a little rounding off going

25 on here. These numbers aren't precise. If you go to 180

1 milligray, you will find that is really not 20 R/minute
2 multiplied by 8.76. There is a little bit of rounding off
3 going on here.
4 Really, the number is 43. something, and we round
5 it to 44, and since we doubled the exposure, we are just
6 doubling that number. You double 88, round it off, and you
7 get close to 180. So, that is the reason for the numerical
8 numbers that we are using.
9 [Slide.]
10 Effectively, it is no change in the limits. Just
11 as an example, I will walk through some of the changes that
12 occur, just to show you how this is going to work.
13 The first instance of a change in the standard
14 occurs on line 505 on page 23, I believe it is, of your
15 handout. Here, I have shown the current wording which
16 involves this conversion factor or this 5.8 times $10^{-5}$ --
17 when we are talking about a small quantity -- coulombs per
18 kilogram, which is equivalent to 100 milliroentgen, becomes
19 the wording down below, "shall not exceed 0.88 milligray air
20 kerma," and now we are using the terminology (vice 100
21 milliroentgen (mR) exposure), vice in the sense of stands in
22 place of, to let you know that the previous unit and the
23 previous quantity and the previous measures, the part in
24 parentheses there, so vice here stands in place of or
25 equivalent to, if you want to think about it that way.

1 [Slide.]

2 We proposed or we talked about at the concept
3 stage doing this a little differently, and that is, instead
4 of working with numbers like 44 and 88, we would have worked
5 with sort of nice rounded off numbers like 50 and 100, but
6 to do that, because of the conversion factors here, it would
7 have been a 15 percent increase in all the limits.

8 While these limits in most cases are maximum, that
9 aren't really reached in most cases, there was enough, I
10 think, discouragement in the comments that we got not to
11 attempt to raise the limits here. So, we have at trade-off
12 at this point. We can raise the limits 15 percent, and they
13 will be nice, convenient, easy to remember numbers like 5,
14 10, 50, and 100, or we can keep the limits as they are and
15 deal with 44 and 88 and 0.33, and things like that.

16 So, that is the trade-off that we are making. We
17 are at this point proposing not to change the limits, but to
18 use the existing limits.

19 [Slide.]

20 What is the impact of this change? Not a lot I
21 don't think. It will change the limits, it doesn't affect
22 product design. Systems that are complaint now will
23 continue to be compliant. There can be some evolutionary
24 change, when appropriate, in terms of labeling,
25 instrumentation, manufacturer's information.

1 This complies with our policy to use SI, and
2 although exposure is an SI quantity, it is not the preferred
3 quantity, and it is the quantity that is disappearing from
4 all the international standards, so this will bring us in
5 line with those. It is in line with current scientific
6 practice standards.
7 [Slide.]
8 That is the end of my discussion of the changes in
9 units. We will just go through the standard and everywhere
10 there was an old coulombs per kilogram, it will become air
11 kerma.
12 There is a couple of places in there where we talk
13 about exposure won't change. There, we mean the term
14 "making radiation," or in the sense of the IEC standards,
15 the x-ray tube loading, so that word "exposure" is not being
16 changed.
17 We will continue to talk about the creation of x-
18 rays as being as exposure, exposing the patient to radiation
19 as opposed to the quantity itself, so it is not a total
20 removal of the word "exposure" from the standard.
21 Now I would like to move into my second topic
22 unless there are some brief questions about the unit change.
23 Just sort of some housecleaning. Back up one
24 there, if you could.
25 [Slide.]

1 I have some sort of housecleaning amendment type
2 things here. Some of these are brought about by some of the
3 other changes we are making, and rather than try to jump
4 back and forth, we thought we would just go through and
5 address all the amendments and the applicability changes
6 here.
7 These are (a) to clarify the intent of some of the
8 requirements. We need to introduce a new word into the
9 definitions because we are using it in a way that we felt we
10 needed to define it, trying to clarify the applicability,
11 and this is principally driven by the fact that our x-ray
12 standard now, particularly the requirements for fluoroscopy,
13 were predicated on fluoroscopy being done with an x-ray
14 system that uses an x-ray image intensifier tube, and we
15 know those are shortly going to be probably like some of the
16 dinosaurs or other species that are less populous than they
17 used to be.
18 There are going to be new image receptor devices
19 used in fluoroscopy, and then that presents a problem in our
20 standard if we are hanging everything on x-ray image
21 intensifiers, so we are trying to make some changes that
22 will anticipate that in this round of amendments.
23 That is what I mean by the technological changes
24 there and to clarify the difference between fluoroscopy and
25 radiography a little bit. There are some housecleaning

1 kinds of things dealing with effective dates. Every time we
2 add an amendment, we have to make it clear when the
3 effective date that that amendment applies to equipment
4 manufactured after some date, but it doesn't apply to the
5 equipment that was manufactured before that date, so we end
6 up with a standard that has lots of different effective
7 dates in it because the requirements become effective at
8 different times.
9 So, that adds a little bit to the awkwardness of
10 the standard is we have to do all that housekeeping.
11 [Slide.]
12 We will start walking through the amendments now.
13 If you want to follow along, I have listed the line numbers
14 here on most of these. It may not be necessary to follow
15 along a lot of these, they are just brief, little changes.
16 I think I just explained line 10, the change we
17 are making there, applicability. It used to mention x-ray
18 intensifier tube, now it will mention fluoroscopic image
19 receptor.
20 Line 16 is some of these products that are coming
21 in as image receptors will be electronically powered as
22 opposed to x-ray film, and we needed to change an
23 applicability statement in line 16.
24 We are adding a definition of automatic exposure
25 rate control. We previously had a definition of automatic

1 exposure control primarily used in the radiographic section,
2 1020.31, but we never had defined automatic exposure rate
3 control, so we are adding that definition. That is on line
4 69.
5 I am not going to stop and read all the changes of
6 definitions. If anybody has questions about the wording, we
7 can address those in the discussion. I just wanted to sort
8 of familiarize you and the audience with the kinds of
9 changes that we are making.
10 In line 117, we have a revision to the definition
11 of fluoroscopic imaging assembly, again required because of
12 the emphasis, change from x-ray image intensifier tube to
13 fluoroscopic image receptor.
14 In line 122, we are adding for the first time a
15 definition of fluoroscopy. This is to help clarify, we
16 hope, a little bit of confusion that sometimes exists as am
17 I doing fluoroscopy or am I doing radiography, does Section
18 1020.31 apply or 1020.32 apply. So, we have laid out some
19 definitions here that we hope will clarify the meaning of
20 these. The next slide, we will talk about these definitions
21 just a minute.
22 [Slide.]
23 One of the things we talked about in the
24 considerations here was using some of the IEC type
25 definitions, the International Electrotechnical group that

1 writes the International Voluntary Standards.

2 They have a very extensive terminology standard,
3 and I think we are reflecting here some of the parochialism
4 perhaps in the U.S., but not going to the term "radioscopy,"
5 because I think many in the U.S. would have trouble figuring
6 out what radioscopy was, so we are sticking with fluoroscopy
7 here, but that, in fact, is the synonym for the word used in
8 the IEC standard of radioscopy.

9 We are describing it as a technique for generating
10 x-ray images and presenting them instantaneously and
11 continuously as visible images for the purpose of providing
12 the user with a visual display of dynamic processes. In
13 other words, fluoroscopy is real-time, you see the image as
14 the image is being caused by the concurrent x-ray exposure
15 going on.

16 Radiography, on the other hand -- and we will have
17 a change in the definition of radiography -- means a
18 technique for generating and recording an x-ray pattern for
19 the purpose of providing the user with an image or images
20 after the termination of the exposure.

21 In other words, you stop exposing, you can still
22 see the image. You can go back and look at it later. That
23 is either a film, a digital recorded image, cine film,
24 something from a solid state imager that goes into a digital
25 memory, videotape, all those things would be radiography

1 because you can look at the image later, and we hope these
2 two distinctions will make this a little clearer as you read
3 the requirements in the standard.
4 [Slide.]
5 Moving on down to some of the definitions. Some
6 changes here again because of the change to air kerma from
7 exposure. I am not going to list all these exposure to air
8 kerma kinds of changes in the standard, but just line 127 is
9 an example of that kind of change.
10 In line 131, we are adding the definition of
11 kerma. It is the standard international definition of
12 kerma, right out of the ICRU.
13 We need to define an item known as the isocenter.
14 This is basically the center of the sphere that a C-arm
15 could describe in all its motion, and it will be talked
16 about by Stanley Stern in his presentation later, so this is
17 a location in space, an imaginary point in space, if you
18 will, that is the center normally where you would put the
19 object being imaged in a fluoroscopic system or where you
20 would like the object being imaged to be.
21 We are defining something called mode of operation
22 for fluoroscopic systems. This is associated with some
23 requirements on information to be given to users, and this
24 is in line 175. The idea here is in our user information
25 section to have information about the various ways

1 fluoroscopic systems can be operated, but we are trying to
2 limit the amount of information that has to be provided to
3 those distinct modes of operation that sort of can be
4 characterized as having a different purpose or a different
5 intent.
6 This is not meant to be every different way you
7 can run the fluoro system and get a different exposure or a
8 different set of techniques, but those general categories of
9 operation, and so this may be a definition people will want
10 to focus on a little bit.
11 In line 187, we are adding a definition for non-
12 image-intensified fluoroscopy. We have never had a
13 definition before, so we thought we have a requirement for
14 that, so let's put a definition in and make clear what we
15 are talking about.
16 In line 208, I have already mentioned the addition
17 of the term radiography.
18 If I am going too fast, wave me down and jump in
19 if you have questions.
20 [Slide.]
21 In line 217, we are revising slightly our
22 definition of recording.
23 Yes?
24 MS. KAUFMAN: Getting back to the mode of
25 operation, because later on there is a discussion about

1 requiring the manufacturers to give various exposure rates
2 or whatever we want to call them these days, I am a little
3 bit confused on the definition.
4 Are we saying they would not have to supply those
5 for various magnification loads or they would?
6 DR. SHOPE: For a given mode of operation, they
7 would have to show us the range within that mode over which
8 exposure can change as you change things like magnification,
9 kVp, so within a given mode, there will be some variability
10 that the operator has under control without changing the
11 actual mode itself, going from cine to digital recording,
12 say.
13 So, the idea here is to, in a given mode, the
14 manufacturer would give the dose during that mode for a
15 typical phantom that he has described and also give the
16 range of variability that can occur within that mode for
17 such things like changing magnification. It doesn't have to
18 give every possible combination, but the range of those
19 changes that can occur with a mode.
20 So, for a given mode, there might be two or three
21 tables or graphs that show how the dose changes.
22 MS. KAUFMAN: So, it would show it for, say, with
23 your typical patient or whatever for 4.5 versus 7 percent.
24 DR. SHOPE: Right.
25 MS. KAUFMAN: Thank you.

1 DR. SHOPE: The next definition is for the new
2 definition of solid state x-ray imaging device. This is our
3 attempt to describe the new technology, and I will just read
4 it.
5 "A solid state x-ray imaging device means an array
6 of small transducer elements, typically in a flat,
7 rectangular panel configuration, that intercepts x-ray
8 photons, and through a single or multistage process converts
9 the x-ray photon energy into a modulated electrical signal
10 representative of the x-ray image. The output electrical
11 signals may undergo analog-to-digital conversion before
12 leaving the device to provide either a fluoroscopic or
13 radiographic image."
14 So, that is our proposed definition for this new
15 certifiable component I guess at this point when we are back
16 to our general section.
17 [Slide.]
18 The next change in definitions is the addition of
19 a term "source-skin distance." We use that in the standard
20 and we have never had a definition, so we have added that
21 source-skin distance. This is just the distance from the x-
22 ray focal spot to wherever the skin is located, either the
23 patient or sometimes it is referring to the end of the
24 collimator or the beam-limiting device.
25 In line 582, we are changing the HVL requirement.

1 The wording here is related to that change in the
2 requirement because it is addressing the beam quality of the
3 beam that is used to measure the attenuation properties of
4 anything in the x-ray system that can be between the patient
5 and the image receptor.
6 In the current standard, there is a reference to a
7 beam quality which will not be typical of the beam qualities
8 used once we change the amount of filtration in the beam
9 with the new half-value layer requirement, so we are just
10 specifying that this measurement of attenuation properties
11 will be done after the effective date a different beam
12 quality. It doesn't really change anything in current
13 designs, it just changes our terminology in the standard so
14 it is consistent.
15 Line 628, we change the applicability in Section
16 1020.31, so we are now down in the specific radiographic
17 section, again just to reflect the change from image
18 intensifier to fluoroscopic image receptor. It looks like I
19 left the word "tube" off that line.
20 In line 918, we are also changing the
21 applicability to the fluoroscopic section 1020.32, again to
22 reflect the change from using an image intensifier to
23 fluoroscopic image receptor.
24 Actually, that last one is line 629. I think we
25 lost count of lines here somewhere, the next to the last

1 one, the 628 should be 629.

2 [Slide.]

3 Here is a reorganization of the section that deals
4 with exposure rate limits during fluoroscopy, the maximum
5 exposure rate permitted during fluoroscopy.

6 Currently, we have two paragraphs, 1020.30(d) and
7 1020.30(e), and (d) is there for historic reasons because it
8 describes the situation as it was prior to our last
9 amendments, and paragraph (e) was the way we wrote the
10 standard after the amendments that became effective in 1994
11 which put limits on the output exposure rate during high-
12 level control mode of fluoroscopy.

13 As we got to working with the standard this time,
14 and adding some things, I have to credit Bob Gagne I think
15 for pushing us to do this, but it became clear that this is
16 very confusing. People would get in and think they are
17 reading the maximum exposure rate requirements, but they
18 would be in the section that applied to a different time.

19 So, if we put them all in one section, with the
20 effective dates associated with each of the requirements, I
21 think it is less confusing to the people that are trying to
22 use the standard, and so that is what we are proposing to do
23 is basically to combine the current (d) and (e) into one
24 paragraph (d), strike out paragraph (e), but in the
25 paragraph (d) we will have the appropriate applicability

1 dates right along with each of the requirements, so you
2 won't be reading a maximum exposure rate limit thinking it
3 applies to new equipment when you are in the paragraph that
4 applies to old equipment, and that effective date part is
5 far away from the paragraph you are reading.
6 So, that is the purpose here and just to outline
7 what we are doing, new d(1), (2), and (3) are the paragraphs
8 that apply to basically the way the standard was in 1974,
9 when we first put it into place in terms of maximum exposure
10 rate limits. That is the old requirements.
11 d(4) and d(5) would reflect the changes we made in
12 1994, that became effective in 1995, which put a limit on
13 high-level control and put in the definition of recording
14 and differentiated between continuous and pulse recording
15 and whether the maximum output limits applied there. We are
16 not changing any of the limits, it is just making it clear
17 when the applicability of each of those section is.
18 d(6) is something new. Here, we are modifying
19 what might be thought of as the previous d(5) and making a
20 new d(6) to remove the capability of not being limited in
21 maximum exposure rate by the act of hooking an analog
22 recording device to the fluoro system.
23 This is sort of closing what people have described
24 as a loophole or a way around or a fix which allows the
25 maximum exposure rates during fluoro to be exceeded by

1 simply adding an analog tape recorder to the system whether
2 the images are ever used or not.
3 So, this makes it clear that the maximum exposure
4 rates apply and sort of says that when you hang an analog
5 recording device, whether it is tape or some other analog
6 device on, that that doesn't give you the exemption from the
7 maximum exposure rate limits.
8 So, that is the reason for d(6), and d(7)
9 specifies the measurement conditions for checking these
10 maximum exposure rates. The new thing in (7) is we are
11 explicitly adding a limit to address the small C-arm type,
12 portable or hand-carried mobile fluoroscopes that have very
13 short SIDs that are intended for extremities, and the
14 measurement conditions that we described previously just
15 really didn't work very well for these, so we are adding a
16 new measurement condition for these small C-arms, as well as
17 in some of the other discussion about the C-arms, you will
18 hear something about source-to-skin distance requirements.
19 So, that is the changes associated with this
20 section. It is just a reorganization with the addition of
21 removing this exemption for analog recording and making
22 real-time fluoro with a tape recorder hooked to the system
23 subject to the maximum exposure rate limits of 10 r per
24 minute or 20 r per minute when there is a high-level control
25 activated, and I have got to learn to say 88 milligray per

1 minute. This is a learning experience for all of us. This
2 is going to be fun, I am sure.
3 [Slide.]
4 So, we just strike out and reserve old Section (e)
5 in 1020.32 because we aren't using it anymore.
6 Line 1167, we have another reference to image
7 intensifier tubes we take out, and in line 1205, we have a
8 requirement for the image receptor on mobile and portable
9 fluoroscopes is modified. What this is doing is requiring
10 that these things have something more than a simple
11 fluorescent screen or the non-image intensified type of
12 image receptor.
13 [Slide.]
14 We previously had a requirement that just said
15 they had to have image intensified, but since we are not
16 going to be so specific to the image intensifier tubes, we
17 need to make it general to the image receptor, incorporating
18 something other than just a simple screen.
19 That sort of concludes my second portion, which is
20 sort of the general changes, the applicability changes to
21 deal with the changes in technology.
22 [Slide.]
23 I would like to talk just a moment about what is
24 the impact of these changes in terms of cost or what will
25 happen as a result of these. I think I have highlighted

1 sort of the main things that we see as the impact of these
2 changes in terms of impact on equipment.
3 The 1020.32(d)(6), that business about preventing
4 analog recorder being considered an exemption to the
5 exposure rate limits will prevent some system configurations
6 that might be being established. This oftentimes happens as
7 sort of an add-on to the system although I think some of the
8 OEMs also in the past have had these kind of features.
9 We don't think the changes to 1020.32(d)(7), which
10 deals with the mini-C-arms, will cause any change to those.
11 They all basically meet this requirement currently. Their
12 exposure rates are below the maximum that would be allowed
13 under those measurement conditions.
14 I think that these changes will help in that they
15 remove some of the ambiguities, may, in fact, prevent us
16 from having to have a lot of variances for solid state x-ray
17 imagers when they come in the door, having to deal with them
18 on a one-by-one basis.
19 We will still have to do that between now and the
20 time these changes become effective, but we don't see these
21 changes as having a major impact or major cost associated
22 with them, and I there is some benefit to be had from them
23 in terms of potential for less ambiguity, clarifying the
24 requirements, and perhaps even permitting some unnecessary
25 exposure.

1 [Slide.]

2 I would now like to move to my third section,
3 which is dealing with a new requirement we mentioned just
4 briefly previously, the establishment of a new section the
5 general portion 1020.30. It starts at line 456.

6 This is the new requirement to have provided to
7 the users or the purchasers of fluoro equipment some
8 specific information about the doses that the various modes
9 result in producing.

10 What we have tried to do in this section is sort
11 of describe using our definition of what the requirement is,
12 and let me see if I can just sort of synopsize the
13 requirement as we go through the next couple of slides.

14 [Slide.]

15 The idea here is that readily findable in the
16 voluminous information that comes with an x-ray system would
17 be this section of information that would be of interest to
18 the users who want to know what are the dose implications of
19 the way I operate the fluoro system, and so there would be a
20 separate section or even possibly a separate document that
21 would be devoted to provide this information.

22 This is kind of like the requirement we currently
23 have for CT systems where there is dose information provided
24 about the CT system. For each fluoroscopic system, you have
25 to have this kind of information, and for each mode -- I am

1 sorry -- my point here is this would apply to all fluoro
2 systems, not just C-arms or interventional, but for all
3 fluoro systems, and this information would have to describe
4 for each of the modes, as defined in that definition of mode
5 of operation, how that mode is selected or engaged, how does
6 one know you are using that mode, what indications are that
7 you are in that mode, and also a description of what that
8 mode is intended for, what is its purpose, why would one
9 normally use that mode, the clinical uses that the
10 manufacturer sees for that mode.
11 This is not meant to be an exhaustive list, but
12 just an indication of why one would want to use that mode,
13 what it was intended for, and then information on that mode
14 related to either -- and it depends on how the mode
15 functions as to which one of these would be appropriate --
16 but if it is a recording kind of mode, then, the air kerma
17 per frame or per image recorded probably makes sense.
18 If it is a continuous exposure kind of mode, the
19 air kerma rate would be the piece of information we are
20 interested in, and the manufacturer can make that
21 determination of what makes sense for each of the modes and
22 give that information.
23 MS. KAUFMAN: So, I guess you are saying that a
24 magnification is not a mode, it is a technique change.
25 DR. SHOPE: It is a variation within a mode.

1 MS. KAUFMAN: I am not sure that is the way the
2 community generally thinks of it. I generally think of it
3 as a different mode of operation.
4 DR. SHOPE: What that gets us into is a huge long
5 list, so we are going to have to do a little educational
6 effort, I think, to get people to understand what we mean
7 here. If you can suggest an alternative terminology maybe,
8 we could consider that.
9 MS. KAUFMAN: I would just consider calling that
10 one thing magnification changes a different mode of
11 operation.
12 DR. SHOPE: But it really isn't because that is
13 just changing the amount of magnification that is going on.
14 The mode really has to do with what is the algorithm the
15 automatic brightness control is using, what is the exposure
16 magnitude, are you doing digital capture or film capture. I
17 mean there are a whole very different list of things.
18 I think the best way to describe mode for me is
19 the difference between normal fluoro and high-level control.
20 That is a change of mode. But within normal fluoro or
21 within high-level control, you can use different kV's,
22 different MAs, different magnifications, different SID's.
23 All those affect patient dose.
24 So, what one would do for the normal fluoro mode
25 is describe what the dose in normal fluoro is to our typical

1 patient or phantom that we have talked about, and then in
2 normal fluoro, give the user how that dose changes as you
3 change magnification, current kVp, SID, whatever is
4 changeable within that mode of operation, so there would be
5 the dose information for normal fluoro and then a table or a
6 graph that shows how that dose rate changes as you change
7 mag mode, so all that information about what happens when
8 you change magnification -- I said a bad word "mag mode" --
9 what happens as you change magnification --
10 MS. KAUFMAN: But that is my point.
11 DR. SHOPE: Well, we have struggled with that. I
12 think we are open to suggestions as to something that might
13 make more sense or be a little bit easier to communicate.
14 MS. KAUFMAN: I think you just made my point,
15 though. I think most of us do think of changing
16 magnification as changing the mode of operation.
17 DR. SHOPE: It is a term that has been there,
18 right. We struggled with technique of operation and other
19 things, but that has another connotation particularly in our
20 standard where technique factors are something else.
21 MS. KAUFMAN: I mean you are asking for the
22 information either way, so I don't know that it is a huge
23 difference, but I think in the general concept of people,
24 they do think of mag modes.
25 DR. SHOPE: Sure. It is mag modes, but not just

1 the mag mode that we are regulatorily defining perhaps, I
2 don't know. We are not the language police here.
3 DR. LIPOTI: Tom, I have a question also.
4 DR. SHOPE: Yes.
5 DR. LIPOTI: I see that you are trying to provide
6 this in a smaller part of a larger manual, and this part
7 would be designed to be extracted from the manual and kept
8 close at hand, so you could refer to it?
9 DR. SHOPE: I would think that would be a useful
10 thing to do. I would hope the manufacturers make this
11 available in a little, you know, user's reference book, and
12 it sort of would be handy to have in the room perhaps for
13 the new people coming to run the machine to familiarize
14 themselves with it as opposed to being over in the file
15 cabinet with all the circuit diagrams.
16 DR. LIPOTI: If there was one thing when I looked
17 through this list of very many things that you have here, it
18 looked to me like technique factors might be something that
19 would lend themselves to being a poster on the wall in the
20 room where this machine was used.
21 Have you given any thought to not just having the
22 user manual, but to requiring some posting that would
23 summarize some of these?
24 DR. SHOPE: Well, I don't think we have thought
25 about it, and probably the reason we haven't thought about

1 it is we regulate the manufacturers, and requiring something
2 to be posted in the room, I guess we could regulate the
3 manufacturers and make them provide such a thing should
4 somebody want to post it in the room, but you see why
5 requiring things to be posted in the hospital is not our
6 authority.
7 DR. LIPOTI: But if you required a poster to be
8 generated, then, states could pick up on that and require it
9 to be posted in the room, but if it isn't produced by the
10 manufacturer, then, we have a hard time requiring something
11 to be posted.
12 I would like to give some consideration to some
13 brief visual summary of all of these things that might be
14 useful to someone using the machine.
15 DR. SHOPE: I think that easily you could have a
16 facility, if you were a state, required to extract the
17 essential pieces of this information and post it, and maybe
18 if that is a requirement, the manufacturers would want to
19 help the facility out by providing it ahead of time.
20 I think we would have to look a little bit. We
21 are trying to make sure that this is not pages and pages and
22 pages of tables and things, so that it is overwhelming and
23 nobody would use it, so we tried to restrict it to, for a
24 given mode, the manufacturer describes the standard phantom
25 that represents how that mode would be used and gives us the

1 dose number for that phantom, and then shows us a range of
2 things that might change within that mode, so we are trying
3 to limit the amount of information required here to a
4 manageable set, and if it lends itself to a chart, I think
5 that is something that we can encourage the manufacturers to
6 do and maybe we can think about that. We will certainly
7 take a look at it. We haven't really discussed it up to
8 now.
9 MS. KAUFMAN: Tom, since you mentioned it, is now
10 the time to discuss this phantom, this typical patient
11 phantom?
12 DR. SHOPE: Sure. Well, I hadn't quite gotten to
13 it.
14 DR. FLETCHER: Why don't we hold off.
15 DR. SHOPE: My next item here.
16 MS. KAUFMAN: Okay.
17 [Slide.]
18 DR. SHOPE: The specific phantom. What we are
19 saying here is we are not prescribing a standard phantom.
20 We are allowing the manufacturer who has designed the
21 equipment -- and it may have different modes, it may have a
22 mode that is for pediatrics, and the phantom for pediatrics
23 would be different than the mode that is for general
24 radiography, or he may have a mode there that is for
25 peripheral work and maybe the phantom there ought to be

1 different than the belly phantom or the chest phantom that
2 is used for generating the typical doses during the fluoro
3 modes that are appropriate for the other types of exams --
4 so, this is a labeling and disclosure requirement for the
5 manufacturer to pick a phantom that he is going to use to
6 make this measurement or attenuation material that he is
7 going to use.
8 It is not a requirement that it be anthropomorphic
9 or anything like that, just this is how much attenuation I
10 had in the beam when I made my dose measurement, so that the
11 physicist or people who want to do comparisons can take a
12 look at it.
13 So, the requirement is for the manufacturer to
14 identify the phantom, describe it, and give the numbers that
15 result from the use of that phantom. I think there are a
16 limited number of things out there in the marketplace that
17 may lead to some standardization.
18 There is work that the American Association of
19 Physicists in Medicine are doing, describing phantoms. They
20 are working with NEMA. There is a new cardiology phantom
21 about to be described, I think, for testing of cardiology
22 type fluoro systems.
23 So, I think there is a possibility here for some
24 standardization. We are not requiring it, and we wanted to
25 leave the flexibility for the manufacturer to make a choice

1 appropriate for the mode that he has designed into the
2 equipment. The phantom you would use in a mini-C-arm is
3 probably very different than the phantom you would use for
4 cardiovascular work.
5 So, the requirement here is for the manufacturer
6 to describe the phantom that he is using to produce the dose
7 number, so that someone could check on it. Also, to give
8 the typical settings that the system would be set for when
9 you are examining a patient that that phantom is
10 characteristic of or intended to represent.
11 So, the dose information would be specified for a
12 mode of operation or set of techniques which make up the
13 mode, the phantom, and the settings within that mode that
14 are variable, that describe what was actually done to the
15 phantom. If it is an automatic exposure control mode, then,
16 you don't have to do the settings, the phantom itself is the
17 thing that determines the settings.
18 We then would, as I mentioned earlier, in No. 3
19 bullet here, have information provided on how radiation
20 output changes within the mode due to things that can be
21 changed while you are operating within that mode.
22 The dose measurement or the air kerma rate, the
23 air kerma per frame numbers would be given as a free-in-air
24 measurement using the same measurement geometries as
25 referred to in our maximum exposure rate limit requirement

1 back in the new section d(7) in 1020.32, and the
2 manufacturer would be required -- and this is probably the
3 thing that bothers the manufacturers the most perhaps -- to
4 state a maximum deviation.
5 In our terminology, a maximum deviation means you
6 go to a machine and the manufacturer has given you the data,
7 and he has also told you, and none of my machines will the
8 data ever be more different than the given number than this
9 amount, that is the maximum deviation statement.
10 So, he might give you a typical exposure rate for
11 normal fluoro for a 20-centimeter plexiglas phantom of 44
12 milligray per minute and tell you the maximum deviation is
13 10 milligray per second, so you would know that you go and
14 make a measurement on that system, the manufacturer has
15 designed the system so that if it is working properly, the
16 output is going to be between 34 and 54, and you would
17 expect to find it in that range, and we would hold the
18 manufacturer to having a specification within that range,
19 but the manufacturer determines how tight he wants to make
20 the specification. It is not a requirement by us to make
21 this within a certain amount of accuracy or precision.
22 So, that is the maximum deviation statement that
23 would go with these numbers.
24 DR. CARDELLA: Tom, I had a question. I am not
25 sure I am clear on this. Are you saying that manufacturers

1 may test and collect their numbers for inclusion in the
2 documents using a specific phantom or any phantom, but they
3 must specify it?
4 DR. SHOPE: They can use a variety of phantoms and
5 specify each one of them if one phantom is appropriate for
6 one mode, and the other phantom or material is appropriate
7 for the other mode, i.e., I could see a situation where you
8 had a pediatric mode and you used a pediatric type phantom
9 or a small amount of attenuation, you had a system that was
10 designed solely for neurological procedures and perhaps they
11 have picked a phantom that is most representative of the
12 attenuation of the skull, or they have picked a general
13 purpose kind of system and they have picked a phantom that
14 is appropriate for the thorax type attenuation, and they use
15 that information.
16 As long as the phantom is identified, one can
17 relate the amount of attenuation to its reasonableness and
18 whether that is representative of the kind of patient exam
19 that would be occurring in this mode.
20 DR. CARDELLA: By doing that, though, you shift a
21 tremendous burden onto the purchaser of the equipment to
22 make comparisons one vendor to another, because, you know,
23 if vendor A uses phantom A and specifies it as required, and
24 vendor B uses B, C uses C, and D uses D, it is difficult to
25 make judgments about which of those different pieces of

1 equipment will fulfill your clinical needs at the lowest
2 radiation levels, and that is becoming a bigger and bigger
3 issue.
4 So, I would like to see at least some proscription
5 about which phantoms are eligible, so that it doesn't turn
6 into a huge free-for-all, because the manufacturers will
7 game the system using the best phantom most favorable to
8 their piece of equipment. I think that is not an
9 overstatement of things.
10 MS. KAUFMAN: That was the point I was going to
11 make, too. I absolutely agree. I think that one
12 manufacturer will say that 3 centimeters is equivalent to a
13 chest, and another manufacturer is going to say, no, no,
14 it's 2.5, and so they are going to show a lower exposure
15 rate. It will pretty much be impossible for the purchaser
16 to do a comparison of exposure rates on units.
17 I understand the problems with skulls versus
18 chests and pediatrics, and all of that, but we could say
19 that they should provide that. Maybe we could make that an
20 additional requirement, but also have one requirement that
21 there be, and maybe it will be two or three phantoms, but
22 that those exposure rates be provided strictly maybe just
23 for intercomparison purposes, so that you could see how the
24 exposure rates differ.
25 Otherwise, we are going to have, we can end up

1 with 100 different phantoms out there, and there would be no
2 way to do an intercomparison.
3 DR. SHOPE: I think we have to pay a little
4 attention to what is the purpose of our standard, and
5 ultimately, I wouldn't disagree that intercomparisons can
6 ultimately lead to lower doses and better radiation
7 protection.
8 Our purpose here is to establish standards dealing
9 with the equipment that are radiation protection related, so
10 I am not sure that going to a standardized phantom -- we did
11 it in CT, so I guess I am about to hang myself by my own
12 noose here -- there is a very much difference there, and
13 that there is still some freedom even in the CT to describe
14 the phantom that the CT manufacturers chooses to use to make
15 his measurements.
16 DR. GAGNE: I think one of the things that we have
17 done here is the background as to why this particular
18 requirement is in there, its genesis is not associated with
19 intercomparison of system to system.
20 Its genesis is more in terms of intercomparison
21 within a system, because one of the things that we were
22 trying to deal with here is the following. We were aware
23 that there were situations on fluoroscopy systems where the
24 manufacturer may have stated that this was a record mode,
25 and when there is a record mode, there is no limit on the

1 entrance exposure rate, and we were concerned that users
2 didn't appreciate the fact that there was no limit, thought
3 it was still in fluoroscopy, and thought they still had the
4 limits in effect, and there were situations when those modes
5 were very high in entrance exposure rate.
6 So, what we are trying to deal with here, yes, you
7 can do a intercomparison of system A versus system B, but I
8 think one of the main things that we are trying to deal with
9 here is to get upfront and personal exactly what kind of
10 levels are we talking about when in a system, so that if you
11 have a system that is called, if you want, a hidden
12 fluoroscopy mode, it would be upfront within that system as
13 to how much the rate changes for it to go phantom within a
14 system.
15 MS. KAUFMAN: Yes, except that if they can pick
16 their own phantom, they can pick a phantom that gives a
17 pretty good exposure rate.
18 DR. GAGNE: Yes, but this is just relative changes
19 now within the system. It is not a comparison of A to B.
20 So, when you don't specify the phantom, I agree, you lose
21 some of that intercomparison, but I think you still can get
22 that relative change really almost no matter what the
23 phantom is.
24 MS. KAUFMAN: Well, not really, because if they
25 use a metal phantom, if they use aluminum, and they are

1 changing kV, then, you may not see those kinds of
2 variations.
3 DR. GAGNE: But if they use a phantom like that,
4 which basically pegs the system at the limit of the entrance
5 exposure rate requirements to fluoroscopy mode, and then
6 they take another mode, which is the interfluoroscopy mode,
7 it would not peg and you still would see the relative change
8 between the two rates. Maybe I am not understanding your
9 question.
10 MS. KAUFMAN: I think you are not, because I am
11 not talking about pegging it. I am just saying that the
12 exposure rate will vary according to the metal that is in
13 there. It is not lucite.
14 DR. GAGNE: That's true.
15 MS. KAUFMAN: And so it may not be a linear, you
16 know, you may not be able to see those kinds of variations.
17 DR. SHOPE: I think I can maybe reflect a little
18 bit on our considerations for where we came out where we
19 did. One is there are a number of sort of standard phantoms
20 that are recognized, the next type phantoms that we have
21 used, some commercially available phantoms.
22 There is a very major effort underway in
23 collaboration between NEMA, National Electrical
24 Manufacturers Association, and the AAPM, to develop a
25 cardiac type phantom for interventional cardiology type

1 systems. I think that shows some promise for some
2 standardization there.
3 So, we thought we would spend an inordinate amount
4 of time getting agreement on the phantom or the three
5 phantoms or the four phantoms or the five phantoms, and as
6 soon as we settled that, there would be another mode of
7 operation that wasn't appropriate for either of those five
8 and we would need a sixth phantom.
9 So, leaving the manufacturer some leeway to pick
10 the phantom, I think the description of the phantom, the
11 description of the techniques would allow this kind of
12 intercomparison, maybe not as simple as it would if
13 everybody used the same phantom, but I think if you take
14 your purchase specs or your information from the
15 manufacturers down the hall to your friendly medical
16 physicist, he can pretty well do a comparison based on what
17 he is told about the phantom, the phantom materials, and
18 give you some pretty good information as to how those
19 machines are going to compare.
20 It requires a little more work to come to that
21 conclusion, but I think this is a valuable discussion we are
22 in, to see what the opinion of the various sectors are on
23 this issue.
24 MS. KAUFMAN: An alternative suggestion, too, is
25 perhaps to come up with a similar to the NRC reg guides,

1 where you come up with a regulatory guide that says these
2 are the phantoms that we suggest, so the regulation would
3 stay as it is, but the reg guide would at least offer some
4 guidance as to what you think is appropriate.
5 DR. SHOPE: I think also we, in our review of the
6 initial reports that manufacturers submit us before going to
7 market, we would be looking at what is the phantom they are
8 using and if there is something outrageous, I think we would
9 be in discussions in the manufacturer about how
10 inappropriate that particular phantom might seem to be to us
11 and maybe learn what the manufacturer's views are on that
12 issue. We sometimes have some influence in those
13 situations.
14 MS. KAUFMAN: Tom, moving on, if we may, you
15 mentioned maximum deviation, and I believe that only applies
16 for the indicated exposure rate, is that correct? That is
17 the only place I saw maximum deviation, is that correct?
18 DR. SHOPE: No, this has to do with -- for each of
19 these modes, the manufacturer gives you the exposure rate
20 for this typical phantom, and he would have to give a
21 maximum deviation statement associated with that and also it
22 would apply to the ranges probably, as well, because it is
23 the same number.
24 MS. KAUFMAN: So, we are not talking about
25 displayed values right now.

1 DR. SHOPE: No, not here. No, this is the
2 information in this user section of the manual.
3 MS. KAUFMAN: Okay. When we get down to displayed
4 values, I have a comment.
5 DR. SHOPE: Okay. I will let Stan address that
6 comment for you.
7 Any other comments on the information for users
8 proposal? The next slide talks a little bit about the
9 implications of this change.
10 [Slide.]
11 We think it is critical to give the users more and
12 better information about what the implications are of all
13 these knobs and buttons they get to select on the system.
14 This is one step. It is certainly not a cinch that
15 everybody that uses fluoro is going to pull out this manual
16 and read it. We recognize that this is also going to
17 require some educational effort to make people aware that
18 this resource is there, let them understand what the
19 information is and how it could be used to encourage people
20 to take advantage of it.
21 There is a new requirement here on manufacturers.
22 They will have to develop this information for their systems
23 and revise and include it in their information to users.
24 This is not a small chore. We recognize that, but we think
25 the value of this kind of information is -- we have tried to

1 limit the amount of information here, so that this is
2 doable.
3 Manufacturers would be required to meet their
4 maximum deviation statements. This is just to keep a little
5 truth in the labeling here. There will be some incremental
6 costs associated with developing this information and
7 providing it in the recordkeeping that the manufacturer will
8 have to undergo to make sure he is meeting his maximum
9 deviation statements and the testing programs that are
10 associated with that.
11 I don't think at this point we can give good
12 estimates of what this cost would be, but we would certainly
13 solicit comments from the industry as to what these kinds of
14 costs might be, so we can judge the cost-benefit ratios that
15 work for this type of requirement.
16 That brings me, unless there are other questions,
17 to the last section I want to discuss.
18 [Slide.]
19 Here, there is a slight change. You have in your
20 book a section that begins at 1205, and you have a
21 replacement page for that section. Maybe you could pass
22 those out. We are not perfect and we found a problem as we
23 looked at this getting ready for this presentation, that we
24 had not dealt with appropriately.
25 So, I am suggesting a revision to the proposal at

1 this stage for Section 1020.32(j). So, the page that Ron is
2 passing out would replace in its entirety the Section (j)
3 that was in your draft that you received earlier.
4 There is only a small change here, and I will
5 point that out. This is a requirement that would require
6 all fluoro systems to be equipped with the "last image hold"
7 feature.
8 This allows the last image that was being
9 displayed during the fluoroscopic acquisition exposure to be
10 terminated and the image remain visible for study
11 contemplation, perusal by the radiologist as decisions are
12 being made about what to do next or how well they have done
13 something without the need for continuous exposure of the
14 patient.
15 It would be required on all new fluoro systems.
16 There are various ways provided to do last image hold. It
17 is conceivable that in some circumstances, you are not
18 looking for the most exquisite image, just for information
19 about where you are perhaps with a catheter. You may not
20 need a real fine last image hold image.
21 There are other situations where if you expanding
22 a stent in a cardiovascular procedure, you may need the best
23 image quality you can get, and you would want this last
24 image hold to be a very good image while you think about
25 what you have done as the physician doing the procedure.

1 So, there may be a need to have last image hold
2 occur differently depending on the selections of the
3 procedure, so there is a provision here, if the manufacturer
4 wants to provide a method to do last image hold differently,
5 say, in different modes, but the selection of how you are
6 going to do your last image hold would need to be made
7 before you start the fluoro run.
8 If the image is displayed on the monitor and it is
9 not a real-time, live image, but a last image hold image,
10 that image has got to be clearly labeled, so that you know
11 it is not the current ongoing real-time image, it is the
12 last image you acquired when you stopped fluoro. Some
13 systems, there will be multiple monitors, and you don't want
14 the confusion of the current image with the previous image,
15 so there would be a labeling requirement on the monitor to
16 indicate what kind of image you have here.
17 There would be a requirement to describe this last
18 image hold feature and any options you have in the
19 information to users, and the last thing here is the thing
20 that got us into trouble in our first draft, that we had an
21 oversight.
22 We were referring back to a section that applies
23 to radiographic systems, and we shouldn't have done that.
24 We should be looking at a particular requirement appropriate
25 for fluoro here.

1 The idea here is last image capture can be done in
2 a number of different ways. Typically, and I don't think
3 there is anything really typical, but there are a lot of
4 different ways manufacturers currently go about doing this
5 or could go about doing this.
6 I think the most common thing is that you are
7 recording digital images or you are capturing images, you
8 have them in a memory, you stop the exposure, you just
9 continually refresh that last image.
10 There are a little bit of problems. If it is a
11 single fluoro frame that tends to be noisy, so sometimes
12 these systems will capture several frames and average them
13 or sum them in order to have not such a noisy image just
14 from one frame.
15 That is probably the way most of the last image
16 hold systems work. It is also possible, however, that you
17 could have an add-on system, for instance, that comes in and
18 the way the controls work is you don't really use any of
19 those fluoro exposures that you were looking at real-time.
20 As soon as you basically take your foot off the exposure
21 switch for fluoro, the system senses that and basically
22 makes a radiograph type image.
23 It captures one more or two more frames or a
24 certain amount of exposure is used to capture an image for
25 display as the last image hold image, and that happens

1 almost simultaneously with the stopping or just immediately
2 after stopping the fluoro exposure.
3 The question then becomes as we have in
4 radiographic, when you have an automatic exposure control in
5 radiography, there is a potential for that automatic
6 exposure control system to go awry and not stop when it
7 should, and there is a backup timer type system for
8 radiographic.
9 The question here is do we need a similar kind of
10 backup thing for those last image hold capture systems that
11 use this. You take your foot off the exposure switch, but
12 the system automatically captures one or two more frames for
13 you. You don't want it to capture 100 or 200 more for you.
14 So, the question here is what kind of limits
15 should there be at the cessation of last image hold to make
16 sure that the primary termination of exposure really works
17 and should there be a requirement for sort of a backup where
18 here we are not relying on the pressure on the hand switch
19 or the foot switch to terminate the exposure, but the system
20 is doing it, and do we need some kind of backup.
21 In the revision that you have there, this issue is
22 talked about down in paragraph 5 and paragraph 6. The first
23 part is just the kinds of things I mentioned earlier. You
24 would have to have a way of selecting the way you want to do
25 last image hold. You would have a clear indication that is

1 displayed in two -- each time you start light exposure, that
2 stored image would be replaced.
3 Information to users in paragraph (iv), and then
4 in (v), we would say something -- and this is a very
5 preliminary proposal. We realize the problem with our
6 earlier submission, and we have tried to come up with a
7 draft, but this is very preliminary. We would encourage
8 feedback and comment on this section partly because we don't
9 have intimate details at hand on all the various ways people
10 do last image hold currently, so I think the manufacturers
11 can help us on comments in this area, as well.
12 But what we saying here is the image presented as
13 the held image may be obtained by means of an exposure that
14 has automatically initiated simultaneously with the
15 termination of fluoroscopic exposure -- this is not a
16 requirement, but a maybe -- provided a backup exposure
17 timing control or other means is provided that will
18 terminate the exposure within a time not to exceed 1 1/2
19 times that of the primary exposure timing control for the
20 last image capture, in other words, if you normally would be
21 capturing four frames for your last image hold, that was
22 your selection, you are going to sum four frames for last
23 image hold, this backup timer would have to kick in by the
24 time you got to eight frames.
25 Then, if that happens, if you have that kind of a

1 backup timer have to come into play, you want an indication
2 that that has happened, because it is telling you something
3 is not right in the system, so that is the reason for
4 Section (vi), that you would get an audible or rather a
5 visible signal to show you that you had used this backup
6 termination, and before you could do any further last image
7 captures, you would have to reset and deal with that
8 problem. It wouldn't prohibit fluoro from continuing, it
9 just means that last image hold mechanism would be turned
10 off.
11 So, that is I think probably in our draft, that is
12 one of the tentative sections at this point that we realized
13 some problems with our first cut and trying to get that
14 straightened out.
15 DR. CARDELLA: Tom, is the issue that some units
16 configure their last image hold, such that when you release
17 the fluoro pedal, the machine in the background snaps a
18 couple of high-dose pictures?
19 DR. SHOPE: Well, not necessarily high dose, they
20 may be at the same frame rate. They may be higher dose,
21 yes.
22 DR. CARDELLA: They may be higher than the
23 fluoroscopy.
24 DR. SHOPE: Yes.
25 DR. CARDELLA: That seems to fly in the face of

1 the reason that last image hold was conceptualized, and
2 maybe rather than going to these convoluted steps to
3 accommodate that performance algorithm in the standard,
4 maybe it should be that that performance standard be an
5 outlier.
6 I was unaware that there were systems like that,
7 but on the surface of it, that doesn't sound like a great
8 idea.
9 DR. SHOPE: We haven't done extensive research on
10 the various ways these operate, so I will be the first to
11 confess that, but there are add-on, last image hold systems
12 that come in and basically get into the control system and
13 capture the signal that fluoro has stopped, and add a few
14 more or add another exposure, and that could be either done
15 by number of frames, it could be done with an automatic
16 exposure control type mechanism, as well, like a
17 radiographic exposure.
18 So, I think there are various ways these kinds of
19 systems could be designed, and it is my understanding that
20 there are some of these designs in some of the add-on
21 systems. If it sounds to the community like not a smart
22 thing to do, we would like to hear those comments, and we
23 can deal with those in the review of this section.
24 DR. CARDELLA: I had one other comment about the
25 last image hold. Somewhere in the document, is there a

1 requirement that the last image hold feature have the
2 capabilities to allow manipulation of the shutters, irises,
3 and filters without reexposing the patient, because there
4 are units in the field now where if you want to set your
5 collimators for a DSA run, for example, you have to re-
6 fluoro to set your shutters and filters in.
7 Is that addressed in this?
8 DR. SHOPE: No, we do not have that as a current
9 requirement or in this proposal, but it is perhaps something
10 that we ought to consider. We had not given that attention
11 in this discussion.
12 DR. FLETCHER: This may be something of an
13 oversimplification, but is it at all possible to overlay on
14 monitor a clock which says last image taken?
15 DR. SHOPE: I am sorry?
16 DR. FLETCHER: A clock, time, you know, just
17 superimpose the time that the last image was taken on that
18 monitor. Is that possible?
19 DR. SHOPE: I am sure it is possible. I am not
20 sure what purpose it would serve.
21 DR. FLETCHER: I mean on the fluoro itself, so
22 that it remains with that picture. If it is referred to
23 later, that last image time is still there.
24 DR. SHOPE: You mean so you would have a record of
25 when the image was obtained, where in the process.

1 DR. FLETCHER: Yes.

2 DR. SHOPE: I am sure it is possible. I don't
3 know if the users feel a need for that kind of information.

4 DR. MARX: I mean in all of the angiographic
5 equipment I use on recorded images, the clock is there. It
6 is not on the fluoro screen when you are looking at the
7 fluoro image. I am not sure that it would add anything.

8 DR. FLETCHER: Except to let you know whether you
9 are looking at real-time or not.

10 DR. SHOPE: I am sure if a manufacturer chose that
11 as the way to distinguish and describe that, we could
12 probably understand, and that is clearly described in the
13 information to users, that the image that you see a time on
14 is the last image held, that is a way of identifying it,
15 that would probably meet our requirement.

16 We will need to, I think, think a little bit about
17 that in terms of whether that is appropriate or not. We
18 would certainly invite further comment on that.

19 Well, that brings me to the end of my discussion.
20 You are probably glad to see that happen here.

21 [Slide.]

22 Just the impact of these changes with regard to
23 last image hold, it will require design changes for systems
24 that don't currently provide this feature, and there are a
25 number of fluoro systems that don't. A lot of the GI type

1 systems may not necessarily do this. Those systems get
2 often used for all kinds of things, not just GI exams, so
3 that was sort of our thinking here.
4 This is the way we are proposing it apply to any
5 C-arm, mini, maximum, whatever C-arm it is. It would
6 require the addition of some perhaps digitizing and display
7 capability involving additional costs, but as the way the
8 cost of frame grabbers and computer memory, and things have
9 come down, we don't anticipate this as a large cost in
10 comparison to the cost of these kinds of equipment anyway.
11 It is a small incremental cost in our opinion.
12 We would certainly invite comments on the
13 magnitude of that incremental cost, and we think it
14 certainly will allow more efficient use of the radiation in
15 these systems, allowing contemplation of what to do next,
16 what has just been done, et cetera.
17 I have a personal interest in this one, I think,
18 because of something that occurred in my family with two
19 different procedures, one done with a system that had this
20 feature and one done previously that didn't have it, and I
21 saw the difference in the amount of fluoro time involved,
22 and it was astronomical in my opinion. So, I think this is
23 a very useful feature.
24 With that, I will turn the podium over to Bob
25 Gagne.

1 DR. LIPOTI: I am not going to let you go yet,
2 Tom, sorry. I think you did an excellent job.
3 Given that this particular last image hold really
4 does have an impact on the total fluoro time for the
5 patient, why is it that it is only required for new
6 equipment that is manufactured a year after the date of
7 publication of the final rule? Why don't we have some
8 phase-in for retrofit of existing machines?
9 DR. SHOPE: It gets back to the whole question of
10 what is FDA's authority under the law, and it has been we
11 regulate manufacturers. The manufacturer sold that
12 equipment two years ago, it is not his equipment anymore, it
13 belongs to the hospital, and we can't force the hospitals to
14 buy or retrofit their equipment.
15 So, I think that is the issue here. As any of our
16 requirements in any of our performance standards under the
17 Radiation Control for Health and Safety Act, which is now
18 part of the FD&C Act, is not retroactive because we regulate
19 the manufacturer of the new equipment, not the users or the
20 owners of the old equipment. That doesn't mean the states
21 couldn't probably institute such requirements.
22 MR. TUROCY: Tom, Bob Turocy. I have a few
23 questions for you concerning the information provided to
24 users.
25 The manufacturer can provide the things that you

1 proposal stage, so between now and the proposed rule coming
2 out, we will have to be trying to gather some of that
3 information and making those initial assessments of the cost
4 associated with this.
5 You are right, all those costs you mentioned are
6 costs that are part of this. I think the issue of did the
7 user use it, I don't know that it is necessary that they use
8 it every time, but certainly in their familiarization with
9 the equipment, they are learning how to operate this
10 particular specific system that they are going to use on a
11 daily basis. They need to get this information.
12 I would strongly encourage hospitals, facilities
13 to institute a credentialing program for their fluoro uses
14 and to make this kind of information part of the knowledge
15 require to be credentialed to use fluoro. We at FDA don't
16 have the ability to require that kind of credentialing
17 program, but I think there is quite a bit of interest in
18 that kind of approach based on our fluoro workshop in '92
19 and some of the other activities that are going on, the
20 ACR's credentialing programs, making sure that the people in
21 facilities that are authorized to use fluoro have had some
22 training appropriate for the particular equipment they are
23 using, and this kind of information is just what I think you
24 need for that kind of a training course.
25 MR. TUROCY: A few other things. The change in

1 units. I will commend the FDA for making that leadership
2 step in incorporating the International System Units. The
3 manufacturers would like to see both units for a period of
4 five years until the transition is completed. If it is
5 possible and not too objectionable to the community to raise
6 those limits, to round them up to that 15 percent increase
7 in radiation dose, as was initially proposed.
8 We know we have to think about that a great deal
9 because it is an increase in dose and may not always be
10 beneficial or whatever.
11 DR. SHOPE: Excuse me, Mr. Turocy, would you
12 comment on what the rationale for that is, or do you need
13 more output, do you think, for certain of the exams?
14 MR. TUROCY: The rationale basically is that we
15 provide systems which have rejection limits which are lower
16 than the specified standard in any case, so that is one
17 rationale. Th other one is easy to understand numbers. So,
18 those are two reasons for that.
19 DR. FLETCHER: I am going to interject here
20 because we could be embarking on an elongated discussion and
21 I would like to stay as close to the schedule as possible.
22 This discussion will continue after the break, so I would
23 ask you to hold any further comments until that time.
24 We are scheduled for a break at this time, so I
25 would like to recess. Dr. Shope will be back at the podium

1 immediately thereafter.

2 DR. SHOPE: I will turn it over to Dr. Gagne to

3 start after the break, and I will be around for any

4 discussions later on.

5 DR. FLETCHER: I will also remind the committee

6 that we will have an extended time for committee discussions

7 on this subject, so we will entertain all of your questions

8 and points.

9 [Recess.]

10 DR. FLETCHER: Bob, did you want to continue your

11 questions of Dr. Gagne?

12 MR. TUROCY: No, I think we will just move ahead.

13 DR. FLETCHER: Let me just make a couple of

14 reminders. Please, everyone who wishes to speak, make sure

15 you, one, speak into the mike, and to facilitate and ensure

16 everybody gets a change to speak, I would appreciate it if

17 you need to ask a question, get my attention, so that I can

18 call upon you. Otherwise, everyone may not get the

19 opportunity to speak.

20 Dr. Gagne.

21 **Minimum Half-Value Layer**

22 DR. GAGNE: What I am going to talk to you about

23 this morning are three pieces of the amendments associated

24 with the performance standard, and those three pieces deal

25 with some basic radiation protection and safety aspects of

1 the performance standard.

2 The first I am going to talk about are the

3 proposed changes to the minimum half-value layer

4 requirements, and this particular requirement in the

5 standard is based on a conclusion that you need some amount

6 of x-ray filtration in order to eliminate low-energy x-rays,

7 which predominantly contribute to patient dose and don't

8 contribute to diagnostic information.

9 So, the question is always present, of course, is

10 how much filtration to put in because the more you put in,

11 then, the more you cut the beam down. So what I would like

12 to do now is to address a little bit what the current

13 requirement is in the standard.

14 [Slide.]

15 The current requirement in the performance

16 standard is predicated in terms of x-ray beam quality, which

17 is really a measure of how penetrating the x-ray beam is.

18 In fact, the actual requirement is expressed in terms of the

19 thickness of aluminum that would be needed to reduce the x-

20 ray beam intensity by a factor of 2.

21 Now, the reason it is stated that way, and not

22 stated in terms of an amount of material, is that in a lot

23 of the requirements in the performance standard, as I have

24 used the word performance, the requirements are written with

25 respect to performance, and not design.

1 So, when this particular requirement was first set
2 out, it was written as a performance requirement, this
3 thickness of aluminum to reduce the x-ray beam by a half
4 instead of saying put 2.5 millimeters aluminum in the beam.
5 So, that is present, in fact, throughout the standards, so
6 they are performance requirements.
7 As I have mentioned before, the rationale for this
8 particular requirement is that what you are trying to do is
9 you are trying to selectively absorb low energy photons and
10 in that process, then, you basically save exposure to the
11 skin because those low energy photons that would expose the
12 skin are taken out of the beam before they have a chance to
13 do that.
14 [Slide.]
15 Now, we have had recommendations in the past, and
16 we presented some of this material to you at the previous
17 TEPRSSC meeting in terms of the concepts. In considering
18 the changes to the standard, we have considered
19 recommendations that we receive from outside groups and
20 activities and other standard-setting organizations.
21 For example, we have gotten recommendations to
22 increase the use of minimum half-value layer through an
23 increase in x-ray filtration, and those recommendations have
24 come through the ACR/FDA Workshop on Fluoroscopy that was
25 held in 1992, and, in fact, there is a specific

1 recommendation there associated with how much to increase
2 the HVL half-value layer at an operating to potential of 80
3 kVp.
4 There is also a draft IEC standard, international
5 standard for interventional radiology equipment where again
6 there is a recommendation in that standard to increase the
7 HVL from 2.1 to 2.5 at 70 kVp. So, there is a basis in
8 terms of other standards organizations and recommendations
9 to increase the HVL.
10 [Slide.]
11 Now, when we thought about proposed changes in the
12 standard with respect to this requirement, we also looked at
13 requirements already on the books, and, in fact, there are
14 some of those already in existence.
15 The ICRP in its Publication 34 requires -- it's a
16 design standard that requires a total filtration of 2.5
17 millimeters of aluminum, and the IEC, through its IEC
18 Standard 601-1-3, requires a quality equivalent filtration
19 not to be less than 2.5 millimeters of aluminum, and so
20 there is precedence here in other standards to have a
21 prescribed amount of aluminum in the x-ray beam to reduce
22 these low energy photons.
23 [Slide.]
24 Now, when we go to the half-value layers, the
25 values of the half-value, the minimum half-value prescribed

1 in our standard, what you find is that the standard was
2 promulgated in 1974, and so when you think about the values
3 of the half-value layer, they are the values you would get
4 if you put 2.5 millimeters of aluminum in the beam for a
5 system, an x-ray system that was present in that era, 1974.
6 Those systems had large x-ray tube target angles.
7 They were on the order of 22 degrees, which is unusual for a
8 system these days, and they had significant high voltage
9 ripple. The high voltage ripple was about 25 percent, its
10 filtration tube angle and ripple that affect HVL.
11 So, what happens is that the HVLs that are
12 currently in our standard are really not reflective of what
13 you would get for HVLs if you put 2.5 millimeters of
14 aluminum in, in a modern x-ray system with a smaller tube
15 angle and smaller ripple.
16 As a result, we aren't getting as much skin-
17 sparing effect in our current standard as we could for
18 state-of-the-art system.
19 [Slide.]
20 So, what we are proposing to do in the current
21 standard is that we are proposing to increase the minimum
22 half-value layer of the x-ray beam, so that it represents,
23 even though it is written as a performance standard, in the
24 final analysis it would represent a total filtration of 2.5
25 millimeters of aluminum, and those half-value layers have

1 been derived by using a state-of-the-art x-ray system, a 12-
2 degree x-ray tube target angle and a 10 percent high voltage
3 ripple.
4 Our intent -- and this is a change from the
5 concept that we prescribed last time -- is that we are
6 intending to have this change in half-value layer to be
7 applicable to all x-ray systems, not just x-ray fluoroscopy.
8 We had initially proposed this in a concept stage
9 only for interventional fluoroscopy, but because of the
10 precedence and recommendations here, we have changed this to
11 be applicable to all systems who represent the state of the
12 art now.
13 By the way, the section that we are talking about
14 here is on lines 520 to 576. I hope I got that right. It
15 is really the minimum half-value layer table, the standard
16 Table 1, and I will talk about that in just a second.
17 [Slide.]
18 The values for the new proposed minimum half-value
19 layers were obtained through the use of a report from the
20 British Institute of Physical Science and Medicine, Report
21 No. 64, and the basis for those values comes from that
22 particular report. We will explain that in more detail, of
23 course, in the proposed rulemaking.
24 Now, in addition to this particular requirement
25 for all systems, whether radiographic or fluoroscopic, we

1 are also providing for an additional requirement for
2 fluoroscopy x-ray systems with high heat load capacity x-ray
3 tubes. The reason for that is that for those kind of
4 systems, which I think you can associate with systems that
5 would do interventional fluoroscopy, you can gain even more
6 in certain clinical situations by adding additional x-ray
7 filtration, and so the requirement in this case is not
8 necessarily a statement of higher minimum half-value layers,
9 but that the manufacturer should at least provide the means
10 to add additional x-ray filtration over and above the
11 minimum requirements when it needs this tube load capacity
12 circumstance.
13 [Slide.]
14 So, what are we talking about with respect to the
15 changes in half-value layer? Well, as an example, if you
16 look at the Table 1, which I hope is in that, as I said, in
17 the lines that I specified, if you are operating at a
18 potential of 80 kVp, what it basically means is that the
19 current minimum half-value layer would be 2.3 millimeters of
20 aluminum, and that would be changed now, and you would be
21 required to have a minimum half-value layer of 2.8
22 millimeters of aluminum.
23 You can see then as a function of measured
24 operating potential what the proposed changes are for
25 minimum half-value layer.

1 [Slide.]

2 So, in summary, what we are proposing to do is to
3 improve the skin-sparing requirement of the performance
4 standard for all x-ray systems and to have an additional
5 requirement to provide means for adding even more filtration
6 in those cases where it is clinically possible for systems
7 that are associated with an interventional fluoroscopy.

8 Now, this change is really just reflective of what
9 is already present in the international arena, for example,
10 and so on, and so forth, and so it really is an incremental
11 change in our standard to come up to par with respect to
12 this other standard.

13 That is all I had on this particular requirement,
14 if there are any questions.

15 DR. FLETCHER: Questions from the committee?
16 Kass.

17 MS. KAUFMAN: A couple of real quick ones. Number
18 one is, is at some point if you increase the filtration too
19 much, you start increasing organ dose, and that doesn't help
20 -- I mean the skin-sparing effect isn't, you know, it is
21 worse to have the increased organ dose. So, I am presuming
22 that that is taken into account with these values, right,
23 correct presumption?

24 DR. GAGNE: I think that you probably could reduce
25 organ dose also in addition to skin sparing, but you can't

1 do it at the same technique factors that you used before.
2 You have to adjust technique factors.
3 One of the ramifications associated with this
4 change is that it will have an effect, slight though it may
5 be, with respect to changes in technique factors, but if
6 those changes in technique factors are implemented, I think
7 you can recognize a reduction in both organ and skin dose
8 from this change.
9 What you are going to lose is -- in fact, I have a
10 paper on this that I handed out at the last meeting -- but
11 what you are going to lose is that your x-ray tubes may run
12 at a little bit higher heat load in order to do this, but,
13 yes, you do have to change the technique factors.
14 MS. KAUFMAN: Because since these won't become
15 effective for several years from now, we are only talking
16 about equipment that would be manufactured after that date,
17 you mentioned the 10 percent ripple, and I think that newly-
18 manufactured equipment has the ripple much lower than that,
19 so I am wondering if these amounts of additional filtration
20 are sufficient.
21 DR. GAGNE: Well, I mean it is really a
22 compromise. There are systems out there that have ripple
23 that is higher than that. There are systems that have a lot
24 less ripple than that. I think if you are thinking about
25 mammography systems, for example, that use high frequency

1 inverters, they have ripple on the order of 5 or less
2 percent.
3 So, yes, it is possible that, you know, the ripple
4 will go down even further, but I think that change from
5 where we are now is much smaller than the change from the
6 current requirements at least to this change, this
7 configuration as far as ripple and tube angle.
8 DR. FLETCHER: Other questions? Bob.
9 MR. TUROCY: Just a comment. Harmonization with
10 the IEC Standards is highly desirable from a manufacturer's
11 perspective. Have you specified the means by which
12 manufacturers would have to attain these values, because it
13 would appear to me that if the filtration was variable, you
14 know, at the discretion of the user to change the filtration
15 depending on the exam that is being implemented?
16 DR. GAGNE: Which requirement are you talking
17 about? Are you talking about the minimum HVL requirement or
18 the additional means?
19 MR. TUROCY: The minimum.
20 DR. GAGNE: No, the minimum requirement, that
21 would have to be present in the system right from the word
22 go. I mean you would have to certify that you meet those
23 minimum half-value layer requirements before introducing
24 into commerce, so that aluminum or whatever it is has to be
25 present before the system gets introduced into commerce.

1 MR. TUROCY: Okay. Then, let's switch to
2 interventional and conventional fluoroscopy. We know that
3 the systems are used for both exams on occasion, so if the
4 filtration was variable, it would be beneficial for the
5 user, and it would also meet the FDA regulations. Would
6 that be a possibility of being incorporated into the system,
7 variable filtration?
8 DR. GAGNE: I am not sure I understand the
9 question correctly. There are two aspects of this
10 particular requirement, maybe I wasn't clear enough. The
11 first aspect is associated with minimum HVL, and basically
12 what we are proposing is that the minimum HVL requirements
13 are going to be increased for all x-ray systems.
14 Those will have to be incorporated in machines
15 before they are introduced into commerce, and so there is no
16 option there. The filtration will have to be present. That
17 is the first requirement.
18 The second requirement is really sort of a
19 requirement that leaves a lot of flexibility still with the
20 manufacturers because we are not telling them what to do.
21 All we are saying is that Mr. Manufacturer or Mrs.
22 Manufacturer, you have to provide, if your system meets the
23 heat load requirements described in the standard, which is
24 normally associated with interventional, then, you have to
25 provide additional means to provide additional filtration in

1 your system, so that if you are doing an interventional
2 procedure that can take two hours, and you think you can
3 help this patient in terms of avoiding a radiation skin burn
4 by putting two more millimeters of aluminum in, that
5 flexibility is left to the manufacturer and the user, then,
6 put that additional filtration in, but at least have the
7 means available to do it.
8 So, I realize it is not a very stringent
9 requirement, but it's an additional requirement to provide
10 the means for doing that.
11 Did I answer your question?
12 MR. TUROCY: Yes, that's fine, but the
13 harmonization with the IEC Standards is highly desirable
14 from our perspective. Thank you on your response.
15 DR. GAGNE: Since I am involved with the
16 International Standard and Interventional Radiology Working
17 Group 24, I don't think that what is being proposed here
18 will not be in harmony with that particular standard's final
19 committee draft.
20 DR. CARDELLA: The column that is labeled
21 "Measured Operating Potential" in the table, how is that
22 going to be defined for systems where the kVp varies? You
23 just take the mid-range of its operating capability or the
24 high end?
25 DR. GAGNE: No, you would, if you could, I mean

1 are you asking in terms of a compliance measurement for
2 this?
3 DR. CARDELLA: Well, even from a definitional
4 standpoint, I mean how much aluminum does somebody have to
5 put in if they produce an x-ray tube that fluoros over the
6 range of 80 to 120 kVp?
7 DR. GAGNE: Well, that table is predicated on
8 putting 2.5 millimeters of aluminum in the beam basically,
9 so that at any particular kV, the HVL requirements would be
10 met. If you had 2.5 millimeters of aluminum in the x-ray
11 beam, and you had those characteristics of the system that I
12 described in terms of targeting, and so on, it would meet
13 the requirements of the HVL in the performance standards at
14 all of the kVp's.
15 DR. LIPOTI: Just one more. I am trying to
16 understand the footnotes and how this all work with dental
17 units. Can you explain that?
18 DR. GAGNE: I didn't mention that, I am sorry. I
19 said all x-ray systems, and I should not have. It does not
20 apply to mammography, and it does not apply to dental, and
21 that is why all those very difficult to figure out footnotes
22 are in there. But I hope that is what the footnotes say.
23 That is what they should say.
24 DR. LIPOTI: I hope so, too.
25 DR. SHOPE: Bob, there is also an effective date

1 footnote, but this doesn't apply retroactively, it is only
2 the new stuff, so there are two columns, the old and the
3 new.
4 DR. FLETCHER: Would you repeat what Tom just
5 said, so that it will be picked up on the mike?
6 DR. GAGNE: What I am saying is that just like any
7 other piece of the standard that gets amended, I mean it is
8 great if you have a standard in 1974 and you don't ever do
9 anything to it because it's nice and clean, but I think that
10 doesn't represent reality in terms of what is going on in
11 the industry. So, that means you have to change it, and so
12 when you change it, you have to say the stuff manufactured
13 before this date meets this, the stuff manufactured after
14 this date meets that. So, some of the footnotes deal with
15 that.
16 Is that a fair statement, Tom?
17 DR. SHOPE: Yes.
18 DR. GAGNE: Let me go on to the next one.
19 **X-Ray Field Limitation and Alignment**
20 The next one that I am going to talk about is
21 associated with x-ray field limitation and alignment.
22 [Slide.]
23 Again, it is basic radiation protection and safety
24 requirement in the performance standard. It is also a topic
25 that we discussed with you conceptually at the previous

1 meeting.

2 [Slide.]

3 The current requirement that is in the standard is
4 basically predicated on the following premise. If you have
5 radiation that falls outside the visible area of the image
6 receptor -- and we are talking fluoroscopy now, we are not
7 talking radiography, I am talking fluoroscopy x-ray systems
8 when I talk about this particular section, in fact, the
9 previous talk on minimum half-value layer was the only time
10 we are going outside fluoroscopy -- if you have radiation
11 falling outside the visible area of the image receptor,
12 whether it is an image intensifier or solid state x-ray
13 imager, whatever, it doesn't provide any useful diagnostic
14 or visualization information.

15 So, the question always will come up when you are
16 trying to set up some requirements in radiation protection
17 and safety in terms of, well, what kind of tolerance should
18 you have with respect to the matching of what you are seeing
19 versus the x-ray field.

20 In the current requirement -- I have summarized it
21 here, but what it effectively is this -- it says that the x-
22 ray field cannot exceed the visible area of the image
23 receptor by more than 4 percent of the source to image
24 receptor distance, 4 percent along the length and width.

25 Now, just to give you something to give you a

1 handle on it, assume the source to image receptor distance
2 is 100 centimeters, then 4 percent is 4 centimeters, and so
3 it says. You have a tolerance where the x-ray field can be
4 4 centimeters larger than the visible area of the image
5 receptor.
6 [Slide.]
7 Now, what I am trying to show here is the
8 ramifications of that particular requirement when you have a
9 visible area which is circular, and in this particular case
10 it is a circular area of 15 cm diameter, a 15 cm image
11 intensifier, for example.
12 Now, the x-ray field can be a square, and it can
13 be a square, since I said 4 cm was our tolerance, 17 cm
14 along the length and 17 cm along the width. So, you can see
15 when you look at this diagram that there is a lot of x-rays
16 that aren't really being used to create an image, where the
17 image is the dark blue and the x-ray is the light blue.
18 [Slide.]
19 In fact, in the previous TEPRSSC meeting, I
20 described for you something that I called geometrical
21 efficiency, and let me define what I mean by that. It is
22 basically a measure of the ratio of the areas of the two
23 things. It is the area of the visible area divided by the
24 area of the x-ray field.
25 If you look at the last column over there, it is

1 telling you what kind of efficiencies are allowed in the
2 current U.S. Standard when you have image intensifiers of
3 the diameters anywhere from 12 to 30 cm, and the efficiency
4 is about 57 or 70 percent.
5 So, we are throwing away anywhere from 40 percent
6 to 30 percent of the photons as not useful as a result of
7 the field limitation requirement.
8 [Slide.]
9 Now, just like in the previous talk, I have tried
10 to present to you some of the precedence or, if you want,
11 some of the things that are in the Act associated with
12 promulgating new standards, include technical feasibility,
13 precedence, and other standards, and so on, and that is why
14 I am reviewing some of these things for you here.
15 Again, in the same standard that I discussed
16 previously from the International community, IEC Standard
17 601-1-3, in their standard, their statement of field
18 limitation is that there has to be evidence of collimation
19 in the visible area. That effectively makes their standard
20 more stringent than ours, because that is not required in
21 the U.S. Standard.
22 Now, I mentioned previously also in the previous
23 talk that there is a draft IEC Standard for interventional
24 radiology equipment that I have been involved with, and
25 actually Dr. Cardella has been involved in also.

1 It prescribes a new requirement on efficiency
2 where this requirement is that the geometrical efficiency
3 has to be 80 percent. So, we have a precedence in these two
4 particular areas for a different way of approaching x-ray
5 field limitation of alignment.
6 [Slide.]
7 Lastly, I wanted to point out that -- and this is
8 a change that I think you have to be aware of -- the last
9 time we proposed this, just like the HVL requirement, we had
10 proposed these things for interventional, what we were
11 calling interventional fluoroscopy equipment, and we have
12 changed applicability of this now, so this is applicable to
13 all fluoroscopy equipment, so I am talking about a situation
14 here when I talk about the change and it will be applicable
15 to all fluoro, not just interventional.
16 But currently available interventional radiology
17 equipment, they do provide continuously adjustable circular
18 collimation. It is either provided as a standard feature or
19 as an optional feature on this new equipment.
20 [Slide.]
21 In this particular schematic, what I have tried to
22 do is to show you the differences between the standards that
23 I have just gone over. The U.S. Standard is over on the
24 left, the IEC Standard is in the middle, the IEC Standard,
25 now what I mean is not the one for interventional, but just

1 the regular IEC Standard, and then a draft standard for
2 interventional equipment.
3 The key point that I want to make is again the
4 sufficiency measure where the two righthand standards are
5 operating at about 80 percent, and the U.S. Standard is at
6 60 percent. So, I guess you are getting the point that I
7 think we need to do something here to bring again the U.S.
8 Standard up to par with what is already available in other
9 standards around the world.
10 [Slide.]
11 So, our amendment, then, is to go ahead and to try
12 to reduce this unnecessary exposure by improving the x-ray
13 field limitation requirement of the standard, and we are
14 intending to make the applicability of this particular
15 change to all fluoroscopy x-ray systems.
16 [Slide.]
17 The section of the regulations that I am talking
18 about -- again, I hope I have the right line numbers here,
19 if I don't, somebody yell out, is lines 980 to 1025 -- what
20 I would like to do is to spend a little bit of time now to
21 talk about what it is that we are proposing here.
22 There are three sections and I am going to try to
23 explain (A) and (B), and I am going to try to explain (C),
24 but I probably won't succeed, so we will see what happens.
25 The basic idea of this change is really stated in

1 statement (A). It basically makes the standard now be based
2 on an efficiency measure. It says that 80 percent of the x-
3 ray field has to overlap the visible area of the image
4 receptor. So, it is forcing the systems to have this kind
5 of efficiency.
6 (B) is a situation when the image intensifier in
7 this case gets to be large, 13-inch image intensifier,
8 actually, an 80 percent efficiency really is not stringent
9 enough, and so we shift back to an absolute measure of 2 cm,
10 and so basically, then, we are proposing that the efficiency
11 go up when the image intensifier size goes up also, and that
12 "or" is not at the right place. That "or" belongs after
13 (B). So, my apologies for that. That is important.
14 In (C), like I said, I am not sure I can really
15 explain this, but this requirement, by the way, is very
16 close talking about harmonization to what is being proposed
17 in the Working Group 24 for interventional radiology
18 equipment, and (C) is to handle a very special case, and
19 those of you that are acquainted with the cardiac Mariner's
20 fluoroscope, in that particular fluoroscope, instead of
21 having a large image receptor and a small focal spot, you
22 have a large focal spot and a small detector. It is
23 actually the inverse of a fluoroscopy system.
24 Because of that geometrical configuration, the x-
25 ray field of the detector is not flat, and so basically,

1 that is why (C) is in there, is to take care of that very
2 special circumstance.
3 [Slide.]
4 So, I have gone over the proposal for you, and I
5 want to talk a little bit about some topics again that I
6 talked to you about at the last meeting of this committee,
7 and I think we are going to talk about this in a proposed
8 rulemaking, is that what we are trying to do, quite frankly,
9 here is promote the use of continuously adjustable circular
10 collimators, or in a more inexpensive way, circular
11 apertures and rectangular collimation.
12 But, in fact, you can meet these requirements
13 simply with standard rectangular collimation and under
14 framing. I will give you a description of what the under
15 framing means.
16 The amount of under framing is actually small if
17 you want to meet the requirement, the 80 percent efficiency
18 requirement, but if you want to try to ensure compliance,
19 having a little bit of empathy with the manufacturers here,
20 the amount of under framing could be large to ensure
21 compliance. So, we are somewhat concerned about that if you
22 take the cheap, inexpensive way of meeting this requirement
23 that you are, in fact, under framing.
24 Let me explain what under framing is.
25 [Slide.]

1 In this particular case, I have a rectangular x-
2 ray field, again it's the light blue, and I have a visible
3 area which is a circular image receptor, which is the dark
4 blue, and really the sections on the outside of the dashed
5 lines are not obviously producing any visible area or any
6 image information, so they would cut off if you are in an
7 under framing situation.
8 So, we know about this, are interested in comments
9 about this, but we still think that the standard needs to
10 come up to par with respect to what is already out there in
11 other communities with respect to field limitation.
12 [Slide.]
13 In summary, then, we are proposing to improve the
14 limitation of x-ray field to the visible area of the image
15 receptor for all x-ray fluoroscopy systems, and we are going
16 to solicit input with respect to this under-framing concern.
17 Thank you. Questions?
18 MS. KAUFMAN: Are the simulators exempt because
19 FDA doesn't have legal authority over them or is it still
20 true -- and this might be a good question for Marlene --
21 that they need that kind of capability?
22 DR. GAGNE: Which capability? I am sorry.
23 MS. KAUFMAN: Why are simulators being exempt, is
24 it because FDA doesn't have legal authority over those?
25 DR. GAGNE: No.

1 MS. KAUFMAN: Or is it because they -- I know at
2 one time they had that need, but I am not sure they still
3 do. Why are they being exempt?
4 DR. GAGNE: I guess the part that I am missing is
5 the need thing, the need for what?
6 MS. KAUFMAN: Why are therapy simulators exempt?
7 DR. GAGNE: Okay, I gotcha. Actually, I really
8 don't know the history of that. Certainly, they would be
9 subject -- Tom probably does -- certainly, they would be
10 subject to the rules and regulation that we promulgate, but
11 I think what has happened is that for therapy simulators, I
12 think it is similar to accelerators where we don't do a lot
13 with respect to standards anyway, is that the concept or the
14 fact that they are used in a situation where a fairly large
15 amount of dose will be impacted on the patient anyway, that
16 it may not be as productive to have requirements associated
17 with that kind of equipment.
18 That is the only reason, I think, is that right,
19 Tom?
20 DR. SHOPE: Yes.
21 MS. KAUFMAN: I understand that, but I mean if
22 that is the reasoning, but it still seems like this would be
23 relatively easy for them to do. It certainly would result
24 in less radiation exposure even though obviously they are
25 going to considerable amount of exposure. I am just not

1 clear on why we are continuing to exempt the simulators.

2 DR. CARDELLA: Bob, on the line 987, 988, it is

3 the subparagraph (b) about the acceptable misalignment for

4 image receptors greater than 37 cm in diameter. Is that 2

5 cm on each side or 2 cm total?

6 DR. GAGNE: 2 cm. It has to be a circular, it is

7 2 cm anywhere around the circumference of the image

8 intensifier.

9 DR. CARDELLA: So, would it be -- let's say you

10 have got a circular ii, and a square radiation field, would

11 it be --

12 DR. GAGNE: To the corner.

13 DR. CARDELLA: It would be to the corners, okay.

14 DR. GAGNE: That is the way I would interpret it.

15 DR. CARDELLA: That would be the most stringent

16 way to write it. I am not sure that it is clear from this.

17 I mean I helped write it, and I still didn't quite

18 understand it. So, I would say to the corners, because some

19 people may think if you go straight diameter, then, you are

20 allowing a cm at each side of the box.

21 DR. GAGNE: We can look at the language there to

22 make sure that is clear.

23 MR. TUROCY: I just want to comment in two areas,

24 and that is, that most manufacturers today adjust the

25 shutters to be undersized to the image receptor, so that is

1 one thing that we strive for, and the other thing is again
2 harmonization with IEC is great from our perspective.
3 DR. GAGNE: Thank you for the comment. I think
4 you are right, I think that is the case anyway, is that
5 there is maybe -- wait a minute, maybe it's not -- there is
6 a small amount of under framing sometimes to see the
7 shutters when they are fully open.
8 I know in our system, in our lab, that is not the
9 case, but it is about 15 or 20 years old, so I don't know --
10 MS. KAUFMAN: In compliance, we see obviously
11 every fluoro machine in L.A. County, and there are a lot of
12 them, that is not the case. We generally don't see the
13 shutters.
14 DR. FLETCHER: Any other question or comment at
15 this point? Joe.
16 DR. ELDER: Just a minor comment. On the text
17 back on the introductory pages, you define the terms dose
18 and kerma, and you say that these terms are defined by the
19 International Commission on Radiation Units and
20 Measurements, and since you make reference to that
21 organization, I am suggesting you might want to incorporate
22 this specific reference, you know, what report number you
23 are referring to. Just a suggestion.
24 DR. GAGNE: I am not sure I made any references to
25 kerma.

1 DR. ELDER: That is line 108 and 131.

2 DR. GAGNE: Okay. We will take that.

3 DR. FLETCHER: Dr. Gagne, are you continuing?

4 DR. GAGNE: Yes, I have one more. You have got me

5 one more time.

6 **Minimum Source-to-Skin Distance**

7 [Slide.]

8 The last thing I want to talk about is a

9 requirement, actually, that has its premise very similar to

10 the minimum HVL requirement in that it is a requirement

11 associated with sparing the skin radiation exposure, and it

12 is a requirement associated with minimum source to skin

13 distance, in other words, the minimum distance from the x-

14 ray source to the surface of the patient.

15 The requirement is based basically on the

16 conclusion that the greater the distance is of the source to

17 the skin, then, the less will be the radiation exposure for

18 a given amount of x-ray photons at the image intensifier.

19 Of course, you can't have the image intensifier 25

20 meters away, so there is always a compromise in all of these

21 things in terms of what you can trade in terms of equipment

22 configuration and still keep some basic radiation protection

23 and safety.

24 [Slide.]

25 In our current requirement, the requirement is

1 stated as follows. It says for x-ray fluoroscopy systems
2 they have to provide means to limit the source to skin
3 distance to not less than 38 cm for stationary fluoroscopes
4 and not less than 40 cm for mobile and portable
5 fluoroscopes.
6 Right from the beginning of the regulations, there
7 was an exception. That was that if you have a specific
8 surgical application where you were required to get the x-
9 ray tube in a configuration which you were not allowed to do
10 if you had a 30 cm distance or a 38 cm distance, you were
11 allowed to take off a spacer and have a minimum SSD of 20
12 cm.
13 There is also a specification there about
14 precautions to the user on removal of spacers during
15 surgical applications, and it really should be put back on,
16 and I am sure that folks in the state programs, and so on,
17 could comment on that aspect. I think a lot of times what
18 happens is the spacer gets taken off and it stays off.
19 At any rate, that is the current requirement in
20 the standard.
21 [Slide.]
22 There has been over the last couple of years, and,
23 in fact, there is an article about it in Medical Imaging, a
24 trade publication this month, which is sort of interesting,
25 something that is called "mini-C-arms."

1 They were initially, several years ago, hand-held
2 devices where what you were trying to do -- and it had a
3 small patient aperture, and what I mean by a patient
4 aperture is the distance between the image receptor and the
5 source was pretty small, 20 cm, something like that, versus
6 40 cm for a conventional fluoroscope.
7 They also have a very short source to image
8 receptor distance, say, like 40 cm instead of 80 or 100 for
9 a conventional fluoroscope again, and they were originally
10 used to confirm breaks, you know, fractures, or whatever,
11 and they were actually used in NFL really for x-raying
12 people on the spot and finding out whether they suffered a
13 fracture or whatever.
14 Well, I am sure that if you remember back at the
15 requirements that I described to you just previously, you
16 can imagine it would be difficult with these systems to meet
17 the minimum SSD requirements.
18 [Slide.]
19 In fact, the current mini-C-arms have a much
20 larger patient aperture, and I used the phrase "bigger and
21 bigger extremities," but what I guess I meant by that is the
22 things that you can image with it get bigger and bigger.
23 Now, the way that we have handled the requirements
24 for these particular devices is that we have had to give
25 variances associated with the minimum SSD requirement for

1 several different manufacturers, and the argument that was
2 used, the basic argument that was used was that everything
3 is scaled down, you ought to scale down the requirements, so
4 that the requirements fit for this particular type of
5 equipment, and we bought that argument basically, and we
6 have approved variances for this kind of equipment.
7 So, there is a need to amend the standard in this
8 particular area to handle these kinds of systems.
9 [Slide.]
10 This is an example of one of these mini-C-arms as
11 they look now where the x-ray source is right here, and so
12 when we are talking about minimum SSD, we are talking about
13 the distance from the x-ray source to the end of this
14 device, which looks very short to me, but I don't know what
15 it is. Here is the image receptor as an image intensifier,
16 and this is the self-contained unit that you can roll
17 around, and so it meets the definition of a mobile C-arm.
18 [Slide.]
19 Now, the amendment is in lines 1173 and 1181 and
20 what we are basically saying is that when you have a mobile
21 and portable C-arm fluoroscope and it has a source to image
22 receptor distance of less than 45 cm, then, the minimum SSD
23 requirements are as follows.
24 You have to provide means to limit the source of
25 skin distance to not less than 19 cm. You have to label the

1 system for extremity use only, and we are still putting the
2 caveat in if there is specific surgical applications where
3 you need to get the source closer to the patient, where the
4 minimum SSD now is not less than 10 cm with spacer removal
5 precautions to the user as previously.
6 So, this is I guess a representation of the scale-
7 down argument and our experience in terms of approving
8 variances for these particular systems.
9 [Slide.]
10 This particular graph I guess I put in there
11 because I wanted to try to show you we are doing this
12 particular change, we are proposing this particular change,
13 but we understand -- and it goes back to my statement about
14 bigger and bigger extremities -- that really these systems
15 in terms of a comparison to convention fluoroscopes, they do
16 provide increased dose to the patient, and they do
17 particularly provide increased dose to the patient if those
18 extremities get bigger and bigger, and the thing gets closer
19 and closer to the x-ray source.
20 So, we are still a bit concerned about the use of
21 this particular source of equipment in that respect, and I
22 think we would want comments on that, too.
23 But what I am trying to show here is if you look
24 along the abscissa, it is basically a plot of patient
25 thickness or extremity size, if you want, starting from zero

1 centimeters all the way to 35 cm.

2 On the ordinate is the increase in entrance air

3 kerma rate associated with the use of this mini-C-arm versus

4 the conventional fluoroscope, where I am assuming that you

5 have the same number of photons at the image intensifier for

6 each one, and the patient thickness then, the extremity size

7 gets larger, and you are doing the imaging tasks on each

8 system and what the difference is in inches there, kerma

9 rate, so you can see that as long as the patient thickness

10 of the extremity size is like 15, 10, 15 cm, or something

11 like that, there is not a large difference between the two

12 systems, but when you get to really filling out this patient

13 aperture, if you want, you would be a lot better off using a

14 conventional fluoroscope in terms of entrance air exposure

15 versus the mini-C-arm.

16 [Slide.]

17 So, in summary, then, we are proposing to go ahead

18 and amend the minimum SSD requirements, and in this

19 particular case, the applicability of this particular

20 requirement is for x-ray fluoroscopy systems that meet this

21 definition of mini-C-arm, which we have tied to source to

22 image receptor distance of 45 cm or less.

23 Comments or questions?

24 DR. MARX: It seems to me that there is not much

25 way to prevent people from using this to check line

1 placements in the ER, I mean central venous access, all kind
2 of things where you could be imaging small children's
3 thoraxes and bone marrow, and all that kind of stuff.
4 It just sort of seems like the system seemed like
5 the bad idea.
6 DR. GAGNE: I don't think -- and some of the other
7 staff probably would disagree with me on this -- but I think
8 when you are talking about a small child, you are talking
9 about a small extremity, and so I think --
10 DR. MARX: What I am saying is that a small child,
11 their whole body would fit under there, so some physician is
12 going to say, well, why take them to Radiology, we are just
13 going to look at their whole body right here, and screen
14 them for whatever injuries they have.
15 DR. GAGNE: I understand, and that is a
16 consideration here. There are going to be these kinds of,
17 if you want, quarrels or battles that will be present, yes.
18 DR. MARX: But that is not the purview of this
19 committee?
20 DR. GAGNE: I don't think in terms of equipment
21 performance it is, but it is certainly something that we
22 ought to be cognizant and be thinking about and doing
23 something about, yes.
24 DR. SHOPE: [Off mike.]
25 DR. FLETCHER: Would you repeat what he said?

1 DR. GAGNE: He said that they will be labeled for
2 extremity use only, and that is true.
3 DR. LIPOTI: Nowhere do you define extremity, and
4 labeling it for extremity use only, is only labeling. I
5 think you have to do something a little more aggressive here
6 to prevent this misuse.
7 DR. GAGNE: Okay.
8 DR. McKETTY: That was going to be my comment,
9 too, that in the real world, I mean in hospitals, physicians
10 do use this not just for extremities, but, you know, just
11 whatever they can fit in there.
12 DR. GAGNE: I think we know that, and we are
13 concerned about that, and I appreciate your comment.
14 MS. KAUFMAN: Since FDA cannot regulate the use of
15 a particular piece of equipment, correct?
16 DR. GAGNE: That's right.
17 MS. KAUFMAN: I think it would have to be up to
18 the states to have that in their own regs if that is what we
19 want.
20 DR. GAGNE: There is one technical detail that
21 mitigates this a little bit that I didn't talk about, which
22 is that when you talk about kerma, you are really talking
23 about exposure to a point, and what you really need to know
24 is the volume exposed, and when you use these particular
25 systems, the volume exposed effectively is smaller than it

1 is when you use a conventional fluoroscope, but it would be
2 a little bit hard to explain right now.
3 That does mitigate things a bit because even
4 though the point value is higher, the total volume to see
5 what you want to see is probably smaller, and so the total
6 organ dose may be somewhat close -- I am hand waving -- but
7 there is that part of it.
8 DR. FLETCHER: Any other comments?
9 [No response.]
10 DR. GAGNE: Thank you.
11 **Displays Required for all New Fluoroscopic Equipment**
12 DR. STERN: Good morning. My name is Stanley
13 Stern. I am with the CDRH, Office of Health and Industry
14 Programs.
15 [Slide.]
16 We have drafted new requirements for displays
17 related to three fundamental aspects of irradiation and
18 fluoroscopic exams and procedures - rate, amount, and
19 duration of radiation emissions.
20 Currently, this information is not accessible
21 directly from the equipment. Display of this information
22 can be thought of as feedback to practitioners. If such
23 feedback were readily and universally available, clinicians
24 and medical physicists facilitating quality assurance could
25 optimize their practices by adjusting protocols for

1 diagnostic visualization to achieve the lowest patient doses
2 practicable. Adjustment of practice based on knowledge of
3 clinical air kerma rates, cumulative air kerma, and
4 irradiation times could lower the collective radiation
5 detriment and significantly improve public health.
6 The requirements we are suggesting would apply to
7 all types of new fluoroscopic equipment - from systems found
8 in cardiac catheterization suites, to equipment used for
9 upper gastrointestinal fluoroscopy, to mini-C-arms. The
10 appropriateness of such broad applicability has been an
11 issue in the development of this draft, and we seek TEPRSSC
12 comments about whether or not the display requirements to be
13 summarized now would be suitable or not for all types of
14 fluoroscopic equipment. Would such displays be more
15 efficacious, for example, just for stationary C-arm
16 fluoroscopes typically used in interventional procedures?
17 Paragraph 1020.32(k) -- and the line number is
18 indicated in the shaded area, I refer to the September 8th
19 draft of the proposed amendments -- that paragraph is
20 introduced to require displays of values of the air kerma
21 rate and air kerma. Air kerma rate and air kerma are
22 defined by the International Commission on Radiation Units
23 and Measurements; they are basic radiological variables
24 related to the amount of kinetic energy liberated by the
25 incident x-rays. Because they are basic quantities, their

1 evaluation is to be made "free-in-air," that is, without
2 significant contributions from scattered radiation.
3 The draft regulation stipulates that displays of
4 their values be provided in particular SI units of
5 measurement - namely, centigrade per minute for the air
6 kerma rate and centigrade for the cumulative air kerma.
7 These units would yield values whose numerical magnitudes
8 would be familiar to people accustomed to the traditional
9 unit of roentgen.
10 Furthermore, the draft stipulates that these new
11 requirements apply for each x-ray tube used during an
12 examination or procedure. If a bi-plane fluoroscopic system
13 were used, for example, in some cardiac catheterization
14 procedure, there would need to be two distinct displays of
15 air kerma rate values and two distinct displays of
16 cumulative air kerma values, that is, one set representing
17 radiation emission values for each x-ray tube of the bi-
18 plane.
19 What follows are the principal ideas related to
20 these draft display requirements.
21 The values of air kerma rate and cumulative air
22 kerma are to be displayed to the fluoroscopist in the
23 fluoroscopist's working position. They should be easily
24 visible throughout the examination and after it ends, until
25 the values are reset for the next patient.

1 Both values are not displayed at the same time,
2 and when either is displayed, the value for air kerma rate
3 must be clearly distinguishable from that for the cumulative
4 air kerma. Here, the intent is that the fluoroscopist
5 easily and quickly identify the quantity to which the
6 display refers.
7 The air kerma rate is displayed only during
8 fluoroscopy or while there is recording during fluoroscopy.
9 According to our draft definition, fluoroscopy is "a
10 technique for generating x-ray images and presenting them
11 instantaneously and continuously as visible images for the
12 purpose of providing the user with a visual display of
13 dynamic processes." Regardless of whether or not there is
14 recording, if fluoroscopy is occurring, then the air kerma
15 rate need be displayed.
16 On the other hand, the value for the cumulative
17 air kerma is updated and displayed only after x-ray
18 production stops. X-ray production can stop either after
19 fluoroscopy - when the fluoroscopist removes pressure from
20 the x-ray tube activation switch - or it can also stop after
21 a radiographic exposure, for example, a spot film.
22 In either case, the cumulative air kerma would be
23 displayed until fluoroscopy resumes again or until the
24 displays are reset at the commencement of a new examination
25 for another patient.

1 The cumulative air kerma value is intended to be
2 cumulative in two senses: In the first place, it represents
3 a "running" subtotal amount of air kerma produced from the
4 time an examination commences, a subtotal which is updated
5 and displayed over the course of an exam whenever x-ray
6 production stops.
7 In the second place, the value displayed includes
8 contributions to the air kerma produced from all
9 radiographic as well as fluoroscopic x radiation. For
10 example, fluoroscopy stops; the rate display goes off, and
11 the cumulative display goes on; then there might be a spot
12 film; the cumulative display is updated with an
13 incrementally larger value that includes the contribution of
14 the radiographic radiation to the cumulative air kerma.
15 In other words, the cumulative air kerma is not
16 simply the air kerma rate integrated over the fluoroscopic
17 irradiation time; the cumulative air kerma includes all
18 radiographic contributions too.
19 The final point about cumulative air kerma is that
20 it does not correspond to any one particular skin entrance
21 location; the cumulative value accrues contributions from
22 fluoroscopic and radiographic radiation irrespective of the
23 entrance location of the x-ray field intersecting the
24 patient skin surface.
25 What is the spatial location for which the air

1 kerma rate and cumulative air kerma values are displayed?
2 In order that air kerma values indicate in the most direct
3 way practicable the potential for patient radiation
4 detriment, the location at which radiation output is
5 represented should be as close as possible to the x-ray
6 field entering the patient skin surface.
7 The draft regulation identifies reference points
8 of air kerma evaluation intended to represent skin entrance
9 locations. These reference locations are defined according
10 to the type of fluoroscope.
11 For fluoroscopes with the x-ray source below the
12 table, the reference location would be 1 cm above the
13 tabletop; when the x-ray source is above the table, the
14 reference location would be 30 cm above the tabletop; and if
15 it were a lateral type fluoroscope, the reference location
16 would be 15 cm from the table centerline toward the source.
17 These locations to which displayed values of air
18 kerma rate and cumulative air kerma correspond are
19 respectively the same locations specified in another section
20 of the regulations for measuring compliance with air kerma
21 rate limits.
22 For C-arm-type fluoroscopes, the reference skin
23 entrance location for displayed values would be
24 significantly different from that for measuring compliance
25 with air kerma rate limits. For C arms, displayed values of

1 the air kerma rate and cumulative air kerma would refer
2 either to a point 15 cm from the isocenter toward the source
3 of else to come other point or points deemed by the
4 manufacturer to aptly represent the location of skin
5 entrance surface.
6 The alternative designation would probably be
7 needed for C-arm fluoroscopes whose source-to-image receptor
8 distances are shorter than 45 cm. In general, we believe
9 that a point 15 cm from the isocenter would better represent
10 the location of the skin entrance surface, particularly for
11 the oblique angles used in a number of projections, for
12 example, in interventional cardiac radiology, than would the
13 point 30 cm from the image receptor, which is the location
14 currently stipulated for measuring compliance with the air
15 kerma rate limits.
16 [Slide.]
17 In support of the new requirements for display of
18 the air kerma rate and cumulative air kerma, paragraph
19 1020.30(h)(6) introduces a requirement that the manufacturer
20 provide the user with particular information related to
21 displays.
22 The manufacturer must provide a statement of the
23 maximum deviations of the true values of the air kerma rate
24 and cumulative air kerma from their respective values that
25 are displayed. This information tells the user how accurate

1 and precise the displayed values are.

2 There must be instructions for calibrating and

3 maintaining any instrumentation for measurement of the air

4 kerma rate and cumulative air kerma.

5 The manufacturer must identify specifically in

6 terms of the geometry of the fluoroscopic system the

7 location or locations to which the displayed values refer.

8 Finally, for C-arm systems, if the manufacturer

9 identifies a reference skin entrance location for displayed

10 values that is different than a point 15 cm from the

11 isocenter toward the x-ray source, then the manufacturer

12 must provide a rationale for that alternative designation.

13 [Slide.]

14 Fluoroscopic irradiation time is a fundamental

15 complement to the air kerma rate and cumulative air kerma

16 and can serve in its own right as an independent variable

17 for radiation control. We are therefore revising paragraph

18 1020.32(h) in two ways - first, to require a display of the

19 fluoroscopic irradiation time, which is new requirement, and

20 second, to require an alert signal in a way different from

21 that of current equipment. Irradiation display and audible

22 signal would be required for each x-ray tube used in an

23 exam.

24 The display should be visible from the beginning,

25 throughout, and after the examination ends, but it is not

1 necessarily visible to the fluoroscopist. The time can be
2 displayed on the control console. The ideas here are that,
3 first, the irradiation time is valuable information for
4 analytical quality assurance purposes; second, it is
5 important that the fluoroscopist be aware of the air kerma
6 rate and cumulative air kerma as variables of consequence
7 for the patient; and, third, there should not be information
8 overload to the fluoroscopist. The value of the irradiation
9 time will be available, but it will not necessarily be in
10 the fluoroscopist's face.
11 At the beginning of a new examination or procedure
12 the time display would be able to be reset to zero, and it
13 would function independently of the audible signal.
14 For every five minutes of irradiation time there
15 must be a signal audible to the fluoroscopist that would
16 alert the fluoroscopist to the passage of irradiation time.
17 Unlike the current timer requirement, the signal need sound
18 for only one second, it can stop sounding after that until
19 the next five-minute interval goes by. It need not sound
20 continuously until reset.
21 When we were drafting this audible signal
22 requirement, we were also thinking of an alternative, and I
23 would like to pose it now for your comments. Instead of
24 requiring that there be an audible signal every five minutes
25 of irradiation time, what if an irradiation time alert could

1 be preset at the discretion of the fluoroscopist? With this
2 alternative, the fluoroscopist could choose a range of
3 duration - shorter or longer than five minutes if desired -
4 after which to have a signal, and one of the options for the
5 fluoroscopist would be not to set an audible signal to sound
6 at all.
7 That is all I have to say. I will take any
8 questions if you have them.
9 DR. MARX: I have a question. Going back to the
10 displays of the kerma rates and the cumulative air kerma,
11 you had very specific points at which those should be
12 measured. Are those the same points at which the user
13 manual referenced, that Dr. Shope talked about earlier? Are
14 they going to be the same?
15 I think that as these numbers become visible to
16 operators, there is going to be increased interest on the
17 part of the operators about what this information means, and
18 so I think that unlike maybe today, I think people will use
19 the manual that you are asking for more than they would have
20 this year because we don't have those numbers to look at.
21 So, if they aren't measured in a similar way, they
22 are going to look dramatically different, so I think there
23 should be some sort of -- what do you call it -- harmony
24 between those things.
25 DR. STERN: I think that is a good point, and I

1 think the way the user information is currently drafted,
2 that particular requirement, it refers to the reference
3 points for measuring compliance with the air kerma rate
4 limits. In a number of cases, they are the same, but for C-
5 arm type fluoroscopes, they are not the same reference
6 points, and so I think it would be a good idea to consider
7 to include some information about that in the user manual.
8 MS. KAUFMAN: I think the way that the C-arm
9 proposal is phrased, it is the one that is different than
10 the others in terms of where this exposure rate would be
11 measured, and I think it is kind of confusing, and I am
12 thinking also in terms of compliance and trying to figure
13 out where this isocenter exactly is, where the measurement
14 should be calculated to, and if we wanted to verify
15 compliance with the accuracy of the readout, I think it
16 would be difficult.
17 I would suggest that FDA reconsider just making
18 that the same as it is for compliance with the exposure rate
19 limits.
20 The second thing is in terms of the accuracy of
21 the display, I can't find it right now, but I think it says
22 that the manufacturer can set their own accuracy, and I
23 would also suggest that FDA reconsider that and put a limit
24 on it. We have seen that same problem currently with
25 radiographic or fluoro, for that matter, kVp accuracy where

1 the manufacturer can set their own limit, and there is a
2 pretty fairly wide variance between what each manufacturer
3 sets.
4 I think that the purchaser doesn't really realize
5 that when they purchase the equipment, and it can make the
6 value of the readout, you know, reduce the value of the
7 readout. If one manufacturer says it is going to be
8 accurate to 10 percent, but another manufacturer says 40
9 percent, then, the accuracy of that readout isn't as
10 valuable to that one who says 40 percent. I don't think
11 that they realize that.
12 I would suggest that we just establish a maximum
13 deviation and just go with that, and say that that is what
14 they have to comply with.
15 DR. STERN: We have talked about issues of
16 statement of accuracy in our discussions, and I think we
17 need to talk about it more. My understanding is
18 historically, it is hard to establish an absolute rule on
19 what the accuracy should or shouldn't be, but I think it
20 merits further discussion consideration.
21 MS. KAUFMAN: I think you could make it fairly,
22 you know, a fairly wide deviation, but at least there would
23 be some limit on it. Obviously, if manufacturers want to
24 have a lower deviation, that would be great, but at least
25 there would be some maximum on there.

1 DR. STERN: Thank you.

2 MR. TUROCY: Currently, we provide a display of kV
3 and mA continuously during fluoroscopy, and then adding the
4 air kerma and air kerma rate, and then you also add the
5 time. Do you really need all these values, say, for
6 example, why don't we eliminate display of mA during
7 fluoroscopy, and then what value does the time really have?

8 DR. STERN: I won't speak to mA per se, but I will
9 speak to time. I believe the time is a valuable parameter.
10 I think the most valuable parameters are the parameters
11 which refer to potential detriment, air kerma rates and the
12 cumulative air kerma. I think time is independently
13 valuable for purposes of analysis and for purposes of
14 readjusting protocols to understand how the exams are done
15 in practice.

16 I think exams are very complicated and how
17 radiologists use their time versus taking spot films versus
18 taking cine films. Nothing is quite linear. It is an
19 independent variable which offers another measure of
20 control, and it merits consideration in its own right for
21 inclusion for that reason. That is our rationale for that.

22 MR. TUROCY: Would you consider eliminating mA as
23 far as one of the requirements in the standard?

24 DR. STERN: I don't know about that. I don't know
25 how valuable it is a parameter for quality assurance, and I

1 think that we would have to talk about it basically.

2 MR. TUROCY: Thank you.

3 DR. FLETCHER: Are there any other questions or

4 comments from members of the committee?

5 MS. KAUFMAN: I think you don't to eliminate mA.

6 For one thing, some of these units or all of these units

7 have manual capabilities too, so you want to have a means of

8 determining what the mA is, and if, for example, your air

9 kerma rate all of a sudden jumped up, you might want to know

10 that it was the mA that caused that increase.

11 One last comment is lateral fluoroscopes, and I

12 would suggest that we consider adding a definition as to

13 what you mean by a lateral fluoroscope, because I think that

14 FDA is thinking something different than what the general

15 public is thinking on what a lateral fluoroscope is.

16 I don't think it was defined when it was

17 incorporated in the regs in terms of where it would be

18 measured, the exposure rate, so I think we need to add a

19 definition for lateral fluoro.

20 DR. STERN: Thank you.

21 DR. LIPOTI: These displays are only as good as

22 the use of the numbers on the display, and it really seemed

23 to me that these regs needed to be complemented by a

24 regulation which would require a notation in the patient's

25 chart for the total time and exposure, and for real use in

1 terms of quality assurance and continual improvement of
2 quality, I felt the records needed to be kept at the
3 facility of each physician's time and exposure per patient,
4 so that you might compare different techniques and show an
5 improvement.
6 Now, I realize that that is not part of this reg
7 because it doesn't directly affect the equipment itself, but
8 it might be in the user manual, it might be required in the
9 user manual as a recommendation for the facility as to how
10 they might best use this new information that they will now
11 be collecting.
12 So, I would just like to suggest that as a
13 recommendation in the user manual. I have one other
14 recommendation, and that is, you do have in the instructions
15 for calibration and maintenance in the information for
16 users, lines 483 to 495, and I would like to suggest a
17 maintenance schedule similar to what you have on line 407,
18 which is a maintenance schedule for the x-ray equipment
19 itself.
20 A member of the public suggested to me that what
21 might be really useful is what we have on our xerox machine.
22 It is a measure of the number of copies that you take, and
23 then you get a little readout that says, okay, it is time
24 for maintenance now.
25 It seemed to me that we might have maintenance

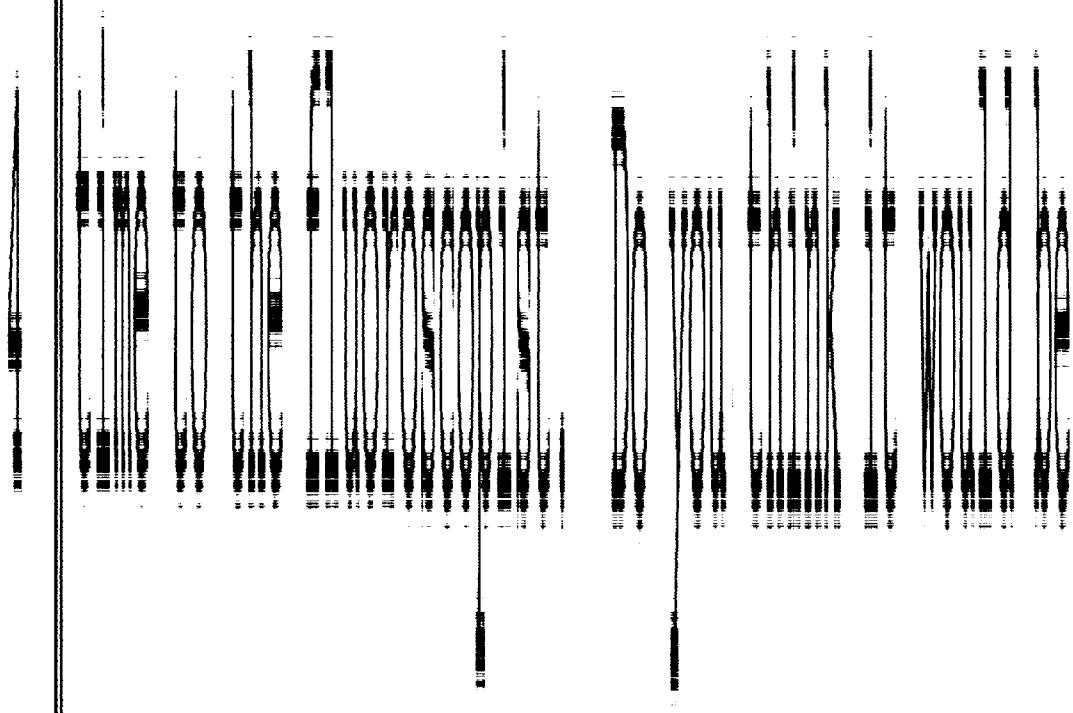
1 schedules that are buried in the user manual, but that are
2 not readily apparent to the user of the equipment, whereas,
3 on the xerox machine it says, you know, 10,000 copies have
4 gone by, call your serviceman and get the thing tuned up.
5 I am just suggesting that there might be some way
6 to have a readout that it is time for service now. I know
7 some of our cars have these little things that light up on
8 the dashboard that say bring it in for an oil change.
9 This seems to be important. The other thing that
10 brought it to mind is that facilities seem to think that,
11 oh, well, the State comes in and checks periodically, that
12 is good enough. When the State comes in, then, I am going
13 to have a maintenance check of the machine. Well, that is
14 not good enough, because states vary in their inspection
15 time frames, and it may not necessarily be in conjunction
16 with the maintenance schedule, and as states experience
17 cutbacks, they get around less and less frequently.
18 So, it becomes more and more important that the
19 facility itself take on the obligation of properly
20 maintaining the equipment. So, I am suggesting also on line
21 501 that where you have the warning label on the control
22 panel that states, "This x-ray unit may be dangerous to
23 patient and operator unless safe exposure factors and
24 operating instructions are observed," that you add the
25 words, "and proper maintenance is performed," which really

1 gets to how important it is to have not only the serviceman,
2 but also a medical physicist come in and check that the
3 machine is still operating within parameters.
4 DR. STERN: Thank you.
5 DR. CARDELLA: I would like to respond to your
6 final question at the very end of your presentation. As a
7 user of this type of equipment, the ideal, to my way of
8 thinking, would be to have the running fluoroscopy time
9 displayed at the fluoroscopist's location, and perhaps every
10 five minutes a chime would sound to call your attention to
11 the fact that another five minutes has elapsed, similar to
12 when my wrist watch chirps on the even hour. Then, I can
13 look at say, oh, yeah, now it is 11 o'clock. That would
14 call my attention to the fact that I am at five, 10, 15, 20,
15 or 30 minutes of fluoro.
16 The important aspect of it is that the five-minute
17 chirp or timer must not inactivate fluoroscopy like it used
18 to be in the old days. I think we have gotten over that.
19 You must be able to continue to fluoro through that warning,
20 because if you are doing a critical part of the procedure,
21 you have no idea that you are coming up to five or 10
22 minutes. You absolutely cannot have deactivation of the
23 fluoro as it used to be.
24 So, I would advocate that the chime go off, it be
25 of finite duration, perhaps one second or two seconds, and

1 that it not require either a technologist, physician, or
2 nurse to go to the control console to push a reset button.
3 That is the way I think it should be and the ideal.
4 The second part of your question was would it be
5 beneficial for the operator to be able to preselect when the
6 chime sounds. Somebody might want to be a three-minute
7 chimer or a four-minute chimer. I think that that adds a
8 level of complexity and maybe some small incremental costs
9 that would not be worth it.
10 I think if people were advised that this machine
11 chimes for you at five minutes, that is plenty to live with.
12 I don't see any reason to shorten the interval unless you
13 are doing pediatrics work, and they are very, very
14 sensitized to fluoro exposure there. They may want a two-
15 minute or a three-minute chimer. I think for the lion's
16 share of fluoroscopy work, a five-minute chime is plenty.
17 Then, coupled with the printout at the
18 fluoroscopist's location, I would be able to integrate, you
19 know, I will be able to see that I am between five and 10
20 minutes if I were so inclined to check that information in
21 between chimes.
22 DR. STERN: If I might respond just briefly. I
23 think you have made a number of points. The way the draft
24 is worded now, it would be a chime, it would happen every
25 five minutes, and the intent was not to be interlocked with

1 the production of x-rays. That hasn't been written in
2 explicitly though.

3 But you made another point about displaying the



1 the production of x-rays. That hasn't been written in
2 explicitly though.
3 But you made another point about displaying the
4 time to the fluoroscopist. Do you think it would be
5 worthwhile to have it in addition to the displays of the
6 rate, the kerma rate and the cumulative air kerma, so you
7 would have displays of multiple information, is that useful?
8 DR. CARDELLA: Yes.
9 DR. MARX: I appreciate FDA's concern about
10 information overload for us, but I would agree with John
11 that I was concerned in past discussions of this, that if
12 you had all three of these things, the time, the air kerma
13 rate, and the cumulative air kerma, all simultaneously
14 displayed that that would be too confusing, but the way you
15 are describing it, the air kerma business, you have only got
16 one of those going at a time during fluoroscopy, the rate,
17 and then that along with the time, I think would be useful
18 for two reasons.
19 One, although there is a variety of things that we
20 can do to control dose rate to the patient, how we are
21 operating, what magnification level we are at, et cetera, et
22 cetera, but the thing that we have the easiest and most
23 control over is the foot pedal.
24 I think a time would be a very useful feedback and
25 I think that once people are used to seeing it, they would

1 pay attention to it. I would discourage the variable use of
2 the buzzer. I agree with an audible signal that just comes
3 on, you go oh, yeah, and then it goes off, but I think
4 having that rate be variable is not a good idea, because no
5 matter what the rate is, and you are saying you could make
6 it be longer, everybody is going to think it's five minutes.
7 So, if one of my partners is doing and he knows
8 it's a long case, and he has it set for every 15 minutes,
9 and then I come in the room to do a case, and the buzzer
10 goes off, and I am oh, it's only five minutes of fluoro time
11 when it has really been 15 minutes, that defeats the sort of
12 the feedback usefulness of it, and many places you are not
13 talking about single operators, you are talking about big
14 labs where there is a lot of people working.
15 DR. STERN: Thanks.
16 **Open Public Hearing**
17 DR. FLETCHER: Let me just point out that even
18 though we are in the period of open public hearing as far as
19 the schedule is concerned, we have no one signed up to
20 speak, so we can continue the question and answers for as
21 long as the committee needs to.
22 The committee is reminded that there is a
23 committee discussion session immediately after lunch, and
24 this is the primary subject for that. You can proceed.
25 DR. FLETCHER: Are there any questions from

1 members of the audience?

2 [No response.]

3 **Committee Discussion**

4 DR. FLETCHER: At this time, we can begin our

5 initial committee discussions about this subject, about what

6 has been proposed, some of the comments that we have already

7 made, and it is also appropriate if we feel as though we

8 would like to give specific guidance rather than comments,

9 we do propose, make motions, and take votes recommending

10 that the FDA proceed in a certain direction.

11 At this time, those discussions are open.

12 MR. SZEGLIN: Has the hard copying any of the

13 doses been addressed or considered after the exam? I mean

14 what do we do with these numbers, do they just go away, we

15 set to zero?

16 DR. FLETCHER: Could you speak a little louder.

17 MR. SZEGLIN: Hard copying the doses that we have

18 just measured during the patient exam, have we addressed

19 that topic at all?

20 DR. SHOPE: We haven't addressed that specifically

21 in these requirements. There is nothing that would prohibit

22 the manufacturer from providing that information, and the

23 idea in our amendments here was to provide the user with

24 real-time feedback in order to allow him to modify his

25 performance while the exam is going on. Certainly, we made,

1 in 1994 and 1995, some recommendations regarding dose to
2 patients undergoing interventional procedures and the value
3 that it might be to record that information in the patient's
4 record for certain procedures where there was a potential
5 for long fluoroscopic exposure times and the potential for
6 skin injury, and we certainly wouldn't discourage facilities
7 from using that kind of information.
8 I think the question would be what is our role in
9 a radiation safety standard for a requirement like that that
10 would facilitate historic activities, but I am not sure it
11 is necessarily related to radiation safety issues per se,
12 but that is a point I am sure we could debate a little bit.
13 But this proposal was meant to affect the real-
14 time exposure of the patient, not what is done with the
15 information historically afterwards. Again, we could
16 probably attempt an argument to require that kind of hard
17 copy recordkeeping.
18 Many of the systems probably have that capability
19 already in their microprocessor control. They keep a
20 history of everything in there anyway. The servicemen can
21 get it. It probably wouldn't be a big stretch for the
22 manufacturer to make it available in terms of a printout.
23 So, I think it is an issue we could discuss, we
24 could get comments on, but no, we had not consciously said
25 that is an area we want to go into, because that gets more

1 into what does the user do with the information where we
2 don't have a regulatory role. We regulate the manufacture,
3 radiation safety aspects of the equipment.
4 DR. GAGNE: I would like to make a comment also.
5 I think when you consider a radiation control program, I
6 think there are many pieces to that radiation control
7 program, and one piece significant is equipment performance,
8 but it is certainly not the only thing that ought to go into
9 a radiation control program.
10 There are pieces associated with use that we
11 should also be getting into and pushing besides equipment
12 performance. So, when we talk about these particular
13 requirements, these proposals, we actually did consider what
14 you talked about, but it is in an area that starts to go
15 more towards the use part of the equipment than the
16 equipment performance in the radiation safety sense, as Tom
17 said, and so we pushed it aside basically, but we are not
18 saying it is not important, it is important, and to a
19 certain extent, if the capability isn't there on the
20 equipment, you know, then, you can't even use it.
21 There is an intermingling here between use aspects
22 and performance aspects. We have tried to separate them out
23 as much as we can because in a regulatory sense we need to
24 deal with manufacturers and equipment, but on a radiation
25 control program sense, we need to look at all of those

1 things.

2 MS. KAUFMAN: Relative to the 5 r limit on units,
3 fluoro exposure rate limit, on units having high level that
4 were manufactured before May 1995, can FDA go back and
5 modify that in these? In other words, when that unit is
6 moved to a new location, it does come under your standard,
7 and since none of us really like that restriction, that is
8 why we have the new regs that allow them to go to 10 r a
9 minute, can we eliminate that 5 r limit and make it 10 r?
10 Do you know what I am saying?

11 DR. SHOPE: The problem there is moving the
12 equipment is not necessarily remanufacturing and changing
13 its internal design, which is what was there originally, but
14 I don't think you would find FDA making a case and taking it
15 to court over somebody who no longer kept it at 5. I think
16 we have basically said that already publicly.

17 MS. KAUFMAN: Right, but that being the case,
18 could we just take it out of the regs? Can you do that? I
19 mean if you could, I think it would be a good thing to do.

20 DR. SHOPE: Again, that reg applied to the
21 equipment when it was originally manufactured or its being
22 in these days, there is a whole issue of refurbishing,
23 remanufacturing, but that really requires a hardware change,
24 so I think the question you are asking could we
25 retroactively somehow require this step to have that

1 hardware change done, no, we probably couldn't. Would we
2 allow it? Yes, we probably would and we wouldn't have any
3 trouble with it.
4 MR. THOMAS: If that is written into the
5 regulations as a requirement, you can't ignore it. They are
6 in violation of the regulation. I tend to agree with what
7 Kass is saying. If we have loosened the regulations for
8 equipment that is being manufactured today versus what we
9 had before, instead of ignoring it, you will have someone
10 that is going to evaluate the performance of a piece of
11 equipment and say you are exceeding the regulation because
12 it was manufactured prior to 1995.
13 DR. SHOPE: I think the other point, at least from
14 an FDA standpoint, is our enforcement program is focused on
15 new equipment. Certainly, the states focus on the older
16 equipment, and are required to harmonize with our
17 requirements basically.
18 MS. KAUFMAN: Tom, when we do federal complaints
19 testing, we could inspect a unit that had been installed
20 within the last year, so if a unit has been moved, we could
21 still inspect it against performance standards for FDA,
22 number one, but number two, many states including California
23 does have a requirement that they have to maintain their
24 equipment in conformance with the FDA standards. So, you
25 know, we are not citing for it either, but if it can be

1 removed, I think it probably would be a good thing to do.

2 DR. SHOPE: We can, as I say, talk with counsel

3 and see what might be possible. I am not sure I see the way

4 to do it right now based on the way we have always done

5 these things, but that doesn't mean there is not a new

6 creative way we might find.

7 DR. CARDELLA: Currently, along the same line, I

8 still have a unit in service where I am under the old 510

9 rule, in other words, in fact, I have still got a two-step

10 fluoro pedal. If I am having an inadequate fluoro image at

11 my standard mode fluoroscopy at 5, then, I tell them to

12 engage the high level control which allows me to go to 10 or

13 20.

14 At my high level control 1 position, I step on the

15 fluoro pedal and I get 5, the image is inadequate, I step it

16 all the way to 10 and get the image that I need. If I

17 didn't have to do that on that old piece of equipment, in

18 other words, if I maybe only needed 6, that would be better

19 than flooring it to get the 10.

20 So, the removal of the old 510 requirement may

21 assist people with aged equipment to get a little better

22 fluoro image without having to go all the way to the high

23 level control 1 or 2.

24 DR. SHOPE: That is the reason we made that change

25 to the regs for new equipment. I think I have to point out

1 also there is another issue here, and that is when you make
2 these kinds of changes, you are talking redesign of the
3 equipment, I think in some cases, and that gets into what is
4 the manufacturer required to do under the good manufacturing
5 practices to validate and verify those kinds of changes,
6 that they are going to be reliable and accomplish what they
7 want to do, and not introduce other faults or flaws into the
8 system.
9 So, it is sometimes a bit more complicated than
10 just telling the serviceman come out and readjust this
11 because that service is being done under the quality system
12 regulation under similar things, ISO 9000 quality systems
13 kind of things, and the manufacturers just don't go out and
14 make miscellaneous changes without making sure that those
15 changes are going to be adequate and controlled, tested and
16 evaluated ahead of time, and there are some economy issues
17 there, as well, because if you are doing a lot of different
18 things for a lot of different people, those expenses can add
19 up rather quickly.
20 So, I am just pointing out there are some other
21 offsetting things that have to be considered in talking
22 about this, we will just fix all the old equipment and make
23 it like new equipment, that's --
24 MS. KAUFMAN: I think we are just saying, though,
25 that they wouldn't necessarily have to do that. We are just

1 saying that it would be legal for them to go up to 10, and
2 so we are making it less restrictive for them. So, I don't
3 think that anybody would have to go back in and do a
4 remodification. If they want to keep it where it is, at 5,
5 they could certainly do that.
6 DR. SHOPE: Let the limits creep up a little bit.
7 MS. KAUFMAN: Exactly.
8 I did have a couple other comments. I would
9 request that FDA again consider not exempting simulators
10 from the future requirements. I think the reasoning for
11 that just isn't necessarily true anymore, so I think we
12 should reconsider that.
13 Are these revisions that we are doing restricted
14 only to fluoro? As long as we are doing revisions, can we
15 throw in a couple of other things?
16 DR. GAGNE: Yes.
17 MS. KAUFMAN: Two real quickie suggestions would
18 be on dental is to limit the fluoro field size to
19 rectangular, which is I think the way generally things are
20 going anyway. Right now they can have a circular beam, and
21 I think that would be an easy thing to do.
22 The second thing would be to require post-exposure
23 mass readout on radiographic units like we are now requiring
24 on mammo units.
25 DR. CARDELLA: I had an additional question for

1 Tom or Bob. In the proposed reg changes, there is not a
2 mention made of the trip odometer or the trip timer where
3 you would have the ability to gather information at a high
4 risk zone, for example, a TIPS procedure or an extended
5 cardiac ablation or cardiac angioplasty.
6 Was it a deliberate omission or an omission
7 omission?
8 DR. GAGNE: I think it was, in fact, a deliberate
9 omission. We had in I believe in the concepts document we
10 did have that particular feature in there, and it seemed
11 like a good idea at the time, and we had quite a bit of
12 discussion about it.
13 We are still open in terms of whether that would
14 be a useful feature or not, but yes, it was a deliberate
15 omission. We knew it was there previously and we decided
16 that that would require again an additional sort of feature
17 built into the equipment to handle that. So, in this
18 particular discussion we took it out.
19 DR. SHOPE: I would add that there is nothing in
20 our regs that would prevent a manufacturer from offering a
21 feature like that should the user want it and there be a
22 demand for it on the part of the customer.
23 So, there is nothing here to prohibit a feature
24 like that provided the other aspects of the reg are met, so
25 there is not a prohibition against that feature. It is just

1 we didn't, in thinking about this, see that that was a
2 feature that we should mandate for all fluoro systems.
3 What you really then get to the sticking point is
4 if you want that on interventional systems. That gets us
5 back into the stick morass of trying to define what an
6 interventional system is, and that we need lots of help on.
7 DR. GAGNE: Well, we tried to do that by trying to
8 tie it to the x-ray tube, which I think is probably
9 appropriate if the number is correct, and we can get
10 comments on that particular number in terms of heat units.
11 So, we sort of defined interventional fluoroscopy by that
12 indirect method, so if there was a need or a suggestion to
13 go along with the trip odometer sort of thing, it could be
14 maybe be tied with that.
15 MR. THOMAS: Was consideration given to, when you
16 were looking at the cumulative air kerma, to have a record
17 somewhere internally in the machine to have the total air
18 kerma over the life of the machine or to date? I could see
19 some applications, not that are clinical, but in terms of
20 evaluating and assessing the performance of the image change
21 over time and degradation of the performance of that. That
22 would be very useful to have.
23 DR. SHOPE: I can say clearly no, we weren't
24 considering that from a maintenance standpoint. There was
25 consideration to this issue of a lot of these systems have

1 the microprocessors in there for service purposes, a lot of
2 this information is already stored in the machine and the
3 serviceman can get at it, but the question here I think
4 becomes partly where do we stop being radiation safety
5 performance related and get into other issues of
6 maintenance, convenience, operational issues, and I think
7 that would be one we would have to think hard about as a
8 radiation safety type feature.
9 MR. THOMAS: I will come back and we will get into
10 the hat where you and I like to discuss the area of digital
11 imaging and digital image system performance. I feel fairly
12 strongly that we are going to see significant degradation of
13 a lot of these direct digital receptors that we have no idea
14 how it is going to degrade, and that is going to have a
15 direct impact on the radiation safety aspects.
16 That is why I bring that to your attention. In
17 thinking about this whole thing, Tom, I am fairly strong in
18 my opinion that we need to require that type of information
19 especially with the rapidly changing technologies that we
20 are seeing in image receptors and our digital imaging
21 systems.
22 DR. SHOPE: For clarification, you are talking
23 about something like a cumulative record of tube loading
24 type information or total mAs or something along those
25 lines?

1 MR. THOMAS: I would even go one step further from
2 what John said, but I don't think I want to go that far, and
3 that is give me a record of everything that has ever been
4 done on the machine in terms of technique, but the short
5 answer is to your question yes, I think if we look at tube
6 loading, as well as to the receptor itself, what the
7 cumulative air kerma was.
8 I see that those are both performance and also
9 radiation safety measurement issues when that piece of
10 equipment starts to degrade over time.
11 DR. CARDELLA: I would like to respond to that.
12 That is an excellent idea. The big need to understand is a
13 little bit about the way x-ray equipment maintenance is
14 going these days. It is very expensive, it is very low
15 prioritized in the eyes of hospital administrators, and for
16 those of us who have to use this stuff, we say to our
17 service team the image is getting lousy, it needs a new
18 image intensifier, they send somebody down and say, yeah,
19 the image is a little bad, they tweak the dose up, they run
20 it a little hotter to make me happy.
21 The patients don't know that is going on.
22 Sometimes I don't know it is going on, and it hard to argue
23 the point that this is equipment that regularly and
24 predictively degrades over time.
25 I think that the manufacturers ought to say, look,

1 this thing is good for 100,000 miles, then, your engine
2 needs tuned up, or if it is John Deere tractor, it runs for
3 200 hours and then it needs the oil changed and the
4 transmission looked at.
5 So, I don't have to argue and beg, borrow, and
6 plead with hospital administration to come fix the stuff, it
7 would be a tremendous advantage to have proscribed
8 maintenance intervals that are acknowledged, reasonable, and
9 recognized.
10 Now, you wouldn't want the manufacturers to say,
11 well, you need an oil change every 500 miles, but if it is
12 reasonable, it does give the physician user and the patient
13 subject of that machine some modicum of confidence that the
14 thing is being properly maintained. That is my point.
15 DR. SHOPE: There is a requirement in the current
16 standard for manufacturers to provide that recommended
17 maintenance information. I think what you are talking about
18 is somehow going a step beyond that to either make it
19 obvious that it is time for that maintenance or to somehow
20 enable a forcing of that maintenance to occur, which I think
21 may be a bit beyond a radiation safety standard capability,
22 but we can talk about it.
23 I wanted to ask, if I could, Mr. Turocy, what the
24 current state of the art is with regard to systems knowing
25 the history of techniques and things in the modern

1 computerized systems, is that something that is typically
2 there, but just available for the serviceman, or is it
3 something that would have to be designed into this
4 equipment?
5 MR. TUROCY: I don't know the answer to the
6 question.
7 DR. FLETCHER: These discussions will continue
8 after lunch, but I think this is a good point to break. I
9 would ask the members of the committee, particularly those
10 who have made suggestions, et cetera, to consider the fact
11 that we need to give guidance, et cetera, to the FDA
12 regarding these amendments, we need to determine whether or
13 not, you know, how we direct them to proceed whether we vote
14 approval, et cetera, or whether there are recommended
15 changes.
16 I would ask if there is something -- and I can
17 tell from some of the discussions there are some points of
18 emphasis -- that you would like to reemphasize. Please be
19 prepared to do that when we come back, so that the committee
20 can give the guidance to the presenters on what we think
21 should be done.
22 We will go into our lunch recess until 1:15.
23 Thank you very much.
24 [Whereupon, at 12:00 noon, the proceedings were
25 recessed, to be resumed at 1:15 p.m.]

1 AFTERNOON SESSION

2 [1:15 p.m.]

3 DR. FLETCHER: We are in the process of continuing
4 our discussions on the presentations made this morning
5 regarding the fluoroscopy proposed amendments. Once we have
6 concluded the discussions, we need to put forth some type of
7 either a motion or directive or something. I prefer a
8 motion because then we can vote on it to give the presenters
9 guidance on this committee would like to see them go.

10 Continued discussion.

11 MR. THOMAS: I want to pick up a little bit on the
12 cumulative kerma. I have got a little concern in terms of
13 the application of that data in assessment of risk. I think
14 we all recognize that that is a meaningless unit in terms of
15 risk depending on the body part being exposed.

16 There will be a tendency -- and I am just pointing
17 out a weakness -- there will be a tendency of people that
18 are not as knowledgeable about radiation risk to equate that
19 value with a risk value. Was that the intent as to equate
20 the procedure with risk or to provide a relative value for
21 comparison of various procedures between patients?

22 DR. SHOPE: I think it is sort of a combination of
23 both of those in one sense. We think that the real-time
24 feedback is useful, and any kind of digital display that
25 gave some indication relative to total exposure would

1 probably be beneficial, any kind of relative display, you
2 know, when you know today I have done three times as much
3 radiation as I did yesterday, the units really don't matter
4 for that kind of relative information, but I think we were
5 also trying in the situation here the deterministic skin
6 effects I think was the thing most in our minds, not to use
7 this as a method for estimating effective dose or issues
8 like that, although I think the information could be applied
9 in that kind of a way, as well, if you know the portion of
10 the body, beam size, and all those other things.
11 But we were really trying to address, I think, the
12 real-time feedback to change performance, and secondly, to
13 provide some information about the potential for
14 deterministic injury.
15 MR. THOMAS: I have no problem if that was the
16 intent, but I think we both recognize that there are folks
17 that would like to use those values in a way that were not
18 really intended for them to be used.
19 DR. LIPOTI: Roland, I thought about some of the
20 issues that we discussed earlier, and I thought maybe I
21 would make some of them in the form of a motion, and then
22 people can discuss the motion and vote it up or down, but at
23 least it is there as a motion.
24 So, the first motion that I am going to make is
25 for TEPRSSC to support the SI unit conversion as written in

1 the copy that we received today with no change in the
2 magnitude of the radiation limits even though they are not
3 nice round numbers.
4 [Seconded.]
5 DR. FLETCHER: It has been properly moved and
6 seconded that TEPRSSC support the SI unit conversion. I
7 don't need to say the rest of that, but that is the gist of
8 it and we have got it on tape.
9 Is there any further discussion on that motion?
10 Yes.
11 MR. TUROCY: The provision of the two units, the
12 SI units, as well as the English units, I would like to see
13 that go on for five years, thereafter, the SI units would
14 take place.
15 DR. FLETCHER: Is that a comment or a proposed
16 amendment?
17 MR. TUROCY: It is a proposed amendment to the
18 suggestion.
19 DR. FLETCHER: It has been moved that the English
20 units continue for a period of at least five years before
21 the SI units take place.
22 Is there a second? Is there a second?
23 MR. SAVIC: I will second.
24 DR. FLETCHER: It has been properly moved and
25 seconded that in this conversion, the current English units

1 continue for a period of five years. We will vote on the
2 proposed amendment first.
3 MS. KAUFMAN: Can we have discussion?
4 DR. FLETCHER: Yes.
5 MS. KAUFMAN: I don't want to limit that to five
6 years. I would like to see it stay longer than that.
7 DR. SHOPE: I just want to make the comment that
8 we will ultimately have a final regulation which will change
9 the Code of Federal Regulations, and that change will
10 include the old units in there. To take them out, we would
11 have to do another amendment to the Code of Federal
12 Regulations at some point in the future, at which point the
13 committee would advise and consent on taking them out.
14 So, if you are telling us only for five years and
15 after five years taking them out, we will have to revisit
16 this issue with the committee in five years or maybe in four
17 years, so we have enough lead time. Actually, we probably
18 should start tomorrow.
19 DR. FLETCHER: Jerry and then Bob.
20 MR. THOMAS: I will pass.
21 MR. TUROCY: Another suggestion would be to
22 provide those units for a minimum of five years, thereafter,
23 they would come out.
24 MS. KAUFMAN: Is that a change to the amendment?
25 DR. FLETCHER: Are you amending your own motion?

1 MR. TUROCY: Yes.

2 DR. FLETCHER: You changed the words to a minimum
3 of five years.

4 Is there a second?

5 MR. SAVIC: Second.

6 DR. CARDELLA: I would like to speak in favor of
7 making the conversion to the SI units clean and decisive
8 without hanging on to the old units. I don't see any value
9 to it and I think that it drags out the credibility and the
10 swiftness with which the conversion is made.

11 MS. KAUFMAN: The value to it is that it is a
12 system that many, if not most, people -- well, everybody is
13 familiar with it -- and the SI system, everyone is not
14 familiar with it, and so if the purpose here is radiation
15 protection, which it is, then I think that the greater
16 comfort level that we have then ultimately the greater
17 radiation protection we can argue that it would make.

18 So, to put both I think is appropriate at this
19 time.

20 DR. FLETCHER: I will take one more comment on the
21 motion and then we need to vote.

22 MR. TUROCY: Switching over to the SI units would
23 leave many test instruments with a scale of the English
24 units. For everyone to convert those, they are going to
25 have to pull out a calculator, and the more effort you place

1 into converting those numbers, you are just capable of
2 making errors.
3 So, providing both numbers is the better
4 alternative.
5 DR. FLETCHER: We are voting on the amendment
6 which essentially states that the current units, the English
7 units, be continued for a minimum of five years prior to the
8 SI conversion.
9 All in favor, raise your hand.
10 DR. McKETTY: Before you do that, would both
11 numbers be there is what we are saying, because what you
12 just said was that old units stay for five years, and then
13 the conversion, but I think what they really want is both
14 numbers.
15 DR. FLETCHER: Both units will be present. That
16 is everyone's understanding? Both units will be present.
17 Please raise your hands, vote aye.
18 [Show of hands.]
19 DR. FLETCHER: Those voting nay?
20 [No response.]
21 DR. FLETCHER: The ayes have it. The vote is
22 carried.
23 Now, the motion itself, that TEPRSSC support the
24 SI unit conversion. Any further discussion on that motion?
25 MS. KAUFMAN: I just want to clarify because there

1 is an important point that Jill had made, and that was that
2 the exposure rates would remain the same as what has been
3 proposed here.
4 DR. FLETCHER: Right. I didn't write down the
5 whole thing. It's all on tape.
6 Now, the amendment has already passed, so the
7 amendment will be attached to this primary motion.
8 Any further discussion?
9 All in favor, please raise your hands.
10 [Show of hands.]
11 DR. FLETCHER: Opposed?
12 [No response.]
13 DR. FLETCHER: Motion carries.
14 Jill, shall we go back to you for the next?
15 DR. LIPOTI: I guess next in importance was that
16 label for extremity use only at page 53, line 1176. This is
17 the label on the C-arm fluoroscopic system, and the system
18 would be labeled "for extremity use only," but there was no
19 definition of extremity.
20 I am going to propose some wording, and I really
21 do expect a lot of discussion on this one because this is
22 really kind of preliminary, but my motion is that the
23 systems would be labeled not for use above the wrist or
24 ankle or on patient thickness greater than 15 centimeters.
25 End of motion.

1 [Second.]

2 DR. MARX: You want to limit its use just to the

3 wrist or the ankle?

4 DR. LIPOTI: Not for use above the wrist or ankle.

5 I am trying to define an extremity, and I don't know what

6 one is.

7 MS. KAUFMAN: We do have a definition for

8 extremities for personnel exposure, and it is below the

9 elbow or below the knee, so that might be a better way to do

10 it.

11 DR. FLETCHER: Let me make sure everybody

12 understands the motion before we go too deep in discussion.

13 Would you restate the motion, please?

14 DR. LIPOTI: My original motion was not for use

15 above the wrist or ankle or on patient thickness greater

16 than 15 cm, and I will accept as a friendly amendment that

17 we change wrist and ankle to elbow and knee, since that is a

18 pre-existing definition of extremity, not in this reg, it's

19 in another reg.

20 DR. FLETCHER: Okay. Comments?

21 MS. KAUFMAN: That is a definition we use for

22 extremity exposures, however, I am not sure for this unit if

23 they -- I think they do use them on elbows, and I think they

24 use them on shoulders, too. I don't know that we want to

25 allow it on shoulders, but I think we do want to allow it on

1 elbows and knees. Knees, I know are a biggie.

2 DR. GAGNE: I think a word of caution, and I have

3 no problems, of course, with what you are trying to tell us,

4 but I think one of the things you have to keep in mind,

5 though, is that when we write these radiation protection and

6 safety standards, they are associated with equipment

7 performance, and you are really getting into a use aspect.

8 It is very difficult to handle in a performance standard.

9 I have no problem with what you are trying to tell

10 us, but I think it would be very, very difficult to try to

11 write that into the regulation. There might be some

12 creative way of doing that, but in a nutshell, we are really

13 talking about use factor here, and not an equipment

14 performance factor.

15 Do you agree with that, Tom?

16 DR. SHOPE: Yes, and I would just add that our

17 discussions, our understanding extremities was from the

18 shoulder down or the hips down on the extremities, not the

19 head or the neck, but the arms and legs. I thought that was

20 the definition of extremity, but maybe we need to make it

21 precise.

22 DR. GAGNE: It is very hard to handle in a

23 performance sense is what I am saying.

24 MR. TUROCY: From my recollection, there was a

25 guidance produced for PBL, and within that guidance it

1 defined other than general purpose, and I don't know if this
2 is true or not, but I think extremities were part of that
3 definition. Maybe someone from the FDA with a better
4 working knowledge of that guidance can speak up.
5 DR. GAGNE: I also understand with respect to PBL
6 the incredible difficulty it was to understand exactly what
7 general purpose was and what wasn't general purpose, et
8 cetera, et cetera. It was very hard to interpret that.
9 There is probably some compliance people here that were also
10 involved besides myself back in those days.
11 So, when you get into the use aspect, and it is
12 really very, very hard -- I am not saying it is not possible
13 -- but it is very hard to apply.
14 DR. LIPOTI: You have on line 1176(A) and 1177 a
15 requirement, such systems shall be labeled for extremity use
16 only. I am only recommending that the label be changed. I
17 am not recommending that you do anything about the use.
18 They will take care of that, but we need a label on there to
19 show what the intended use is.
20 So, that is what I am recommending as the change,
21 a change to the labeling.
22 DR. GAGNE: Okay.
23 MS. KAUFMAN: Or that we do put in a definition of
24 extremity, because right now there is a definition of
25 extremity having to do with personnel monitoring, but it is

1 not the definition that I think you want applied here,
2 because it is below the elbow the elbow and below the knee.
3 So, you might want to put in a definition, otherwise, it
4 could be interpreted as meaning that.
5 Maybe you want to say arm including the shoulder
6 and leg excluding hip.
7 DR. FLETCHER: Do we want to be more specific in
8 this committee?
9 MS. KAUFMAN: I think we have offered our
10 guidance.
11 DR. CARDELLA: In practice, the so-called mini-C-
12 arms are used frequently in the insertion of total hip
13 arthroplasties, so if it is the intend to specifically
14 exclude the use in total hips, because it is getting to
15 fluoro through a pretty thick body part, then, you should
16 specifically exclude that, but if the sense of the group is
17 to give direction to what an extremity is, I would say from
18 the shoulder joint down and from the hip joint down. The
19 elbow and the knee, I think is an unnatural division for the
20 way they are talking about extremity here.
21 DR. MARX: I would agree with that. The two ways
22 I would think of doing it is to say the body part and I
23 think the shoulder and the hip are logical places for that,
24 or to just specify the body thickness, since that is what
25 really drives the dose up, body part thickness.

1 DR. GAGNE: That is hard to do also because, as I
2 said, these things started off by being used in the NFL, and
3 if you think about NFL players' thigh or knee, and so on,
4 they are not exactly the same sizes.
5 DR. FLETCHER: I just want to make an
6 administrative comment. During committee discussions, we
7 like to limit the discussion to the members of the committee
8 and those who we are addressing.
9 There will be time in -- well, there was time this
10 morning for public participation, and other subjects will
11 have time for public participation, but this is going to be
12 limited to the committee's discussion.
13 DR. SHOPE: If I might ask Dr. Cardella just for a
14 bit of clarification. You referred to C-arm used in the
15 hips application, but is that these small, mobile C-arms
16 with the SID of less than 45 cm? Are those type used there?
17 DR. CARDELLA: You are correct. I stand
18 corrected. The fluoroscopy units are bigger than 45 cm. I
19 wasn't thinking about that.
20 I agree with Dr. Lipoti that I think that the
21 definition of extremity should be tightened. It should give
22 either a body size restriction or it should give an
23 anatomical description.
24 DR. FLETCHER: If there are no further comments on
25 the motion itself, then, we should go ahead and take a vote.

1 MS. KAUFMAN: What is the motion?

2 DR. LIPOTI: I don't think the motion was

3 seconded, so you might try and see if Dr. Cardella could

4 make a better motion.

5 MS. KAUFMAN: Can I offer a suggestion? Let me

6 make a motion that extremity be defined as being the arms

7 including the shoulder, and the legs excluding the hip.

8 DR. FLETCHER: Is there a second to that motion?

9 DR. CARDELLA: I will second.

10 DR. FLETCHER: Dr. Cardella seconded that motion.

11 Do we need to have any further discussion on that

12 motion?

13 Seeing none, all in favor, raise your hand.

14 [Show of hands.]

15 DR. FLETCHER: Those opposed, raise your hand.

16 The ayes have it. The motion passes.

17 Is there any additional motion? Dr. Lipoti had

18 made an earlier motion which I thought was seconded. I mean

19 that is what I thought we were operating on.

20 DR. LIPOTI: No, that motion involved also a

21 patient thickness of greater than 15 cm. I just got that

22 off your little chart. It wasn't seconded. I don't know

23 how people feel about putting in something like that.

24 I just want to take care of the problem that Dr.

25 Marx brought up about using this kind of a machine on

1 children. I want to find a way to advise people through the
2 labeling requirement that that is not what its intended use
3 is.
4 DR. MARX: My reason for dissenting was not so
5 much that I disagreed with the theory, but I thought the
6 label was going to get awfully long and then no one would
7 read it. One thing that might take care of both of these
8 things is to label it that it specifically is prohibited to
9 use it on the torso. Maybe that is an imprecise definition
10 also. That is something to think about.
11 DR. FLETCHER: I think you can appreciate the
12 committee's comments and what we are trying to preclude.
13 DR. GAGNE: Yes.
14 DR. FLETCHER: I am not sure that we need any
15 additional motion to get that across.
16 MS. KAUFMAN: I voted for it, but I was thinking,
17 number one, that that was just going to be the definition in
18 here, and that the label would probably still just say
19 extremities.
20 DR. GAGNE: That is probably the way we would
21 approach it.
22 MS. KAUFMAN: And I don't know the answer to this
23 about doing it on babies, I don't know if that is a good
24 thing or a bad thing because it's an awfully small field
25 size.

1 DR. GAGNE: I don't either.

2 MS. KAUFMAN: And it may be that it is a good

3 thing to use it on babies, I don't know.

4 DR. GAGNE: I am not sure that I could prejudge

5 whether these systems should or should not be used on

6 pediatric patients. Maybe pediatrics is the wrong word,

7 maybe neonatal or whatever, small, very small.

8 DR. MARX: My concern is that it allows for the

9 performance for increasingly complex procedures under

10 increasingly unsupervised circumstances. That is my

11 concern.

12 DR. GAGNE: I appreciate that, but that is almost

13 a different problem, though, really, to a certain extent.

14 DR. CARDELLA: The other concern that I have is

15 that the smaller throat unit, the 45 cm unit is given

16 special consideration for source skin distance, which is

17 reduced, so if you allow the x-ray source to be closer to

18 the skin of a small patient, you have cut that unit more

19 slack than it deserves compared to a fixed installation, and

20 I think the SSD reduction is what bothers me anyway, I

21 shouldn't speak for others.

22 DR. GAGNE: We can all envision circumstances

23 where whether it a mini-C-arm or a regular fluoroscope, that

24 you can get the system in the geometric configuration which

25 is not appropriate. You know, the tube is right up on the

1 patient, and the image intensifier way away, that is not the
2 way you should be doing this anyway, to start off with,
3 whether it's a regular conventional fluoroscope or a mini-C-
4 arm. So, that problem existed with both systems to a
5 certain extent. I am not trying to defend either one, but
6 that can happen both ways.
7 DR. FLETCHER: I do want to emphasize the fact
8 that a lot of the pointers that the committee is giving to
9 you need to be really looked at closely and incorporated
10 where practicable, whether there is a motion made or not.
11 I do want to move on because we still have a
12 couple more proposals to deal with.
13 Dr. Lipoti, do you have another?
14 DR. LIPOTI: The next one would have to do with
15 the maintenance of the equipment and the fact that there is
16 a schedule of maintenance which is provided by the
17 manufacturer, but there is no readout that it is time for
18 service now, and so I am going to try and get at it again
19 through a warning label.
20 So, on page 23, line 500 and 501, there is a
21 warning label that says, "This x-ray unit may be dangerous
22 to patient and operator unless safe exposure factors and
23 operating instructions are observed," and I would like to
24 add the words, "and proper maintenance is performed."
25 DR. FLETCHER: Is there a second?

1 MR. SZEGLIN: I will second.

2 DR. FLETCHER: It has been properly moved and
3 seconded that the warning label be revised, that is on page
4 23, line 501, 502, that warning be amended to add the words,
5 "and properly maintained."

6 Any discussion?

7 MR. THOMAS: I hate to twist words here, but
8 "properly maintained" is very vague. What is proper to me
9 is not proper to someone else. I support the concept, but I
10 am uncomfortable with the wording because we are asking
11 people to do something that is not defined as to what is
12 meant by properly maintained.

13 DR. FLETCHER: Is there a maintenance period
14 associated with --

15 DR. LIPOTI: On line 407, the manufacturer is
16 required to provide a schedule of the maintenance necessary
17 to keep the equipment in compliance, and that is the
18 schedule on which the maintenance should be performed, but
19 again I just didn't want the warning label to get so wordy,
20 but I would really like to go a lot further than a warning
21 label and have the readout right there on the dashboard
22 where the operator is positioned, that says oil change
23 necessary or call your serviceman now, but I thought that
24 was getting a little overly prescriptive, but I really, I
25 feel very strongly about the importance of maintenance and

1 to support the doctors who are using this, that a serviceman
2 be called, that a medical physicist be called whenever they
3 are experiencing a degradation of their image quality.
4 I don't know how to make it any stronger than
5 putting it on a warning label, but I would like to make it a
6 lot stronger.
7 DR. FLETCHER: Does anyone have language that
8 might substitute?
9 DR. CARDELLA: I would propose instead of "and the
10 equipment is properly maintained," perhaps have it read,
11 "This x-ray unit may be dangerous to patient and operator
12 unless safe exposure factors and operating instructions are
13 observed and the equipment is maintained according to the
14 manufacturer's recommendation" -- or "And maintenance is
15 performed according to the manufacturer's schedule" or some
16 words like that.
17 DR. LIPOTI: I agree with the spirit and maybe we
18 can allow the FDA the latitude to come up with the words,
19 but I think they know what we are trying to say.
20 DR. FLETCHER: Would it be then reasonable to
21 state the motion that those two lines be amended to
22 incorporate a specific reference to the need for
23 maintenance, and just leave it at that? I know I shouldn't
24 be amending your motion.
25 DR. LIPOTI: I will accept that amendment.

1 DR. FLETCHER: Is there any further discussion on
2 that issue?
3 Seeing none, all in favor, please raise your
4 hands.
5 [Show of hands.]
6 DR. FLETCHER: Opposed?
7 [No response.]
8 DR. FLETCHER: The motion carries.
9 Back to you.
10 DR. LIPOTI: I do have one more. This one is the
11 requirement I talked about for the material in the user's
12 manual to be summarized in the form of a poster. This would
13 be an amendment on the area between lines 466 and 471, which
14 is where you have this summary of user's manual, which is
15 intended to be easily referenceable.
16 What I would like to suggest is that you require
17 it to be in the format that would be suitable for posting.
18 DR. FLETCHER: Is there a second?
19 The motion is that from line 466, I guess, to 471,
20 on page 21 be put in a format that is suitable for posting.
21 Is there a second? Is there a second?
22 The motion dies for lack of second.
23 Did you want to discuss the rationale?
24 DR. LIPOTI: No.
25 DR. FLETCHER: Are there any other motions that

1 you would like to present? Dr. Marx.

2 DR. MARX: I would like to go back to the issue of

3 the last image hold feature, and I think I understood that

4 there are some ways of achieving the goal of last image hold

5 where the radiation doses rates is actually increased in

6 order to achieve that goal. Was I right about that?

7 DR. SHOPE: That is possible.

8 DR. LIPOTI: It seems to me that to achieve a last

9 image hold image -- to need a higher dose rate than what you

10 have been fluoring at to achieve that goal, when the goal is

11 to decrease the dose, is sort of at odds with each other, so

12 I think that you shouldn't be making last image hold systems

13 where you are increasing the dose rate to get that picture.

14 Do you see what I mean?

15 DR. GAGNE: I can certainly think of a scenario

16 where you might want to do that. If you are in a cardiac

17 application or something like that where you have something

18 which is moving very, very quickly, then, you may not want

19 to use a last image hold which involves integrating, say, 10

20 frames.

21 What you might want to do instead is just take a

22 very quick frame, so you can freeze the motion, and not get

23 the blurring associated with 10 frames over that period of

24 time, but just take that one frame, but take it at the same

25 exposure value that corresponds to the integration of the 10

1 frames together, so that you get the same noise
2 characteristics if you want.
3 So, in the way that we propose it, it is sort of
4 leaves the flexibility available to do something like that
5 if you want to take away temporal blurring and you want to
6 try to freeze it. That is one case where you might see that
7 approach to do the last image hold, but I think it would be
8 unusual really, but there may be circumstances like that
9 where it might be a little bit of an advantage to go ahead
10 and take a higher exposure single shot instead of 10 lower
11 exposure but spaced in time further pop shots that blur the
12 image out.
13 DR. MARX: Okay.
14 DR. GAGNE: So, it leaves that flexibility. Quite
15 frankly, we don't really have a lot of experience at how
16 these things are done, and I would look to some of our more
17 experienced people here. I am saying that from my seat, but
18 we don't have a lot of experience as to how the last image
19 hold is implemented.
20 I think in most cases it is implemented in terms
21 of taking additional frames and just integrating them
22 together, but it seems like the scenario that I proposed
23 might be a candidate where you might want to do it.
24 DR. MARX: Okay.
25 DR. SHOPE: I just want to make the comment also

1 that, you know, you get some temporal integration going on
2 in the eyes, you look at fluoro image, you get one after the
3 other, but when you stop and you only get one, you have just
4 got to notice that one --
5 DR. MARX: That wasn't what concerned me. There
6 was something you said where it sounded to me like there are
7 some systems where it is not that they take more fluoro
8 frames, it is that they actually increase the rate of
9 exposure to achieve the image. Somehow that seemed
10 inconsistent with the goal of using this technique, but if
11 there is applications where you need that flexibility, then,
12 that makes sense.
13 DR. SHOPE: I guess I would also make the comment
14 that even if you do a few extra frames or you do a few
15 frames with increased exposure, that compared to another
16 minute or another 30 seconds of fluoro at normal rates is
17 still a considerable dose-saving probably even if those last
18 few you use for your last image hold is increased compared
19 to continuing the fluoro to do the observation is a
20 reduction.
21 MR. TUROCY: Just a comment. Many manufacturers
22 manufacture different systems. Some have the last image
23 hold as an option, which is fine, and that occurs basically
24 on digital systems. I would recommend that that remain an
25 option.

1 DR. FLETCHER: Let me, first of all, thank all
2 three of you for your presentations. I think you can gather
3 that the committee, one, is very interested in the
4 amendments you propose; two, have some very, very, I think
5 significant and thought-provoking comments that we
6 encourage, in fact, this is provided for you to take into
7 consideration as you further develop these amendments.
8 We do overall, I think, support what you are
9 doing, and I want to make sure that you understand that,
10 but, please, as you can tell from the discussions, there are
11 some concerns that you believe you should take into account
12 and incorporate in your amendments.
13 Having reached a point where I have to check the
14 watch, I will allow one short comment.
15 DR. SHOPE: Just one question, that is, the fact
16 that we haven't had comment on a lot of the other amendments
17 that we discussed, we will take as concurrence with
18 proposing those for public comment.
19 DR. FLETCHER: Thank you very much.
20 At this point we would like to move ahead in our
21 schedule. Our next presentation will be on the CDRH
22 Radiation Program Reengineering. Joanne Barron.
23 **CDRH Radiation Program Reengineering**
24 [Slide.]
25 MS. BARRON: I would like to talk to you today

1 about what a reengineering committee in the center is
2 working on, and you do not have to do anything as a
3 committee except to understand what we are doing and if you
4 wish to advise us, you may do so. This is not for a
5 performance standard, so it is not an official function of
6 the committee. We are simply asking you for advice.
7 [Slide.]
8 The team is made up of people throughout the
9 center. The various offices throughout the center are
10 involved in this process. In addition, we have someone from
11 the regional office in Dallas, so we have some people who
12 are familiar with the field functions and are familiar with
13 what the states are doing.
14 [Slide.]
15 Reengineering is being driven by the fact that our
16 operating dollars are continually decreasing, and we are at
17 the point now of trying to figure out how to keep the
18 operation going, let alone figure out how to continue any
19 programs. So, this is a pretty definite reason for trying
20 to make some improvements.
21 [Slide.]
22 In terms of the Radiological Health Program, back
23 in 1978, we had a full program that was the largest it had
24 ever been of about 400 FTEs. When the Bureau of
25 Radiological Health merged with the Bureau of Medical

1 Devices, it was down slightly, but a conscious decision was
2 made because the Medical Device Program was in such dire
3 need, that the Radiological Health Program was going to be
4 basically cut in half. We took a 50 percent cut at about
5 200 FTEs, and it leveled off there for about five years.
6 After that, several other things happened within
7 the Agency that caused that to drop, so what we are left
8 with today is approximately 60 to 70 FTEs in the
9 Radiological Health Program in general plus about the same
10 amount now in MQSA, which is a specific mandate.
11 [Slide.]
12 The reengineering effort began in November of '96
13 with the intent to improve the efficiency and effectiveness
14 while still achieving our public health goals, and the
15 method that was chosen is a business process improvement
16 method.
17 [Slide.]
18 Basically, that method looks like this. The
19 intent is to understand the customer, then understand the
20 process, and assess the process, and then to improve the
21 process to come over here and look and see if we can come up
22 with a 10 percent gain or a 10 times gain, look and see what
23 else is out there in terms of other federal agencies or
24 other scientific programs that have made some improvements
25 and benchmarks, look and see what is applicable to us, and

1 then simply the more traditional methods of improvement in
2 efficiency and effectiveness.
3 [Slide.]
4 The team decided to first look at the scope, what
5 are we really trying to cover, and we decided the first
6 thing we had better do is define what we mean by
7 radiological health. We went back to a 1970 department
8 document and defined radiological health as the art and
9 science of protecting human beings from injury by radiation
10 and promoting better health through beneficial applications
11 of radiation.
12 We would like to continue that and we even decided
13 that that is our core values. Core values should not be
14 reengineered. If, however, we decide our core value is
15 something different, then, we need to reengineer according
16 to that.
17 [Slide.]
18 The rest of the scope that we were trying to
19 decide -- this is going to be a little difficult to see --
20 in Tab F of your book, if you haven't found it yet, this
21 diagram is in there.
22 The venn diagram shows the three primary laws that
23 the center is enforcing, and the part that the Reengineering
24 group is looking at is this circle on the left marked RCHSA,
25 the Radiation Control for Health and Safety Act is the part

1 where we are going to concentrate for reengineering.

2 Where there is overlap with the medical device

3 law, we will be looking at only those areas where there is

4 something unique that we need to address. We won't be

5 looking at overlap with any of the medical device issues per

6 se, because the center has 12 other reengineering groups

7 that are addressing those issues.

8 The mammography quality area will probably not be

9 addressed at all because of that specific mandate and the

10 political ramifications.

11 [Slide.]

12 The specific issues for radiological health

13 include the shrinking resources and the expertise. Because

14 we have reduced so many FTEs, we don't have all of the

15 radiological health disciplines that we used to have, and we

16 don't have new hires coming in to fill in for people who are

17 retiring, so we are losing some of that expertise, and one

18 of the main issues we want to deal with is how do we

19 maintain the appropriate level of expertise to maintain a

20 functioning and appropriate program.

21 We have a problem of all that reduction causing

22 scattering of the activities that are going on, and we don't

23 have very good coordination throughout the center. That is

24 one thing we want to look at.

25 Of course, new technologies, we have difficulty

1 keeping up with. The relative priorities within the center
2 gets a little tricky sometimes. We have solved a lot of
3 problems and we don't do a good job of documenting them, so
4 that we can come back and say that is what we did and that
5 is how we can deal with it again, or it has already been
6 taken care of, we don't have to do it again, and sometimes
7 we lose track of that.
8 The basic reengineering question, should someone
9 else be doing it, for example, is there something the states
10 can do, is there something we can get academia or industry
11 to do, and so forth, and what happens if we stop, because
12 something is going to stop.
13 [Slide.]
14 Real quick, just to give you some of the things we
15 are looking at, in the ionizing area there is a lot of
16 different products that have issues that are current, things
17 that we are not getting to. Fluoroscopy, you are addressing
18 this morning. Cabinet x-ray has got some issues with new
19 technology. The people scanners, you are going to talk
20 about today.
21 The same old problems with TVs and VDTs, it is
22 still going on, and we have mostly because of a lot of the
23 imported products, companies in Third World countries that
24 give us problems that we are not getting to.
25 [Slide.]

1 In the non-ionizing area, the issue with sunlamps
2 that you will be hearing later today, the use by children in
3 high school, the laser pointers, things of that sort giving
4 us problems, airplane pilots with the lasers, those are
5 problems that we are not getting to as well as we would like
6 to, maybe we are doing as much as we should be.
7 Wireless technologies are just exploding and we
8 have barely touched the surface on that.
9 [Slide.]
10 I believe this one is in your book. What we
11 started with was the mandates to try to figure out what is
12 the law really trying to tell us to do, not that we are
13 going to be able to do all the mandates. In the device
14 area, there have been several parts of the device law the
15 center has just basically said we can't do them, we don't
16 have the resources.
17 That same thing may occur here, but we thought we
18 would at least start there. The main thing that is of
19 difference, and it is difficult for the center managers to
20 deal with, is that the device law is dealing with products.
21 The products are supposed to be safe and effective.
22 In the Radiation Control Act, what it says is that
23 we control the radiation exposure. It is just that the
24 products are the source of the radiation, and sometimes I
25 think we get too stuck on just the products, and it is a

1 bureaucratic mentality, I am sure, but we want to try to
2 make sure that we get back to dealing with exposures.
3 On the premarket side, we don't have any mandates.
4 We have some authorities, but we don't have any mandates.
5 On the standards area, we have specific requirements, as all
6 of you are familiar with, to not only develop the standards,
7 but to enforce them.
8 That is not true at least in the device arena, but
9 we now have in the device area and possibly under this
10 authority here, under the new Food, Drug, and Cosmetic --
11 no, Food and Drug Administration Modernization Act, FDAMA.
12 That law gives us the authority to recognize
13 standards, and basically put it in a self-certification
14 process. The implications of that and its overlap with the
15 Radiation Control Act has not been explored thoroughly, but
16 it is something we would definitely want to look at.
17 The next part that is unique, in the other laws we
18 have inspection authorities. What the Radiation Control Act
19 says is that we shall monitor industry testing. The
20 authorities it gives us are inspections and reporting from
21 the manufacturer.
22 In addition, this testing products mandate, down
23 here, that is unique, gives us a third option for monitoring
24 industry, testing actually. So, that is one thing we want
25 to look at to see if we are best utilizing our resources to

1 achieve that mandate.

2 These others, research, evaluating exposures,
3 conducting training, providing information and liaison, the
4 liaison is in the law to coordinate with industry and with
5 the academia. We think it is very important, but we are
6 trying to figure again how do we balance that.

7 [Slide.]

8 I don't know if you can see this picture, a
9 stakeholder, the customer. That is where we want to start.
10 The handout that was just given to you is the first
11 questionnaire that we sent out to try to get a handle on
12 some of the issues, and we sent them to all of the previous
13 TEPRSSC members, so those of you who are new may not have
14 gotten this.

15 In addition, we sent it to about five other
16 organizations, mostly trade associations. In looking at
17 that, we wanted to mostly see what were the areas where the
18 user -- in our form we use the term "customer," but what we
19 really meant was the user -- what are the user needs and
20 then what are the general stakeholder needs, and then what
21 are general stakeholder needs.

22 That little box up in the lefthand corner is what
23 we were trying to get at. If you will notice in the scoring
24 from the few people that have responded so far, we are
25 getting good confirmation that we have probably the right

1 user needs.

2 You will notice that for the stakeholder needs, it

3 looks like it is going to vary depending on the group of

4 people we are dealing with, but it looks like there is some

5 of the things that the center was interested in may not be

6 of interest to stakeholders and others that are of more

7 interest. So, that is one of the things we are going to be

8 trying to balance.

9 [Slide.]

10 One of the things that we are asked to look at are

11 those outrage factors, and the primary one is this first one

12 up here. "I didn't know I was exposed, and I didn't choose

13 the risk." One of the biggest outrages that we have to deal

14 with is people not choosing risk, and how do we deal with

15 that issue.

16 [Slide.]

17 The first thing you look at reengineering is what

18 does it look like now, so we are trying to assess the

19 current processes. If we have decreasing resources, and in

20 some cases we have only one person left in the center who

21 knows how to deal with something, and who knows when that

22 person is going to leave, we are not current on technology,

23 how do we feel with that issue.

24 The process is disjointed because there are so

25 many pieces that are spread all over the center, but they

1 are so small that they are hard to deal with each other.

2 We suspect there are a lot of disconnects more

3 than there are duplicates in those processes.

4 [Slide.]

5 So, we started out by looking at all the various

6 activities. This one was in your handout before, that is in

7 your book in Tab F. Each of the offices has primary

8 responsibility on certain things. We are going to be

9 looking at those that are most resource-intensive, those

10 that are probably the most important to achieving whatever

11 vision we set, and we will be looking at how expensive those

12 are and what we might do to improve those processes.

13 [Slide.]

14 I don't know if you can see this, but basically,

15 what we did was we took a look at the mandates in the law,

16 and there are four primary ones that we thought that

17 Congress was really trying to get us to hone in on. The

18 first is minimizing emissions and exposures.

19 If we look at those operations that we can

20 characterize within the center, research comes out at about

21 15 percent, and that is research, testing, also trends

22 analysis, so there is a little bit extra thrown in there.

23 Test methods and techniques to minimize came out

24 less than 1 percent, and yet it came out higher than what we

25 had originally intended so far in the stakeholder responses,

1 so maybe that would be something we would look at, whether
2 or not that needs to actually be improved.
3 Under performance standards, the review of
4 industry reports, the inspections, the product tests are
5 taking 34 percent. Unfortunately, we don't at this point
6 have a way of breaking that apart. Hopefully, with the next
7 center survey, we will be able to do that, but that
8 indicates to us that is the biggest bulk of what we are
9 doing, and probably is a prime candidate of where we need to
10 look.
11 Just managing non-compliances with the performance
12 standards is taking about 6 percent. Our legal actions and
13 imports problems are taking up at least 3 percent of our
14 activities.
15 The liaison and information is difficult to tease
16 apart, and some things may be in here that shouldn't be, and
17 some things aren't in here that should be, but it is running
18 probably something on the order of 25 percent. That is one
19 of the areas we are going to look at very closely and see if
20 we can pull that one apart, as well.
21 The studies and recommendations, this analysis of
22 the controls, the gaps, what the states are doing, what are
23 we doing with antiquated equipment, all those kinds of
24 things that are in the law are probably not something that
25 we are doing enough of, because I think if we did, we would

1 probably have a better program, so we are looking to see
2 what we might need to do there.
3 The reason I am showing you this is because one of
4 the things that we need to help us to reengineer any of
5 these is to have an overall vision, and so many of us in the
6 center are so buried in doing that day-to-day activity that
7 it is hard to step back and come up with that vision.
8 All of you have a different perspective, and I
9 think you can help us develop that vision.
10 [Slide.]
11 The second part of this is to look at what should
12 the processes look like. We want efficient and effective
13 processes, we want some specific goals, some known
14 priorities, and sufficient expertise to carry them out.
15 We decided that one of the first things we would
16 look at is what are the outcomes of whatever products that
17 we give to our customers, what is it we really intend to
18 achieve.
19 We decided that basically we want safe products
20 going on to the market. We don't want unsafe products
21 staying out there in users' hands. We want effective
22 products that are doing what they are intended to do. We
23 want efficacious products that have some kind of benefit to
24 society or at least if it is a medical purpose, it's a
25 medical benefit.

1 Efficacious use, this is where it differs from the
2 device law. The device law doesn't address that, and our
3 performance standards cannot address it, but the Radiation
4 Control Act says we are supposed to address it at least
5 through information processes. How do we deal with that or
6 who do we cooperate with to do that? Last, the educated
7 user.
8 [Slide.]
9 In our original survey, we had given people a list
10 of products we give our customers, and that little handout
11 you got today, I think it is on the third page. These are
12 just a couple of them, but basically, we were asking for
13 agreement, are those what you think we should be doing, and
14 we even estimated which ones we thought were highly
15 effective at achieving those outcomes that we wanted, of
16 safe products, effective products, educated users, and so
17 forth.
18 We got very few comments that anybody differed
19 with us except that the concept of scientific understanding
20 is not an output we give our customer. In a sense it is,
21 but in a sense it isn't, and so it is difficult for people
22 to understand what that is. But basically, what we want is
23 how much of a level should the center be in terms of
24 national expertise or international expertise or how much of
25 that should be outside the center. That is basically what

1 is built into that.

2 [Slide.]

3 So, if we go back to this process, to date we have
4 done a number of things to understand the customer,
5 primarily that questionnaire that we sent out. We have also
6 done some discussions with a couple of groups. I have
7 talked with primarily the Consumer Electronics Manufacturers
8 to get some input from them.

9 We have talked to a couple of other people,
10 specifically just to get some ideas more than anything else.
11 We have done a lot of that brainstorming that I told you
12 about. We are planning to do some workshops, probably
13 within the center for the most part, but we may want to
14 invite people in. If any of you are interested in
15 participating in that kind of a process, I would be
16 interested in hearing about it later.

17 We are also going to do peer-to-peer phone calls
18 to try to get input, so that the engineers within the center
19 can talk to engineers in academia or industry to get their
20 input, M.D.'s talk to M.D.'s, and so forth, and we think
21 that we will get a lot better rapport going that way.

22 In understanding the process, we have brainstormed
23 and ranked those outcomes and outputs I told you about,
24 categorized our activities, and we are just now starting the
25 flow charts to try to get down to the process level, which

1 is where the reengineering needs to occur.

2 [Slide.]

3 Our time line is basically that we are somewhere

4 in this process right now between process charting and

5 getting more input from the outside stakeholders. We are

6 going to continue with that flow charting process and try to

7 come up with a program direction within the next few months,

8 and we suspect by the first of the year we will be starting

9 to design some pilot.

10 When we tried our reorganization, if it is

11 something that is real simple to do and we can do it

12 basically and know what we are doing, we can just go ahead

13 and make that change quickly, but some of the other things

14 that are going to affect so many people, the idea is to

15 pilot-test it and see if it is going to work, number one,

16 and who it affects, number two.

17 If it is going to affect the industry, overly

18 burdensome, but it is not going to achieve the purpose,

19 there is no point in continuing, but a lot of them have gone

20 through the pilot phase very well and have gone directly

21 into implementation within the center. A couple of others

22 have gone back for a second phase of pilot.

23 [Slide.]

24 Our questions to you. Are there things that the

25 center is doing that somebody else should be doing? Should

1 the states be doing it? Should academia be doing it?
2 Should industry be doing it? Should nobody be doing it?
3 Those are the kinds of things we are interested in
4 getting back from you. We are going to get into this how
5 and how much. We are going to actually get down to the
6 process level and figure out the nitty-gritty on our end,
7 but in terms of a vision, we need your help.
8 What should we do that we are not doing? What can
9 we stop doing?
10 [Slide.]
11 In addition to the questionnaires, the committee
12 is open to any input that you have. There is an E-mail
13 address: Reengineering -- government is the code --
14 rego@cdrh.fda.gov. You can send an E-mail at anytime to
15 that address, or you can send it to me at jxb@cdrh.fda.gov.
16 I will be glad to entertain questions.
17 MS. KAUFMAN: Could you put up the overhead that
18 had the three circles? I think it is about the third or
19 fourth one that you had.
20 Is it only those items in the upper lefthand
21 corner in that circle are the ones that were being
22 considered for reengineering, that list?
23 MS. BARRON: We are going to start with that
24 circle.
25 MS. KAUFMAN: So, you are including those overlap

1 areas.

2 MS. BARRON: Yes, we are including it, but this is

3 where we are going to start. We are going to start at what

4 is radiological health first, because once we move into

5 these two sections, we have got two other laws that get

6 tangled in.

7 MR. WILSON: Have you got any data that shows how

8 much time you actually spend on the different categories

9 within that area?

10 MS. BARRON: Yes. This one. Those are based on a

11 time reporting system that the center has, twice a year, for

12 two-week periods, everybody voluntarily reports their time

13 into specific categories.

14 We did a little bit of crunching to take those

15 numbers and put them into here, because they don't quite

16 fit. That is why we are hoping with the next time reporting

17 we can split some of those apart and get some better idea of

18 how those break apart.

19 MR. WILSON: I guess my question really is if I

20 look at television receivers, microwave ovens, laser

21 pointers, CD players, all of those, which are the areas that

22 you are having to spend all your time in that fits into

23 this?

24 MS. BARRON: Oh, by product area.

25 MR. WILSON: Product area.

1 MS. BARRON: I am not sure we have a good
2 mechanism to do that. We would have to try to tease that
3 out specifically through a center meeting of some sort, I
4 suspect.
5 MR. SAVIC: Would it be possible to reproduce some
6 of these presentations that you have used especially that
7 one for those of us that may be interested in further
8 participation?
9 MS. BARRON: Certainly.
10 MR. TUROCY: Joanne, have you benchmarked any
11 other systems, such as the FDA -- not saying that the FDA is
12 bad -- but have you benchmarked, say, for example, Canada or
13 some other country?
14 MS. BARRON: Haven't for Canada yet. The primary
15 ones I have looked at so far, some of the states and their
16 programs, Department of Energy, and we are just barely
17 touching the surface trying to pull that in.
18 One of the things the center has been looking at
19 is the method that the European governments have been using
20 for doing less of setting criteria, letting other
21 organizations do that, doing less of the assessment,
22 conformance assessment, and having third parties and
23 accredited bodies, and so forth, take up part of that
24 process.
25 MS. KAUFMAN: I just want to insert a note of

1 caution because you mentioned one of the things that you
2 look at is what the states might be already doing or be able
3 to pick up, and I think one thing that FDA needs to keep in
4 the back of their mind is that whatever you do, that there
5 will be some states who will never do it, and that there are
6 states now who may be doing it, who may not be able to
7 provide that service in the future.
8 So, I don't think that you should go into this
9 depending upon any state performing any one function.
10 DR. LIPOTI: Joanne, I guess we are going to talk
11 in more depth later, but I picked up everything off of the
12 web site that FDA has on their reengineering, and I duly
13 impressed because it is not just the effort that you have
14 detailed here, but it is a whole effort in dealing with
15 FDAMA, Food and Drug Administration Modernization Act, and I
16 went through all this material, and I found that you must
17 have read all the same management books that I read, because
18 I picked up on 11 things that are very effective management
19 strategies that you already have employed or are endeavoring
20 to employ to really improve your process for dealing with
21 many, many items.
22 Because I was very impressed, I put this in a
23 letter to Dr. Burlington, 11 nice things I said about you,
24 so then you will forgive me if I ask you five questions.
25 These are the areas that I don't think you have

1 reached closure on, and I will try and help you, but I am
2 not sure -- I mean I don't have answers to these. I am very
3 concerned about how you employ your most experienced
4 reviewers, because I think that it is essential that you
5 deploy what remaining staff you have in the right function,
6 and it may be that what they are most necessary for is
7 determining when you get a new application for something,
8 whether or not it constitutes a whole policy change, whether
9 it fits within your regs or employed in some screening, so
10 that you can then put it in the right category.
11 There are certainly some things that can be done
12 routinely and improved routinely, but there are others that
13 require more thought, and I am worried about whether things
14 are getting in the right bin.
15 The second thing is that I am concerned about the
16 fact that you are not getting new people into your agency
17 very much, and that -- did you call yourself gray hairs --
18 but that gray hairs are retiring at a rather rapid rate, and
19 I am very worried about whether you have the pay scale to
20 attract good people into your organization, and how you
21 train the new people that come in.
22 I am a little bit unclear on which of the things
23 that were detailed on the web site, the 11 good things you
24 are doing, which you are exactly doing or which you are
25 planning on doing. I am not sure whether you are in the

1 implementation phase or have just thought of them and are
2 trying to implement them, but as impressed as I was with the
3 words that were written down, I am very concerned that it
4 actually takes root beyond your team, thinking of the right
5 way to review something, that the guy who has it on his
6 desk, or woman, change the way they do business, that they
7 don't review things exactly the same way they did yesterday,
8 that there is a change in their thinking.
9 I am not sure how you change the culture of the
10 organization. I know that is extremely important and
11 certainly it is important in nuclear power plants that are
12 trying to turn around their culture and become more safety
13 oriented, for you to now become risk-oriented, risk-based
14 and to make prioritization decisions, and for everyone
15 through the organization to do that is going to be tough.
16 MS. BARRON: May I address that? We actually have
17 a three-phase process for reengineering. The first phase is
18 to do the assessment and to do the pilots. The second phase
19 is to give it back to the offices for them to pilot it, and
20 in that process, all of the staff people are retrained, they
21 are able to try using it, figure out where the problems are,
22 rework it, and so forth, and then a third phase where it is
23 actually integrated into the culture. So, I think the
24 center is addressing that basic issue.
25 DR. LIPOTI: The last one I will talk about is how

1 states can help. I am very concerned about you trying to
2 foist off the routine inspections and say, oh, the states
3 will do them, so that you can concentrate really on your
4 targeted inspections, which I believe is what is highlighted
5 on the web site.
6 What are the incentives for states to help out
7 with this?
8 MS. BARRON: Part of the difficulty, but the
9 challenge of going to cooperative efforts is to find
10 something that has benefit to both parties, so if it has
11 benefit to the states and it has benefit to the center, that
12 maybe then that will proceed. If we don't have benefit on
13 one side, it will be awfully difficult to get those
14 cooperative programs to continue.
15 DR. LIPOTI: I would just warn you that states at
16 this point are targeting their inspections and going after
17 the bad actors and leaving the good actors alone, because we
18 only minimal staff, too, and so the routine inspections fall
19 very low on our priority list, too, particularly inspections
20 of new equipment where most of them conform, and there is no
21 benefit to spending a four- or five-hour inspection.
22 MS. BARRON: Right.
23 DR. FLETCHER: Let me just add one other thing
24 that as you perhaps explore new relationships with states,
25 be sure to understand what states are doing now. We have

1 talked on several occasions about the limitation in the
2 regulations that apply strictly to the manufacturer and the
3 device, and states are already doing everything else, so
4 have that in mind, because it is very difficult to take on
5 more.
6 Thank you very much.
7 MS. BARRON: Thank you.
8 DR. FLETCHER: The next subject to be presented is
9 one entitled People Scanners. We have Dan Kassiday and
10 Irving Smietan.
11 **People Scanners**
12 MR. KASSIDAY: Hi. My name is Dan Kassiday, the
13 Office of Compliance. I am doing this presentation because
14 we got a request to find out more information on backscatter
15 x-ray systems which are used to detect weapons carried by
16 people basically.
17 [Slide.]
18 This is Secure 1000, which is the first product of
19 this type that we looked at. It is also the first one that
20 made it to market. There are two manufacturers of these
21 types of products. It is not a very large industry. This
22 type of system uses a beam which sweeps in a roster pattern,
23 and then backscatter radiation is detected and interpreted
24 by software, and you can see here where it is showing what
25 this gentleman is carrying. It looks like plastic

1 explosives, that sort of thing.

2 These units do not use transmission of x-ray, it's

3 all backscatter. As you can see, there is a front and a

4 back view here. A normal scan will also involve side views,

5 so a four-sided scan.

6 [Slide.]

7 This is the other system, the Body Search by

8 American Science & Engineering. The Secure 1000 is

9 currently manufactured by Rapiscan. This one looks like it

10 has a bit higher resolution. I don't think there are very

11 many of them out there right now. It doesn't seem to be as

12 high a priority for that company.

13 [Slide.]

14 What did we do when we got this thing in-house?

15 Well, we had a look at it and after a couple of years'

16 reviews, memos, and that sort of thing, we have come to the

17 conclusion that it is not a medical device, it is an

18 electronic product which emits radiation, and it is not

19 covered or rather there is no standard which applies to it,

20 at least none of the FDA standards.

21 [Slide.]

22 These are the requirements for any manufacturer of

23 a product, electronic product, which doesn't fall under a

24 standard. They are required to file reports and records,

25 which is how we found out the details of the interlocks and

1 how much dose, and all that sort of thing, which gave us an
2 idea of what we should expect from this sort of system.
3 If something goes wrong with the system, they are
4 required to notify us if there is a defect or we can notify
5 them that we have determined there is a defect. I will get
6 back to that later. If there is a problem, we have got
7 basically a recall authority where we can require a
8 purchase, repair, or replacement of defective products, and
9 of course, if they were foreign manufacturers, which both of
10 these are not, they would be under the import regs.
11 [Slide.]
12 The expected dose from these sort of systems, and
13 the manufacturer's specifications and our calculations
14 confirm this, tend to be about 3 to 5 micro -- that is not
15 milli -- it's microREM for scanner Secure 1000. The dose is
16 mostly a skin dose, because this thing runs at about 50 kV,
17 and conservatively, we are going to go ahead and just
18 compare that to a whole body dose even though the
19 penetration of this radiation is not really deep enough to
20 be affecting more than the lens of the eye and the skin.
21 [Slide.]
22 Of course, we rely on the NCRP limits for doing
23 most things. This is the most recent batch from their new
24 report 116. When the system came in originally, it was
25 report 91 that we were looking at.

1 I have gone ahead and rewritten the units in
2 comparable format to what kind of dose. Remember Secure
3 1000 gives you about 5. NCRP says if you have got a
4 frequent exposure, then, what you should be looking at is no
5 more than 100,000 microREMin one year. Remember you are
6 getting 5 from one scan. That would be equivalent to 20,000
7 scans.
8 Then, of course, lens of the eye is higher of
9 skins, even higher than that, and we took a look at embryo
10 fetus. That is 50,000 in one month, and that is based on
11 calculations done from the Handbook of Selected Tissue Doses
12 for Projections Common in Diagnostic Radiology.
13 [Slide.]
14 Another concept that NCRP lists in there, a little
15 table of recommended doses, there is something called
16 negligible individual dose level, and it is 1,000 microREM.
17 The reason they have set it there is because the magnitude
18 of the dose is so small, it is difficult to detect the dose
19 or the health effects from something like that, and the
20 estimated risk for the mean and variance of natural
21 background kind of blurs something like this out.
22 [Slide.]
23 I told you I would get back to defect. These are
24 the kinds of conditions under which we can say there is
25 something wrong with a product like this. If it fails to

1 conform to its specifications, if they told us 5 microR is
2 the limit, that is the limit. They go above that, then, it
3 is defective, they would have to repair, repurchase, or
4 replace.
5 If it emits radiation unnecessary to the
6 accomplishment of its primary purpose, which creates a risk
7 of injury, we would have to use that. If another
8 manufacturer came in and wanted to use more exposure, we
9 would have to say, well, the job can be done with this. You
10 are using more exposure, why is that necessary, and if they
11 can't show us good rationale why that is necessary, they
12 would have to come down to meet the lowest achievable dose,
13 or if the thing simply didn't work, and Mr. Smietan is going
14 to I assume tell us that it does work and what they found
15 with them in use.
16 [Slide.]
17 So, if we do declare a defective -- I think you
18 are all aware of this -- these are our options. We can
19 force a recall, we can go to injunction, and we can do civil
20 penalties. We don't seizure authority.
21 [Slide.]
22 I have put together a couple of comparisons.
23 Another example of a product which we use for security
24 purposes, which we have a performance standard, is cabinet
25 x-rays even in all the airports.

1 They are both used to detect weapons, just ones in
2 baggage, ones on people. The standard for cabinet allows up
3 to 500 microR one hour, which if you do some conversions,
4 you could get 5 microREM by standing next to a leaking
5 system, in other words, one that is at the limit of the
6 standard, and under a minute. Most people aren't going to
7 dwell there, but, you know, lines go slow, you might end up
8 hanging around there while someone is fooling around with
9 the change in their pocket.
10 Also, cabinet systems tend to operate at a higher
11 voltage level, so more penetrating when they do leak.
12 Scanners right now have no standard although it doesn't say
13 that we can't write one for them. It is unlikely you are
14 going to go through one more than once in an hour.
15 [Slide.]
16 Similar argument for television. Television
17 receivers are again a non-medical product which we allow to
18 leak at up to 500 microR an hour. Actually, this is a rate
19 the cabinets in one hour. That is a maximum rate for these.
20 Similar comparison. The television receiver creates an
21 image. Well, this creates an image after it scans with x-
22 rays.
23 Television receivers are a much more widely
24 dispersed product. There is probably one in every home, if
25 not two. There is relatively few people that are going to

1 ever be exposed to these security systems compared to the
2 number of people that are going to be exposed to television,
3 and if you are going to say, well, most people sit far back
4 from the television, yes, that is probably true, but if you
5 have ever seen a child watching television, I am sure you
6 are well aware that they are not going to respect that
7 distance too well.
8 [Slide.]
9 Another question that has come up is what is the
10 benefit. Well, we agree that radiation exposure must
11 provide a benefit. Diagnostic x-ray, obviously, it is going
12 to help the patient. Cabinet x-ray, when you are just
13 talking about the baggage system, you are going to protect
14 the passengers that are getting on the plane and allow them
15 to go where they want to go. If they didn't want to walk
16 near it, they don't have to go where they want to go. It's
17 a cost. A television receiver theoretically provides
18 information. We will reserve judgment on that.
19 Cosmic rays, when you are taking an aircraft
20 flight, you are going to get a lot more dose from flying on
21 a plane than you would from going through a Secure 1000.
22 And people scanners, yes, you are giving radiation
23 to people, but they are getting a benefit from it. You are
24 protecting some population from possibly smuggled weapons,
25 and if you want to go to an area which is secured using one

1 of these, that is just the cost for going to where you want
2 to go. One of the uses, I guess, is visitation at prisons,
3 and that is a privilege, not a right.
4 One of the things we did look at when we looked at
5 these originally is what is the worst case failure, and the
6 worst case failure they came up with is if the beam stops
7 moving. That means you are going to have a dwell time, it
8 is going to be a small area exposed, and it is based on how
9 long it takes the interlocks to cut in, and it is 400
10 microREM, and the thing is interlocked, it moves in a sweep
11 pattern. There is interlocks from moving up and down, there
12 is interlocks from moving back and forth.
13 From what I remember there is interlocks on beam
14 current and fillables.
15 [Slide.]
16 How did we get to where we are? We discussed this
17 at what we used to have PMS committees which are internal
18 committees for reviewing various product areas. We went in
19 front of the Radiation Products Committee back in 1990. No
20 one seemed concerned about it then. We received comments
21 from our various offices, Device Evaluation, Science and
22 Tech, and again everyone generally agreed that the dose is
23 low enough, we are not going to decide this is instantly
24 defective, it is not instantly a hazard to health.
25 We attempted to talk to TEPRSSC back in 1991, and

1 as you know, there are a lot of meetings missed before now
2 and then, and we didn't make that meeting.
3 What I would like to do now is turn the mike over
4 to Mr. Smietan, so he can talk about the effectiveness of
5 the product. Additionally, the manufacturer of Secure 1000
6 has a representative here, and they are on the public
7 comment section. If you want more details about how the
8 system operates, we can maybe work them into this segment if
9 there is time.
10 DR. FLETCHER: If we could have one question.
11 DR. CARDELLA: Can you give us some idea of how
12 many such units are in the field?
13 MR. KASSIDAY: Right now I think it is about 50 or
14 so, 20 in the United States.
15 MR. SMIETAN: My name is Irving Smietan. I am
16 with the National Institute of Justice, which is an agency
17 of the Department of Justice. I am an engineer and the
18 program manager nationally for their program, Justice
19 Department's and probably the Defense Department's program
20 on concealed weapons detection on people.
21 In this program, we are not at all interested in
22 packages, trucks, whatever, only interested in what is on
23 people. Most of the work we are doing on this is aimed at
24 law enforcement and corrections. The primary users, since
25 there are many more of them at the state and local level,

1 that is where we are aiming it for. Defense, of course, can
2 take advantage of that, and we meet with them, and we
3 discuss all this.
4 We have a number of programs in this concealed
5 weapons detection program, probably about 12 now, but only
6 one of which employs this technique of backscatter imaging.
7 About two and a half years ago, or three years ago,
8 somewhere in that area, when we were examining the
9 technologies, at the time we had a request for grants out,
10 grant proposals, a number of different technologies came in,
11 and we have had successive requests for proposals out.
12 About three years ago I guess it was one of the
13 grant proposal requests that came in was from a company
14 called Nicolay, who developed it, and I guess sold the thing
15 to Rapiscan, but Nicolay is the one who we initially dealt
16 with. It looked interesting. We had not seen this
17 technology in use, so we gave them a grant -- well, it
18 wasn't a grant -- we contracted with them and we leased two
19 of them, two units, which we subsequently bought, the
20 government bought.
21 Our purpose was to expose the different law
22 enforcement corrections agencies within the United States to
23 this technology to see if it was of interest to them and how
24 could they use it. It seemed pretty effective to us.
25 Now, I am an engineer, so I look at it in terms of

1 how does it work and does it look like it works, but we had
2 a lot of input from the practitioners themselves in law
3 enforcement and corrections folks.
4 To make a long story short, and cover three years
5 I guess, two and a half, three years, we have placed these
6 machines at various places in the federal and state and
7 local systems. I believe Dr. Smith said there were 20.
8 Most of them I believe -- we have two -- and I think most of
9 the others are in the California State system. They liked
10 it after a trial period.
11 So, we have tried them all over. We have tried
12 them, as I said, in the federal system, we have tried them
13 in state systems, and local law enforcement corrections. We
14 didn't start out with any particular objective in mind as to
15 where to put it, just whoever seemed interested we would
16 lend them the machines for a few months.
17 I can give you some anecdotal information on them.
18 They have been very effective in my estimation. Some people
19 have considered them to be less effective. The main reason
20 is, gee, they haven't caught anything. Well, that is really
21 what they are supposed to do, not bring contraband into
22 prisons, for example.
23 In fact, I think all of the uses we have used them
24 are in jails or prisons, and this is not something you can
25 hand-hold. You saw the size of it there. It weighs about

1 600 pounds, and it is heavy even though it is on wheels, and
2 believe me, I have lugged this thing around myself with one
3 or two others helping or I have helped them, I guess, and it
4 is heavy. So, it is not something you casually walk down
5 the street with a long cord to plug in. So, jails and
6 prisons seem to be a more opportune place to use it.
7 I can give you some things that have occurred. We
8 used this in a federal jail. There were some prisoners
9 awaiting trial on drug charges. There were quite a few of
10 them. All of them were facing life imprisonment, and
11 according to the U.S. marshals had a standing offer out on
12 the street, $5 million apiece for anyone who can get them
13 out. These are not folks to play around with. I don't know
14 how many people are involved in the prison system, that is
15 another world.
16 Anyway, they knew that one of the prisoners, for
17 example, was carrying a weapon into court with him every
18 day. They searched him. They discovered that when they
19 noticed on the floor of his cell -- he was isolated, each
20 one of the prisoners had their own little cell -- where he
21 was sharpening it on the floor, a cement floor.
22 They could not find it, searched him, body cavity
23 search, strip search, tore the cell apart, couldn't find it.
24 He would go into the court. They would tear the cell apart
25 again, couldn't find anything.

1 We rolled the machine in and he went into court,
2 he left it in his cell. It was a piece of copper pipe about
3 so long, sharpened on one end, which he had hidden in his
4 rectum. They could not find it with a body cavity search.
5 He didn't know it at the time, but the machine would not
6 have found it, but he didn't know what the machine could do.
7 So, they were quite pleased with it in that even though they
8 couldn't find it, the deterrence factor was there, he didn't
9 know that, he felt that they would catch him with it, better
10 they find it in his cell than on him.
11 Other examples, we used this in a jail on the
12 prisoners coming back from work details. It was effective
13 in terms of finding contraband. They really weren't
14 concerned about weapons. These were guys who were going to
15 get soon, it was under a year, but they just didn't want
16 them bringing contraband back in. But they found that,
17 well, they had to strip search them anyway, and do body
18 cavity searches, and so they said, well, we are not going to
19 use this much because we still have to strip them down.
20 So, the moved it out to the visitors area, and I
21 am not sure whether they actually used it there or not, but
22 word got out to the visitors. The visitors were every
23 Saturday and Sunday, but they had the machine out there. I
24 don't think they used it. If they did, they used it for a
25 very short time, but they said once word got back what the

1 machine was, they would wander through the parking lot in
2 plain view, in the cars they would find weapons and drugs
3 and all sorts of stuff just lying in the car, not that they
4 felt these people were trying to smuggle them in, they just
5 didn't want to leave them at home when they left.
6 I spoke to the representative, technology head of
7 the California Department of Corrections as they had most of
8 them, and he was telling me they are now using them
9 extensively in the prisons and couldn't be happier with
10 them. They are using them on visitors as well as the
11 inmates.
12 What he says they found is they found they had
13 problems where they didn't even know they had problems.
14 They were finding things that they never knew were being
15 brought in by the visitors, and now they are finding drugs
16 and money and cigarettes, and not very many weapons, because
17 unless you are going to bring in -- well, it is just hard to
18 bring in. Most metal will be detected by the metal scanners
19 that they use. But they were finding all sorts of stuff in
20 the bushes, at the entranceway, the toilets, and the waiting
21 area before they came in, and he said it was just amazing,
22 they were discovering problems that they never knew that
23 they had.
24 That is a couple of anecdotal uses of the thing.
25 We have inquired and we are still not through rotating it.

1 We have used it in state prisons, I said in the local, and
2 again I am not a practitioner, I have to rely on the prison
3 people, jail people, to use it. We train them in it, which
4 takes about four hours, and that is what they use.
5 It has proven to be very effective in the
6 corrections world. The price has been a factor in why a lot
7 of places haven't bought it, but that is up to them to
8 determine the applicability, whether or not they can justify
9 the expense of it.
10 I have got some other stuff, but if anybody has
11 any questions?
12 DR. FLETCHER: Questions or comments? You say
13 there are 20 units in the field?
14 MR. SMIETAN: No, that is what Dr. Smith said. He
15 represents Rapiscan. Most of them I believe are in
16 California. We have two that the Justice Department owns,
17 and we lend these out. I don't know where the others are.
18 He may know, but he said there are 20, but we have two of
19 them. They are not in actual operational use consistently
20 because we move them around to different state and local
21 governments that ask for them.
22 DR. FLETCHER: So, they are mobile units.
23 MR. SMIETAN: Well, no, they are on wheels. We
24 pack them up in crates and we put them on trucks, and we
25 take them somewhere, and then we take them off, uncrate

1 them, and move them. I have done that, and it's heavy.

2 MS. KAUFMAN: I have some comments and then some

3 questions. I am from California, so I am very familiar with

4 the unit and the way it is being used in the California

5 prison system, and, in fact, I am not aware that they are

6 using it on inmates at all. I think that they are solely

7 using it on visitors.

8 Someone made a comment that if you don't want to

9 go into an area, then, you don't have to be subjected to

10 this. That is not true for visitors. If they want to visit

11 their loved one in prison, then, they must go through this.

12 The prison does not offer another option.

13 MR. KASSIDAY: Right. Visitation is a privilege

14 if they want to visit their loved one --

15 MS. KAUFMAN: May I finish? And you can say they

16 don't have to visit, but the biggest reduction in recidivism

17 for an inmate results from them maintaining ties with their

18 family, and I believe that that is what we all want is for

19 them not to get out and repeat crimes, so I don't think that

20 you want to have a policy that discourages if not outright

21 prohibits visiting.

22 The second thing is that someone made a comment

23 that people choose their risks. Under this environment,

24 they are not choosing their risk. They have no options,

25 number one. Number two is that they don't even know that

1 this thing produces x-rays. In fact, the guards who are
2 operating it don't know that it produces x-rays.
3 So, no one understands any risk that might be
4 associated with it, and they don't know that it produces
5 radiation. What they are actually doing in the California
6 prisons, one of the big issues on dose -- and I have seen a
7 unit, we measure dose -- I did get a higher dose than what
8 has been reported here, but we clearly are talking about a
9 low dose. However, distance is obviously a huge issue when
10 it comes to radiation dose, and there is no fixed distance
11 involved, and, in fact, what they are doing in California is
12 for the babies and small children, the mother holds the baby
13 up in front of the scanner, and then turns the baby around
14 and does the back, and then she holds the baby on her hip
15 while she is being scanned, so that the baby or small child
16 is actually getting double, if not quadruple, the dose what
17 anyone else would normally give.
18 The metal detectors in prison can be set to a
19 degree of sensitivity that they will pick up a filling in
20 your tooth, so when it comes to any kind of metal object, a
21 metal detector will absolutely work.
22 The inmates are always strip searched after a
23 visit, and their clothes are also searched, so it is not as
24 if there is just free-wheeling thing going back and forth.
25 It is certainly true that some things get into prison, but

1 if we are talking about drugs, it has to be a pretty small
2 quantity getting in through visitors because every inmate is
3 strip searched after any contact with the public, and I am
4 sure that is true nationwide.
5 MR. SMIETAN: Excuse me, ma'am, it isn't.
6 MS. KAUFMAN: Every prison that I have talked to
7 it is true. It is certainly true in all California prisons.
8 Now I lost my train of thought.
9 MR. SMIETAN: Sorry.
10 MS. KAUFMAN: If we look at CDRH's core value,
11 which Joanne was just talking about a few minutes ago, it
12 mentions that the core value is the art and science of
13 protecting human beings from injury by radiation. I think
14 FDA certainly did meet that standard when they looked at the
15 unit, but the rest of that core value is and promoting
16 better health through beneficial applications of radiation.
17 I think that one might be hard pressed to make the
18 argument that this is beneficial to the person being scanned
19 when there are clearly other means that they can achieve the
20 same things.
21 You were comparing to a cabinet x-ray unit and a
22 TV set, but this is the only unit that is specifically
23 designed to expose humans to radiation for non-medical
24 purposes, and that puts it in a completely different
25 category than a cabinet x-ray unit, where the radiation is

1 completely incidental, number one, and number two, the
2 cabinet units generally aren't -- it's not many people, many
3 of the people in the public who are exposed to that kind of
4 radiation off of a cabinet unit.
5 Lastly, and it is not really a part of this
6 committee's consideration, but I would like to bring up the
7 issue of privacy, because to some degree it is almost as if
8 the person is standing there naked, and, in fact, I have
9 heard from other inspectors in the state that the guards
10 were having a real hoot over looking at these images of the
11 visitors, and so I think invasion or privacy is clearly an
12 issue.
13 Now, I guess I am just making an argument that I
14 think that one might be able to make an argument that
15 inmates are a different population who certainly have lost
16 some rights, but when it comes to the public, I think that
17 that is an entirely different issue, and I think that the
18 radiation exposure is not the only issue that needs to be
19 addressed.
20 I recently went to -- I saw a videotape of a
21 course where they were talking about evaluating risk and how
22 the public looks at risk, and we all think of risk in terms
23 of scientific numbers and $10^{-6}$ risk of cancer induction, and
24 all of that. That is not the way the public looks at it.
25 The way the public looks at it is hazard plus

1 outrage equals risk, and when it comes to radiation
2 exposures, there is a certain amount of outrage, and I think
3 that we in our deliberations need to take that into account,
4 that even though we recognize that the risk of this
5 radiation exposure is small, you know, we have to represent
6 what the public wants from us.
7 That being said, I guess I don't have a question.
8 I think I just wanted to make a comment that I have some
9 real serious concerns about this unit. There has been talk
10 about putting it in airports, and I think that we just need
11 to think about what the public expects us to do, not only
12 what the actual exposures are.
13 I have been told that the California Radiologic
14 Society seriously opposes this unit, and so does the
15 California Radiologic Technology Society. There have been
16 lawsuits in California over the use of this unit. There is
17 one ongoing, and my understanding is that there is about to
18 be another one filed.
19 It is not an issue that the visitors are accepting
20 this. Number one is mostly they don't even know what it is,
21 they don't even know they are being exposed to radiation,
22 and once they find out, they are not at all happy about it,
23 and as I said, they really don't have an option. There is
24 no alternative other than not visiting their loved one at
25 all, which I don't think is an alternative that any of us

1 would like to impose upon anyone.

2 So, that's it.

3 DR. FLETCHER: Let me ask one question. Are these

4 units registered as x-ray units with the State and regulated

5 by the State at this point in time?

6 MS. KAUFMAN: A couple of them were, most of them

7 had not been registered. We were not aware that they were

8 out there even the ones that had been there, because we

9 didn't have any registration difference in terms of how they

10 would be identified, so we were not aware that they were

11 there until a lawsuit was filed, and that is when it came to

12 our attention.

13 MR. SMIETAN: If I may respond. First of all, let

14 me say that I have no financial interest in selling this one

15 way or the other. I don't really care. It's a technology

16 that is out there, and if state and local people want to buy

17 it, that's up to them to do. As far as the way California

18 uses it, I have talked to them, but that is a process that

19 they have to determine how they use it, and where they use

20 it, and what procedures and processes it is.

21 May I point out to you that while metal detectors

22 will detect all metals, and whatever sensitivity you can

23 give down to the fillings, guards can be and have been

24 killed, and prisoners have been killed by plastic and

25 various forms of plastic which can be made into knives and

1 sharp instruments.

2 In addition, depending on the sensitivity, and

3 prisoners are not supposed to have metal on them, I am not

4 sure I know what the California is, I know more the federal,

5 the federal prison system, they virtually have no metal on

6 them whatsoever, so if they set off a metal detector, there

7 is probably something wrong. I don't know if California is

8 the same way, it probably is, but I am not sure.

9 Most systems are similar to that, prisoners are

10 not supposed to have any metal, but they can get by with

11 plastic, which will go through, and plastic can kill just as

12 easily as anything else.

13 I really can't address the fact that visitors are

14 being put through these machines. I will tell you that I

15 have a very difficult time myself understanding how anybody

16 can recognize anybody on a machine. You can tell it's a

17 male, you can tell it's a female. I mean I myself have gone

18 through the machine, and I look like the Michelin man

19 without it, I look like a fat Michelin man in there, and I

20 must tell the inventor who is sitting in the audience I

21 think he made a terrible mistake in the software, everybody

22 looks short and fat in there. Had they made them tall and

23 thin, the machine might have had better acceptance.

24 But other than that, I don't think there is any

25 way you can -- you know, I have never been able to identify

1 who a person is, knowing who they are, looking at them
2 there, can't possibly tell who they are, I mean as far as
3 after the fact. I can tell it's a male, I can tell it's a
4 female.
5 MS. KAUFMAN: Right, but if you are standing right
6 there watching somebody being scanned --
7 MR. SMIETAN: Of course, of course, but I mean you
8 can't look at the picture and say, gee, that's someone.
9 There are ways around that procedure. Maybe for
10 females, you have female guards, I don't know. I mean
11 that's a procedure problem I feel. As I said, I am an
12 engineer, I am not a social scientist.
13 But as I said, I think that the effectiveness
14 certainly in the corrections world has been well proven. I
15 am not going to comment because I don't know the process, I
16 don't know the procedures on loved one visiting prisoners,
17 and how well they are searched.
18 I do know there are many videos I have seen of
19 visitors passing contraband items to the prisoners. Not
20 everybody strip searches after the visit. I know that.
21 The effectiveness has been fairly well established
22 in the corrections world. It is effective at deterring a
23 lot of the contraband that comes into the prison, which is a
24 source of a lot of problems. Again, I am not a prison
25 expert, I don't know. I look at it as --

1 DR. FLETCHER: I have one over here.

2 MS. KAUFMAN: Can I respond to him?

3 DR. FLETCHER: Briefly.

4 MS. KAUFMAN: In terms of effectiveness, I think

5 that that would diminish over time as soon as the visitors

6 or inmates realize what the unit could see and what it

7 couldn't see, and the unit that I saw --

8 MR. SMIETAN: But in order to get the

9 effectiveness, ma'am, you have to do it first.

10 MS. KAUFMAN: Right.

11 MR. SMIETAN: So that they understand what it is.

12 MS. KAUFMAN: But I am saying that the unit that I

13 saw, I think if you had something plastic taped to you, you

14 would not have been able to have seen it unless it was

15 pretty dense. In them manufacturer's own literature, they

16 say that out of the trial period, they used the unit on

17 9,621 visitors, and out of those, they found 17 cases where

18 they had something on them, which included cosmetics, money,

19 $2,000, some prescription drugs, safety and hat pins, and a

20 pager. I mean the only thing that I would be concerned

21 about on that list relative to health and safety would be a

22 hat pin. In other words, out of this study, they really

23 didn't find a lot.

24 MR. SMIETAN: Safety pins.

25 MS. KAUFMAN: A safety pin and a hat pin, 17 out

1 of 9,621. So, one question is, is it worth using this on
2 that volume of people to find -- I don't doubt that some
3 stuff comes in through visitors, the question is, is it
4 worth scanning thousands of visitors, you know, hundreds of
5 times to find that small an amount.
6 MR. SMIETAN: I am not sure they are scanned
7 hundreds of times, they are just scanned once.
8 MS. KAUFMAN: Over the lifetime of a course of a
9 visit.
10 MR. SMIETAN: Anyway, the corrections people I
11 have talked to think it's fine, they like it. The main
12 problem appears to be the cost of it, and that is something
13 with the state and local people to determine is that a
14 reasonable thing to do, but it will find things that nothing
15 else will find other than a strip search.
16 DR. LIPOTI: I have a few comments. First of all,
17 is the Justice Department aware of the state requirements
18 for registration of x-ray equipment, and when you bring this
19 into a state, do you register?
20 MR. SMIETAN: No, ma'am. We just turn it over to
21 the state, and it is up to the state to take care of
22 whatever local requirements are required.
23 DR. LIPOTI: Let me advise you that when you turn
24 it over to the state official, that you turn over along with
25 it a list of the state radiation programs, and that will

1 assist them in properly registering this x-ray source.
2 State programs have requirements for this, and I think that
3 perhaps you are doing an injustice to those that you believe
4 you are serving by showing them a piece of equipment, but
5 not assisting them in properly complying.
6 MR. SMIETAN: As far as I know, all the states we
7 have turned it over to have gotten their legal departments
8 before they have gotten it to examine the regulations within
9 the state.
10 DR. LIPOTI: No, they have not.
11 DR. FLETCHER: I would just ask that you -- the
12 committee is giving you some information that is useful.
13 MR. SMIETAN: I am sure that is true.
14 DR. FLETCHER: I would advise that you listen and
15 take it in the spirit it is given.
16 MR. SMIETAN: I am sorry.
17 DR. LIPOTI: The second point. I think this is
18 really a slippery slope, that it is used now in prisons. At
19 first you mentioned it was used to search prisoners, now we
20 find that it is used to search visitors to prisons, it has
21 been recommended for use at airports. I imagine that it can
22 be used to search people who are going to serve on juries in
23 their county courthouses, and high schools, as well. What
24 about high schools? They have a problem with weapons and
25 drugs. Why not use it use it a high schools? And well, the

1 middle schools, that is getting to be a problem, so maybe we
2 should install a few at middle schools, and, well, those
3 elementary schools, those sixth graders are trouble.
4 So, I just think it is a slippery slope when you
5 start saying that this can be widely used anywhere without
6 any restriction as to its applicability, but I think that
7 perhaps the FDA has limited authority in recommending its
8 area where it can be used, in which case the State
9 Government has the authority to restrict its use.
10 However, in the literature which was marked
11 confidential, on page 21, there is instructions --
12 MR. KASSIDAY: That has been fixed. We wrote them
13 a letter, they responded. They are taking out that
14 information, I believe.
15 DR. LIPOTI: Thank you because this is misleading
16 and wrong.
17 MR. KASSIDAY: I agree. That is why we wrote them
18 a letter.
19 DR. LIPOTI: But, nevertheless, it was in the
20 package that was supplied to us only several weeks ago, so I
21 am not sure it has been corrected, and I would like to see
22 evidence of that sent to me right after this meeting.
23 Sandia Labs, I am shocked and dismayed by the way
24 that they tested this piece of equipment. When I look at
25 the executive summary, it says that testing personnel were

1 volunteers, male and female, FAA Headquarters people,
2 Customs Headquarters, San Diego sheriff's office served as
3 subjects during the testing. I don't think you need to test
4 this on people. I think that you can use dummies for the
5 testing of this thing, and I really find Sandia should not
6 have done that.
7 And I guess the last point is the one thing that I
8 liked about this presentation, it was when you said that if
9 any other company comes in with something that does what
10 this thing does, but has a higher dose on it, FDA would find
11 that it was not acceptable?
12 MR. KASSIDAY: That would be what we would
13 attempt.
14 DR. LIPOTI: So that at least this is an upper
15 bound on the dose that these pieces of equipment would ever
16 be allowed to produce.
17 MR. KASSIDAY: Yes and no, because the only thing
18 we have is the defect provision, so we are going to have to
19 go through and make sure we can meet that definition, and I
20 believe we can since we have something that is effective at
21 a lower dose, but that could possibly get tested in court,
22 so I can't say that that will work.
23 DR. LIPOTI: When we get to the next committee
24 discussion, I am going to make a motion to suggest that this
25 committee go on record as putting a recommendation to FDA to

1 ensure that nothing higher than this dose ever gets used in
2 this manner.
3 MR. KASSIDAY: That would require a performance
4 standard which may be worth considering for these sorts of
5 products, and that might be a way to address the issue of
6 use. While we can't regulate use, we can certainly make
7 recommendations or recommendations for labeling, but through
8 a performance standard.
9 MR. THOMAS: This is not technology. This
10 technology I looked at in 1984-85 time frame. AS&E had a
11 medical scanner that was using the same technology, just a
12 different detector. They are using Photomultiplier in this
13 one.
14 I am sorry, I am not a state regulator, and
15 therefore maybe I am missing the point. I don't get quite
16 as emotionally wrapped with some of these issues, but I do
17 share some concerns here. The focus has been on benefit-
18 risk in the discussion and the benefit-risk has been what is
19 the benefit to the individual.
20 We normally think of that as result of
21 occupational exposure or from a medical exposure. This,
22 also, I see has a societal benefit, and the societal benefit
23 is very significant in the applications that it is being
24 used. I think, though, that we need to also strongly
25 recommend that it not be cavalierly moved from one prison to

1 the other with disregard to the regulations within that
2 particular state. I think that is what has been pointed
3 out. I am concerned also that we may have operators who do
4 not understand they are working with an ionizing radiation
5 source. Is that a problem with this piece of equipment?
6 Not if it is used correctly. But if somebody takes it
7 apart, it could be a potential problem for somebody getting
8 next to the tube.
9 If you look at the source to skin distance, that
10 varies, but again you are dealing with dose rates on this
11 particular piece of equipment that appear to me to be
12 relatively insignificant, and quite frankly, the biological
13 risk is quite small.
14 I am concerned about the way children are being
15 handled from what was reported. I think that is probably an
16 inappropriate way to evaluate that individual. I think that
17 I would look very critically at the techniques that are used
18 for evaluating people of different ages.
19 The fear factor, your parenthetical was wonderful,
20 going through the parking lot and picking up the contraband.
21 I am sure that something like this, the fear factor is very
22 effective in reducing some of the problems that we do have
23 in prisons.
24 Looking at some of the physics that I saw on this,
25 this appears to me to be incredibly effective looking at

1 backscatter, so plastics concealed on a body or, God forbid,
2 a plastic explosive should be very easily detected. Is that
3 a true statement?
4 MR. SMIETAN: We found that in tests. I have not
5 actually operationally gone when they have operated it, but
6 in our tests, we found plastic knives and plastic things
7 that could be explosives, could be anything, could be your
8 lunch, but it shouldn't be on the body, it is not normally
9 there, will show up very, very well.
10 MR. THOMAS: I guess my last comment is I agree
11 that -- I grew up in New Mexico, I know Sandia Labs well,
12 and the National Labs well, but I am very concerned about
13 the skills sets of the individuals who did the evaluation,
14 and their failure to appreciate that there might have been
15 better ways to evaluate the performance of this piece of
16 equipment, and I would recommend that if you are involved in
17 having it evaluated, that you have somebody who has
18 demonstrated skill sets and credentials in understanding
19 both radiation safety and also the associated imaging
20 components of the system.
21 I, for one, think that the system has a place in
22 society, and does indeed provide a benefit in consideration
23 of the risk, but I also recognize that our society is fairly
24 intolerant of using ionizing radiation indiscriminantly
25 because of the associated fear factor with what those doses,

1 even trivial doses, might be to them. They take far greater
2 risks driving down the road to get to see their loved ones.
3 I do support many of the comments that have been made, but
4 just in a little different way.
5 MR. SAVIC: It appears that there is a significant
6 degree of advocacy and enthusiasm at least on your behalf
7 for this type of a product. I am not really qualified to
8 comment on its use in prison population although I would
9 certainly share Kathleen's concern for the population that
10 is visiting, the small children, and being exposed to
11 radiation without any clear beneficial goal.
12 I am concerned, though with expanding this type of
13 product for the traveling public. I certainly hate to think
14 of passing by one of those with the ushers looking at me as
15 I pass there, but furthermore, there is a traveling public,
16 and I am not sure what that number is, but I would suspect
17 that it is in the 230 million plus annually, and I think
18 that would take this thing to an entirely different level of
19 public health risk.
20 From that perspective also, I felt that the
21 enthusiasm for the machine did a little bit of injustice in
22 comparing the exposure from that machine to the television
23 standard, which as you know is 500 microroentgen per hour at
24 5 cm from the screen.
25 I think it is unfair to use that as a comparison,

1 first of all, because that is when measured under certain
2 specific test conditions which involve worst-case component
3 faulting, misadjustment, and so on.
4 In reality, television sets do not emit exposures
5 anywhere close to that, probably hundreds of times lower in
6 typical installations and I think if you were to look into
7 that, you would probably find that the television picture
8 tube, by virtue of the type of construction that it has,
9 lead, barium, et cetera, and its glass, probably reduces the
10 background radiation directly in front of it, so I would use
11 that as a comment on your comment about children sitting
12 close to it. I think it is totally unfair. I think if you
13 performed the measurements, as I did, you will find that
14 television picture tube is probably a better shield for the
15 radiation in the 20 kilo electron volt, let's say, 50 kilo
16 electron volt. So, I would just urge you not to use that
17 comparison.
18 DR. MARX: I would share the concern of other
19 members of the committee that the biggest concern about a
20 device like this is the wider spread use with a much larger
21 population of people being exposed.
22 I would also suggest that even in the uses that it
23 is currently in, that there be some sort of labeling applied
24 to it to pregnant women or people who are potentially
25 pregnant know that it is ionizing radiation even if we can

1 all sit here and say, well, the fetus is really going to get
2 no dose from this because it is more than a centimeter deep,
3 et cetera, et cetera.
4 I think that the manufacturer and the users, the
5 people who are owning the equipment are putting themselves
6 at severe liability because 5 percent of babies are born
7 with some sort of defect, and if a woman finds out later
8 that she was exposed to radiation unbeknownst to herself,
9 she will feel outraged. So, I think that there should be
10 some sort of labeling.
11 MR. TUROCY: You mentioned the four-hour training
12 program given to the operators. Could you expand on that
13 training and what will you do in the future if it is used
14 elsewhere, or is that training sufficient for the operator
15 to understand that is really happening?
16 MR. SMIETAN: I said four hours, it could be a
17 little more than that. I don't remember the exact amount of
18 time, but there is a training process that was given to the
19 operators as defined by the manufacturer, and in most cases,
20 the manufacturer has done that, has done the training
21 themselves.
22 It tells them how the equipment works, gives them
23 the general philosophy of how it works, how to determine the
24 software, what to look for. I don't remember, frankly,
25 whether there is as much emphasis on what this device is and

1 the fact that there is ionizing radiation there. Certainly,
2 to the extent that you would like to see it, I just don't
3 know. I don't remember what the training consisted of.
4 DR. McKETTY: In the literature that we received
5 it said the training was just two hours. Now you say it is
6 about four.
7 MR. SMIETAN: I am sorry, I don't know.
8 MR. KASSIDAY: The information you received is
9 what was submitted to us by the manufacturer.
10 MS. KAUFMAN: The operators that we have
11 interviewed -- and this includes the operators in
12 Mississippi, which I believe is the only other state other
13 than California that has one of these units other than the
14 Department of Justice -- I am not sure that any of the
15 training involved a discussion of radiation. The training
16 involved how to use it and how to interpret the images, and
17 that sort of thing, and so, as I said, I don't any of it
18 involved that.
19 Oh, I did want to mention that there are some
20 states whose regulations specifically preclude this unit
21 because they designate that ionizing radiation can only be
22 used for medical purposes, so I don't know if this unit has
23 been given to any of those states, but in those states it
24 would be illegal to use it in a state prison at all.
25 MR. SMIETAN: I assume the state hasn't requested

1 it.

2 DR. FLETCHER: I didn't hear you.

3 MR. SMIETAN: I said if it is illegal to use in

4 the state, then, I assume the state has not requested it. I

5 don't know which states those are.

6 MR. KASSIDAY: In discussions with some of the

7 field people with the Department of Justice, they are well

8 aware of certain state restrictions, and we discussed the

9 issue at least on one or two occasions. I think Rhode

10 Island was mentioned.

11 DR. FLETCHER: I would just encourage that you

12 remind whomever your point of contact is to check with the

13 radiation control program of that state to ensure that they

14 are abiding by the regulations.

15 DR. LIPOTI: In the training when they finish

16 familiarizing themselves with the operation of facilities,

17 it is safe to say they then scan each other, so they can

18 practice?

19 MR. SMIETAN: Was that a question or a comment? I

20 am sorry.

21 DR. LIPOTI: It is a question. During the

22 training, after they --

23 MR. SMIETAN: I don't know, ma'am.

24 MR. KASSIDAY: I do not know either.

25 DR. LIPOTI: One of the first things we teach rad

1 techs is that they don't take unnecessary x-rays and that as
2 part of their training, they do not x-ray each other.
3 MS. KAUFMAN: If we are going to come up with
4 requirements for these units, I have a couple suggestions.
5 MR. KASSIDAY: We really not to that stage yet.
6 MS. KAUFMAN: Let me just mention a couple of
7 issues, though. On dose restrictions, because we have
8 talked about that, it is really difficult to measure the
9 dose on these units because it is low and the
10 instrumentation is difficult, so that it would be a
11 difficult issue to test out in the field as we test other
12 types of equipment.
13 The distance issue is an important one in terms of
14 right now the only thing that precludes distance is the
15 issue of scanning the entire body, so, for example, a short
16 person or a small child could be a whole lot closer and get
17 their whole body on, so that is another issue.
18 There is no indication of technical factors, so
19 that if one started drifting or something like that, you
20 might not see that.
21 MR. KASSIDAY: As I understand it, the units use
22 fixed technical factors.
23 DR. FLETCHER: Once again, we appreciate the
24 presentation. I want you to understand that you have a
25 wealth of experience here on this committee. We have got a

1 lot of circumstances that perhaps you are not aware of,
2 those who want to use this device are not aware of, and what
3 you have received, I believe, is a very good consultation
4 about the use of this device, and I encourage you very
5 strongly to take it into account as you go forward.
6 We will have at 4:30 and 5:15 the opportunity for
7 additional discussion on this matter. We thank you very
8 much.
9 MR. KASSIDAY: Can I make one more statement just
10 to remind the committee?
11 DR. FLETCHER: Real quick.
12 MR. KASSIDAY: FDA does not have authority to
13 regulate the use of the product. We have authority to
14 regulate the performance and safety of the radiation
15 emissions. So, discussions involving the appropriateness of
16 the product as far as privacy issues don't belong in this
17 discussion really.
18 DR. FLETCHER: Let me say once again you have a
19 committee in front of you from a lot of different agencies
20 and a lot of different experiences. The comments that we
21 have given you, please, take them into consideration because
22 it will affect the operation of this device throughout the
23 country.
24 MR. SMIETAN: If I may make one comment. There
25 have been some comments, talk about use in airports. I

1 can't speak for the FAA, I am not from the FAA, however, we
2 do talk to the FAA on a variety of things, and so far as I
3 know, and the people involved in the FAA who would have a
4 say on this thing, there has been no consideration of using
5 this in airports or travelers in aircraft, so I am not sure
6 where that information came from.
7 MR. KASSIDAY: We did discuss this product with
8 the FAA back in '91, '92, and while they were interested in
9 evaluating it, they had no intention of deploying it anytime
10 in the near future was my understanding.
11 MR. SMIETAN: I have talked to them more recently,
12 like this year and last year, and they have no interest.
13 DR. FLETCHER: Once again, we thank you very much
14 for the presentation.
15 It is now time for our afternoon break. Please be
16 back by 3:45. Thank you very much.
17 [Recess.]
18 DR. FLETCHER: Our final presentation of the
19 afternoon deals with U/V Product Safety. Three presenters
20 are listed: H. Cyr, Janusz Beer, and Jerry Dennis.
21 Please begin.
22 **U/V Product Safety**
23 DR. CYR: Thank you. I am Howard Cyr from the
24 Office of Science and Technology.
25 [Slide.]

1 For about six or seven years now I have been
2 joining our fellow photobiologists in looking at the risks
3 associated with UV emissions from various lamps. We have
4 had a couple of publications, UV Emissions from Sunlamps.
5 We have done something on UV from fluorescent lamps, and
6 also tungsten halogen lamps.
7 Today, we are going to focus only on sunlamp
8 products.
9 [Slide.]
10 This is a CDRH evaluation of UV-emitting sunlamp
11 products. Myself, and then there has been for some time an
12 ad hoc committee on sunlamps, many different people coming
13 and going, and actually, there have been a couple of
14 committees, ad hoc committees.
15 You will notice a don't have a sun tanning salon
16 up here or a sun bed. The only thing that I had in Power
17 Point that resembled UV at all was the sun, and you will
18 notice that the sun is setting, and that is a little
19 inconsistent with the topic because you are not going to get
20 much UV out of a setting sun. But anyway, that is as good
21 as I get.
22 [Slide.]
23 A little bit about the industry. These numbers
24 are guesstimates. We don't really have good numbers, but
25 this came mostly from the industry itself. We think there

1 are about 28 million users of sun tanning -- I said parlors
2 here -- let me do a brief interruption here.
3 I just got back from a meeting at NIH. We had a
4 three-day meeting on the risk and benefit of UV-emitting
5 lamps and also in tanning, a very good meeting on the
6 biology of things. I presented a similar talk here and used
7 the words "tanning parlors," and was rather moderately
8 chastised for that. The word in the industry is salon.
9 I think of a parlor as a nice living room in a
10 Victorian home. They think of a parlor as connected with
11 the word "massage." Please forgive it when I have put up
12 parlors here. I have made a faux pas.
13 We think there are about 50,000 salons. I have
14 heard 25,000, too, so I don't really know, and it is
15 debatable as to what constitutes a salon now. You can have
16 some with many bed, and others, you know, where there is one
17 lamp in a health club, and that could comprise a salon.
18 A $4 billion industry, 830,000 workers -- again,
19 take this with a real grain of salt -- here again, they have
20 full-time workers at a large salon versus a high school kid
21 that may work part time after hours in a health club that
22 had the one lamp there.
23 Some 700,000 home units, and the industry, in
24 addition to the 28 million users, has a couple of campaigns
25 here trying to target new customers, bringing in new

1 customers, particularly trying to get males to come to
2 salons. The users for the most part predominantly, I mean
3 there a rather high percentage, tend to be young women.
4 [Slide.]
5 Is there a health problem? We estimate 800,000 to
6 1.2 million cases of non-melanoma skin cancer. Most of
7 these are basal cell carcinomas. There is about 1,500
8 deaths from non-melanoma cancer, most of those from squamous
9 cell carcinoma. The more malignant form of skin cancer is
10 melanoma. We think about 40,000 cases and 7,000 deaths.
11 Now, when you compare these numbers to other
12 cancers, you will note that the number of deaths are not
13 large, maybe a total here of around 8,000 cancer deaths.
14 That is not large compared to something like lung cancer,
15 stomach cancer, breast cancer. The number of cases,
16 however, are gigantic. So, we are talking most about a
17 morbidity thing, not by mortality thing. An awful lot of
18 incidence is the problem, not death. Death is a problem. I
19 mean there is 7- 8,000 of them there.
20 [Slide.]
21 What do we know about these problems? Non-
22 melanoma skin cancer, we know that there is a connection
23 with solar exposure, and it is fairly well defined. There
24 is lots of studies. In particular, non-melanoma skin cancer
25 or the basal cell in part is probably connected with

1 intermittent exposures to sunlight, intermittent, probably
2 large exposure, sunburn type exposures to sunlight, as is
3 melanoma.
4 Squamous cell carcinoma, on the other hands, tends
5 to be more associated with a cumulative exposure, all
6 exposure to solar light is connected with squamous cell
7 carcinoma.
8 Melanoma is, as I say, I have it here as less well
9 defined. The dose response curve is not known well. The
10 connection again, although it has been connected somewhat
11 with intermittent, large exposures, the association is not
12 as clear-cut as it is for basal cell carcinoma.
13 The situation with sun tanning salons is even less
14 defined. There are a few studies out there, probably less
15 than a dozen, maybe four or five which have a positive
16 connection between tanning salon exposure and skin cancer.
17 The confidence limits of these studies are mostly epi
18 studies. The confidence limits for odds ratios are
19 enormous, lots of problems within each and every study.
20 [Slide.]
21 There is widely differing views on the magnitude
22 of the health problem. I am going to give you three views,
23 that of the dermatology community, that of the tanning
24 industry, and what I am going to label as "our own view."
25 The dermatology community looks upon any exposure

1 as dangerous. Tanning salons have contributed to skin
2 cancer including melanoma, and at one point even came as
3 close to saying that tanning salons should be banned. They
4 hedged off a little on that statement, but their initial
5 proclamation was that we should ban tanning salons.
6 The view of the tanning industry is that sunburns,
7 not tans, are the culprit. In fact, they have said that
8 tans, in fact, protect against skin cancer, are not only not
9 bad for you, they are good for you.
10 [Slide.]
11 Okay. I am so bold as to present our view. We
12 know that the basic biology of UV and tanning support
13 concern about some risk. I mean if you look at the
14 molecular biology, if you look at the things that are going
15 on at the cell level, pyrimidine dimers, strand breaks, and
16 things like that, there is a real connection there. There
17 has got to be some risk between UV exposure and tanning.
18 We don't know what the risk is actually with
19 sunlamps, but whatever that risk is, we need to compare it
20 with the risk from solar exposures. One of our concerns way
21 at the very beginning, and now, is these people who are
22 going to tanning salons, if you didn't go there, could get
23 the same thing by going outdoors for the most part during
24 the summer, maybe here in the wintertime you are not going
25 to get a tan, but you can get a tan from the sun, too, the

1 traditional way, and we also think much more data is needed
2 before the risk from sunlamps can be better defined.
3 [Slide.]
4 This, you may be familiar with. The FDA has a
5 sunlamp performance standard. It is in the Code of Federal
6 Regulations, 1040.20. It was written and entered into that
7 Code of Federal Regulations in 1980. In 1985, we made some
8 amendments to that standard, and shortly thereafter,
9 actually, I think the letter was written before the
10 amendments were published, but around that same time, there
11 was a policy letter written and sent out to all the
12 manufacturers on maximum timer interval and exposure
13 schedule.
14 The standard calls for a recommended exposure
15 schedule, how frequently one should get these tanning
16 sessions, particularly in the beginning it differs, I mean
17 you don't want to end up burned on really sensitive skin, so
18 you have a build-up schedule and then after a time that your
19 skin is acclimated, you have a schedule for maintaining that
20 tan.
21 This was never explicitly put into the standard.
22 It just says that manufacturers should recommend a schedule.
23 We explicitly put out a policy letter for such a schedule
24 and sent that out. As I say, that came around 1985, so
25 there is a policy letter on an exposure schedule.

1 [Slide.]

2 I have already hinted at this. The medical
3 community came to us and were very concerned about the
4 possible link between tanning salons and melanoma. This was
5 in 1994. What really spurred them was an article that came
6 from out of Sweden with just such a link, and I will speak
7 about that in just a minute, in some detail I will speak
8 about that.

9 More recently, we have received a citizen's
10 petition asking for changes be made to the dosage, that is,
11 the exposure schedule, also dealing with things that we deal
12 with here in CDRH, but our FDA thinks tanning accelerators,
13 sunscreens, these are drug products and sometimes cosmetic
14 products, and also asked us for an increased educational
15 effort to warn people about the dangers that can be gotten
16 from sunlamps. Of course, we have always had the ever-
17 present inquiries from press, medical community, industry,
18 and Congress.

19 [Slide.]

20 The 1994 request came from the medical community,
21 the American Medical Association, the American Academy of
22 Dermatology, the American Society for Dermatological
23 Surgery, and the Society for Investigative Dermatology --
24 and I remembered them all.

25 They got together and initially starting out

1 asking for a ban on suntanning lamps, and then a little
2 later on, taming that request down, but did ask us to make
3 changes to our standard to have an increased educational
4 effort. So, I said they initially wanted to ban interstate
5 sales of tanning equipment and/or increase the educational
6 efforts to warn patrons of the risk from sunlamp exposures.
7 [Slide.]
8 Here was the study. As I said, it was a Swedish
9 study linking melanoma with UV exposures from suntanning
10 salons done by Westerdahl, et al., in 1994. One of the
11 things was significant, a relative risk of 4.2, range from
12 1.6 to 11.0 melanoma on the trunk, I think for women only,
13 not for men. As I said, other epidemiological studies have
14 shown a similar correlation, others have not.
15 Again, this may be the sunburn versus tanning
16 issue controversy. They said they corrected for solar
17 exposure and other exposures. They gave no details on how
18 they did that. A lot was published in the press about one
19 other endpoint. It was again a melanoma, and I forget what
20 the site was, and they have a relative risk of 7.0, and the
21 confidence limits went all the way from 0.9 up to about 77,
22 or something like that, so you can see the data wasn't
23 terribly right on.
24 [Slide.]
25 The CDRH ad hoc looked at this request, looked at

1 that particular study, looked at other studies, and
2 concentrated only on the melanoma connection. We did not
3 really do much with basal cell or squamous cell carcinoma.
4 One of the problems we had with melanoma is that
5 there is only one available action spectrum right now, at
6 the time that we were looking at this. There are others
7 being developed right now, but at the time there was a
8 melanoma action spectrum done on a fish model. This is a
9 very little fish that does develop melanoma. Not many
10 animals develop melanoma. That is one of the problems.
11 This particular fish does.
12 They did the action spectrum on it. The studies
13 were done up in Brookhaven. Since then, there is a
14 marsupial that is being used out in New Mexico, and we have
15 gotten some data on that. I think there are a couple other
16 beasties out there. There is a goat. You can look at areas
17 around the nose and around the ear which aren't covered by
18 hair, and possibly get some data there. Goats and horses,
19 the horse is another one. You can't use those in a
20 laboratory situation, it is prohibitively expensive, and the
21 time frame for doing experiments would be out of sight.
22 One of the other problems was has enough time
23 passed to observe melanoma increase from sun salon use. We
24 know that when we get exposure to a carcinogen, there is
25 usually a latency period before the tumors develop, and I

1 have heard it said that there is probably as much as a 20-
2 year latency period between repeated exposures and the time
3 that you would expect a melanoma to show up.
4 So, one of our advisers said, you know, the
5 massive use of tanning parlors and massive use of sunlamps
6 has been relatively recent, and there really just hasn't
7 been enough time for us to see these things, so he
8 questioned the connection between melanoma and suntanning
9 salon use.
10 The other thing is there is a rather large
11 increase in melanoma. There are some hints that it may be
12 flattening off now in the last few years, but over the last
13 decade or so, the increase has been really dramatic, a
14 straight line increase of, as I said, up to maybe a few
15 years ago, and some people are saying that this is due to
16 solar exposure, maybe a little bit to suntanning salons.
17 Others are saying be careful, some of this
18 increase may be due to increased surveillance and the fact
19 that we can now look at thinner biopsies and smaller tumors,
20 and doctors are really out there, and they are searching for
21 these things, and so some of this massive increase may be,
22 as I said, due to surveillance.
23 [Slide.]
24 So, in terms of the melanoma situation and what
25 the medical community was asking us, we concluded the

1 evidence is suggestive but not conclusive of an association
2 between UVA and malignant melanoma. Although we have no
3 plans for an immediate ban on sunlamp products, we will
4 certainly monitor the biological and epidemiological studies
5 very carefully, and we will reconsider our original decision
6 if this seems warranted.
7 That concludes the stuff from 1994.
8 [Slide.]
9 A couple of years later, we have now gotten what
10 is called a citizen's petition. This came in 1997. We have
11 been looking at it for about the past year. We have a draft
12 response about ready to be mailed out. It has a few final
13 clearances to go through.
14 What was asked for in this was that we set maximum
15 annual doses. In addition to the recommended exposure
16 schedule, which was three times a week to get your buildup,
17 and then once or twice a week after that to maintain the
18 tan, there is an implicit annual limit in there, but not
19 explicit. He was asking for an explicit annual dose.
20 The International Standard done by the IEC has
21 such an explicit recommended maximum annual dose. He is
22 recommending that we do something similar. He is also
23 asking that we put in a melanoma warning despite the
24 fuzziness of the data linking melanoma with this, he said to
25 be safe in terms of public health, we should include a

1 melanoma warning on sunlamps.

2 Also, that all the warnings would be put into

3 users manuals. Well, it turns out that that is already a

4 requirement, so he is a little bit wrong on that request,

5 however, an extension of that would be to put the warning

6 labels into promotional materials.

7 He would like to have an educational pamphlet be

8 included for every client that comes into a tanning salon,

9 that they be warned about the dangers of UV exposure, and a

10 training certification program.

11 Some of these, like training certification

12 programs, some things about maximum doses, and all that,

13 would probably have to be done at the state level. These

14 are things that we here in FDA don't do. We do get together

15 with the states and come up with recommended state

16 regulations, so there is a role in terms of our making some

17 recommendations, but things like training certification

18 programs would probably, as I say, almost surely would be a

19 state program.

20 And he wanted us to go after tanning salons and

21 other people that make false claims like UVA is totally safe

22 or a tan is totally safe, it is only sunburns that are a

23 problem. Again, FDA has a role here, but also the Federal

24 Trade Commission has a role in going after false claims.

25 [Slide.]

1 This is not of concern to us, but I will tell you
2 there were additional parts to the petition that involved
3 other things that, as I say, the Center for Drugs and the
4 Center for Food Safety would be involved with.
5 They wanted warning labels on drugs and products
6 that are used indoors and tanning salons, and wanted to
7 remove unapproved tanning accelerators. These are lotions
8 and potions which sometimes claim to speed up a tan.
9 Sometimes they are just really SPF0 products, just baby oil
10 that does nothing. It doesn't give you a sunscreen, doesn't
11 really increase or accelerate it at all, but they are called
12 tanning accelerators.
13 He wants to have all of these products meet the
14 requirement of sunscreen monograph. This is a gigantic
15 volume that is being written by Drugs and has been in the
16 works for a number of years, and they have received -- what
17 could I call it -- ultimatum from Congress that this thing
18 will be done next year, so we can expect that the sunscreen
19 monograph will be finished next year.
20 They want to remove unapproved oral and vitamin
21 therapy claims, and inspect manufacturers of accelerators.
22 This one here, it would take me longer to explain what a
23 category II claim is, anything that changes metabolism, drug
24 products, in other words, they want them to remove products
25 with drug claims if they haven't been approved.

1 [Slide.]

2 What have we been doing? We have been looking at
3 our standard, our performance standard, and seeing if there
4 is any deficiencies in it. We have been working with
5 international agencies trying to see if we can get some
6 agreements on the units of exposure and in particular on
7 acceptable exposure guidelines.

8 One of the things I will mention in just a few
9 minutes is our definition of minimum erythemal dose -- we
10 abbreviate it MED -- is a little bit out of line with what
11 is being used in International Standards right now. It is
12 quite a bit lower that what is being used presently in
13 International Standards.

14 We have been sponsoring several symposia to help
15 define what these risks are. I mentioned one that happened
16 last week down at the NIH. About three or four weeks ago,
17 we had one at the National Institutes of Standards and
18 Technology on measurements, dosimetry of lamps, and as I
19 say, we have also been working with inter-agencywide
20 recommendations related to risk.

21 What we wanted to do to make sure was that if we
22 are responding to the citizen's petition that CDRH doesn't
23 come out and say that the risks from sunlamp exposure are
24 horrendous and have our sister agency, the Bureau of Drugs,
25 say that in terms of sunscreens, that the risks are trivial,

1 so we wanted to make sure we are talking with one voice on
2 this.
3 We have an inter-agencywide group. We abbreviate
4 it Photonet, Photobiological Network. We have been working
5 with the other two FDA groups to make sure that we know what
6 the risks are and can speak knowledgeably about those risks.
7 We are proposing to make amendments to the sunlamp
8 performance standards, and I will tell you about six items
9 that we are considering in response to this citizen's
10 petition, and in response to our evaluation of the risk from
11 sunlamp exposures.
12 One, I have already mentioned, and that is, let's
13 get an updated definition of MED. Our minimal erythemal
14 dose is low. It is 156 joules per $m^2$ as compared to what is
15 used in present International Standards, which are around
16 200 to 250.
17 We have one of our members, Janusz Beer, who is on
18 the IEC Committee, and will be going within a few weeks, I
19 think, to Stockholm to participate in this meeting and bring
20 this subject up. In fact, he is head of that working group
21 to come up with a new definition of MED.
22 Second, we would like to put the recommended
23 exposure schedule into the standard itself. As I pointed
24 out, right now it is in a policy letter only that was
25 written back in 1985. It is repeated in the state

1 standards. We repeat it frequently, and all that, but it is
2 no per se in the standard itself, and we are considering
3 doing that.
4 Let me say, though, that these are all
5 considerations, not we are going to do this, these are
6 considerations of things that we are going to do.
7 Number 3. We indeed are going to consider a
8 melanoma warning. It is justified, is it needed? That will
9 be debated.
10 Number 4. We are going to clarify the definition
11 of who is a manufacturer. If somebody in a salon changes
12 the bulbs and does something to them, that could make them a
13 manufacturer, and we want to make that perfectly clear.
14 Number 5. We would like to put the warning labels
15 -- they are already in the users manual -- but we would like
16 to consider putting them into catalogs, specification
17 sheets, and brochures, advertising, in particular.
18 The last one. We would like to get some hold on
19 replacement lamps and classify them. We would like to come
20 up with something, we are calling it an "erythemal efficacy
21 rating scale," so that when a lamp goes out, a salon will
22 know that lamp B over here is very, very similar to the one
23 that just came out of here, and I could switch one without
24 burning somebody or causing an adverse situation. So, we
25 are having an effort to put lamps into different dosage

1 classifications.

2 So, that is what we are doing. We are considering

3 changes to the sunlamp performance standard. I will take

4 questions. My two other colleagues, Jerry Dennis and Janusz

5 Beer, who may not have arrived, he had a conflict here, are

6 open for questions. They are not going to present anything,

7 they have left it to me, but we are open for questions.

8 DR. FLETCHER: Thank you.

9 Questions from the committee?

10 DR. CARDELLA: I was curious during your

11 presentation, many times you kept saying "he," instead of

12 "they." Is this one single individual's petition?

13 DR. CYR: One single individual signed it. I do

14 know that he had the support and was in collaboration with

15 other people, but it did come from a single person, yes. It

16 was signed by a single person.

17 DR. CARDELLA: I am curious in terms of your

18 opinion about the quality of the science. Are there any

19 good studies that show no effect or a strong effect, or is

20 it all so-so science?

21 DR. CYR: One of the epidemiologists, Richard

22 Gallagher, Vancouver, calls it "weight of evidence" when you

23 look at epidemiological studies. Most of these are

24 epidemiological studies in terms of cancer versus exposure.

25 There are an awful lot of them having a fairly

1 good connection between UV exposure and solar exposure, but
2 it is very difficult to break out tanning salons out of
3 that, because no one just goes to a tanning salon. Usually,
4 those people that go to a tanning salon also go to the sun
5 and have solar exposures.
6 Another complication is that in terms of solar
7 exposure, we get a good part of our solar exposure early on
8 in life, as kids, going out at recess and noontime and what
9 have you. We get burned, and usually by the time that we
10 are teenagers, we learn whether we suffer real sunburns and
11 should get out of the sun or not, but most of our exposure
12 is early one in life.
13 I guess the answer is I think in terms of solar
14 exposure that the weight of the evidence is fairly decent
15 that there is a good connection. Certainly, if you go back
16 and look at cellular studies and molecular biological
17 studies, things that elicit DNA repair and look at
18 pyrimidine dimers, and things like that, we have every
19 reason to believe that there is damage.
20 If you look at another endpoint, not just skin
21 cancer, but aging, photoaging, that is easy to see that
22 people who spend an awful lot of time in the sun get large
23 amounts of wrinkles, a good deal of freckling, nevi in the
24 skin, and things like that. So, yes, I mean there is a
25 great connection between UV exposure and that particular

1 endpoint.

2 The part with the tanning salons itself is

3 suggestive, not really strong.

4 DR. CARDELLA: Is the weight of evidence

5 sufficient in your mind that you would justify putting a

6 warning on a tanning booth that says, "This may cause

7 melanoma," similar to the warning that is put on a package

8 of cigarettes, for example?

9 I think personally the evidence is not that

10 strong, but I am curious to your opinion.

11 DR. CYR: I have heard both ends of that story. I

12 mean some people say you are right, the evidence is

13 suggestive only, it is not strong at all, enough to put a

14 melanoma warning on.

15 The other people will come back and say if you

16 really want to be cautious and to err on the side of

17 caution, then, you could put it on just to be on the safe

18 side, not that the evidence is really convincing, but just

19 to be on the safe side. That is where it is coming from.

20 We haven't made a decision on that one. That one is going

21 to be heavily debated, I am sure.

22 DR. ELDER: Following up on this point about

23 weight of evidence and connection with risk, this is

24 newspaper knowledge, but a couple of months ago there was an

25 article talking about a study coming out of Duke University,

1 where they were showing that UVA, if I remember correctly,
2 was causing a particular chemical change in the skin,
3 creating a very reactive molecule that could then cause then
4 additional effects on other chemicals, which is a little bit
5 different from what we had heard. You know, we are quite
6 familiar with dimers, and so forth, and so if you are not
7 aware of that paper, that work, you might want to look into
8 that, because it bears on the issue of mechanism relative to
9 an effect. Granted it is a giant leap of faith from that to
10 "melanoma."
11 DR. CYR: I am not sure I am familiar with that.
12 DR. ELDER: But it seems like a very significant
13 advance in the field.
14 DR. CYR: The conference we just came from at NIH
15 had several similar papers, and indeed there are lots of
16 molecular mechanisms that do not involve DNA and pyrimidine
17 dimers, but even with pyrimidine dimers, there are events,
18 there are molecules on the outer surface which are
19 triggered, and then trigger other molecules. There is a
20 whole cascade of things involving cytokines and
21 interleukins, and things like that, that go to different
22 target molecules and start a whole series of repair
23 processes and reaction to damage.
24 I think it is being worked out particularly well
25 for immunological -- and there is an immune suppression

1 phenomena also involved in ultraviolet radiation. That is
2 where I think I first heard of this cascade phenomena. The
3 molecule on the outside, I think is -- urocanic acid is the
4 receptor molecule for this immunological suppression effect.
5 DR. FLETCHER: Kass.
6 MS. KAUFMAN: I had read that article, too, and
7 originally, it is my recollection that these things
8 originally used UVB bulbs and that that discussion revolved
9 around maybe going to the UVA wasn't such a good thing. I
10 am wondering what your thoughts are. Are we still convinced
11 that UVA bulbs are safer than the UBV bulbs?
12 DR. CYR: We have certainly had a tremendous
13 debate about that. You are right, I think earlier on there
14 was more UVA in the bulbs -- UBV, excuse me. UVB can cause
15 burning, so you stand a chance of burning. When you switch
16 more toward the UVA, you end up with more tanning and less
17 burning.
18 What the industry was finding out, however, is
19 that if you went solely to UVA, it took longer to get the
20 tan, much longer apparently, and they started going back to
21 bulbs that contained some UVB. So, I think most of the
22 bulbs in this country have some UVB in there, as well as the
23 UVA.
24 Controversy centers around -- at one time there
25 was the statement UVA is totally safe, and it is relatively

1 safe. If you look at the action spectrum for erythema, if
2 you look at it for non-melanoma skin cancer, and you go into
3 the range where UVA is, it is order of magnitude less
4 effective at producing at the effects than is UVB.
5 However, we have had some other studies more
6 recently, this one that came out I described action spectra
7 on fish, that came out and just sort of oh, what we are
8 seeing in the UVA range is a whole lot worse than we thought
9 it was. If you looked at in terms of UV, the effectiveness
10 in producing in producing non-melanoma skin cancer was like,
11 say, 4 orders of magnitude less than UVB, however, in terms
12 of producing melanoma in this fish, it is only an order less
13 than UVB, and that scared people, saying, aha, UVA may be a
14 lot more dangerous that we previously thought.
15 That is one of the things, that, in conjunction
16 with the epidemiologic study out of Sweden, is what prompted
17 the medical community to come to us initially.
18 Every meeting you go to that this question is
19 asked, what is it with this fish, can we believe it, and I
20 guess as time goes on, more and more people say that's being
21 really cautious on this particular model, it's a strange
22 beast, and it has provided us with an action spectrum, but
23 its significance to humans is really in question.
24 MS. KAUFMAN: So, I take it the consensus is
25 still, though, that a pure UVB bulb, or as pure as you can

1 get, it is still more dangerous than that having UVA or UVA
2 combined.
3 DR. CYR: Well, you stand a chance of getting
4 burned more, although I mean on the other hand, I have heard
5 some people say let's do it that way because that is
6 nature's signal telling you you have got too much radiation,
7 so I have heard that side, too.
8 MS. KAUFMAN: In terms of the tanning versus
9 burning issue, where the tanning salons are saying that
10 actually it is safer because the tan protects you, was there
11 any resolution on that or is it under study still?
12 DR. CYR: It's a complicated matter because the
13 protection that UVA gives you -- and, as I say, there is
14 considerable UVA in these lamps -- UVA tan is a little
15 different than a UVB tan. There is more than just a tan in
16 terms of protection. You also get thickening of the skin,
17 so in addition to increase in melanin production, it also
18 has skin thickening, and I think you don't get as much skin
19 thickening, if at all, with UVA.
20 In the degree of protection that you get with UVA,
21 the numbers I have heard are not great. I mean its
22 protection factor is on the order of 2, I think, 2 or 3, so
23 you might be able to get double the dose that you could have
24 if you hadn't of built up this UVA tan.
25 DR. FLETCHER: Dr. Marx.

1 DR. MARX: I am not sure if this is a reasonable
2 question to ask, but I am just trying to get straight in my
3 own mind issues of relative risk, because this is not
4 something I have ever really thought about before, but as
5 you are trying to consider what to do about this technology,
6 would you say that the weight of the evidence for the
7 connection between skin cancer and tanning salon use is
8 stronger or weaker than the evidence linking silicon breast
9 implants to autoimmune disorders like lupus?
10 DR. CYR: Fortunately, I don't know that much
11 about it.
12 [Laughter.]
13 DR. MARX: That is the first thing that came into
14 my mind when you started talking about this.
15 DR. CYR: I can't answer because I don't know.
16 The only thing I know about breast implants is what I read
17 in the newspaper. I have been out of that loop.
18 DR. ELDER: I am not going to answer Dr. Marx's
19 question either, but on one of your slides, you made the
20 statement that much more data is needed before risk from
21 sunlamps can be better defined.
22 What can you tell us about what is going on in
23 that arena, has FDA or any other federal agency or
24 professional society developed a research strategy or
25 research needs document to identify what kind of work is

1 being done, is anybody actually doing that work?

2 DR. CYR: That was the purpose of the meeting that

3 we just came back from that was held at NIH. It was exactly

4 that, to bring in the people from around the world, and we

5 really did bring in people from around the world to see

6 where the holes were in research and what needed to be done.

7 We had the three-day conference and then the

8 people went away. The main participants had another meeting

9 afterwards and just gave us and the federal agencies their

10 recommendations as to what projects should be funded and

11 where do we go from there.

12 DR. ELDER: Is that going to end up being a

13 written document?

14 DR. CYR: I don't know. The proceedings will be

15 written. The proceedings were videotaped and will be

16 available in its entirety. Whether we are going to come up

17 with a written document of recommendations, I don't know. I

18 think we are still going to have some more meetings. We

19 were tired after three days, and we debated for an hour and

20 then went home and said we will finish this up later on.

21 I don't know if there will be a set of written

22 recommendations or not.

23 One of the things I should bring up, we are

24 talking about are the data sufficient for us to do something

25 stronger on that, more warnings, and what have you. Let me

1 step back because part of the problem that is being asked of
2 the medical community and others is that the things that we
3 have in place aren't being followed. It is a question of
4 tanning salons not following anything, people coming in and
5 day after day after day, timers being reset, going from one
6 parlor to another, and what have you. Part of the problem
7 is that our regulations, as they stand, are sometimes not
8 being adhered to, in addition to do we need changes, is how
9 do we get them to be compliant with what is already there.
10 DR. ELDER: You mentioned that FDA is about ready
11 to go out with a draft response to the Citizen's Petition.
12 My question is what are your plans for that, are you just
13 writing him the letter or are you planning to reproduce that
14 letter and send it to, say, states or to other federal
15 agencies? Is it just essentially going to be an FDA fact
16 sheet, because I, for one, would like a copy of that.
17 DR. CYR: I don't know the legalities of whether
18 that is made public or not. I know when the petition came
19 in, it goes over to the Dockets Office and everybody can
20 look at it. I know that the person who wrote it had no
21 qualms about discussing it, so everybody in the whole world
22 has seen the petition.
23 DR. ELDER: I am only talking about the FDA
24 response.
25 DR. CYR: I suspect that when we give a response

1 back to him, if he is in the same mind set, he will probably
2 give it to everybody, and it will be an open document
3 anyways, but I don't know if those things are public or not.
4 DR. ELDER: It is my understanding, I assume he is
5 a private citizen, so once it goes to him --
6 DR. CYR: I have been told that our response will
7 be public, yes.
8 State regulations, as far as I know, there is a
9 wide variation in what states do. Some have a great program
10 and there are quite a few that do essentially nothing.
11 DR. FLETCHER: That is exactly right. Just as a
12 follow-up to that comment, I know of eight states that
13 regulate tanning salons with varying degrees of requirement,
14 but most of the other states don't at this point in time.
15 DR. LIPOTI: This is a question which goes to
16 FDA's reengineering and prioritization, less going towards
17 the science of tanning, but it has a list of all of the
18 things that FDA is required to do and all the products that
19 you are required to look at, and when I look down the
20 ionizing spectrum, I see a bunch of products that you are
21 working on, and then I look at non-ionizing, and I see
22 sunlamps, lasers, cellular telephones, wireless
23 technologies, RF sealers, but I don't have a good way of
24 determining how much of your resource are used, for
25 instance, on the sunlamp tanning issue versus the laser

1 issue versus cellular telephones, or wireless technologies
2 or RF sealers.
3 How are your resources allocated among those, and
4 have you considered a risk-based allocation?
5 DR. CYR: I guess I am probably not the person to
6 answer that.
7 MS. BARRON: We do not have any information yet on
8 how we have been allocating. We are planning to try to get
9 some information. We are going to devise a prioritization
10 scheme, and we will definitely be bringing that back to this
11 committee to look at.
12 DR. LIPOTI: Maybe just a shorter question. How
13 many FTE know about sunlamps or are dedicated to sunlamps?
14 MS. BARRON: I am going to take a guess. Six.
15 DR. CYR: I know in OST we have some engineers,
16 and we have people in our Division of Life Sciences,
17 Radiation Biology Branch. In the Radiation Biology Branch,
18 there are probably four people, but they are not full time,
19 so maybe only two FTEs out of there, and in terms of the
20 engineers, I don't know, three at least.
21 DR. JACOBSON: I am Liz Jacobson from the Center.
22 We had information that we can pull together for
23 you on that, but one of the things that has been driving our
24 priority setting is what we have product performance
25 standards for, because those are on the books and we have to

1 enforce them.

2 I think if you noticed the earlier slide that was

3 put up on where we were spending our resources, something

4 like 50 percent of the available FTEs are going towards

5 supporting our performance standards, so that our priorities

6 are sort of set.

7 That is one of the reasons for reengineering

8 process for the rad health program, because we may not be

9 putting our resources to products that have highest

10 priority, and that is what we need to do and want to get

11 there, but right now I would say the standards program is

12 probably driving to a great extent where we are putting our

13 resources, and we have a product performance standard for

14 sunlamps.

15 DR. FLETCHER: Any other questions or comments?

16 MR. SAVIC: I would imagine it is fairly difficult

17 to quantify the types of exposures from UVA, UVB suntanning

18 salons to the outdoor ski area or seaside area either

19 because of the emission lines that are probably always

20 present in the suntanning lamps or I am not sure exactly if

21 any of the emission lines were somewhere in the UVA or UVB

22 range, but can you give us an idea for the relative

23 intensity or luminance or exposure, whichever unit you want

24 to give us, about the intensity of the UVA-UVB spectrum or a

25 portion of the spectrum from one to the other source, from

1 natural to artificial?

2 DR. CYR: If one goes frequently to a tanning

3 salon, you can get more UVA from the salon that you could

4 from the sun. Again, it is because the way the sunlamps are

5 set up there, there is more UVA coming out of those

6 proportional to the UVB, so you can, in fact, get more UVA

7 out of a suntanning salon than you could from the sun. You

8 have to go quite frequently.

9 I think Sharon Miller and I have a paper on this.

10 We did some calculations for people who went 100 times a

11 year. I think in terms of UVA, they got double, three

12 times, something like that, more UVA than they would have if

13 they got what a normal person would get, not someone who

14 goes to the beach all the time, but normal solar exposure.

15 MR. SAVIC: I did not mean on an integrated basis.

16 I am looking for instantaneous rates, not cumulative.

17 DR. CYR: Many of those in use I think are similar

18 rates to the sun, although there are some newer products in

19 which the dose rates are getting faster and faster, and

20 there is some -- what are they called -- high pressure UVA

21 units out there, which deliver the dose in a very short

22 period of time. Not many of them on the market, but there

23 are some there.

24 We brought this up saying that these are newer

25 units in terms of getting these higher dose rate exposures

1 at the meeting that was just held at NIH, and one of the
2 grand old men of photobiology, Jan Vander Luen, from the
3 Netherlands, got up and said they are not so new. He said
4 way back in Germany, when people used to work in the mines,
5 they didn't get enough solar exposure to produce adequate
6 Vitamin D, so they had to have some UV exposure from lamps.
7 The owners of the mines did not want these people
8 having 20, 30 minute sessions with UV lamps, and they
9 developed lamps that could give them the dose they wanted in
10 a few seconds. So, this kind of high dose rate lamps have
11 been around for a long time. They took them off the market
12 because, you know, man, if they ever mixed them up with
13 other lamps, and gave a 20-minute exposure with these
14 things, you would have some crispy critters on your hands.
15 MR. WILSON: On your six action items that you had
16 presented, from my viewpoint, I would like to support you
17 moving forward with those except for your third item on the
18 melanoma warning, because I would be concerned about
19 creating an undue alarm without enough data to support that
20 there actually is a problem, but the other action items that
21 you have on here I think make a lot of sense, and we ought
22 to consider supporting that.
23 DR. CYR: Thank you. I think that any melanoma
24 warning would have to be an iffy melanoma warning, possible
25 connection to melanoma.

1 DR. ELDER: In one of your slides you talked about
2 the view of the tanning industry being that sunburns, not
3 tans, are the culprit and tans actually are protective
4 against skin cancer.
5 What can you tell us about the weight of evidence
6 for the tanning industry position? My assumption is it is
7 considerably weaker than what the other weight of evidence
8 might be, but I am interested in your opinion on it.
9 DR. CYR: What I think came out of the conference
10 is that a tan is not innocent, there is damage with a tan,
11 but that sunburns probably are worse, so it is not
12 either/or, it is not that tans are completely safe and you
13 only worry about sunburns.
14 You probably worry about both of them, however
15 sunburns probably are worse. Certainly, there is a stronger
16 linkage between basal cell carcinoma and melanoma with
17 sunburns that with just tanning. There is a problem there,
18 though. I mean the association is pretty strong between
19 sunburns and these skin cancers, but people tend to remember
20 sunburns where they don't remember how much tanning dose
21 they got. You remember a severe sunburn, not well.
22 By that statement I mean they went back to people,
23 how may sunburns did you get, and they will come up with a
24 number. If you go back to the same people and ask them
25 again what their exposure regime was, how many sunburns did

1 you get, you don't get a consistent answer from the same
2 people. Trying to figure out people's exposure schedules,
3 how much dose you had over your lifetime is an iffy sort of
4 science.
5 DR. ELDER: So your comment on the degree of the
6 weight of evidence is?
7 DR. CYR: I think the weight of the evidence is
8 that tanning is probably bad for you, but sunburns are
9 probably even worse. I would not let the tanning industry
10 off that tans are safe.
11 DR. FLETCHER: I am going to cut off discussion at
12 this point because we are a little behind. We do appreciate
13 the presentation and additional discussion can take place
14 later this afternoon.
15 I understand that we do have someone signed up for
16 the open public hearing. Dr. Smith.
17 **Open Public Hearing**
18 DR. SMITH: My name is Steve Smith. I am
19 representing Rapiscan, one of the manufacturers of the
20 backscatter personnel security screening systems. I have
21 about a 10 to 15 minute slide presentation, which I think
22 will go over a lot of the questions you had earlier, which
23 the two representatives weren't able to answer, that really
24 should be answered by the manufacturer, and after that I
25 will be glad to answer any questions.

1 [Slide.]

2 This is the Secure 1000. It is physically about

3 the size of a large refrigerator. The person being screened

4 stands in front of it for 3 seconds.

5 [Slide.]

6 Then, he turns around and faces away from it for 3

7 seconds, and at that time immediately on the monitor is

8 displayed this kind of image.

9 [Slide.]

10 This is an image you have already seen, but I have

11 seen images additionally that you haven't seen which we will

12 talk about.

13 [Slide.]

14 These were actually taken from the Sandia report.

15 The objects you see up in the corner are film dosimeter

16 badges, which I will mention right now that after scanning

17 over 500 times, they all come back no reading, so those were

18 just a secondary check on the radiation measurement.

19 This object here is actual sebor plastic

20 explosive, [deta] sheet, neither of which is detectable by

21 any other kinds of explosive detection systems. This is

22 what people refer to as a plastic gun. It actually has

23 about 2 ounces of metal in it, but all of the handle and

24 most of the barrel and most of the receiver is all plastic.

25 That is also very difficult to detect with conventional

1 metal detectors.

2 You notice some other items on here, a metal tie

3 clasp. Here we have coins in individual pockets, metal

4 watchband. So, really, there is three advantages of this

5 system over conventional technology. First, it will detect

6 much smaller amounts of metal than conventional metal

7 detectors will.

8 The FAA views the limit of walkthrough metal

9 detectors is about 2 ounces of metal. This will detect as

10 small as about 100 times lower sensitivity in metal than

11 that, as little as a few grams, which in a prison setting

12 could be handcuff key or a razor blade.

13 The second advantage is it will detect non-

14 metallic objects including plastic explosives and drugs

15 which no other technology can detect.

16 The third advantage is it shows you where the

17 object is located. Of course, the conventional metal

18 detector just beeps and you have no idea where the object is

19 located on the person.

20 [Slide.]

21 I get a lot of questions about what female images

22 look like in the images. This is probably slightly more

23 benign than most female images are. This is one we use for

24 our distribution in literature.

25 What you see in a female image is the general

1 outline of the body. You can see wrinkles. If the woman
2 has large breasts, you can see lines delineating the
3 breasts. If you ask women generally what the object to in
4 the images, you get a lot of very diffuse answers, such as I
5 don't like the general idea, I don't like people looking at
6 the outline of my body. You don't get them centered on any
7 one particular thing, you get a whole range of comments
8 about why they object to it for invasion of privacy
9 purposes.
10 [Slide.]
11 As previously mentioned, the Secure uses a
12 backscatter imaging technique. We take a small x-ray source
13 using a fixed anode operating at 50 kV and 5 mA, make that
14 into a narrow pencil beam of x-rays, which then raster scans
15 over the body. At these energies, the most likely thing
16 for the x-ray to do is penetrate about a half a centimeter,
17 backscatter back out of the body where they are detected by
18 these large detectors, everything gets fed into a digital
19 computer and forms the electronic image.
20 [Slide.]
21 The system is very easy to use. This is the only
22 menu the operator has to worry about. The operators do not
23 have to be computer literate. There was a question earlier
24 about how much training the operators receive. If I was to
25 take anyone in this audience. it would take about 10 minutes

1 to show you how to actually use all the controls of this
2 system and conduct scans. The remainder of the time is
3 strictly image interpretation, the operators just looking at
4 image to image to image to be able to identify different
5 kinds of objects and also learn how to deal with people
6 coming through.
7 So, the question is about whether it is a two-hour
8 training session or a four-hour training session, really
9 just depends on how proficient the operator becomes in
10 interpreting the images.
11 [Slide.]
12 Next, we come to one of the issues which, of
13 course, is very controversial, and that is, is it safe,
14 particularly for things like pregnant women, infants,
15 children, people with pacemakers, and operators.
16 As the manufacturer, the answer we give is this is
17 absolutely and unquestionably safe. As a scientist, people
18 often ask me how I can make that strong a statement that
19 this system is absolutely safe with no uncertainty. Well,
20 on the next few slides I will show you why I maintain that
21 position and why the manufacturer maintains that position.
22 [Slide.]
23 The radiation dose produced by the Secure is 3
24 microrem per scan, and again, there is some controversy
25 whether it is 3, whether it's 5, whether it's 4, but it is

1 generally in that range. It is certainly not 10 microrem
2 per scan. When you get to these levels, it is very
3 difficult to do the dosimetry on them.
4 I will ask you to remember that number 3 microrem
5 because we will refer to that in later slides. Again, this
6 is 3 microrem, not 3 millirem.
7 [Slide.]
8 With radiation levels this low, the only realistic
9 thing you can compare them to is background radiation. The
10 radiation doses we are using is literally tens of thousand
11 time lower than medical radiography, but on the other hand,
12 we are exposing essentially the entire body whereas medical
13 radiography, of course, only exposes a small section of the
14 body. So, generally, medical radiography is a very
15 important comparison.
16 In comparison, background radiation is something
17 which is approximately the same energy level and it does
18 expose the entire body to the radiation as does the Secure
19 1000 scan.
20 [Slide.]
21 Here is a very nice graphic showing background
22 radiation compared to the Secure 1000. This is on an annual
23 basis. If you look at a person living in a high level city,
24 such as Denver, at 6,000 feet, you receive about 200
25 millirems or about 200,000 microrems each year. If you are

1 living in San Diego, such as the manufacturer, you are
2 hitting about 100,000 microrem per year. A single medical
3 x-ray at about 30 millirem, this is the additional radiation
4 you receive by living in a brick house for one year because
5 of the radioactive elements in brick.
6 This is a single cross-country airplane flight.
7 This dose from the Secure 1000 does not represent a single
8 scan. This represents two scans per day every day of the
9 year for the Secure 1000. So, that sort of give you a
10 general idea about the relative level of the Secure 1000 is
11 compared to these other, every-day sources of radiation.
12 Now, there is really three different ways you
13 could justify the safety of the Secure 1000 in terms of
14 using it in either prisons or other general purpose
15 applications, and I want to be very specific about these, so
16 I will number them.
17 The first one is the one that we have heard most
18 about today. You might make the claim that the Secure
19 1000's radiation dose is legitimate because you weigh it
20 against the society's need or an individual's need. Well,
21 then, that is a matter of what radiation protection
22 officials do. You say on this hand we have some risk, on
23 this hand we have some benefit, and we weigh the two of
24 those.
25 This is not how the manufacturer claims the safety

1 of the system. Well, it may be very true that the benefits
2 justify the risks. This is not how we are justifying the
3 safety of the system anyway.
4 The second way you might justify the risk of this
5 system is to say, well, the Secure 1000 radiation dose is
6 very far below background radiation and therefore it is
7 safe. Well, that may be a compelling argument and it may be
8 true, but that is also not how we are using that to justify
9 the safety of the system.
10 Well, the third one, which is the most compelling,
11 and which is why you can claim the system is absolutely
12 safe, is that the radiation dose from the Secure 1000 is
13 small compared to behavior-induced variations in the
14 background dose, and that is kind of a relative long
15 statement, so let me explain what I mean by that.
16 You get up in the morning. You walk into your
17 closet. You make a decision about whether you are going to
18 wear a sweater or if you are going to wear a sportscoat.
19 Well, throughout that day you are going to be exposed to
20 about 300 microrem of radiation for background radiation.
21 The decision about whether to wear a sweater versus
22 sportscoat or other kind of clothing is going to perturb
23 that radiation, natural background radiation, by a few
24 percent, and in effect, the decision to put on a sweater
25 versus a sportscoat is a 3-microrem decision for one day.

1 So, literally, if you classify the decision to put
2 on a sweater versus a sportscoat as unconditionally safe,
3 you also have to classify a 3-microrem dose from the Secure
4 1000 as unconditionally safe, and you can go on with these
5 examples forever.
6 For instance, the one that I like is if you make a
7 decision do you put your bed that you are sleeping in on the
8 second floor of your house or on the first floor, well, the
9 additional radiation because of that 10-foot additional
10 elevation is equivalent to two scans per week of the Secure
11 1000 if you go through the numbers.
12 So, literally, the Secure 1000 is unconditionally
13 safe because its risks from the radiation exposure are no
14 larger than the risks from daily activities that we all
15 consider unconditionally safe and that we do not make
16 decisions based on those kinds of risks.
17 [Slide.]
18 I want to make a few comments about what the
19 National Council on Radiation Protection and Measurements
20 has to say about low levels of radiation. This is from a
21 publication they put out in 1987 where they define something
22 called the negligible individual risk level.
23 This was prompted by their question, is there a
24 lower limit to which ALORA can be applied, and the answer
25 they came up with is yes, and the answer at the lower limit

1 is called the negligible individual risk level. They define
2 this to be up to 1,000 microrem per year for a single source
3 or practice, up to 10,000 microrem per year for all sources
4 or practices with the idea that if a single source might be
5 giving you 1,000 microrem, you might be exposed to as many
6 as 10 additional sources which could give you a total of
7 10,000 microrem per year.
8 What they stated about these radiation levels were
9 they are trivial, completely insignificant, are not required
10 to be considered for purposes of radiation protection, and
11 efforts to reduce the radiation exposure are unwarranted,
12 and again, these aren't my words, these are words from the
13 NCRP. I would like to point out that the NCRP has not
14 endorsed the Secure 1000 or tested it or otherwise evaluated
15 it. These comments by them are strictly related to
16 radiation levels and our dosimetry and outside agency's
17 dosimetry supports the dose of the Secure 1000 at 3
18 microrem.
19 As a manufacturer, we live by these kinds of
20 recommendations. When we are asked questions such as are
21 operators scanning each other when they are in the training
22 process, and the answer is yes, absolutely. You say, well,
23 "Are you concerned about that for radiation protection?"
24 Absolutely not. Trivial. Completely insignificant. Does
25 not need to be considered for purposes of radiation

1 protection.

2 [Slide.]

3 We currently have about 20 systems in operation in
4 the United States. Ten are in use in California, six have
5 recently been ordered, one in Mississippi, the National
6 Institute of Justice has two which they roam around the
7 country, and we currently have four systems operating in
8 Puerto Rico.

9 Our competing manufacturer, American Science and
10 Engineering, also has one system operating in a prison in
11 Montana.

12 This is typically how they are used. It is my
13 understanding that they are almost always used on visitors,
14 it is very seldom that they are used on inmates although
15 they may have some occasion to do that.

16 [Slide.]

17 I am sure one of the questions on everyone's mind
18 is where is this technology going to be going in the next
19 year and in the next five years. When we first envisioned
20 this technology and developed, we, of course, thought that
21 airports would be the final largest market.

22 The Secure 1000 has been on the market since 1992,
23 so it has been on the market for six years. During that
24 time, we have been able to generate 20 sales and over two-
25 thirds of those have happened in the last two years. So,

1 certainly this technology is not expanding at a rapid rate.

2 At the present time, the only facility in the

3 United States that we have a system installed in is in a

4 prison. Every time we have tried to install a system in

5 some other kind of facility, such as a courthouse, airport,

6 military facility, those kinds of things, the system has not

7 been successful, not because of radiation protection issues,

8 but because of invasion of privacy issues.

9 So, you ask me where do I think this technology is

10 going in the next two years, the next five years. Well, you

11 are going to see it in places that are already doing hand

12 searches on people, corrections, prisons, jails. You may

13 see a few precious metal applications that are concerned

14 about their employees stealing from them although we have

15 never had one installed in that kind of facility yet.

16 You may see them at Customs check points either

17 for security or contraband detection, but again one has not

18 been sold for that purpose. We haven't been able to

19 convince either Customs or another agency to sell it for

20 this purpose.

21 Law enforcement may use it in correctional

22 agencies, and again we may see some military applications

23 particularly for protection of nuclear materials. The

24 places I think you are not going to see these in the next

25 five years is lower security facilities, particular power

1 plants, embassies, courthouses, airports, and governments.
2 I would be extremely surprised in the next five to 10 years
3 if a Secure 1000 is sold to any of these.
4 [Slide.]
5 So, in terms of your general attitude about how
6 fast this technology is proliferating into other lower
7 security applications, that at the present time is not a
8 concern you should have, and my advice to you is that you
9 monitor the technology and reevaluate it in a few years to
10 see if these kinds of organizations do have an interest in
11 it, but at the present time, there are no sales pending in
12 these kinds of applications, and I do not believe there will
13 be a sale made in those in the next short period.
14 That is all of the slides I have. I would be glad
15 to answer any questions on the technology.
16 MR. SAVIC: If you could go back to I think second
17 or third slide where you have the image side by side.
18 DR. SMITH: I went over that very quickly.
19 MR. SAVIC: Way, way back in the beginning.
20 DR. SMITH: It's the second to the beginning
21 slide. I went over that quickly because Mr. Kassiday from
22 the FDA already showed that.
23 [Slide.]
24 MR. SAVIC: Am I seeing wrong or is there a gonad
25 shield or some type or is there an edited slide?

1 DR. SMITH: You have a good eye for images, very
2 few people can recognize that. Yes, it turns out what we do
3 is have something called a cloaking feature. We actually
4 use a computer algorithm to work its way up the groin,
5 identify the groin. We place a square patch with a material
6 which is a color and texture similar to background material,
7 and so it actually removed the detail in this one.
8 Some of our customers use that, some of them don't
9 use that. That was primarily put in place when we were
10 demonstrating the system at trade shows, and we were having
11 some objection from the people just in terms of them walking
12 by.
13 MR. SAVIC: I have a couple more questions. On
14 one of those slides you said, which is a typical use, I
15 believe, there was a female standing, and I am not
16 interested in the sex of the individual, but you said this
17 is a typical use.
18 Does that mean that a person that may be using
19 this routinely may be standing just a couple of feet away
20 from the individual that is being exposed and perhaps
21 getting some exposure each time a person walks up to this
22 machine?
23 DR. SMITH: The operators are instructed not to
24 stand in the main beam. If they are not standing in the
25 main beam, the only x-ray exposure they get is from the x-

1 rays that have been backscattered from the person.

2 If you go through the calculations, the radiation

3 doses are extremely low even for an operator in continuous

4 use, it is only a few millirem per year.

5 MR. SAVIC: Let me try and understand how this

6 thing works. You actually scan the beam, and then the

7 scanning unit is moving up and down, and that is what takes

8 about three seconds, I take it, it either drops or comes up?

9 DR. SMITH: Yes, that is exactly right. The

10 horizontal component of the raster scan in the horizontal

11 direction is accomplished by a rotating chopper wheel which

12 happens very rapidly. Then the vertical component of the

13 raster scan is obtained by physically translating the entire

14 x-ray source and chopper wheel about four feet.

15 MR. SAVIC: Okay. Now I want to get into the

16 dosimetry. What is the instantaneous rate of exposure if I

17 were to start the beam, what would I measure and what type

18 of instrument is used to measure and report the 3 microR

19 exposure?

20 DR. SMITH: That is two separate questions. In

21 response to the first one, what the instantaneous dose rate

22 is, if you could imagine that you were an ant on the surface

23 of a person, well, the radiation dose that that ant receives

24 is as this narrow pencil beam of x-ray sweeps by then, in

25 approximately a 50-microsecond period, they receive the 3

1 microrem of dose, so the instantaneous dose rate they would
2 receive is 3 microrem divided by 50 microseconds, whatever
3 that turns out to be, and the total dose they would end up
4 receiving is the 3 microrem.
5 The second question about the dosimetry, we knew
6 at the outset of this we were going to have trouble not only
7 from a documentation standpoint of getting this system to
8 people believed it was a low radiation dose, but just in
9 terms of manufacturing and how the dose would be measured in
10 the field.
11 The way we came with was to use a Victorine 450P
12 ionization chamber, which you just put that ionization
13 chamber directly in the beam and scan across it, and at that
14 time you can directly measure the 3 microrem.
15 Now, you might argue that that one is 30 percent
16 low for this reason or 40 percent high for this reason, and
17 you would have an instrument that measured, in fact, you can
18 get different readings in the range of about plus or minus a
19 factor of 50 percent or maybe a factor of 2.
20 The reason we chose that one is because it is very
21 repeatable and it is very easy to use in a manufacturing
22 setting and for field service.
23 MS. KAUFMAN: Hi, Dr. Smith.
24 DR. SMITH: Hello.
25 MS. KAUFMAN: When I was out at Rapiscan and you

1 were there, and we had a microR dosimeter, and we took some
2 measurements, and, in fact, you were the guinea pig for
3 that.
4 DR. SMITH: And I am still alive.
5 MS. KAUFMAN: And we got 11 microrem per scan.
6 And then we also did some work with the TLD, which we taped,
7 and I am specifically referring to the one that we taped
8 right on the inside, and that worked out to be about 14
9 millirem per scan.
10 Now, that distance was closer than anyone could
11 stand. I mean because you have got at least a couple of
12 inches for the panel, and you can't use inverse square log
13 because this is not anything like a point source, but the
14 dose can vary quite considerably depending upon obviously
15 distance where you are standing.
16 I think the 11 microrem probably is a real
17 reasonable number. I think that the 3 microrem probably is
18 too low. I think under my circumstance we are talking about
19 very low microrem levels, but I think that they are a bit
20 higher than what you reported in the literature.
21 DR. SMITH: Let me back up and ask you a question.
22 At one point today you said 14 millirem instead of microrem?
23 MS. KAUFMAN: Millirem, that is correct.
24 DR. SMITH: But that was the one that you taped
25 directly to the source as it was traveling up.

1 MS. KAUFMAN: No, we didn't, we weren't able to do
2 that. We taped it in one location on the front. We took
3 off the front panel, put a piece of tape across the front,
4 and just taped it in that one location, and the unit
5 continued to scan.
6 DR. SMITH: But that would be over 1,000 times
7 difference that what the -- if that is the case, I mean
8 there would be something very dramatically wrong. That is
9 representing the doses by a factor of 1,000.
10 MS. KAUFMAN: I can only report to you what the
11 results --
12 DR. SMITH: I would like to see those.
13 MS. KAUFMAN: Sure.
14 DR. SMITH: In response to your other question
15 about the 11 microgram, which the other meter read, and,
16 yes, I went through the calculations also. I would have
17 come up with -- to make it an apples to apples comparison
18 with some of the other tests we have done before and how we
19 were reporting it, and averaging over the entire field of
20 view, I would have claimed that was really an 8 microrem
21 reading, but the difference between 8 and 11, I think is a
22 matter of argument of how you measure it, but that, in fact,
23 was the highest reading meter we have ever tested it with,
24 and the problem is if you test it with that meter, and then
25 test it with the Victorine 450P ionization chamber, they

1 don't agree within a factor of 2.

2 So, we wouldn't claim that we know what the dose

3 is within probably a factor of 50 percent or 8 percent.

4 MS. KAUFMAN: What was the quantity of plastique

5 that was taped to that individual?

6 DR. SMITH: This is one-half pound. This is one

7 pound.

8 MS. KAUFMAN: It is a pretty large quantity.

9 DR. SMITH: This one is simulated plastic

10 explosive. If we can go one slide forward --

11 MS. KAUFMAN: That is lot of plastique.

12 DR. SMITH: The best baggage x-ray scanners cannot

13 detect one-half pound of plastique, so you think about if

14 this quantity is completely undetectable in luggage, if you

15 look for a comparison, Pan-Am 103, they believe that one-

16 half pound of plastique was used on it.

17 MS. KAUFMAN: I am just saying in terms of in

18 prisons, if we try and compare this to a plastic object,

19 which I realize this isn't, but I am just saying that I

20 think it takes a fairly large object made out of plastic

21 before you will see it on one of these scans.

22 DR. SMITH: Exactly. Of course, any security

23 system has its lower limit of detectability. Generally, in

24 public meetings, we don't like to reveal exactly what those

25 limits are for obvious reasons, if people hear about them

1 and learn how to defeat the system. I would be glad to
2 discuss that with any of the members of the committee after
3 the break what the actual limits of detectability are.
4 MS. KAUFMAN: In terms of metal detection
5 capability, as I mentioned before, the metal scanners in
6 prisons can be detected -- they are not anything like the
7 metal detectors that you go through at the airport -- they
8 are set at a much higher level of sensitivity, and they
9 literally can be set to a degree of sensitivity where they
10 will pick up a filling.
11 So, in terms of the metal detection capability, a
12 metal detector can do anything this unit can do, but it
13 doesn't pick up plastic.
14 DR. SMITH: I would very much dispute that.
15 MS. KAUFMAN: I know this for a fact.
16 DR. SMITH: When you are looking at a metal
17 detector, of course, you can turn the level of sensitivity
18 up. The question is what kind of accompanying false alarm
19 rate do you have with that detection sensitivity.
20 For instance, you mentioned the fillings in the
21 person's teeth. You say, for example, this one right here
22 is approximately one gram of metal. How could you possibly
23 detect one gram of metal on a person when they have
24 approximately 10 grams of metal in their teeth already. How
25 do you discriminate if they have that extra one gram of

1 metal on them or not? So, those are the problems.

2 MS. KAUFMAN: Dr. Smith, I have visited someone in

3 prison, and I can tell you they can pick up fillings. They

4 can set them at an incredibly high sensitivity level.

5 I just want to make a point again. You mentioned

6 choice, you know, in terms of a sweater or whatever, but

7 this patient, these visitors, I have a very compliant

8 population. They are scared to death where they are. They

9 are scared to death that the inmate that they are visiting

10 is going to suffer some kind of repercussions if they make a

11 squabble, and I don't think that this is a population that

12 really does have a choice on this issue.

13 Finally, I just want to mention that sometimes the

14 cure is worse than the disease, and this may be one of those

15 cases where what they are trying to find isn't worth the

16 exposure that we are making them undergo.

17 DR. SMITH: Certainly one of the comments I would

18 have related to that is if we were talking about a non-

19 trivial exposure, that argument may have some merit, but if

20 you believe the National Council on Radiation Protection and

21 Measurements, there is no risk here. Everything we are

22 talking about here, the radiation exposure is trivial,

23 completely negligible, and does not need to be considered

24 for purposes of radiation protection, and I think those

25 statements by them speak for themselves.

1 If you say we are protecting them from some risk,
2 what risk are we protecting them from?
3 MR. SAVIC: I am sorry, I am still not clear on
4 the dosimetry. If you use an ionization chamber, you would
5 be both time and space averaging, and maybe I need to
6 understand the size of the x-ray beam as it scans across the
7 visitor, if that is the case. Can you tell me what that
8 size is?
9 DR. SMITH: Sure. When it intersects the patient,
10 the beam is approximately 1 cm by 1 cm, and the ionization
11 chamber is perhaps -- whatever the standard is, 3 inches in
12 diameter, something like that, 2.5 to 3 inches.
13 MR. SAVIC: So, getting back to my original
14 question on the instantaneous rates, they could, for
15 example, if you used a small TLD at 10, 11 millirem, they
16 could be as high as 10 or 11 millirem instantaneously, is
17 that what we are talking about?
18 DR. SMITH: No, I don't believe that. I mean if
19 the reading she took of being 10 millirem were true, I mean
20 we wouldn't have a product, it would be immediately taken
21 off the market. But I mean in the last five years of us
22 taking radiation measurements, we have not seen anything
23 even nearly like that, and actually if you just look at the
24 physics, if you do the calculation of how much radiation can
25 be produced from an x-ray tube at 50 kV, 5 mA, using the

1 geometry, the number you get out is something like 3 to 5
2 microrem. So, we will just have to go back and look and see
3 what that number really is.
4 I am just putting that number aside right now with
5 the caveat that if that number ever turned out to be true,
6 we would out of business and you wouldn't even be hearing me
7 today. So, if you took a TLD and actually placed it on the
8 person's chest, you, in fact, would measure the 3 to 5
9 millirem, or if you believe the readings of the other
10 electronic one, maybe as high as 8 microrem -- 3 to 5
11 microrem or as high as 8 microrem.
12 MR. SAVIC: Have you done any TLD measurements at
13 all on these things?
14 DR. SMITH: Yes. In the early stages, before we
15 submitted the information to the FDA, we did the dosimetry
16 on it using many different methods. We used TLDs,
17 ionization chambers, direct calculation from the kV and mA,
18 by looking at the signal to noise ratio and inferring how
19 many x-rays were present, those kinds of measurements.
20 MR. SAVIC: And these were small TLDs, so that
21 they would be calibrated for this size? In other words,
22 they would be entirely immersed in the radiation field or
23 calibrated that way?
24 DR. SMITH: Yes. They would have been a 16th of
25 an inch diameter, something like that. We can certainly get

1 you all of that testing data. That is not only on file with
2 us, with the FDA also.
3 MR. SAVIC: I would be interested in instantaneous
4 rates. I know that most of the conventional science goes
5 against cumulative effects of radiation, but there is some
6 interest in instantaneous rates also.
7 DR. FLETCHER: Do you want to come forward.
8 DR. SERRA; Frank Serra from CDRH.
9 I haven't made any measurements, but perhaps I can
10 shed a little bit light on your question about the
11 instantaneous exposure.
12 If you just look at the mA, kV, and the x-ray tube
13 infiltration, within that 1 cm by 1 cm beam, at 1 meter
14 distance from the focal spot, you get about 10 mR per
15 second, but because the beam is moving so fast, there is no
16 way that any part of your body will receive that much unless
17 the beam has stopped and the interlocks did not work, and
18 even then, only that 1 cm by 1 cm square area would receive
19 10 mR per second.
20 So, it is possible that if you stop the beam and
21 you have 1 TLD in that location, that you will read that
22 much, but that is the only way.
23 MS. KAUFMAN: I can only report what the TLD said.
24 The way we did it, and the distance was closer, I forget.
25 This is 50 kV, and I forget, what is the mA? 5 mA. So,

1 this is like a dental unit. Dental units, you know, usually
2 have an exposure on the order of, you know, gosh, at 50 kVp,
3 of course, those are three-second -- well, you know, we are
4 usually looking at 4- or 500 millirem on a dental exposure
5 for a 3-second exposure at 50 kVp and 5 mA.
6 But the TLD was taped in a location that was
7 probably about 2 inches closer than the nearest location
8 that someone could stand. It was taped in one location, but
9 the tube swept up and down as it normally would, the tube
10 was not stationary.
11 We ran a series of scans, I forget the number, a
12 lot. I sent the TLD out for evaluation. When I got it
13 back, if I divide that number by the number of scans that we
14 took, it comes to be 14 millirem. That's all I can tell
15 you. It would need to be corrected for distance in terms of
16 population exposure, but that is a much more complicated
17 issue.
18 Dose on this thing is difficult. It is a very
19 difficult issue. That is one of the concerns is in terms of
20 compliance out in the field if these things are all over the
21 place, is evaluating dose out in the field would be very
22 problematic.
23 DR. FLETCHER: Other discussion?
24 DR. CARDELLA: Was the cabinet opened when you
25 were doing that? I mean could it be scatter radiation that

1 was contaminating the TLD, because that is a huge
2 difference.
3 MS. KAUFMAN: Actually, in this case, there was
4 much less scatter than under any other circumstance because
5 the front panel had been removed, so that is another issue,
6 is there wasn't the attenuation of the front panel, but I
7 was told that the front panel only attenuates -- Rapiscan, I
8 think Dr. Smith, said that the attenuation was going to be
9 on the order of 30 percent, so, in fact, this was a
10 situation where there was probably less scatter than under
11 any other type of situation.
12 For example, when we did the measurement with the
13 diode using an instrument, Dr. Smith actually held it on
14 his body, so there was backscatter -- well, no, actually,
15 there wasn't, because that diode has a backing to it that
16 precludes backscatter.
17 DR. SMITH: The answer to your question about how
18 much the backscatter affects it, it is about 30 percent.
19 Since we do a technique with backscatter, we know a great
20 deal about what the quantitative effects of r, and that
21 would only change the reading by about 30 percent, nothing
22 like the factor of 1,000 that we are talking about.
23 DR. GAGNE: I have no idea what kind of TLDs you
24 were using, but I do have experience with TLDs in CT
25 dosimetry, and in the TLDs that we use in CT dosimetry, I

1 think that the background noise on the TLD was on the order
2 of 10 mR. I don't know what you are using, but I am just
3 saying for those particular chips, we were talking about
4 systematic errors in the TLD value, about mR's anyway.
5 Is that right, Frank?
6 DR. SERRA: Yes.
7 MS. KAUFMAN: Actually, for TLDs, I think it is a
8 bit lower than that.
9 DR. FLETCHER: Let me get everybody's attention.
10 We are having comments coming from all over the room, they
11 are not being recorded and they are not being recognized, so
12 I need to reexert the chair's privilege.
13 I have called on Joe to comment just a minute ago,
14 and I am not sure he ever got his comment in.
15 DR. ELDER: My question is kind of minor, and it
16 really was different from this conversation, so please
17 proceed.
18 DR. SHOPE: Along with Bob, having some history
19 with TLDs and CT, I had the question. How many TLD
20 dosimeters were used, what was the reproducibility of that
21 kind of measurement or was this just a one TLD shot?
22 MS. KAUFMAN: We had a control TLD, number one,
23 and number two, the dose is so low that you couldn't get it
24 with one scan. I think -- I would have to look at my
25 numbers -- but I think we took like 100 scans on this

1 particular TLD, and that is why I am saying is if I take the
2 total dose and divide by the number of scans that we took,
3 that is where I am coming up with the --
4 DR. SHOPE: But even the variation in the doses
5 for 100 of these scans in TLD, I think you would need to do
6 a whole bunch of TLDs, and average that result.
7 MS. KAUFMAN: I absolutely agree. I can put a lot
8 of quantifiers on that dose, and I am only reporting that
9 that is what that one was.
10 DR. FLETCHER: Dr. Smith.
11 DR. SMITH: Can we just make a last comment on
12 this? Eight years ago, that is one of the ways we did
13 measure, is with the TLD, and we knew about these kinds of
14 problems with the readout noise.
15 What we did is we enlisted the aid of Landauer's
16 chief scientist who happened to be up the road from us. He
17 guided us through the experiment. We ended up scanning
18 special aluminum oxide TLD, so they were very sensitive.
19 We scanned them 500 times, and within one hour of
20 being read out, we scanned them and had them read out again
21 under his direction in order to accomplish those kinds of
22 things, handle those kinds of errors.
23 Did you take a standard reading, a TLD which
24 hadn't been exposed at the same time?
25 MS. KAUFMAN: There was a control TLD.

1 DR. SMITH: Oh, there was a control. Excuse me.

2 MS. KAUFMAN: When they did their TLD, was it in

3 air? Was the exposure in air?

4 DR. SMITH: Yes.

5 MS. KAUFMAN: And what was the distance?

6 DR. SMITH: The face of the scanner, taped to the

7 face of the scanner.

8 MS. KAUFMAN: On the other side of the scanner. I

9 can only report what it said. Dose, measuring dose on these

10 things is very problematic, I absolutely agree.

11 DR. SMITH: That goes back to my original

12 statement. Coming into this, we wanted to have some

13 dosimetry method, which is very repeatable both in the

14 manufacturing and in the service, and even though it may not

15 be the most accurate, it is the most precise.

16 DR. LIPOTI: Dr. Smith, you represent Scan 1000?

17 DR. SMITH: Yes, that is correct.

18 DR. LIPOTI: You could make a commitment for the

19 manufacturer of these units? You speak for them?

20 DR. SMITH: Yes.

21 DR. LIPOTI: Would you be willing to work

22 cooperatively with FDA on some voluntary types of things,

23 which might make the use of this more acceptable to states?

24 DR. SMITH: Very much so. We have had some

25 preliminary conversations with the FDA, and it would be very

1 much to our advantage to do that.

2 DR. LIPOTI: In a moment I am going to make some

3 recommendations. I am glad to hear your commitment.

4 DR. FLETCHER: Thank you all very much. Dr.

5 Smith, thank you very much.

6 We have now entered the time period for Committee

7 Discussion on all of the presentations. As you recall from

8 our earlier discussions, this is the time that we can either

9 put forth recommendations of actually put forth a motion

10 that we vote on to give guidance to those who have presented

11 information to us.

12 The floor is open for further discussion or

13 specific recommendations.

14 **Committee Discussion**

15 DR. LIPOTI: I wrote down a rather lengthy two-

16 part motion here, but let me just first describe what I am

17 trying to do and then we will go through the wording of the

18 motion, because people may have ideas.

19 The first thing that I want to do is I would like

20 to request that FDA do two things. In the immediate future,

21 I would like them to begin to work cooperatively with the

22 manufacturer of people scanners, and I have four goals for

23 that cooperative effort.

24 The first is to make sure that state regulators

25 are made aware of the use of any of these devices within

1 their state.

2 The second is to make sure that the x-ray machines

3 are properly registered.

4 The third is to ensure that users are properly

5 trained. I have a lot of respect for the NCRP, and they are

6 a terrific scientific organization. Their policy in this

7 case is set by the regulatory agency, and I believe that the

8 curriculum must include a description of the fact that x-

9 rays are produced from this machine, that there are

10 biological effects of x-rays, and that ALARA principles

11 should be used including one should not scan each for

12 practice.

13 The fourth one is that the units are properly

14 labeled. I put together a warning label based on what is in

15 the other regs that FDA does, but the specifics here are not

16 important. What is important is the principles.

17 For the longer term, I would like to request that

18 FDA work on a performance standard to preclude any other

19 manufacturers or any further people scanners, and I would

20 like to set a dose limit as the limit which the manufacturer

21 stated comes from these machines, which is 3 microrem.

22 Now it may be in debate as to whether this thing

23 actually makes 3 microrem or 4 microrem or more, but I think

24 that we should hold the manufacturer to the specifications

25 that they have put in our packages, which was 3 microrem.

1 So, that is the gist of the motion. Now I will go
2 through the specifics.
3 Did you want to hold discussion first, so I might
4 make a better motion?
5 DR. FLETCHER: Does anyone want to contribute
6 comments or perhaps give a different direction to anything
7 that has been discussed? Dr. Savic.
8 DR. CARDELLA: I think that I agree with
9 everything you say, Jill. I think it is going to be a
10 little tough to regulate to 3 microR. My preference would
11 be to say 3 to 5, because I am not sure that (a) we know
12 it's 3, and (b) it's very difficult to measure as we have
13 heard from several speakers. So, if we could give a little
14 bit of latitude, I believe that 3 microrem is still low, and
15 I think that it would not give the appearance of being
16 exclusionary.
17 In other words, if the best radiation number he
18 cna give us is 3 microR, and he says, you know, sometimes it
19 is 7, sometimes it's 5, and you make him and hold him to 3,
20 then, you have closed the industry down, and I don't know
21 that that is your intent. I think your intent is to not
22 have one come on the market that is 50 microR.
23 If you are in agreement with that, then, I think
24 we should give a little latitude.
25 DR. FLETCHER: What I would recommend at this

1 point, if there are no other specific comments to that part,
2 why don't we --
3 MR. THOMAS: I agree in principle, but there are
4 two points, Jill, that you have raised that cause me a
5 little bit of concern. The one concern that John just
6 raised was one of them.
7 Quite frankly, the dosimetry on this, there are
8 those of us that have done this for a living, and I am not
9 sure I agree with the way it has been done or discussed or
10 reported in this meeting by members of the panel, as well as
11 members in the public.
12 There are experts within the United States that
13 can properly measure that. I don't think it has been
14 appropriately measured, so it is inappropriate to set any
15 limit for doses.
16 The other thing I have got great concern with is
17 the implication of the biological effects of x-rays.
18 Biological effects are a function of multiple factors, beam
19 energy, beam quality, area exposed, time of exposure,
20 exposure rate.
21 To make a general statement that says x-rays are
22 dangerous because they have been shown to be cause
23 biological injury is a true general statement, but may be
24 necessarily inappropriate for the radiation quality, half-
25 value layer coming out of this piece of equipment. I am

1 concerned making a statement without scientific fact basing
2 it, that it would be based on.
3 So, I would suggest that when we look at the issue
4 of user training, the user training needs to indicate what
5 the true risk for this particular piece of equipment is
6 based upon currently known scientific evidence if that is
7 the committee's feeling that that needs to be foistered --
8 not foistered -- but needs to be included into the
9 recommendation.
10 I do, however, strongly agree with both the short-
11 term goals and long-term goals in general. I think this is
12 a product that has a place in our society. I also think it
13 is a product that needs to be appropriately managed and
14 regulated by the FDA.
15 DR. FLETCHER: Stan.
16 MR. SAVIC: Just one minor comment. I was writing
17 down the four suggestions that are part of the motion, and I
18 agree with Jerry Thomas' statement fully. I added a fifth
19 item, which would fall in the category of radiation
20 characterization, which I think would be addressed by FDA
21 either internally or through use of outside experts to
22 indeed fully characterize the type of radiation before we
23 talk about the amount of emission.
24 DR. FLETCHER: Kass.
25 MS. KAUFMAN: Dosimetry on this thing is very

1 problematic, and frankly, I don't think this unit will meet
2 the 3 microrem per scan limit if that is what you are
3 thinking.
4 I just want to go on record as saying that,
5 frankly, I don't think this unit has a place in our society.
6 I think that currently, there are many other means to detect
7 what they are looking for and that, on principle, ionizing
8 radiation ought to only be used for medical purposes on
9 humans so long as there are other means of detection.
10 DR. FLETCHER: At this point what I suggest is
11 that we go ahead and put the motion on the floor. There can
12 still be further discussion if need be, but at least once
13 discussion was done, we could go ahead and take a vote.
14 Let me ask the question. Since there were four
15 parts, perhaps now five, do you want to break it down and
16 vote on each part? Okay. Why don't we do that.
17 DR. LIPOTI: The motion is that TEPRSSC go on
18 record as urging FDA to immediately begin to work
19 cooperatively with the manufacturers of people scanners to
20 ensure that state regulators are made aware of their use or
21 potential use within their state.
22 [Second.]
23 DR. FLETCHER: It has been properly moved and
24 seconded that TEPRSSC go on record as recommending to the
25 FDA that they work with the manufacturers to make sure state

1 regulators are aware of the device in their state.

2 Is there any further discussion on that part of

3 it?

4 Hearing and seeing none, all in favor, please

5 raise your hands.

6 [Show of hands.]

7 DR. FLETCHER: Opposed?

8 [No response.]

9 DR. FLETCHER: That motions carries.

10 DR. LIPOTI: That TEPRSSC go on record as urging

11 FDA to immediately begin to work cooperatively with the

12 manufacturers of people scanners to ensure that the x-ray

13 machine is properly registered.

14 DR. FLETCHER: Is there a second?

15 [Second.]

16 DR. LIPOTI: To elaborate, registration within the

17 state will mean that the user pays a fee.

18 MR. THOMAS: I have a general question.

19 DR. FLETCHER: Let me finish this part of it

20 first.

21 It has been moved and properly seconded that

22 TEPRSSC do all the things we talked about as far as people

23 scanners, and ensure that the devices were registered in

24 each state.

25 Are there any questions?

1 MR. THOMAS: Yes. One question. What is the
2 current requirement for registering this piece of equipment
3 following its manufacture?
4 MS. KAUFMAN: Registering with FDA?
5 MR. THOMAS: No, just in general. Is there
6 requirement to report to the FDA when a piece of equipment
7 like this has been manufactured?
8 MS. KAUFMAN: No.
9 MR. THOMAS: So, there is no reporting
10 requirements.
11 DR. FLETCHER: Any other questions?
12 MR. KASSIDAY: 21 CFR 1002.12 requires an
13 abbreviated report for this type of product before it goes
14 into production or into commerce.
15 So, they have to file basically an initial product
16 report with us describing the product fully, and then they
17 are required to file annual reports every year on how many
18 they produce, their radiation testing, and any complaints,
19 radiation safety things they have gotten.
20 MR. THOMAS: Okay. But not --
21 MR. KASSIDAY: Not each individual product.
22 MR. THOMAS: Not each individual product.
23 MR. KASSIDAY: That is correct.
24 MR. THOMAS: That was what my question was.
25 DR. CARDELLA: The proposal is that the unit be

1 registered with the state, not with the federal agency you
2 are talking about.
3 DR. FLETCHER: All those in favor, please raise
4 your hand.
5 [Show of hands.]
6 DR. FLETCHER: Those opposed?
7 [No response.]
8 DR. FLETCHER: The motion carries.
9 DR. FLETCHER: You can just say the preamble.
10 DR. LIPOTI: The preamble and that users are
11 properly trained.
12 DR. FLETCHER: Is there a second?
13 [Second.]
14 DR. FLETCHER: It has been properly moved and
15 seconded that TEPRSSC go on record as advising or
16 recommending to FDA they work with the people scanners to
17 ensure that users are properly trained.
18 MS. KAUFMAN: Do we want an amendment thing
19 relative to radiation issues? I think they would contend
20 they are already trained.
21 DR. LIPOTI: I went on before and included a bunch
22 of staff, but maybe we had better just say curriculum to
23 include x-ray production --
24 DR. FLETCHER: Radiation safety training.
25 DR. LIPOTI: -- radiation safety training.

1 MS. KAUFMAN: That's good.

2 DR. LIPOTI: So, we are amending the motion.

3 DR. FLETCHER: We are amending it to say radiation

4 safety training.

5 MR. THOMAS: You are amending it to say that

6 training should include radiation safety training.

7 DR. FLETCHER: All those in favor, please raise

8 your hand.

9 [Show of hands.]

10 DR. FLETCHER: Those opposed?

11 [No response.]

12 DR. FLETCHER: The motion carries.

13 DR. LIPOTI: The preamble and the units are

14 labeled. Now, I wrote down the warning that was in the

15 medical device one. I am not sure it really applies here.

16 Maybe we shouldn't wordsmith for FDA. This really should be

17 something FDA works cooperatively with the manufacturer on.

18 But the stuff I wrote down was warning, this x-ray

19 unit may be dangerous unless safe exposure factors and

20 operating instructions are observed. But I am willing to

21 leave that up to FDA.

22 DR. FLETCHER: Is there a second to the motion?

23 MS. KAUFMAN: I will second.

24 DR. FLETCHER: It has been properly moved and

25 seconded that we follow the same process adding now that the

1 equipment should be properly labeled. We are going to leave
2 the exact labeling up to the those negotiations between the
3 FDA staff and manufacturer.
4 DR. ELDER: This labeling is specific for this
5 device being a x-ray producing machine.
6 DR. LIPOTI: Yes.
7 MR. THOMAS: Is the word appropriate maybe better
8 than the word proper?
9 DR. FLETCHER: Appropriate accepted.
10 All those in favor, please raise your hands.
11 [Show of hands.]
12 DR. FLETCHER: Opposed?
13 [No response.]
14 DR. FLETCHER: The motion carries.
15 DR. LIPOTI: I am going to try and combine the
16 last two points, and this is for the longer term. That FDA
17 work on characterizing the radiation that actually is
18 produced by this unit and after they characterize it, they
19 work on a performance standard to preclude any people
20 scanner from emitting a dose greater than that which they
21 have measured.
22 That gets around the problem whether it is 3.
23 microrem or 5 microrem, they go out and they really measure
24 this darn thing.
25 DR. FLETCHER: Is there a second to the motion?

1 MS. KAUFMAN: I will second.

2 DR. FLETCHER: It as properly moved and seconded
3 that TLD recommends that FDA work with the manufacturer to
4 characterize what the dose actually is and once
5 characterized, ensure that no device is authorized the
6 manufacturer that exceeds that dose.

7 MR. SAVIC: Mr. Chairman, I think the motion was
8 to characterize the nature of the radiation including the
9 dose, but not only the dose.

10 DR. FLETCHER: Nature of the radiation including
11 the dose. Any comments from the panel? Jerry.

12 MR. THOMAS: Let me make a comment here. I am a
13 little bit concerned, quite frankly, about the direction
14 that this discussion is going. This piece of equipment,
15 when we are looking at characterization and saying I want to
16 characterize the beam, that characterization, you are
17 forgetting the other end of the beam, and that is the
18 receptor and the display associated with it.

19 Receptor technology is changing. Again, I won't
20 get into arguments, but my real concern is that I don't
21 think we want to go on record making recommendations that
22 are scientifically soft and also are failing to recognize
23 technology that is coming down the pike.

24 The receptor in this system is a relatively
25 inferior receptor to some of the receptors that we are going

1 to see in the future. It is an effective receptor that they
2 are using. It's a screen film. It's a florescent screen,
3 photomultiplier tube. It is kind of elegant, but at the
4 same time, there are better receptors, and the point that I
5 am making is I support -- I really don't want to see
6 anybody's limits.
7 I understand what you are saying, but there is no
8 difference between 50 microR and 5 microR in terms of the N
9 virological point, none whatsoever, and I think we are
10 getting hung up on something. I think the real point that I
11 am hearing is that this is a product. Some members
12 disagree on this panel as to whether this product has
13 meaning or not.
14 If we decide that it has no societal benefit,
15 then, we are wasting our time. Then, we should say to the
16 FDA we recommend that this piece of equipment not be allowed
17 to be manufactured because there is a risk to society.
18 On the other hand if there isn't a risk to
19 society, the difference between 5 microrem and 50 microrem
20 in the biological arena is not significant.
21 Now, when we start adding cumulative exposures, I
22 can still make biological arguments here, but I don't want
23 to go any further other than to say I am very uncomfortable
24 tying a dose to this piece of equipment as a recommendation,
25 that you shouldn't exceed a dose.

1 We have to ask the question what is being looked
2 for and what is the benefit of looking for that before you
3 tie a limit to a dose.
4 DR. FLETCHER: Kass.
5 MS. KAUFMAN: I have already gone on record as
6 saying I don't think this thing does have a societal benefit
7 and I stand by that. I think at this time I don't think it
8 does.
9 I don't care whether it is manufactured, I just
10 don't want it to be sold in the United States. I don't care
11 if some other country wants to buy it.
12 I think you have we have to keep in mind two
13 things. One is the fact that, for example, in California,
14 there is a proposal that would require that all the guards
15 undergo scanning every time they enter the leave the prison
16 or every time they enter and leave contact with inmates.
17 This could be multiple, multiple times a day, and we are
18 talking about an asymptomatic population that we are talking
19 about screening here, and that does put the level of
20 acceptance of risk at a much higher standard than one for
21 diagnostic x-ray, where it is not an asymptomatic
22 population.
23 So, I think if we are going to say that we are
24 going to put limits on this unit, I think we do want a
25 restriction. I don't know what it should be, I am not

1 saying. I don't think it should be 3, but I don't think it
2 should be 50, but I kind of agree with -- if this committee
3 doesn't want to say that this thing shouldn't be allowed,
4 and I don't think they do, then I think we do want to have
5 some kind of statement that we are at least concerned about
6 dose, and we think there ought to be some restriction to it.
7 DR. LIPOTI: Could I ask Dan to come up and put
8 the overhead up that dealt with defects where you stated
9 that if another manufacturer came in and it had a thing like
10 this, that this is the highest dose that could have that
11 benefit and therefore, the other manufacturer wouldn't be
12 allowed to exceed this dose.
13 That is what I am trying to get at here, and I am
14 just not sure the defect thing really does it, so I wanted a
15 performance standard that would band-air it.
16 MR. SAVIC: I agree with that comment. I don't
17 think that definition of defect could hold water as far as
18 finding a product defective according to that definition. I
19 don't think they could enforce the number, whatever that
20 number is, from the first manufacturer as a defect or
21 standard ot a defect definition from that point on, I just
22 don't see holding water at all.
23 DR. FLETCHER: Dr. Marx.
24 DR. MARX: I lost my train of thought.
25 DR. FLETCHER: Dr. Jacobson, did you want to say

1 something?

2 DR. JACOBSON: I think I just want to inject a

3 little bit of reality testing to this conversation. We

4 certainly hear your deep concern about this product. That

5 is coming through loud and clear. I think we value the

6 recommendations that you are making, and we are going to

7 look at them, but I do need to be very straightforward and

8 clear about this.

9 You know, we can support things like the need to

10 meet state regulations, but that is something that we would

11 do as a support kind of thing. I don't want you to walk

12 away with false expectations as to what we can deliver in

13 terms of these making measurements, looking at these devices

14 and producing a performance standard.

15 I mean one of the things that we are struggling

16 with, and we talked about it in the reengineering discussion

17 was the need to look at our priorities in the rad health

18 program. When you are talking about 7 FTEs, you have got to

19 be very, very careful about where you spend those FTEs.

20 Priorities are made up of a lot of things -

21 biological risks certainly comes into it. Relative risk

22 comes into it, too, though, and things like societal

23 benefit, you know, that is a different type of benefit that

24 we are not used to thinking about, and I am not sure how to

25 factor that in.

1 I think numbers of units, numbers of people
2 scanned, other priorities. You have heard lots of other
3 things today, and you are going to hear thing tomorrow. We
4 need to consider that, but I think that to make -- you know,
5 we will listen to the recommendation, but you need to
6 understand what you are asking for when you recommend that
7 we write a performance standard for this kind of a device
8 emitting at these kinds of levels, for such a small number
9 of people, in such limited applications.
10 We have a tremendous rad health responsibility, we
11 are not trying to duck that, but we do have to be reasonable
12 about things.
13 MR. KASSIDAY: One quick point about defect.
14 [Slide.]
15 The first one there, if a manufacturer tells a
16 specific number, that hold them to it pretty well. The
17 other one is on much shakier ground where, you know, this is
18 what is out there, we would like to hold you to that. That
19 is a little bit shakier. But, number one, if they tell us
20 this is it, that had better be what it is. Of course, then,
21 we would have to prove that it isn't.
22 DR. LIPOTI: Have you done an independent
23 verification of the 3 microrem claim?
24 MR. KASSIDAY: Frank Serra did a calculation based
25 on an NIST reference beam for the 3 microrem based on the

1 speed of the beam, and all that sort of thing and it comes
2 out to about 4.3. So, what should be coming out of that
3 beam for how fast it is moving, and all those factors,
4 pretty well confirms the 3 to 5 range. We have not done
5 measurements. I am not sure whether our labs are equipped
6 to do those measurement. Probably.
7 DR. SHOPE: I just want to make a comment. I
8 think we appreciate the interest and the concern in the
9 views that the committee are expressing. I think, though,
10 my view of your resolution is you are almost trying to write
11 the performance standard here today as opposed to saying
12 FDA, go look at the need for a performance standard and if
13 you think there is a need there, or consider our views that
14 there is a need and then develop the appropriate technical
15 approach, and then come back and tell us what you have done.
16 The other point I wanted to make is this limit you
17 are talking about or the exposure rate that this system uses
18 in the design that this manufacturer has come up with, with
19 this source and this detector system, produces an image of a
20 certain quality.
21 These systems are going to be just like any other
22 imaging system using radiation, that is a photo limited kind
23 of random process that the quality of the image is a
24 function of the does you deliver, and so there may be
25 situations where the doses that this system produces is not

1 sufficient to do the imaging tasks you might want in a
2 slightly different application, trying to detect something
3 slightly different, so I think you have to keep in mind that
4 there is always this tradeoff between image quality and the
5 dose delivered, and a resolution now that says this is the
6 dose limit, you have also just set the image quality limit
7 unless there is some significant technology change here.
8 I just wanted to make sure people were thinking
9 about aspect of it, that setting a dose limit also sets the
10 performance limits on the imaging side as to what it can do.
11 DR. FLETCHER: Any restatement or amendment or
12 further comment?
13 DR. MARX: I would say that I think that to try to
14 have a dose limit is premature and now what this committee
15 should do.
16 DR. FLETCHER: Stan?
17 MR. SAVIC: I think we have come about as close to
18 suggesting to FDA to go ahead and start to work on
19 promulgating a performance standard as we can with the
20 specific items that we have done here, and I am not even
21 sure what the difference between doing that other than the
22 formal words of saying go ahead and go develop a standard
23 would be, but I think for a thing that potentially invites
24 10 years from now might be, you know, in airports and in who
25 knows, schools, grammar schools, maybe that is the right

1 thing to talk about at least at this meeting as to whether
2 we do want to make that suggestion.
3 DR. FLETCHER: Jerry, were you going to contribute
4 to this part of the discussion?
5 MR. DENNIS: Yes. I am Jerry Dennis from the
6 Compliance side of CDRH, and I would just like to clarify
7 one point with respect to Item 2 of the slide on defects.
8 When we look at item 2, what we really mean by "unnecessary
9 level of radiation," it is dangerous to put that in terms of
10 what another product may do, because in the reality product
11 and technological development, we see that there are
12 economic factors, there are many factors that come into
13 consideration and making an agency determination as to
14 whether a particular level of radiation is necessary or not
15 for the accomplishment of the product's intended function.
16 Thank you.
17 DR. FLETCHER: Dr. Smith, you wanted to make a
18 comment?
19 DR. SMITH: Just a few comments on the dose level.
20 From the manufacturer's point of view, we would very much
21 welcome a performance standard which actually indicate a
22 very specific dose level. There are several reasons for
23 that.
24 First of all, you say what would a reasonable dose
25 level be. Well, first of all, prior to the Secure 1000 and

1 the Body Search by AS&E, no company had succeeded in
2 producing one of these kinds of systems before. We now have
3 a system on the market which has seen significant sales in
4 the United States, and that by itself has made a de facto
5 standard for saying the useful level of image quality, this
6 is the radiation level you need.
7 So, just from a practical standpoint, the way
8 things have developed over the last two decades, in effect,
9 the way the system has just equalized itself is to a system
10 using 3 to 5 microrem, so that turns out to be a very
11 natural dose to use.
12 The second thing, the reason why we would support
13 an actual number in there is for the last three or four
14 decades, a security community's opinion on these kinds of
15 devices, you can't use them. You approach a security
16 manager prior to five years ago and say we want to use x-
17 rays for this kind of purpose, he would think you were
18 absolutely crazy.
19 He would think that you would not know what the
20 technology was about, did not know the FDA's position on it,
21 and did not know anything about x-rays. The reason we would
22 very much support an actual number on, it just give the
23 technology some credibility, saying yes, this is the number
24 below which you can use it, this is the number above which
25 you cannot use it, and while that number has to be a little

1 bit arbitrary and may restrict some things in the future,
2 for now it would be very appropriate, we feel.
3 DR. FLETCHER: Thank you.
4 Dr. Lipoti and then Jerry.
5 DR. LIPOTI: I have just been convinced to
6 withdraw the motion.
7 DR. FLETCHER: Jerry.
8 MR. THOMAS: I was going to suggest that she
9 reword it and specifically the suggestion was -- and I will
10 just make the motion -- I move that the committee recommend
11 that the FDA development standards for people scanner.
12 DR. FLETCHER: Is there a second?
13 [Second.]
14 DR. FLETCHER: Is there any further discussion?
15 Kass.
16 MS. KAUFMAN: I just wanted to make one quick
17 comment and actually, what Dr. Smith said set off alarms in
18 my head because then we are saying, this committee is then
19 saying that it is okay to use ionizing radiation, to scan
20 little babies, you know, kids in schools, for detection of
21 contraband purposes, and I just don't think that that is an
22 appropriate use of ionizing radiation.
23 DR. FLETCHER: Other comments?
24 DR. CARDELLA: I have bit my tongue about as long
25 as I can. I personally believe that the radiation risk from

1 a radiobiology standpoint that we are talking about is
2 indeed, honest to God, trivial, and if the use of this kind
3 of device could have prevented the downing of one terrorist
4 747, you know, what is that worth to society.
5 I mean I hear a lot of warm and fuzzy things about
6 invasion of privacy, but what about 500 people going down in
7 a 747 that was dropped by a pound and a half of C4? That to
8 me as a consumer of the airline industry, you know, the
9 security that I might not be the next one going down is
10 worth quite a bit to me, and I would subject myself and my
11 11-year-old son to 3 to 5 microrem to make sure that the
12 plane I get on isn't going to get knocked down by a pound
13 and a half of C4.
14 That, I think is the up side value. Everybody
15 sort of puts that out of their mind. Or what about the
16 child who goes to school and is gunned down in the
17 playground because a kid brings a gun to school? I mean
18 there are some redeeming features of this type of
19 technology.
20 I don't think this is a devious, draconian measure
21 whereby Big Brother is going to snoop in our pockets every
22 time we go through something. That is a device and
23 technology that has some legitimate societal value, and I
24 would ask the committee to consider that.
25 MS. KAUFMAN: I have just got to respond to that

1 because I want to remind you that the manufacturer admits
2 that the plastique wasn't on a person on that. This device
3 would not have prevented that plane from going down, and in
4 terms of a gun or something like that, an ordinary metal
5 detector that does not ionizing radiation will absolutely
6 pick that up.
7 So, the point that I am trying to make is that
8 there are other detection capabilities that can serve these
9 purposes that don't involve ionizing radiation.
10 DR. FLETCHER: Is there any further discussion?
11 DR. ELDER: Just to add to that conversation, it
12 seems to me that -- well, I am impressed by the very low
13 level of radiation that this device produces, and
14 considering it is in its very early stages of development,
15 who knows what is going to happen with the ability to
16 detect, you know, improve the image, and so on, and so
17 forth, that I think I am very reluctant to kick something
18 like this into the ground before it has had a chance to see
19 what it can do for us.
20 DR. FLETCHER: Hearing that, I am going to end
21 discussion and ask that all those in favor of the motion --
22 I will let Jerry do it.
23 MR. THOMAS: I will restate the motion. The
24 motion was that the committee recommends that the FDA
25 develop standards for people scanners.

1 DR. FLETCHER: All those in favor, please raise
2 your hand.
3 [Show of hands.]
4 DR. FLETCHER: All those opposed?
5 [No response.]
6 MS. KAUFMAN: Well, I am going to abstain. I mean
7 if we have got to go with it, then I want them to do
8 standards, but I don't think it is an appropriate unit.
9 DR. FLETCHER: The motion does carry.
10 Is there any further discussion before this body?
11 I thank you all very much for your patience, your
12 indulgence, your comments, all of the things that make for a
13 good committee meeting.
14 We will convene once again, tomorrow morning, at
15 8:30. Thank you very much.
16 [Whereupon, at 5:40 p.m., the proceedings were
17 recessed, to be resumed at 8:30 a.m., Thursday, September
18 24, 1998.]
19 - - -

# *CERTIFICATE*

I, **ALICE TOIGO,** 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.

Alice Toigo

ALICE TOIGO