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FOOD AND DRUG ADMINISTRATION

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE

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

2 CHAIRPERSON MONSEES: Good morning. We are going
3 to be continuing this morning with some presentations and
4 some updates.

5 Just for your information, the agenda that was
6 distributed, I'm going to change and modify just a little
7 bit; that is, after we have the 9:30 to 10:00 review of
8 summary minutes and future meetings, we're going to have a
9 break, because I don't anticipate we'll be having lunch
10 today. We may end right around that time or stay late to
11 finish what we need to do, but probably not break for lunch.
12 So that will give those of you on the panel a chance to
13 check out if you need to mid-morning.

14 For our first presentation this morning, there is
15 an information packet available. There are overheads with
16 this. People on the committee have a copy of the overheads.
17 We're talking about mammographic collimation update. I know
18 there are a number of manufacturers in the audience very
19 interested in this topic.

20 Our presenter is Richard Kaczmarek, and he's from
21 the Radiation Programs Branch. I understand that he's going
22 to give a didactic presentation, and--

23 MR. KACZMAREK: Really?

24 CHAIRPERSON MONSEES: --you're going to give a
25 presentation and then Q&A. Is that right? You tell us what

1 you want to do.

2 MR. KACZMAREK: I was just going to discuss
3 mammography collimation and where we at the FDA think we're
4 going to go with this after that.

5 CHAIRPERSON MONSEES: Great.

6 MR. KACZMAREK: I guess I'm open to suggestions,
7 whatever you want to do. But you can switch to the next one
8 there, Wally.

9 Okay. This is written from the MQSA final regs
10 here. This is how it stands. This is how the wording
11 stands now. And this is in the equipment section. This is
12 hardware, deals with hardware, mammography collimation. And
13 it says all systems shall have beam-limiting devices that
14 allow the useful beam to extend to or beyond the chest wall
15 edge of the image receptor, and it's repeated again in the
16 equipment QA section, with the variation of no more than 2
17 percent of the SID on the chest wall side. And this is
18 good, but when people read this over, us and manufacturers
19 and clinicians, there's some potential problems with the
20 interpretation of this because--for reasons we'll see on the
21 coming slides and also because there's no upper limit
22 specified on this.

23 So, again, this is how the wording is in the final
24 regs, and this will become effective next year in April, I
25 believe, if we don't act to change it.

1 Okay. Wally, you can change to the next one.

2 Now, there's also the Food, Drug, and Cosmetic Act
3 which the equipment is regulated by, is subject to, and
4 those regulations are in Title 21, Part 1020 of the Code of
5 Federal Regulations. This is the subchapter C there. The
6 third line is electronic product radiation control. That's
7 the acronym, EPRC, that you'll hear the FDA throw around.
8 MQSA EPRC. And on the bottom there is the typical capsule-
9 thumbnail summary that the MQSA is more focused on
10 mammography quality, the EPRC is more concerned with
11 radiation safety. In other words, the mission of the laws
12 are different.

13 Next slide, please?

14 Now, I've reproduced here the current wording of
15 1020.31 and 21 CFR, which regulates the manufacturers.
16 What's important here is the highlighted area where it says
17 the transmission through any image receptor port--wait a
18 minute. I think you got them out of order there, Wally.
19 Could you go to the next? Put the next one up and see.

20 Yes, this is better. Let me do this one first.
21 The highlighted area there, these two slides are from
22 1020.31, and they deal with mammo collimation, and I'm just
23 going to read this one first. Means shall be provided to
24 limit the useful beam, feel that the plane image receptor
25 does not extend beyond the edge of the image receptor at any

1 designated SID, except the chest wall edge.

2 Now, if you reflect on this, you'll see that
3 there's apparently a contradiction here with the final regs
4 and the MQSA because we were just reading that we were
5 allowed to go beyond the edge of the receptor. In other
6 words, blacken the entire film. The film is the receptor,
7 image receptor.

8 So we've got this situation which needs to be
9 addressed, and you can put the next one up, Wally.

10 Just to be complete, this is also in the equipment
11 regulations, and it concerns transmission through the
12 primary barrier, which, of course, usually ends up being the
13 image receptor support, and there's an exposure limit that's
14 there. So this is something--again, this reflects the fact
15 that these laws are primarily aimed at radiation safety, and
16 that's why these are there. And these are what the--these
17 last two slides are what the manufacturers go by when they
18 design and manufacture the equipment.

19 Next overhead, please?

20 Now, if we did not change the final regs, we could
21 work around that situation. Facilities could apply--or,
22 actually, manufacturers could apply, too, for alternative
23 requirements under the MQSA. They could also go the route
24 of seeking a variance from the equipment standards, and we
25 could work around it that way. You'd still have the safety

1 issue because of the possible confusion on the
2 interpretation of defining exactly how far the field can go
3 outside of the image receptor.

4 So, as a result of this, we're thinking of
5 amending the language to say that we would allow the field
6 to--in the last two lines there--extend to or beyond the
7 chest wide side of the receptor and, of course, apply the
8 limit of 2 percent on all edges. So this would now give an
9 upper limit so we wouldn't have any safety issues, but we'd
10 also have, we feel, the best situation because now it's
11 between the manufacturers and the clinicians how they want
12 to specify their receptor coverage, coverage of the image
13 receptor.

14 I guess you can go to the next one.

15 At the same time--the previous one was the MQSA
16 900. This would be how we're thinking of changing 1020.31
17 to also change the language to allow the field to extend
18 beyond the receptor 2 percent of the SID, retain the
19 transmission requirement, and say that the support--indeed,
20 verify, re-emphasize that the support would be the primary
21 barrier, and the only place you'll have primary going past
22 it is on the chest wall side.

23 So we feel that this not only will eliminate any
24 possible misunderstanding or, say, contradiction between the
25 interpretation of the two different regulations, but it will

1 also harmonize them in the sense that they will say the same
2 thing. You know, they'll be in agreement.

3 So I guess that's the last one, so, again, just to
4 summarize, this is where we feel we need to go to address
5 this situation.

6 I guess I can take questions.

7 CHAIRPERSON MONSEES: Can we have the lights?

8 Okay. First I want to hear questions from the
9 panel members, and then we're going to call on the audience.
10 I know there are people--yes, Dr. Sickles?

11 DR. SICKLES: I think I understand everything that
12 you said. What concerns me as a clinician is whether there
13 are regulations that--I'm not sure I see it in here, but one
14 of the things clinicians will want to see is the ability to
15 eliminate as much as possible of the white areas on the
16 film, the non-exposed areas on the film, because although in
17 some circumstances they can be masked, especially with a
18 curved upper end or away from the chest wall side, and it's
19 very hard to achieve good masking. I didn't see anything in
20 there to prohibit a curved upper end of a collimation
21 device.

22 MR. KACZMAREK: Right. My interpretation of this
23 is it leaves it up to you to specify how you want it. In
24 other words, it's between you and your manufacturer that you
25 buy the equipment from to decide how you want the--

1 DR. SICKLES: Well, the clinicians can discuss
2 whether that's advisable or not, but--

3 MR. KACZMAREK: Right.

4 CHAIRPERSON MONSEES: We don't like light.

5 MR. KACZMAREK: Oh, I understand perfectly. I
6 understand what you're saying.

7 CHAIRPERSON MONSEES: Any other comments--

8 DR. SICKLES: Is there anything--so there's
9 nothing in the regulations--well, what concerns me is, as a
10 clinician, if I went to my manufacturer of equipment that I
11 already had purchased and said I don't want a curved upper
12 end, there's nothing in these regulations that would force
13 them to give me one, is there?

14 MR. KACZMAREK: Well, does he ever want to sell
15 you anything again?

16 DR. SICKLES: I don't think it--

17 MR. KACZMAREK: I would assume that your
18 relationship with your equipment supplier is such that
19 they'd be willing to work with you to address your needs.

20 DR. SICKLES: Well, mine might be, but it's
21 different when you speak to me as an individual as opposed
22 to an average practitioner who might not have as much clout
23 with a manufacturer.

24 CHAIRPERSON MONSEES: Mr. Pizzutiello, you have a
25 question or comment?

1 MR. PIZZUTIELLO: Yes, maybe I could clarify why
2 this is an issue. It started back a number of years ago
3 when physicists started doing surveys on these machines, and
4 in order to show that there was adequate collimation on the
5 edge of all the films, the only way the service engineers
6 could make sure it worked all the time was to provide an
7 extra margin of safety around the edge, which seemed like it
8 met the requirements but it was at opposition with the
9 clinician's goal of not having any lots of light come around
10 the side of the image. So I have to say this has been going
11 on, to my knowledge, for at least four years, and I'm very
12 happy to see some bringing together of it.

13 So I think that also we have to recognize the
14 role, at least the way I see it, of regulation versus
15 quality. The regulation has to set the minimum standard
16 that everybody needs to adhere to, and at least we'll have a
17 consistent standard instead of sort of ignoring it like
18 we've been doing. But I also agree with Dr. Sickles that
19 it's important that individuals make their preferences known
20 to the manufacturers. I think that the manufacturers want
21 to provide equipment that meets the requirements of all the
22 people. The question is: How far do you go in setting a
23 regulation to force them to do that rather than allowing the
24 market forces to drive the design and modification of
25 equipment that's out there?

1 So I think this is a sensible approach, but I
2 think it should not substitute efforts on anyone's part to
3 say if you've got old equipment which still sort of meets
4 the regulations but it's inconvenient to use because of
5 difficulty of masking and so on, then pressure needs to be
6 brought to bear on the manufacturers. But perhaps the
7 regulatory angle is not the way to do it.

8 CHAIRPERSON MONSEES: Okay. I'm going to take
9 questions from the audience. Let's start with Dr. Hendrick.

10 DR. HENDRICK: I was confused by Dr. Sickles'
11 question and by the response to it. I thought your question
12 was: Is there anything in the current final rules to--or in
13 the final rules to prevent D-shaped collimation? And I was
14 confused by the answer to that because what is in the final
15 rules says that the X-ray field has to go to the edge of the
16 film, which would prevent D-shaped collimation. So I was
17 confused by your--

18 MR. KACZMAREK: I guess I misinterpreted his
19 question, probably.

20 DR. HENDRICK: So is that--

21 CHAIRPERSON MONSEES: Okay. What you're talking
22 about is a little bit different, I think, than--

23 MR. KACZMAREK: Yes, I'm thinking ahead to how it
24 will be when--

25 CHAIRPERSON MONSEES: Some of the compression

1 plates, anyway, have a radiopaque handle, especially for the
2 compression spot devices, so that you still end up with
3 white on the film. I don't know how that would interfere
4 with this, too. How would you interpret that? Are you
5 familiar with what I'm talking about, the small compression
6 spot devices.

7 MR. KACZMAREK: I know what you mean.

8 CHAIRPERSON MONSEES: They're attached to the unit
9 by something that's radiopaque. What would happen in that
10 situation? Would those be not allowed, according to the
11 regs?

12 MR. KACZMAREK: My opinion is that wouldn't apply
13 because what this--what I have talked about pertains to the
14 X-ray field relative to the image receptor, the definition
15 of field relative to the image receptor. So anything else
16 that's in there is a separate issue. That's the way I see
17 it.

18 DR. FINDER: One other thing I'd like to clarify--
19 Dr. Finder--is that in the regulations it just states that
20 the equipment must allow this. It doesn't require that you
21 have to do it. Even though the equipment under the final
22 regulation as written would require that the beam would have
23 to extend that far, it doesn't force anybody to do that.
24 That's always up to the clinician. We didn't take that away
25 from them.

1 So your issue really isn't addressed in this
2 regulation. If somebody wanted to, they could still use
3 whatever collimator they wanted.

4 DR. SICKLES: Ed Sickles. Now that Dr. Hendrick
5 tried to clarify what I asked, I need to clarify it, because
6 maybe I don't understand it as well.

7 Does this unification of regulations result in a
8 requirement that the beam extend close to the edge of the
9 receptor, or is there no lower limit? Can the beam be
10 allowed as small as a postage stamp?

11 MR. KACZMAREK: Yeah, I guess so, you could in
12 practice--I mean, it wouldn't be practical.

13 DR. SICKLES: In practice, it wouldn't be
14 practical.

15 MR. KACZMAREK: Yeah, so you'd never purchase
16 something like that. Manufacturers wouldn't--

17 DR. SICKLES: I understand that. I understand
18 that. I'm just concerned about regulations permitting
19 especially, as Ed Hendrick said, the D-shaped type
20 collimation, which is very hard to mask. Or do they really
21 not allow for that anymore? See, that was really my
22 question. May one have a D-shaped collimation with your
23 revisions, your proposed revisions of the regulation?

24 MR. KACZMAREK: And I think you could, if that's
25 what you want. I think the thinking behind this--I mean,

1 we've discussed this eternally, you know, quite a bit around
2 the center, and there's pro and con arguments, just like
3 everyone has. So we've tried to make a consensus, but the
4 thinking is that this is really least burdensome for the
5 public because now it's pretty much up to the people who
6 practice to decide for their individual case how they want
7 to do their radiographs.

8 DR. SICKLES: Could you provide us some background
9 information on what the burden really is? How many of the
10 mammography units in service now don't meet the current
11 specification but would meet the new specification, et
12 cetera?

13 MR. KACZMAREK: What I could provide you is things
14 I've heard and been told by manufacturers who have
15 situations where they've designed their collimation systems
16 to leave the borders so they could pass the product
17 standards, and now when they see the final regs, they feel
18 they're in real trouble because the final regs are
19 apparently saying to darken the whole film. So that's--

20 CHAIRPERSON MONSEES: There are manufacturers in
21 the audience--

22 MR. KACZMAREK: As a matter of fact, I think there
23 was a presentation--

24 CHAIRPERSON MONSEES: --that I'm sure can address
25 this issue, if you want to know--

1 MR. KACZMAREK: --yesterday about it during the
2 comments.

3 CHAIRPERSON MONSEES: We had a presentation
4 yesterday, if you recall, that alluded to this and the large
5 cost. And I'm sure there are manufacturers in the audience
6 that would testify that this, in fact, is the case.

7 MR. KACZMAREK: The burden is looming in the
8 future in the sense that if we don't reconcile this now,
9 we'll have to go through the variance process, the
10 alternative standard, so it will just make life easier.

11 CHAIRPERSON MONSEES: Mr. Kaczmarek, what I
12 thought we were starting with was basically where the field
13 was going to be with respect to the receptor, and what we're
14 ending up with is talking about collimation that people
15 place in the field, click on by magnets or they close it
16 down automatically, and things like that. Are we addressing
17 that now, or are we really talking about the field and what
18 is the defined receptor? Can we limit it to that right now
19 and then we can do the rest during the discussion later?

20 MR. KACZMAREK: That's fine with me.

21 CHAIRPERSON MONSEES: When we have other time.

22 Yes?

23 DR. HENDRICK: I'm still confused by the answer
24 because we can back to the question, could under these rules
25 a site have D-shaped collimation, and as I understood your

1 answer, it was yes. There's nothing to prevent them. But
2 as I read this, and the intention, I think, in writing this,
3 it says all systems shall have beam-limiting devices that
4 allow the useful beam to extend to or beyond the chest wall
5 edge of the image receptor, and--that's the chest wall edge.

6 MR. KACZMAREK: I think what's happening is I'm
7 thinking ahead again to how it will be if we--

8 CHAIRPERSON MONSEES: I can't hear you. Could you
9 speak more into the microphone?

10 MR. KACZMAREK: I think what's happening is I'm
11 thinking ahead to how the laws will be if we can change
12 them, you know, conceptually, like I've just discussed. But
13 the way he's interpreting the current written final regs,
14 you have to darken the entire film. You know, he's
15 interpreting it literally, which I--

16 CHAIRPERSON MONSEES: Well, the reason that's of
17 concern is those of us who are interested in reading
18 mammograms do not want unexposed film.

19 MR. KACZMAREK: I understand.

20 CHAIRPERSON MONSEES: Okay. And so it was
21 somewhat welcome to see that there were going to be regs
22 addressing that, but the part that's a problem is when it
23 gets to the technical specifications, I believe, and whether
24 they're achievable and whether or not it would cost a
25 fortune to retrofit units to give us a--to eliminate a

1 minuscule white border. That's the way I understand it.

2 DR. FINDER: If I could just bring up the point
3 that was brought up yesterday by Dr. Sandrik, what we're
4 looking at is the possibility of a large number of machines
5 not meeting the requirements written, and the number that I
6 heard, if I'm correct, was \$200 million to fix this within
7 the next year, which is more than the total expected cost of
8 the rest of the program.

9 So in order to address this, we are looking at
10 ways to solve this problem and bring the two different
11 competing standards into alignment.

12 DR. SICKLES: Ed Sickles. What I was trying to
13 get at with my question is: To what extent is the \$200
14 million in relation to the fine point of whether the beam
15 comes within 2 mm of the edge and 2 mm beyond the edge, and
16 to what extent is the problem the beam being much, much more
17 small, with leaving large areas of white on the film? I
18 have very little problem with leaving 2 mm of white on the
19 edge, as most clinicians would. We have more of a concern
20 leaving large amounts of white. And I never have heard the
21 extent of that part of the problem.

22 CHAIRPERSON MONSEES: Okay. Did you have an
23 answer to that, Dr. Nishikawa?

24 DR. NISHIKAWA: No. I have a question.

25 CHAIRPERSON MONSEES: You have a question?

1 DR. SICKLES: Well, Dr. Sandrik may have.

2 CHAIRPERSON MONSEES: Okay. Let's ask this first
3 because he may be able to answer both. Go ahead.

4 DR. NISHIKAWA: I have actually two questions, one
5 to the radiologists. Right now there is a white border
6 around three-quarters of the film. Is that a big problem?

7 CHAIRPERSON MONSEES: Well, it depends how big it
8 is, is what Ed was saying.

9 DR. NISHIKAWA: Does it vary by manufacturer?

10 CHAIRPERSON MONSEES: Yes.

11 DR. NISHIKAWA: Is the manufacturer objectionable?

12 CHAIRPERSON MONSEES: I can't hear you.

13 DR. NISHIKAWA: Is any machine that's manufactured
14 currently in use, the white border objectionable?

15 CHAIRPERSON MONSEES: Yes.

16 DR. NISHIKAWA: Okay.

17 CHAIRPERSON MONSEES: The particular one that he's
18 talking about is--are you talking about currently
19 manufactured or in the field?

20 DR. NISHIKAWA: Yes, currently.

21 CHAIRPERSON MONSEES: Okay, because--

22 DR. NISHIKAWA: Well, either.

23 CHAIRPERSON MONSEES: In use, the ones that are a
24 particular problem are the ones that leave a big white area
25 that comes around the breast. Very hard to mask those.

1 Those are older units. They're not really ones that are
2 currently manufactured.

3 DR. NISHIKAWA: But there's nothing manufactured
4 like that anymore?

5 CHAIRPERSON MONSEES: I don't believe so. Are
6 there any manufactured like that? We'll ask the
7 manufacturers. Do you have another question or is that--

8 DR. NISHIKAWA: My question is to the presenter.
9 Can't you grandfather in existing units, say units
10 manufactured after April 28, 1999, must follow the MQSA, and
11 everything that's existing in the field can be used?
12 Because these older units are going to be out of service
13 eventually.

14 CHAIRPERSON MONSEES: Well, mammographic units
15 have a very long life span. They can be resurrected for a
16 long time.

17 MR. KACZMAREK: Traditionally, we did that with
18 the equipment standards. When they were revised, they would
19 apply, when they become effective, to anything manufactured
20 after a certain date. So anything that was out there before
21 that was still okay to use.

22 Now, I think the MQSA doesn't quite work that way.
23 I think that applies to anything that's used no matter when
24 it was manufactured. In other words, when the law becomes
25 effective, even if you've got a piece of equipment that was

1 purchased X number of years ago, my understanding is it
2 still has to comply.

3 CHAIRPERSON MONSEES: Okay. Do we have anybody in
4 the audience--Dr. Sandrik--who could address the issue that
5 Dr. Sickles was asking about? What percentage of units
6 would have a minor problem as opposed to a major problem and
7 the kind of cost estimates we're talking about?

8 DR. SANDRIK: The percentage of units is 100
9 percent.

10 CHAIRPERSON MONSEES: There you go.

11 DR. SANDRIK: As Mr. Kaczmarek pointed out, we
12 have the previous 1020.31(f)(3) that said you must be within
13 the border, and generally the guidance was show a clear
14 border to show that you're in compliance with that, because
15 we could be inspected under the performance standards just
16 as you can be inspected under MQSA. So essentially every
17 system was designed to have a border, and you have to
18 realize that we don't have any control over the cassettes or
19 the films, screen film cassettes, so we're trying to make it
20 so that any possible X-ray system will work with any
21 possible screen film cassette and still never go beyond the
22 image receptor. So under those kinds of constraints, we
23 were probably more conservative in terms of defining where
24 the edge of the field would be so that you could choose any
25 possible screen film combination and not be outside--so our

1 field would not be outside the border of the film.

2 As you know, the film does move around inside the
3 cassette, so that cutting of the films has some tolerance in
4 it. The internal dimensions of the cassette has some
5 tolerance to it, and we have no control over that as the
6 manufacturers of the equipment. That's under the control of
7 the screen film manufacturers.

8 So I guess perhaps to address some of Dr. Sickles'
9 question, I think from GE's perspective--by the way, this is
10 John Sandrik, GE Medical Systems.

11 CHAIRPERSON MONSEES: Right.

12 DR. SANDRIK: Sorry, folks. We kind of view this
13 as something of a tiered development. The bulk of the cost
14 comes from the possibility--you know, what the likelihood
15 would be that we had to do this for every single possible
16 combination. For example, if the regulations require that
17 you have an 18-by-24 and 24-by-30 field of view, it also
18 says--talks about having magnification capability and small
19 focal spots and all the rest of it. So if you kind of lump
20 that into this collimation requirement and assume that we'd
21 have to have full film blackening from everything from 18-
22 by-24 large focal spot to 24-by-30 small focal spot, it
23 becomes a very expensive proposition to do that.

24 And so, I mean--

25 CHAIRPERSON MONSEES: Let me ask you simply, does

1 this fix your situation? Does this fix it?

2 DR. SANDRIK: It helps us a lot, and I guess just
3 a couple comments and maybe some questions that come to
4 mind.

5 CHAIRPERSON MONSEES: Okay.

6 DR. SANDRIK: Thank you for doing this. I
7 appreciate that. I think another--and the comment point
8 also that I would like to see that what's stated in the
9 regulation be clear in terms of the permissibility of this
10 requirement and that it not be an element that, say, goes
11 into a preamble to the regulation somewhere that would be
12 stripped out when it's finally published in a CFR format and
13 then people start interpreting things again in the field.

14 The last question, or the real question is: What
15 sort of time frame are we talking about? Would all this
16 possibly be in place before April 28, 1999? Yeah, me, too.
17 If it's in place before April 28, 1999, then there's a lot
18 of pressure taken off in terms of having to refit thousands
19 of mammo systems in less than a year now. Again, talking
20 about going to the 24-by-30 small focal spot, we don't even
21 have an X-ray tube that can do that at this point, so that
22 means developing a new tube and deploying it in less than a
23 year when X-ray tube developments are usually two- to three-
24 year programs.

25 So this helps if it can roll back the April 28,

1 1999, deadline, can allow us to maybe respond a little more
2 individually to customers' demands. If 18-by-24 large spot
3 is the biggest thing, most important thing to you, and maybe
4 24-by-30 large spot is the next most important thing, and
5 24-by-30 small spot is very unimportant, we can probably
6 work on that--

7 CHAIRPERSON MONSEES: Okay. We don't need to hear
8 all the details, I think. But I think what we have here is
9 a misfit between, pardon the pun, the regulations and the
10 intention of the regulations and then implications of it.
11 And I think we need to fix it. And I think we need to come
12 up with some suggested language that will be an easy fix.

13 Do you have any--if this is done here--and you
14 said it does not meet all your needs--do you have a simple
15 other solution that might make it--basically fix the
16 situation so that we don't have to go rush and retrofit all
17 these units?

18 DR. SANDRIK: As I say, I think the language meets
19 our needs. It's the implementation time frame that's the
20 uncertain part. We still have the April 28, 1999, deadline
21 imposed by MQSA. If this isn't done before that, we still
22 have to worry about that deadline coming up.

23 CHAIRPERSON MONSEES: Okay.

24 DR. SANDRIK: So the language looks fine--

25 CHAIRPERSON MONSEES: So this would be okay if it

1 were changed before the '99 deadline?

2 DR. SANDRIK: Right.

3 CHAIRPERSON MONSEES: Okay. Thank you.

4 Yes?

5 DR. SICKLES: They didn't answer the question.

6 DR. HENDRICK: I have a rough proposal, which is
7 that the intention of this was for contact mammography, non-
8 magnification mammography. This should be a requirement
9 only for the large focal spot with either 18-by-24 or 24-by-
10 30. The point, the original intention was to eliminate D-
11 shaped collimation and to not have too much white area on
12 any edge of the film. So, in addition to limiting it to a
13 requirement for the system operating in contact mammography
14 mode with the large focal spot, it might be reasonable to
15 have some small limit on how far the collimation can come
16 with--leave a white border within the image receptor,
17 something like 2 percent of the SID within the image
18 receptor, as well as 2 percent of the SID beyond the image
19 receptor, meaning the film in the cassette.

20 This still represents a small problem for some
21 sites--actually, a real problem for some sites, because some
22 sites leave a rather large white strip along the distal part
23 of the film to allow their flash system to operate. So this
24 would probably not allow that to continue. I don't know
25 that that's all bad. There are pluses and--I mean, it's

1 going to cost some money for them to make that change. But
2 I think what you really want to do is eliminate D-shaped
3 collimation as being consistent with the final rules. You
4 don't want to cause everyone to have to replace their X-ray
5 tubes when this goes into effect, and a reasonable way to do
6 that is to make it apply to the large focal spot contact
7 mode and allow some, say 2 percent of the SID leeway on
8 either side of the match between the X-ray field and the
9 three edges of the film, the non-chest wall edges.

10 CHAIRPERSON MONSEES: Dr. Sickles?

11 DR. SICKLES: Ed Sickles. I'd still like to ask
12 Dr. Sandrik to answer the question I've been asking all
13 morning, and that is, to what extent is D-shaped collimation
14 a burden on manufacturers if it were to be eliminated? How
15 much of the \$200 million is D-shaped collimation, which is
16 what clinicians are telling you is the most important
17 imaging problem? If it's only \$1 million out of the \$200
18 million, then maybe that should stay in the regs. If it's
19 \$150 million out of the \$200 million, maybe it's too
20 burdensome to consider right now.

21 DR. SANDRIK: I guess I'm a little confused
22 because I'm not aware of us having a D-shaped collimator.

23 DR. SICKLES: Maybe it's not GE. I'm talking
24 about the whole industry, if you could address that. Maybe
25 you can't.

1 DR. SANDRIK: I can't address that, I'm afraid.
2 My estimate was based solely on what I know about GE's
3 requirements. If any other manufacturer wants to respond,
4 they're free to do that. But as far as I know, we don't
5 have any D-shaped collimators in any modern equipment that
6 we've been selling.

7 DR. SICKLES: I don't mean what you're selling
8 now. I mean what's out there in practice.

9 DR. SANDRIK: Even going back to 500T, 600T, I
10 think they basically had--I mean, the major apertures were
11 square, rectangular openings. I mean, there were some round
12 optional ones, but, you know, nothing--there was always
13 essentially the full field, 18-by-24 or 24-by-30 rectangular
14 option available, at least going back to 500T. Maybe there
15 were some things earlier than that, but--

16 DR. SICKLES: Okay. Another--Ed Sickles. Another
17 question for anyone in the audience, any manufacturer in the
18 audience or anybody else in the audience. If what's on the
19 screen there, these amendments under consideration, allowed
20 for the leeway that is being proposed, but also did not
21 allow for D-shaped collimation, to what extent would that be
22 a burden for existing units? If there's nobody here who
23 says that's a burden, then maybe the FDA should seriously
24 consider not allowing D-shaped collimation to persist after
25 April 28, 1999, because in terms of image interpretation it

1 impairs the ability of the radiologist to mask the film
2 properly, and masking is already recognized in the MQSA
3 regulations to be very important.

4 CHAIRPERSON MONSEES: Yes, and then I'm going to
5 call upon the audience to respond directly to that.

6 MR. PIZZUTIELLO: Bob Pizzutiello. In the absence
7 of the manufacturers who represent, the only machines that I
8 know of off the top of my head that have that are the older
9 Phillips units, and we have a practice with about 100
10 different mammography units over a wide range of areas,
11 rural and city. And out of the 100, we might have two
12 currently in place, just to give you a ballpark idea. It's
13 a very small portion of the population.

14 The reason why this is important is those
15 manufacturers would either have to build a new non-D-shaped
16 collimator or replace the unit, which would be, in my
17 opinion, fine. It's a very outdated machine.

18 The other manufacturers have machines where the
19 collimators are somewhat adjustable, and in terms of
20 adjusting the collimation, we're talking about a couple of
21 hours of a service engineer to make the adjustments on the
22 whole. And as long as the regulations allow the beam to
23 extend to the edge, which these new regulations would, those
24 manufacturers would be free to have their service engineers
25 make the adjustments that clinicians want. And so that's

1 why it's important to have this change, because a year ago,
2 when we called up the manufacturers and said we'd like that
3 X-ray beam to extend to the end of the film, the most
4 conservative view was: We can't do that because it violates
5 21 CFR 1020. So now that has gone away, so the impact of
6 the D-shaped I believe would be a very small percentage.

7 CHAIRPERSON MONSEES: Mr. Showalter?

8 MR. SHOWALTER: Charlie Showalter, ACR, formerly
9 with FDA. I was with FDA when we were discussing this whole
10 situation, and let me just give you a little bit of
11 philosophy, which I think Bob basically captured here in his
12 last comment.

13 This conflict has been real for a long time, and
14 we all know that, and we have been working to try to get it
15 fixed. I appreciate your concern about collimation smaller
16 than the image receptor. However, I think you really have
17 to seriously consider what's the appropriate role of federal
18 regulation and what's the appropriate role of clinical
19 practice. And I think you will all agree that federal
20 regulation should--cannot prevent poor practice in all
21 cases.

22 There is a role for the clinician, and that always
23 should be the case, and federal regulation, particularly
24 under the Radiation Control Health and Safety Act, should
25 try to prevent hazardous radiation exposure situations, and

1 it probably should stop there under the Radiation Control
2 Act.

3 Now, I think the situation is a little different
4 under MQSA because MQSA is oriented towards quality. But I
5 think it's a hard thing to say that you never want the beam
6 under any clinical circumstance to be less than some
7 percentage to the edge of the image receptor. There may be
8 circumstances that we can envision, even with contact
9 mammography, even with a large focal spot, where that's
10 appropriate. And I think it would be unfortunate if we made
11 a regulation that precluded that. And I think that's the
12 danger you run if you go beyond what has been proposed here.

13 What has been proposed, I think, allows the
14 clinician freedom to work with their manufacturer to get the
15 collimation the way they need it clinically, so long as it
16 doesn't extend beyond the primary barrier, so long as it
17 doesn't extend beyond the edge of the image receptor by 2
18 percent. And in my view, that's where federal regulation
19 probably ought to end, and it ought to be up to the clinical
20 practice, just basically as Bob just said, to tailor the
21 situation individually to what's needed in that clinical
22 practice.

23 Now, having said that, let me add one other
24 comment that's sort of relative to this whole discussion.
25 We are very concerned at ACR about the impact on some

1 practices by the general equipment regulations if the
2 practices don't do something right away to clarify whether
3 their current equipment meets the regulations, the final
4 regulations that will go into effect a year from now, and if
5 they don't take some action fairly quickly in the case where
6 their equipment will fail next April.

7 We are planning--and have already drafted, in
8 fact, and we're working on trying to get it final--something
9 for the ACR bulletin to try to sensitive facilities that
10 they ought to be working with their medical physicists, the
11 physicists ought to be looking at their current equipment.
12 If they're going to have a problem next April, they ought to
13 be planning right now to start fixing it because this is
14 only one of the new equipment requirements. There are many
15 others. And next March is going to be too late if they
16 start thinking about it then because, as John Sandrik has
17 said, there's going to be a lot of pressure on vendors over
18 this next year to try to work with all of the facilities
19 that have older equipment that may not meet these final
20 regs, and they really need to start planning for that now.

21 CHAIRPERSON MONSEES: Okay. Is there anybody in
22 the audience, by the way, before we conclude this
23 discussion, to answer Dr. Sickles' question? Is there
24 anybody that cannot--you're an equipment manufacturer.

25 DR. HENDRICK: Yes, I--

1 CHAIRPERSON MONSEES: And anybody else needs to
2 come up and speak about this if this is going to be a
3 problem. Go ahead, Dr. Hendrick?

4 DR. HENDRICK: One of the sources of data, which
5 is not an equipment manufacturer source, is review of
6 phantom images that come into the ACR accreditation program.

7 CHAIRPERSON MONSEES: Okay. That's a valuable
8 source.

9 DR. HENDRICK: And over the last year, I would
10 say--and I arrived at this number independently of Bob--
11 between one in 30 and one in 50 of the sites that I review
12 phantoms on has D-shaped collimation. So I would say that
13 represents sort of the current population of that kind of
14 collimation.

15 CHAIRPERSON MONSEES: That's a good--

16 DR. HENDRICK: Can I go on and make a comment
17 about Charlie Showalter's comment?

18 CHAIRPERSON MONSEES: Yes, go ahead.

19 DR. HENDRICK: I think you have a real problem
20 here that isn't fixed by leaving things alone, and I sort of
21 interpreted Charlie's comment as if you leave everything
22 alone, the manufacturers and the physicists will fix it.
23 And, yeah, they will, but it's going to be a huge cost, huge
24 sort of difficulty for mammography facilities. And what you
25 need to come up with is something reasonable.

1 My understanding is right now the equipment
2 regulations for manufacturers still say you have to
3 collimate within--a piece of equipment being sold today or
4 tomorrow or probably next year will still have to face this
5 regulation that says the collimation has to come within the
6 film. So I think that you need to have a reasonable
7 approach to this that does eliminate D-shaped collimation,
8 that doesn't have too large a white border on the films that
9 are being produced, but also doesn't pose a huge burden on
10 manufacturers and sites and physicists to solve a problem
11 for which many manufacturers don't yet have a solution
12 because it would be in conflict with the manufacturing
13 standards.

14 So I think the FDA and this committee need to do
15 something to direct a solution toward the problem.

16 CHAIRPERSON MONSEES: Mr. Showalter?

17 MR. SHOWALTER: Charlie Showalter, ACR.

18 Apparently I didn't state very clearly what I meant. What I
19 meant was that I believe both the diagnostic X-ray standard
20 needs to be amended and the MQSA requirements as written
21 need to be amended in accordance with what Rick has
22 presented here. And in my view, that is one solution.

23 I completely agree with Ed that we cannot leave
24 things alone, and I'm sorry I didn't say that because that
25 is what I meant. What I meant was that I believe this

1 solution possibly as amended--it's not necessarily perfect,
2 but it goes a long ways towards fixing the current conflict,
3 which I completely agree has to be fixed.

4 CHAIRPERSON MONSEES: I thought I understood that.
5 Is there anybody else--no, not just with your last
6 comment, but when you said it before.

7 Any other comments before we conclude this
8 discussion? Yes?

9 DR. SICKLES: Ed Sickles. Is it the aim of this
10 discussion to get a sense of the committee's opinion to
11 advise the FDA? I don't know if we've gotten that. I don't
12 think we have.

13 CHAIRPERSON MONSEES: Right. My understanding is
14 that we give a message to the FDA, and I think they've heard
15 the message, that we cannot leave it alone.

16 DR. SICKLES: Okay.

17 CHAIRPERSON MONSEES: That they need to act
18 quickly, and that it needs to be solved prior to--and we can
19 ask whether everybody believes this or anybody dissents from
20 this--that it needs to be fixed before it becomes an issue
21 for equipment manufacturers and for facilities which may not
22 be able to use their units after April of 1999.

23 So I think we've made that pretty clear.

24 DR. SICKLES: Barbara?

25 CHAIRPERSON MONSEES: Yes?

1 DR. SICKLES: Can I amend what you said with one
2 further comments?

3 CHAIRPERSON MONSEES: Yes.

4 DR. SICKLES: Ed Sickles talking now. I'm in
5 complete agreement with everything that I've seen from these
6 proposed amendments to both EPRC and MQSA. What I would
7 like to see--and I'd like to get a sense of the committee--
8 is that these amendments also eliminate the possibility of
9 D-shaped collimation because it will not be a burden to
10 existing units. It's one in 50 or one in 30 units. That's
11 not a burden. And it would seem to me that if we allowed
12 the wiggle room that we're trying to put in here but we also
13 didn't allow the D-shaped collimation, we'd have the best of
14 both worlds. And I'd like to get a sense of the committee,
15 if we could, on that.

16 CHAIRPERSON MONSEES: I'm getting the impression
17 that, in fact, the original committee had that same sense
18 and that we are just concurring with that.

19 Is there anybody that disagrees with what Ed
20 suggested?

21 [No response.]

22 CHAIRPERSON MONSEES: All right. So I think we
23 all agree with that.

24 Has the FDA given you everything you--has the
25 panel given you everything that you need?

1 MR. KACZMAREK: Oh, I think so.

2 CHAIRPERSON MONSEES: Okay. Do you think, for
3 those manufacturers in the audience who are wondering, do
4 you think that you can accomplish this in time so that they
5 don't have to get into high gear?

6 MR. KACZMAREK: Well, we will try. I believe
7 we're on track for the EPRC and then hopefully to publish
8 something in the Federal Register, in other words, actual
9 text, actual proposed new language, this summer. There
10 would be a comment period, and then we would go back and,
11 you know, give everybody an opportunity again to send in
12 comments and then come up with a final regulation from
13 there.

14 I don't know exactly where the MQSA amendment
15 stands, but I believe that would go through a similar
16 process, publish for comment.

17 Let me just add a footnote to that. This approach
18 conceptually agrees, as the manufacturers are probably
19 aware, with the IEC's--their final draft for safety of mammo
20 equipment, International Electrotechnical Commission.
21 Manufacturers are familiar with that body. But our approach
22 here today also harmonizes with this international equipment
23 standard. I just wanted to make that point.

24 The only other thing I'd like to say is I don't
25 think going forward that the manufacturers are going to be

1 looking to make equipment with features that clinicians
2 don't want.

3 CHAIRPERSON MONSEES: Okay. Now, because
4 manufacturers need a certain amount of lead time to change
5 things, are you extremely confident that this will be
6 accomplished in time? Or are you extremely confident that
7 inspectors will not preclude people from using the equipment
8 that is existent?

9 MR. KACZMAREK: You're always going to be able to
10 use the equipment because you're always in a pinch going to
11 be able to get a variance or an alternate standard. So
12 there's always going to be a way to work around a problem
13 that comes up. Nobody's going to be out of business.

14 As far as time frame for getting all these changes
15 accomplished, we'll do our best to get them done as
16 expeditiously as possible.

17 CHAIRPERSON MONSEES: A last comment?

18 MR. PIZZUTIELLO: On the subject of the time
19 frame, it's also important that we communicate with the
20 medical physics community, because it's the physicists who
21 are out there doing the surveys who advise the client that
22 this machine is or is not going to be compliant with the new
23 regulations. So it's communication not only with the
24 manufacturers but also with the medical physics community,
25 and I think we should work together to make sure that

1 happens.

2 CHAIRPERSON MONSEES: Thank you.

3 All right. Unless there's some other urgent issue
4 relating to this or comment that really impacts on what
5 we've just discussed--you have a comment? Come forward
6 please.

7 MS. DiPALERMO: Maria DiPalermo, Siemens Medical
8 Systems.

9 I just want to clarify some of the points that Dr.
10 Hendrick made or alluded to. The concept of the small focal
11 spot imaging, which you all referred to also, perhaps there
12 needs to be made clarification in the MQSA that this
13 collimation regulation really applies to full-field imaging
14 on film and that any spot imaging is either not applied or
15 further collimation be up to the individual facility or
16 physician. Does that make sense?

17 CHAIRPERSON MONSEES: Yes. All right.

18 MS. DiPALERMO: So that, you know, not everybody
19 interprets that you have to have every spot compression
20 image, whether it's done with large or small focal spot, and
21 still has to expose the whole film, which you sometimes
22 can't.

23 CHAIRPERSON MONSEES: Okay. The FDA has heard
24 that comment; we've heard that comment. We're going to move
25 on. Thank you.

1 We're going to move to States as Certifiers, and
2 we're going to have two presenters, Chet Trybus and Ruth
3 Fischer from the Mammography Standards Branch.

4 DR. FINDER: It's Dr. Finder. I just wanted to
5 state, for the next couple of topics that we're going to be
6 discussing--actually, having updates on, these are just
7 updates. They're really not meant for long-term discussion.
8 It's just to inform the committee about what's been
9 happening since the last meeting. So these are not really
10 discussion issues.

11 MR. TRYBUS: Good morning. I think it would be
12 best if we hold the questions until the end of the
13 presentation.

14 CHAIRPERSON MONSEES: Go ahead.

15 MR. TRYBUS: Next slide, please.

16 This presentation will cover the key issues
17 pertaining to the MQSA States as Certifiers program,
18 including the status report. There have been numerous
19 activities ongoing recently, and I'll just bring you up to
20 speed on what's happening.

21 Subsection Q of the MQSA authorizes the state
22 program--that's the States as Certifiers program; it's
23 referred to as "state program" in the act--and per
24 subsection Q, FDA may delegate certain mammography
25 facilities' certification responsibilities to states.

1 Next slide, please?

2 Just a brief program overview, and this was
3 covered somewhat yesterday by Mr. Brown. The authority
4 delegated to states under the state program is that they may
5 issue and renew certificates, suspend and revoke
6 certificates, conduct annual inspections, and impose
7 sanctions.

8 Next slide, please?

9 The authority retained by FDA is that the agency
10 is permitted to approve accreditation bodies, establish
11 quality standards, collect fees, approve and withdraw
12 approval of state certifying bodies, and maintain oversight.

13 Next slide, please?

14 There is also dual authority under the program,
15 this being that both the state and FDA may suspend and
16 revoke certificates, impose sanctions, and issue
17 injunctions. FDA generally will not act under this dual
18 authority unless there is a serious violation, and if there
19 is a serious violation, FDA can impose additional sanctions
20 on top of those imposed by the states.

21 Next slide, please?

22 The current accreditation bodies include the ACR,
23 the states of California, Iowa, and Arkansas. The only
24 certification body to date is the FDA. In the future, we
25 anticipate that the current accreditation bodies will

1 continue. There is the possibility of additional
2 accreditation bodies coming on board. It's uncertain at
3 this particular time. In the future, FDA will be maintained
4 as an accreditation body in addition to the states.
5 Certification, sorry.

6 Next slide, please?

7 As far as the program implementation is concerned,
8 there is in place a States as Certifiers working group which
9 began in the spring of 1996. Its purpose is to assist FDA
10 in development of the States as Certifiers program. It's
11 comprised of radiation control program directors from the
12 states listed and a representative from the ACR.

13 These particular states were chosen because they
14 include the three accreditation body states along with a
15 state from each FDA region. There have been three meetings
16 held to date. The next meeting is scheduled for May 16,
17 1998.

18 Next slide, please?

19 Also part of our program implementation is the
20 demonstration project. The purpose of this project is to
21 pilot test the program before regulatory implementation.
22 The working group assisted in the development of the
23 demonstration project. They, among other things, reviewed
24 the application to become a demonstration project state, and
25 they also reviewed the evaluation criteria.

1 An information session pertaining to the
2 demonstration project was held on December 15th of 1997.
3 Approximately 40 states participated in this information
4 session, and basic information on the project was presented
5 to those states.

6 Applications to participate in the demonstration
7 project were due to the agency by February 16th of 1998. As
8 Mr. Brown mentioned yesterday, we received two applications,
9 one from Iowa, one from Illinois.

10 Next slide, please?

11 The application review is currently underway.
12 It's a performance-based approach. The demonstration
13 project is scheduled to begin on or about July 1, 1998, and
14 continue for one year, with an option for a one-year
15 renewal. FDA will evaluate the state certification
16 activities during the demonstration project per evaluation
17 criteria that we've developed.

18 Next slide, please?

19 This slide pertains to the \$509 fee for
20 inspection-related services that Mr. Brown mentioned
21 yesterday, and the intent of this slide is to indicate what
22 services will be provided during the demonstration project
23 to the states for that fee. These include billing
24 facilities for fees due for the annual inspections,
25 collecting facility payments, training and certification of

1 inspectors, development of instrument calibration procedures
2 and calibration of instruments used in the inspections,
3 supplying, repairing, and replacing inspection equipment,
4 design programming and maintenance of inspection data
5 systems, administrative support attributable to facility
6 inspections.

7 I think that the activities that comprise the
8 majority of the--that we provide the most will be the
9 training and the data processing.

10 Next slide, please?

11 As was mentioned yesterday, there is a controversy
12 with respect to the states not being permitted to collect
13 the inspection fees under this program. This has been an
14 issue of ongoing discussion within the agency to try to
15 determine how best to handle this. We obtained a ruling
16 from our department level general counsel indicating that
17 states were not permitted to collect the inspection fees per
18 the current MQSA language. So what we are proposing to do
19 as part of the MQSA reauthorization is to revise this fee-
20 processing language so that states essentially will be
21 permitted to collect fees under the program. And this is
22 the proposed language. A state with an application approved
23 under subsection Q(1) may assess and collect fees from
24 persons who own or lease mammography facilities to cover the
25 costs of inspections of these persons' facilities conducted

1 under subsequent Q.

2 Next slide, please?

3 Regulation development. This is on a parallel
4 track with the demonstration project. We anticipate that
5 the proposed regulation format will be similar to the MQSA
6 final regulation for accreditation bodies and contain
7 application standards, evaluation withdrawal, and hearing
8 section. The targeted implementation date for the program
9 is approximately July of 2000.

10 Thank you. That's the end of my presentation.

11 CHAIRPERSON MONSEES: Lights on.

12 Ms. Fischer, you're not making a presentation; is
13 that correct? You're just here to answer Q&A?

14 MS. FISCHER: Correct.

15 CHAIRPERSON MONSEES: Okay. Questions from the
16 panel, comments from the panel?

17 MR. FLETCHER: Roland Fletcher. Two questions
18 regarding your upcoming meeting with the working group. Is
19 that going to be in Arizona?

20 MR. TRYBUS: Yes, it is.

21 MR. FLETCHER: And is it open for other
22 participants?

23 MS. FISCHER: In order for a state to be part of
24 this working group, it's according to an FDA rule which
25 allows it, and so we have to--we have a process of

1 confidentiality slips and so forth that have to be done in
2 order for a person to be a participant.

3 MR. FLETCHER: What about just being--you know,
4 auditing the meeting, not necessarily being part of the
5 working group but to hear the proceedings? Would that also
6 require formal application?

7 MS. FISCHER: I believe that it would, but I'll
8 check that for you, Roland.

9 CHAIRPERSON MONSEES: Any other questions or
10 comments here? This was meant to be information, but...okay
11 We'll move on then. Thank you very much.

12 The next part of this morning's session will be
13 the voluntary stereotactic accreditation programs update,
14 and we have two presenters. One is Dr. David Winchester,
15 Professor and Chairman of the Department of Surgery,
16 Evanston Hospital, and then the second presenter will be Pam
17 Wilcox-Buchalla from the ACR.

18 Do you want to sit down or do you want to stand
19 up? However you want to do it.

20 DR. WINCHESTER: Both.

21 CHAIRPERSON MONSEES: Okay. Both. You want her
22 to sit and you to stand?

23 DR. WINCHESTER: We'll take turns.

24 CHAIRPERSON MONSEES: You'll take turns. Okay.

25 DR. WINCHESTER: Good morning, and I bring you a

1 message of progress this morning. We, you may recall at the
2 last meeting of this committee, had a discussion about
3 personnel requirements, radiologists and surgeons, for the
4 performance of stereotactic breast biopsy. An agreement has
5 been reached between the two colleges. That is done.

6 At the February 1998 Board of Regents meeting of
7 the American College of Surgeons, a joint accreditation
8 program with the American College of Radiology was approved,
9 and basically what that means is that the now existing
10 accreditation program of the American College of Radiology
11 is being spliced with an accreditation program by the
12 American College of Surgeons.

13 The American College of Surgeons will be
14 responsible for verifying education and experience of
15 surgeons wishing to perform this procedure, and they will
16 subcontract with the American College of Radiology and the
17 latter will continue to accredit radiologists, medical
18 physicists, radiologic technologists, and the facility.

19 By this mechanism now, I think we have clearly
20 agreement between the two colleges about the qualifications
21 for performance of this and the setting in which that
22 occurs.

23 The Colleges have met just about two or three
24 weeks ago to develop details and application forms that are
25 necessary for a joint accreditation program to move forward.

1 Many have asked us at the American College of Surgeons how
2 many surgeons are doing this in the United States. We do
3 not know. We plan to send out a survey to all the fellows
4 of the American College of Surgeons, around 60,000, and
5 ascertain that number and in that communication underscore
6 the importance of complete participation in the, quote,
7 voluntary accreditation program, realizing that we have to
8 have full penetration of our membership in order for this to
9 work effectively. And as such, we intend to include in that
10 communication an application form to those who wish to
11 become accredited as surgeons performing the procedure.

12 That concludes my report, and Pam then will give
13 us an update on some details.

14 CHAIRPERSON MONSEES: Okay. I think we'll reserve
15 the questions for you for after we hear Pam's presentation.

16 MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla, ACR.

17 As Dr. Winchester indicated, there was a meeting
18 on April 16th between the ACR and the American College of
19 Surgeons to come to the next phase of our agreement about
20 accreditation for stereotactic breast biopsy. And the
21 agreement is in process. We're working on a contract as we
22 speak.

23 The College of Surgeons, as Dr. Winchester
24 indicated, would oversee their own accreditation program.
25 Documents would be very similar to those used in our

1 program, and the criteria would be identical. But most
2 important, of course, is the physician criteria.

3 In the document that was just passed out to you by
4 Dr. Finder, that is the ACR accreditation program overview.
5 It does include the credentialing section that addresses
6 both non-MQSA-qualified physicians and MQSA-qualified
7 physicians. So that's probably the area of most interest.

8 When this program for the College of Surgeons goes
9 active, applications will be submitted directly to the
10 College of Surgeons. They will review the physician
11 qualifications. If the physician meets the criteria, then
12 the application will be forwarded to the ACR for the rest of
13 the review of credentials for technologists, medical
14 physicists, clinical image review, phantom image review and
15 dose, evaluation of the quality control program. There will
16 also be a component for an appeal process, as there will be
17 in any accreditation program. And there will be a provision
18 for on-site surveys, and that will be a random selection of
19 sites.

20 When an on-site survey is performed for a surgical
21 facility, the team will include a surgeon appointed by the
22 College of Surgeons and the normal team that we use in our
23 accreditation program--a radiologist, a medical physicist,
24 and a technologist who has experience and expertise in
25 stereotactic breast biopsy. So the programs will be very,

1 very parallel.

2 I want to report to you where we are with the ACR
3 voluntary program at this time. We have 333 facilities that
4 have applied. We have 216 accredited. We all have some
5 concerns that this isn't moving as quickly as this committee
6 advised us to push the applications at the last meeting. If
7 the deadline is January 1 of the year 2000 to have close to
8 100 participation, we need to be more proactive in getting
9 applications in.

10 I think there are a couple of things that both our
11 colleges can do. One is Dr. Winchester's plan of sending
12 the survey with entry applications. We will also send entry
13 applications to all of the mammography facilities in our
14 program. I think that one of the delays has been that
15 facilities were waiting, number one, to see what the FDA was
16 going to do and waiting to see if they were going to be
17 required. And I'm not sure that the word is really out
18 there yet that if they don't participate in a voluntary way
19 that it will become required and they will be inspected on
20 it. And so we will be doing notices in our bulletin. We'll
21 send notices to facilities participating in mammography.

22 But I think that the other thing that I would
23 strongly urge the FDA to consider--and I hope the Advisory
24 Committee will support this--is that they do some kind of an
25 informational piece in Mammo Matters, and perhaps even a

1 special mailing to all facilities saying that these are the
2 options, even if you go to requiring accreditation, if
3 they're not in the loop they're going to be in a problem
4 where they may not be able to practice. So encouragement
5 from the FDA to participate I think is a strong need.

6 I think some of the other places that we could put
7 information is on our Web sites, and I would encourage,
8 again, that FDA do something on their Web site.

9 Finally, I think that we've moved far. I think
10 this is a real step in the right direction for cooperation
11 between the two colleges. Just because FDA stood over us
12 with a whip, I think it was still effective, and we've done
13 that and we're moving ahead. And I think it's going to be
14 very successful.

15 There are opportunities for surgeons or other non-
16 MQSA-qualified physicians, and I will tell you that just
17 this week we had OB-GYNs calling asking how they could
18 accredited. So there are alternatives for non-MQSA-
19 qualified physicians to do this and to be teachers of this
20 process to other physicians. So I think we've covered all
21 the bases, and the two colleges have worked hard to come to
22 reasonable agreement.

23 Thank you.

24 CHAIRPERSON MONSEES: Okay. Do we have any
25 questions here from--Dr. Sickles?

1 DR. SICKLES: Ed Sickles. I have a question. I
2 think it's better directed to Dr. Winchester.

3 I think the ACR has a reasonable handle on
4 facilities that might be doing stereotactic biopsy that are
5 radiology facilities because principally they would be
6 facilities that are also doing mammography. The mammography
7 facility population would contain all of the stereotactic
8 biopsy equipment.

9 How will the college or, if the College of
10 Surgeons doesn't have a good handle on this, how will the
11 FDA--maybe Charlie Finder can answer this--identify all the
12 surgical sites that are doing this procedure so that you
13 have some concept of whether you're getting close to full
14 participation?

15 DR. WINCHESTER: I don't have a good answer to
16 that question. Surveys are voluntary. They're not
17 mandatory, and you're not going to capture all of the
18 independent free-standing surgical centers in existence. So
19 I don't know how we can arrive at those unknowns.

20 DR. SICKLES: I share your statement. How will
21 the FDA deal with this?

22 DR. FINDER: Well, part of--it's Dr. Finder. Part
23 of the next update, we'll tell you some of the information
24 that we've obtained about the number of units that are
25 actually out there.

1 CHAIRPERSON MONSEES: Yes?

2 MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla. I
3 would wonder if perhaps the FDA could send a special notice
4 to all the facilities, because, of course, even for ACR,
5 we're not the only AB. And if you would send a notice to
6 facilities saying contact the places that they refer
7 patients for biopsy and let them know, give them a form
8 letter that they could send on to those facilities, it might
9 be--

10 DR. FINDER: I think there are a lot of ways that
11 we can address it, and we have heard some of the
12 suggestions, and I think we'll take those to heart.

13 CHAIRPERSON MONSEES: I'd like to ask a question.
14 How widely has this been, let's say, distributed as a
15 document among the two colleges so that the constituency of
16 the colleges has had a chance to comment? Is this the
17 leaders of each of the colleges that have designed this, or
18 have any of the constituencies of the college had the chance
19 to comment and give you feedback about the program that
20 you've designed?

21 DR. WINCHESTER: Winchester. College of Surgeons
22 have had broad feedback from the surgical community, have
23 consolidated all of those inputs and come up with the
24 revision, and we are now going to publish this in the
25 bulletin of the American College of Surgeons next month,

1 which will describe the revised personnel requirements and
2 the accreditation program. And I think, Pam, the ACR is
3 planning the same sort of communication through their
4 college's publication.

5 CHAIRPERSON MONSEES: Are you through the feedback
6 portion so that you've really got the final product here?
7 Or do you think that there might be any additional feedback
8 that will come that will tweak this program a little bit or
9 make some changes?

10 DR. WINCHESTER: Well, there's two questions
11 there. One is feedback and one is tweaking.

12 CHAIRPERSON MONSEES: Right.

13 DR. WINCHESTER: I had additional feedback from
14 Dr. Dowlat this morning at breakfast, a good point, but it
15 doesn't change the document. It just changes the form of
16 the document.

17 CHAIRPERSON MONSEES: Okay.

18 DR. WINCHESTER: It doesn't change any rules, and
19 we will take care of that. Tweaking is something that's
20 been addressed here. We're going to do everything we can to
21 make this a universally applied program.

22 CHAIRPERSON MONSEES: Okay. Thank you.

23 I have one observation that I might just make,
24 having looked at the other document that came previously and
25 then the current document, and that is that with the

1 radiologist and the surgeon practicing collaboratively, it
2 looks like the radiologist is made responsible for oversight
3 of all quality control and quality assurance activities, but
4 it doesn't say that there's any responsibility by the
5 surgeon to participate in that. And I would like to see
6 that as part of this program, because I think there should
7 be an obligation to participate and make sure that all of
8 the cases are reported, et cetera, that may be done by a
9 surgeon in the absence of the radiologist who is being made
10 responsible for this.

11 Do you have any comment on that, Ms. Buchalla?

12 DR. WILCOX-BUCHALLA: So if I can be clear, Dr.
13 Monsees, you're saying that there should--the item that is
14 in the collaborative practice, it says be responsible for
15 all oversight--for oversight of all quality control and
16 quality assurance activities, that there should be some
17 reference back to that in the surgical section?

18 CHAIRPERSON MONSEES: I think so.

19 DR. WILCOX-BUCHALLA: I think we can take that
20 back and take it into consideration. This document has been
21 circulated widely. It's been published in the ACR bulletin
22 and in the College of Surgeons', had minor changes. Most
23 recently, it's been approved by our boards at least twice.

24 I think that perhaps one way to deal with that is
25 in some of the more detailed discussion of what this means

1 rather than in revision of the actual agreement. We can
2 talk about it as part of the accreditation that there has to
3 be--because medical audit is required, it's addressed in
4 sort of an indirect way, but I think we can deal with that
5 issue.

6 CHAIRPERSON MONSEES: Thank you. Any other
7 comments from panel members?

8 [No response.]

9 CHAIRPERSON MONSEES: We have one--I'll
10 acknowledge one from the audience.

11 MS. EDGERTON: Trisha Edgerton, State of
12 California. I have just two comments.

13 One is you need to be careful when you send out
14 the information to surgeons in that currently California
15 only allows a collaborative model, doesn't allow an
16 independent model. So you don't want to confuse surgeons
17 more than they are in California, which has occurred from
18 the previous letter sent out to surgeons of California that
19 was brought up at a previous meeting here. I wasn't
20 referring to surgeons being confused in general.

21 The second thing is that states--for instance, I
22 can tell you that we have out of 900--well, in addition to
23 the 910 facilities in the State of California, I know of
24 about 20 that are biopsy-only facilities that don't have
25 accredited, certified machines. And so that's a significant

1 amount of facilities that you wouldn't reach through ACR or
2 through FDA mailings. And you may want to contact the
3 states and see how many of those facilities--because most of
4 us states keep track of everyone, and we certify
5 stereotactic units, in addition, and inspection them, in
6 addition. So that's another option.

7 CHAIRPERSON MONSEES: Thank you. And, Ms.
8 Buchalla, I just wanted to ask a question. The ACS used to
9 keep track of places that were accredited before voluntary
10 accreditation became mandatory for mammography units and
11 facilities. Is the ACS a source of information to women in
12 the community who want to know facilities that are
13 accredited on this particular topic?

14 MS. WILCOX-BUCHALLA: The ACR does provide a
15 monthly updated list to the American Cancer Society of
16 accredited stereotactic facilities, and that will also be
17 part of the process with the College of Surgeons-accredited
18 facilities. The list will be provided at the same time the
19 ACR list is provided.

20 CHAIRPERSON MONSEES: Is that currently available
21 information--

22 MS. WILCOX-BUCHALLA: Yes, it is.

23 CHAIRPERSON MONSEES: --people call the American
24 Cancer Society, ACS?

25 MS. WILCOX-BUCHALLA: Yes, it is.

1 CHAIRPERSON MONSEES: Thank you.

2 Do we have any other questions?

3 [No response.]

4 CHAIRPERSON MONSEES: Okay. We'll move on. Thank
5 you very much.

6 We're going to move on to interventional update,
7 presenter Ruth Fischer.

8 MS. FISCHER: Good morning. The first thing
9 you're going to see is that I don't know Power Point, and,
10 therefore, my slides have no color, no fancy designs. This
11 is basic low-rent black and white.

12 I'd like to go over some of these points also for
13 the benefits of the new members of the committee here today
14 who don't have the background on this issue.

15 First of all, when we're talking about
16 interventional mammography, what exactly are we talking
17 about? It's mammography performed during invasive
18 interventions for localization or biopsy procedures. And
19 the two primary types are stereotactic core biopsy and non-
20 stereo grid wire localization.

21 Under MQSA, the statute defined mammography as
22 radiography of the breast, and that was so sweeping that I
23 don't believe Congress exactly understood the ramifications
24 of that because all of the data that they were looking at,
25 at that point in time I was providing testimony for, was

1 dealing with screen film units. But it came out radiography
2 of the breast.

3 Our very second Advisory Committee meeting, we
4 brought up the localization issues, and we were advised by
5 the original committee then that there was so much that
6 needed to be done in the development of the final regs that
7 to undertake the invasive procedures at the same time was
8 just too overwhelming a task. And so what happened is that,
9 September 30th of 1994, we published some amendments in the
10 Federal Register which clarified screening and diagnostic
11 mammography. We used definitions according to the ACPR and
12 ACR guidelines, their definitions, that would clarify the
13 scope of present regulated activities. So that excluded
14 interventional and all those dealing with experimental
15 research studies, many of the digital studies that are going
16 on today.

17 About two years later, we heard back that we
18 should reconsider including the interventional mammography
19 under MQSA, and we had a lot of anecdotal information coming
20 in. We had Advisory Committee members urging us to do so.
21 And so we were starting to take a look at that.

22 At the time that this was coming up, a joint task
23 force was formed between the American College of Radiology,
24 the American College of Surgeons, and the College of
25 American Pathologists. And they were a national task force,

1 and they were convened because it was felt that diagnostic
2 radiologists, surgeons, and surgical pathologists must work
3 together to achieve optimum patient outcome. And as you
4 have just heard through a series--the task force published
5 their report in CA, Cancer for Clinicians, in May-June of
6 '97. That was the issue. And it talked about
7 recommendations for equipment standards, QC/QA, and outcome
8 analysis.

9 And as you've heard just previously, the ACR and
10 ACS have been working diligently to work out the details of
11 qualifications for the physicians. We also were hoping that
12 there would be more participation at this point in time, and
13 we certainly are encouraging it.

14 In October '97, FDA did receive letters from the
15 executive directors of both ACR and ACS urging us to allow
16 their voluntary programs to really have a chance rather than
17 for us to step in and regulate. And we strongly agree with
18 that.

19 I think perhaps accreditation also may not have
20 gone along as quickly because of the waiting for resolution
21 on physician qualifications, and now that that's been
22 achieved, that in itself may help increase the enrollment in
23 the voluntary programs.

24 Last week, Bob Pizzutiello and Dr. Dowlat
25 graciously invited me to come to the American College of

1 Surgeons spring meeting, and at this time there was a 16-
2 hour session on image-guided breast biopsy, and the course
3 was divided into 8 hours of didactic and 8 hours of hands-
4 on. And I heard Bob's lecture on radiation issues related
5 to image-guided breast biopsy, and I must admit that, being
6 a non-physicist myself, I was observing the surgeons in the
7 room. They were captivated. It was amazing. His
8 presentation of the physics was so engaging. And I had a
9 chance to see firsthand the two colleges, you know, really
10 working together in this area.

11 Next, please? Next and last.

12 Data collection. What we did since the last time
13 was get the best possible estimate that we could for the
14 number of stereotactic units that are out there, and what we
15 did was contact the six major manufacturers and ask them to
16 provide us based on their sales of stereo units from the
17 point of initial manufacture. And we got reports of 1,207
18 upright units, 1,692 prone units, for a total of 2,899
19 units.

20 Now, this is probably an underestimate since some
21 smaller companies also manufacture this. But it comes very
22 close to the less than 3,000 that was previously estimated
23 by this committee last time.

24 When we do regulations, we have a very serious
25 need for data, and there was a lot of data collected on the

1 film screen, which was very powerful when it was presented
2 to Congress about the problems in the quality. And what we
3 are going to be doing--what we have also asked--what we're
4 also doing in the area of data collection is that the CRCPD
5 is doing a survey. That's the Conference of Radiation
6 Control Program Directors. It's rather anecdotal. It's
7 asking them about adverse events that they know of
8 pertaining to stereotactic units or interventional
9 mammography.

10 But we have to also have scientific research to
11 back regulation, and FDA's mission is not a research
12 mission. However, we do have one very strong vehicle
13 available to us historically. We have been providing Nex(?)
14 surveys for many years, and we currently have a survey that
15 will deal with interventional mammography that is supposed
16 to go out sometime this summer. That will give us hard
17 scientific fact. But we are also at the same time
18 encouraging the academic research institutions and agencies
19 whose mission is research, such as the National Cancer
20 Institute, to really take a look at this and, again, provide
21 all the supporting data that we need in this area.

22 We will do whatever we can to promote the
23 voluntary accreditation programs. We believe that this is
24 where the success is really going to lie in the community
25 regulating itself. We hope that the community will take

1 that message seriously to regulate themselves, and the last
2 step would be regulation, if necessary.

3 CHAIRPERSON MONSEES: Thank you. Can we have the
4 lights?

5 Do we have any questions or comments from panel
6 members? Dr. Sickles?

7 DR. SICKLES: Very briefly. What is the progress
8 of FDA's position on the issue of radiologists using
9 equipment to do wire localizations that has not yet come
10 under purview of MQSA because these units are used only for
11 wire localization?

12 MS. FISCHER: We're not regulating it.

13 DR. SICKLES: I know. I know you are not at this
14 point. It was my understanding at the last meeting of this
15 committee that suggestion was made or advice was given to
16 the FDA that you look into regulating these. Have you done
17 anything about that yet?

18 DR. FINDER: It's Dr. Finder. Basically, this is
19 part of the data-gathering procedures that we're involved
20 in--in fact, a part of the Nex survey and the discussions
21 with CRCPD, and their questionnaires address this. So we
22 are in the process of gathering data to find out just how
23 big a problem and how we can address the problems.

24 CHAIRPERSON MONSEES: I agree with Dr. Sickles
25 that the committee felt strongly that those units should be

1 accredited units. I think that was pretty universal among
2 us, so I think it's important to gather the data. But it
3 was pretty clear that if there are units out there that
4 people should be on notice that it's being looked into.

5 Any other questions?

6 MS. FISCHER: I do have to respond that it is not
7 a trivial matter for FDA to make a regulation, and we have a
8 very extensive process, and we do need data to support the
9 decision. So we have to gather what we can.

10 CHAIRPERSON MONSEES: Right. Thank you very much.
11 I would like to particularly thank the American College of
12 Surgeons and the American College of Radiology for their
13 efforts, and it looks like a fruitful outcome here. Thank
14 you very much, and thank your organizations for doing this.

15 We will move on to the summary of the minutes.
16 Those of you who are on the panel have a packet that
17 includes the summary of minutes, if you would pull that out.
18 Does anybody have any comments or corrections of the minutes
19 from the last meeting which was October 28-29, 1997?

20 [No response.]

21 CHAIRPERSON MONSEES: None? Okay. It's noted
22 that there are no corrections or comments.

23 Then we're going to address future meeting dates
24 and when they might be. We're not done after this, mind
25 you. We're going to address--we're going to open the

1 discussion for other things that FDA may need guidance on.
2 We have three questions that remain from yesterday after
3 John McCrohan's talk, and I'm going to give the opportunity
4 to the panel to bring up any other issues they want to. But
5 let's focus on this first, and then we're going to have a
6 break.

7 Okay. So, Dr. Finder, take it away.

8 DR. FINDER: It's Dr. Finder. Basically, the act
9 requires that we have two meetings a year. We've had one
10 this year. We have to have another one. The question is:
11 What's a good time for everybody?

12 We have August, September, October, November, and
13 December. So I leave those choices up to you. I realize
14 that there are going to be a lot of meetings in various
15 months, RSNA and things like that. But if anybody has any
16 ideas of what is available, when they think they might be
17 open, we can try and plan the meeting for that time. And if
18 you can't give me an answer right now, we certainly will
19 have our fax machines open, and you can fax us dates that
20 you have available. But if you have anything that you know
21 is especially bad right now, you might as well tell us, and
22 we can try and cross those out.

23 MS. MCCARTHY: Kendra McCarthy speaking. October
24 is Breast Cancer Awareness Month, and for advocates, we are
25 real, real, real busy. And I think mammography centers are

1 pretty busy then, too.

2 CHAIRPERSON MONSEES: Oh, yes.

3 MS. McCARTHY: So if we could steer clear of
4 October, that would help.

5 DR. FINDER: So much for October.

6 DR. WINCHESTER: Charlie?

7 DR. FINDER: Yes?

8 DR. WINCHESTER: I would echo October. That's the
9 month the college has their clinical congress, and just
10 generally speaking, the later you go in the year, the more
11 complicated it's going to get, except perhaps for December.
12 But the national meetings, committee meetings, academic
13 meetings, get heavier and heavier. The lightest time is
14 August.

15 DR. FINDER: The only problem with August, that
16 doesn't leave us a lot of time to prepare anything to have
17 for fruitful discussion.

18 DR. MENDELSON: How about early November as a good
19 compromise? That's between the September meeting of the
20 American College of Radiology at the end of September. It's
21 before the RSNA, which is the big radiology meeting. And
22 it's after Breast Cancer Awareness Month. Early November is
23 what I would--

24 CHAIRPERSON MONSEES: What does the surgical
25 calendar look like for early November, do you think?

1 DR. WINCHESTER: That's all right.

2 CHAIRPERSON MONSEES: Any physics meetings in
3 November?

4 DR. DOWLATSHAHI: Dowlat. I think I'd support
5 November. I think August most people are on vacation, those
6 who have kids, they take kids to vacation.

7 CHAIRPERSON MONSEES: That's right.

8 DR. DOWLATSHAHI: I think November--I agree with
9 Dr. Winchester--is a good time for us to meet.

10 DR. SICKLES: I can tell you just for myself, UCSF
11 runs a meeting the second week in November, so if you were
12 to hold it the second week in November, I would not be able
13 to attend. But that's just me.

14 CHAIRPERSON MONSEES: How about the first week?

15 DR. SICKLES: The first week would be fine.

16 CHAIRPERSON MONSEES: Well, this gives us a first
17 cut. It gives us a first cut. What he'll do is he'll send
18 out information about the possibilities, and then people
19 will respond, and then he'll get the best return possible
20 based on the proposed dates.

21 Okay. So with that, we're going to go to break.
22 We're in good shape time-wise. It's 20 until 10:00. This
23 will give you an opportunity to check out, if you need to,
24 from the hotel. We're going to break for 25 minutes.
25 That's going to be 10:05. We'll come back at 10:05, and

1 we'll do a continued discussion of agenda items.

2 [Recess.]

3 CHAIRPERSON MONSEES: Okay. We're going to
4 reconvene.

5 We have some unanswered guidance issues where
6 NMQAAC input was solicited. I will read those things for
7 those of you in the audience who don't know what we're
8 talking about. I'm talking about the document, the last
9 page of the document that was given to us yesterday. Right.
10 The MQSA inspection procedures that John McCrohan presented,
11 and then the last page had the input questions. And we've
12 done everything but 3, 4, and 5. I've spoken with him.
13 He's no longer here, had to leave and go to the office.

14 No. 3, he said he has no problem with. That's
15 answered. So we're going to do 4 and 5, which I'll tell you
16 in a minute, and then another question which has come up.

17 So, first, let's address this issue. How should
18 we implement what is acceptable documentation for the 8
19 hours of new modality training requirement? And
20 particularly what he was asking us to give him some guidance
21 on was: If somebody has credit, for example, for a new
22 modality say on digital, but they've already counted it
23 towards their CME credit, can they use it? Can they count
24 it twice, in other words? Can they use it? And then in the
25 future, how should that be used? Do you get the gist of

1 that?

2 We may have a new modality that comes online.
3 They may have used that as education towards counting
4 towards their CME, and now if they have enough to go
5 forward, can they use those numbers, yes or no? And what do
6 we do, therefore, in the future?

7 Then there's another related issue: If you count
8 as a starting date for your initial qualifications one date
9 and then another starting date for your initial
10 qualifications for a new modality, it could get kind of
11 sticky if we have two different starting dates. So how
12 should the FDA do that, handle that? I think that's less of
13 an issue compared to the first question that I asked.

14 So did I make myself clear as to what the question
15 is? Okay. Those of you who are nodding maybe have some
16 comments. We'll start with Dr. Sickles.

17 DR. SICKLES: Ed Sickles. I have a question
18 before I try to handle the answer. Are the new modality
19 requirements only initial requirements, or are they
20 continuing requirements?

21 DR. FINDER: It's Dr. Finder. They're both. You
22 have the initial 8 hours, and then there's a continuing
23 requirement of 6 every three years.

24 DR. SICKLES: Okay. And the question is
25 basically: Can you use the same new modality hours also to

1 qualify for the basic--

2 DR. FINDER: 15.

3 DR. SICKLES: The basic 15.

4 DR. FINDER: Right.

5 CHAIRPERSON MONSEES: The basic 15, and then as
6 part of your continuing 15 every three years.

7 DR. SICKLES: I understand.

8 CHAIRPERSON MONSEES: Or should it be in addition
9 to it?

10 DR. SICKLES: My understanding is that, in part
11 for practical reasons but also because it would be effective
12 training, new modality hours will not just come from
13 Category 1 CME but also will come from other types of
14 effective education, such as applications training by the
15 manufacturers, which I think is a very good idea.

16 On the other hand, that type of training will be
17 very equipment-specific and not mammography-specific, so
18 that I'm not sure that type of hours should be counted as
19 the 15. If it were--if digital mammography hours that
20 really integrate--and it's going to be very hard to
21 implement. That's why I'm thinking that it's not practical.
22 But digital mammography hours that really integrate
23 mammographic teaching into digital imaging could effectively
24 be used for both purposes, but applications training
25 probably wouldn't be. So maybe you just want to say

1 anything Category 1 CME could be used for both, but other
2 things not?

3 CHAIRPERSON MONSEES: Okay. That's a good
4 comment.

5 Did you have a comment?

6 DR. NISHIKAWA: This is Bob Nishikawa. My feeling
7 from what was said earlier in the meeting that these
8 requirements are sort of broad in nature to try to encompass
9 different types of training, which I think then would fall--
10 would include training on new modalities, but after hearing
11 what Ed said, I agree with that, that the CME should count
12 towards both and specific training maybe only count towards
13 the 8 hours.

14 CHAIRPERSON MONSEES: Okay. What about for the
15 ongoing requirement? For the initial requirement, we
16 addressed it that Category 1 could count for both, and then
17 particularly, since there may not be enough courses out
18 there and because it's eight credits that need to be
19 obtained, applications may suffice for the new modality.
20 But then once that expires and you're talking about three
21 years later need six more credits, should applications be
22 sufficient at that time, or do you think it should be
23 Category 1 credit at that point? Do you have any opinions
24 on that?

25 DR. NISHIKAWA: I'll think about it.

1 CHAIRPERSON MONSEES: You have to think about it.
2 Okay.

3 Yes?

4 MR. PIZZUTIELLO: Bob Pizzutiello. I have to
5 agree that the applications training is so equipment-
6 specific that I think the Category 1 is an important piece
7 of it. So perhaps if the applications could be used as the
8 initial training, then everything else should be Category 1.

9 CHAIRPERSON MONSEES: Okay. That's what I was
10 alluding to. Maybe that would be another solution, and that
11 the applications would not count towards your 15 hours of
12 CME. So if some of it were Category 1 that would apply to
13 both, you could count those hours for both. But the
14 applications part couldn't be called your 15 hours of
15 general CME.

16 Yes, did you--

17 DR. SICKLES: Ed Sickles. The more I think of
18 this, the more I see some wisdom in allowing anything that's
19 Category 1 CME to go both ways. I mean, eventually
20 radiologists are going to be faced with--and, for that
21 matter, other physicians will be faced with having hours in
22 mammography and having hours in digital and having hours on
23 stereotactic, and it's going to--it could be very onerous to
24 try to make sure that you have enough of everything if you
25 can't overlap. We may wind up with a situation 10, 20 years

1 from now where people will ultimately have to get three
2 times as many hours just because of the different
3 categories. Allowing overlap would relieve some of that
4 burden.

5 CHAIRPERSON MONSEES: Okay.

6 DR. NISHIKAWA: Bob Nishikawa. Then maybe for
7 continuing education you could count whatever type of
8 training they receive. I can see a problem maybe in the
9 future, maybe just after the regulations are in place, that
10 there won't be a lot of opportunity for CME in digital
11 mammography, because there won't be many machines out. And
12 you might only get training through the manufacturer and
13 maybe one or two hours at a national meeting. So it could
14 become a problem otherwise.

15 CHAIRPERSON MONSEES: Yes?

16 MR. PIZZUTIELLO: Bob Pizzutiello. If you look
17 historically, when stereotactic first came online, the
18 manufacturers sponsored Category 1 programs. So I think
19 that since there's a very viable market, shall we say, for
20 the manufacturers to pursue, that they will find it valuable
21 for them to sponsor Category 1 serious academic programs
22 which people can go to for a weekend and get the courses.
23 So I think that once there's that market out there, the
24 system will drive itself.

25 CHAIRPERSON MONSEES: Okay. Any other comments?

1 DR. MENDELSON: Ellen Mendelson. I would just
2 agree, and I think that Dr. Sickles' comment about overlap
3 is something that we should keep in mind. In addition to
4 accountants for the IRS, we'll need CME accountants in the
5 coming years.

6 [Laughter.]

7 DR. MENDELSON: And I think that that would be
8 good, and also, Bob Pizzutiello's comments about the
9 evolution of new modalities is well taken.

10 CHAIRPERSON MONSEES: Okay. Any other thoughts on
11 this? Does FDA have what it needs for guidance? Okay.
12 We'll take these questions.

13 MS. FISCHER: This is Ruth Fischer. This is just
14 a comment to the committee.

15 Although our division is not directly involved in
16 the approval of digital devices, we do work with the Office
17 of Device Evaluation. And when manufacturers come in, we do
18 stress the modality training, so that we are informing them
19 at the time that this 8-hour requirement is there.

20 CHAIRPERSON MONSEES: Thank you.

21 Did you want to make a comment?

22 MR. MOURAD: Yes, I have a question, actually.
23 Wall Mourad, FDA.

24 Suppose people have been taking digital
25 mammography training or another new modality back in 1994 or

1 even earlier, but let's say 1994, and they've been counting
2 it for both ways. If we say the person achieved--or did
3 take 8 hours in 1994, and by the time the regulations
4 actually start next year, are you going to allow that as the
5 basic training has been met? Is that too old? Are you
6 still going to accept that?

7 CHAIRPERSON MONSEES: Okay. So people that would
8 have had this training more than likely would have been
9 people that were involved in digital early and probably have
10 the most expertise. So how do we feel about that credit
11 that was earned early on in the experience? Do I have some
12 comments here?

13 DR. DOWLATSHAHI: Barbara, I didn't quite get the
14 beginning of the discussion. When you referred to--

15 CHAIRPERSON MONSEES: Dr. Dowlat, go ahead.

16 DR. DOWLATSHAHI: I'm sorry. Dr. Dowlat.

17 When you asked about the modalities, you referred
18 to interventional as well as diagnostic?

19 CHAIRPERSON MONSEES: No.

20 DR. DOWLATSHAHI: I'm sorry.

21 DR. FINDER: The only thing we would be talking
22 about here would be a new mammographic--and maybe by using
23 the term mammographic modality rather than the word modality
24 we lessen the misunderstanding. We're talking about
25 mammography, new techniques, basically, and the only one

1 that we're seeing on the horizon is digital mammography. So
2 that's the only thing we're really talking about at this
3 point.

4 CHAIRPERSON MONSEES: We're talking about
5 regulated modalities, and interventional is currently not
6 regulated, and from what we heard this morning may not be
7 regulated. But mammography is regulated, and there will be
8 new modalities. We're not talking about ultrasound here.
9 We talked yesterday, addressed scintimammography, which is a
10 nuclear medicine technique, and that's not going to be
11 included. But digital mammography is a new mammographic
12 imaging modality, and so that's what we're talking about
13 specifically. And there may be others, but we don't know
14 what they are yet.

15 Dr. Sickles?

16 DR. SICKLES: Ed Sickles. Historically, thinking
17 back to many years ago, the only CME that was offered on
18 digital mammography really was talks looking to the future
19 about what its capabilities would be, not what they are,
20 because there were no such units around, as a practical
21 matter. How effective that instruction is is quite limited.
22 It just tells people what to expect. I don't know how
23 helpful--I mean, if you're looking at educating people and
24 showing that they really know what they're doing using the
25 equipment, I'm not so sure that training back from 1994

1 would be particularly effective.

2 CHAIRPERSON MONSEES: But there may be more
3 physics-centered meetings for developers, people who may
4 have been interested and people such as yourself or Dan
5 Copands(ph), or people that may have attended that meeting
6 who we don't know their names that really may be leaders in
7 this field and may or may not be able to count towards
8 those--

9 DR. SICKLES: Ed Sickles. Barbara, anybody who's
10 a leader in the field will have 8 hours without thinking
11 about it. That's not the problem. We're talking about the
12 people who are in the audience, not the people who are
13 teaching.

14 DR. FINDER: Right. Dr. Finder. Let me try and
15 focus this a little bit into the way I'm looking at it in
16 terms of inspections, what we're going to possibly look for.
17 I'm almost getting the feeling that now we're asking the
18 inspector not only to look and see that these people took a
19 course of 8 hours, but the quality of that course. You
20 know, we have to worry about what we're talking about here
21 in terms of what we can actually expect to inspect against.
22 So am I hearing that any--the committee would recommend that
23 any CME obtained before a certain date would not be
24 acceptable? Is that what I'm getting here?

25 CHAIRPERSON MONSEES: Let me hear some comments

1 from down here first.

2 DR. SICKLES: No, no. I--

3 CHAIRPERSON MONSEES: Mr. Fletcher, first.

4 MR. FLETCHER: Roland Fletcher. I have to feel as
5 though I'm operating at a disadvantage because I'm hearing
6 variations in the time of training, the level of training,
7 et cetera, and I'm being asked to make a decision on how to
8 apply that to the future. And I don't really think that I'm
9 in a position to even give you a good opinion.

10 My feeling is if we had established criteria that
11 is being met by those in the field, they shouldn't be
12 penalized for meeting that criteria. Something needs to be
13 addressed so that they're not penalized for doing what they
14 were told was the appropriate thing to do.

15 MR. PIZZUTIELLO: Bob Pizzutiello. We have never
16 said in the past that any training that anyone receives in
17 any breast-imaging-related modality had to be within the
18 last X number of years. The initial training is sort of
19 initial training.

20 Granted, there are some limitations. People who
21 went through residency in 1974, that probably isn't all that
22 applicable to what mammography is going on today. I think
23 that, again, this gets into the area of how much do we
24 expect FDA to regulate versus what is probably a good idea
25 from a practice and educational point of view.

1 I share Dr. Finder's concerns about putting an
2 inspection in a position of trying to decide what's a good
3 program. I guess you could say an arbitrary date. I tend
4 to favor not doing that. I think that any program in
5 digital imaging for the breast would be valuable and
6 contribute to a person's knowledge. Since there haven't
7 been many, many out there, it's not very likely that we're
8 going to have lots of people who show up with an 8-hour
9 training program that's very far out of date. They may have
10 been to one or a couple of one-hour lectures years ago, but
11 this is largely going to be driven by things in 1998 and
12 henceforth.

13 So since I see the problem as being relatively
14 small, a small number of people, a small number of hours, I
15 favor not regulating the detail of when they occurred, but
16 only regulating that they occurred.

17 CHAIRPERSON MONSEES: And my other point was--
18 maybe I didn't explain it very well--that the people that
19 are likely to have accrued it by now are the people that are
20 instrumental in bringing this to the community. And,
21 therefore, the people that are out there that haven't a clue
22 about it at this point in time would not be in the position
23 of having those CME credits digital. So I think we're okay
24 by counting it at any point in time.

25 Another comment, and then I'll call on Ms.

1 McCarthy. Go ahead.

2 DR. SICKLES: Ed Sickles. The more I think about
3 this, the simpler it would be not to have dates or anything,
4 just, you know, any CME in the past on digital mammography
5 you might as well count. There wasn't a lot out there
6 before, and people who have managed to collect 8 hours
7 already on digital mammography have been attending an awful
8 lot of mammography courses. I wouldn't worry about those
9 individuals.

10 CHAIRPERSON MONSEES: Or they went to physics
11 meetings. Yes?

12 MS. McCARTHY: Kendra McCarthy. A question.
13 We're saying that the initial training can be a combination
14 of the equipment training and the CME Category 1; correct?
15 That pretty much--

16 CHAIRPERSON MONSEES: Yes.

17 MS. McCARTHY: Do we want to perhaps consider
18 specifying a certain amount so that all of the hours would
19 not be equipment-related? Would we want to say at least 5
20 would have to be CME?

21 DR. FINDER: It's Dr. Finder. We'd have to work
22 within the current regulations, and the regulations just
23 state a number. They don't specify--and we had discussions
24 about whether we should go into the details of how much at
25 other committee meetings, and the decision was that if we

1 get down to that kind of specific level, we'd get way too
2 involved and would decrease the flexibility that people
3 would have.

4 Obviously, physicists would be more into the
5 physics area, but they still might need some of the clinical
6 issues. So we didn't want to get into that. And the same
7 for the clinicians. While it would be good to have a lot of
8 clinical education, they'd also need some of the physics.
9 But how much, we didn't want to get into specifying.

10 CHAIRPERSON MONSEES: The other things, it really
11 is mammography, and it's not like you're teaching somebody a
12 totally new modality. What we've learned about mammography,
13 we will utilize fully in looking at digital images. It's
14 really what they need to learn in addition, is how to
15 manipulate the images, how to pick windows. These are the
16 kinds of things that they will learn from applications
17 training.

18 So I feel confident that if they've got CME and
19 they're qualified interpreters and that if they have
20 applications training, it will help them to get what they
21 need to be able to look at and manipulate and interpret
22 those images. I think it's okay.

23 Yes?

24 DR. DOWLATSHAHI: Maybe we should define what this
25 new knowledge is all about, knowledge that you're trying to

1 teach the trainees, radiologists or even, for that matter,
2 surgeons, is what is the difference between digital and film
3 screen and how much time is needed to teach that new
4 information to the person. And then you can--once you know
5 the scope of the information to be transferred, then you can
6 put a number on it and say 1, 3, or 5 hours.

7 CHAIRPERSON MONSEES: Okay. The only problem with
8 that that I see is right now we have this modality that we
9 can talk specifically about, but can we say we're addressing
10 specifically digital mammography, or do we have to, because
11 we're giving the FDA guidance about all, quote, future
12 modalities, that it has to apply to all?

13 DR. FINDER: Again, what we're talking about, we
14 have the regulation which defines it. Anything that we
15 would discuss now would be guidance which would just be a
16 way to--one way, not the only way, to meet this. The
17 regulation says 8 hours. We're talking about how to
18 implement that in the best manner, achieve the goal that we
19 want, without creating undue burdens. And that's what we're
20 trying to do here.

21 We can make this very, very complicated, with
22 different starting dates and requirements here and there.
23 Do we achieve anything by doing that? That's one of the
24 issues that we have to always keep in mind.

25 I would say that what we would be talking about

1 again here is guidance where the only thing we're thinking
2 about is digital mammography? Could this apply to something
3 else that's coming down the pathway in the future? It
4 might. But then we could always have some additional
5 guidance for that with the recommendations.

6 CHAIRPERSON MONSEES: So would you like somebody
7 to clarify what digital mammography is for you?

8 DR. DOWLATSHAHI: I don't need that, but I just
9 need the scope of it. As you said, windowing, processing,
10 et cetera, is the--I mean, looking at the details, nowadays
11 I can magnify the image five times, can see a lot more on
12 micro-cals as well as masses. How does this thing correlate
13 to the film screen? Because in your brain, that's what
14 you're trying to do, is to interpret the signals coming to
15 you by digital versus film screen.

16 DR. FINDER: Again, I would try and go back to the
17 issue of--we specified a certain amount of training that has
18 to occur. We've left it up to the training program to
19 provide the information that they need, and it's going to be
20 different depending on the individual machine, possibly, or
21 it may be the same for the whole general idea of digital.
22 We didn't want to get into the specifics.

23 The organizations that will be giving these
24 training sessions have a vested interest in making sure that
25 what they're teaching is important. You know, we're going

1 to be having--hopefully the manufacturers give specific
2 training on their equipment. They're going to have to
3 provide a good program; otherwise, people won't know how to
4 use their equipment, and they won't be able to sell it.

5 CME courses obviously, and these will be Category
6 1 for the physician, are courses that are approved. A lot
7 of them are given by some of the people sitting at this
8 table or people that they know. So I wouldn't worry too
9 much about the scope of what's going to be covered, because
10 I believe that the important issues will be covered in great
11 detail.

12 CHAIRPERSON MONSEES: Maybe you can clarify this
13 in more appropriate terms, but if we go to digital
14 mammography, this will have to be an approved modality by
15 the FDA. It has to be an equivalent modality to current
16 mammographic technique. So the issues that you raise
17 pertaining to what you can see and, you know, can we detect
18 and diagnose diseases accurately, I think that it's a given
19 that if it's allowed as an imaging technology, that it will
20 have that equivalency. Is that--

21 DR. FINDER: Right. Before the equipment can be
22 used commercially, it has to go through an approval process
23 or a clearance process by FDA, not part of MQSA. That's a
24 whole different area. The Office of Device Evaluation. And
25 as Ruth mentioned, we are working with them to make sure

1 that the manufacturers are aware of our requirements as well
2 as ODE's requirements that it has to meet certain standards,
3 and they have to do that before they will be cleared for
4 marketing.

5 In fact, some of the people here are involved with
6 some of the trials that are going on for that.

7 CHAIRPERSON MONSEES: So we don't have to worry
8 about if it's equivalent. That's another thing.

9 DR. FINDER: Right.

10 CHAIRPERSON MONSEES: If it's approved, which we
11 anticipate that it will be--that's why the panel's being
12 asked to comment on this because it's likely it will be--
13 then we have to address what kind of requirements people
14 will need to meet in order to be able to fulfill the new
15 education requirements or new modality requirements for
16 education. Okay. So I think we've given you the guidance
17 that you need.

18 Is there any other--okay. Let's move on to the
19 next issue, which would be: What's the minimum number of
20 films per quarter to be included in the repeat analysis for
21 quarterly QC? Now, I understand that the panel once
22 addressed this. I see Dr. Hendrick in the audience wincing.
23 So the question is: Is 250 films adequate? That means the
24 first--I'm sorry, 250 exams, the first 1,000 films adequate?
25 Should it be all the films? What should be included in the

1 repeat analysis? What becomes burdensome for a facility to
2 do? What's reasonable?

3 I would add that if we're going to limit it to 250
4 patients, 1,000 films, that we'd have to make sure that they
5 were sequential so that there wouldn't be a selection bias,
6 because that would be a problem, obviously, if they didn't
7 include certain types of patients in the analysis.

8 So the FDA is still asking us for guidance here,
9 so I'd like to hear some comments from people on this panel.
10 Yes?

11 MR. PIZZUTIELLO: Bob Pizzutiello. Just for a
12 little bit of background, the number 250 is sort of not a
13 magical number. It's a number that seemed reasonable that
14 was chosen a number of years ago. You don't want to do a
15 repeat analysis on 10 or 20 patients because that could
16 obviously not give you very good statistically significant
17 information. But nobody really knows if 250 is better or
18 worse than 300 or 400, but it's a number that people have
19 been comfortable with. And when you look at these results--
20 and I look at these results all the time when I look at
21 facilities' QC programs--you see that 250 gives them a
22 reasonable number of repeats. Repeat rates are on the order
23 of, say, to pick an easy number, 2 to 5 percent. So if you
24 have 250 patients, 1,000 films, you're talking about maybe
25 20 to 30 to 50 films that get repeated in the period. And

1 that gives them a reasonable sense of what things are
2 causing repeats and what things are not.

3 If you were to increase it to 1,000, I honestly
4 don't think it would change the statistics very much.
5 You've got enough to get an idea. But I also think that if
6 you go down to 50, then you could get a really skewed idea
7 of what's going on because it's limited. So I think that
8 250, while it's non-scientific, we have some empirical data
9 that says it gives us a good idea of what's going on. So I
10 would not favor changing it. I think a minimum of 250. I
11 think that the time period should be contiguous, as you
12 suggested, Dr. Monsees, and I think that it should not be
13 required to be all films in the calendar quarter, because
14 some facilities do thousands of films in a quarter. And I
15 think that that's a lot of work for no conceivable benefit
16 that I can see.

17 CHAIRPERSON MONSEES: Likewise, it should be that
18 all units in the facility contribute towards the number,
19 because if you have only part of the facility contributing,
20 then you might not have information about a particular unit.
21 So all units have to be included in that repeat analysis.

22 Any other comments? So is the consensus that 250
23 should be adequate--250 patients, 1,000 sequential, as long
24 as they come from all the units in the facility?

25 Any comments in the audience on this issue?

1 [No response.]

2 CHAIRPERSON MONSEES: Has FDA heard us? Do they
3 have adequate information? Okay.

4 Then one other issue which was not on the list
5 here that I've been asked to get your input about is
6 technologists' continuing experience. Now, Ms. Heinlein in
7 the audience was talking about this the other day, and she
8 gave her strong opinion--I don't think she's here. She gave
9 her strong opinion that when somebody was learning, for
10 example, in a hands-on teaching course, that that shouldn't
11 count unless an image resulted from it so they could get
12 some feedback. But there are still some questions related
13 to that.

14 If somebody's being taught, for example, and a
15 teacher is--there's four hands, two pairs of hands working
16 here, a teacher and a student, and then you have resultant
17 images, who should get credit? Should it be the teacher and
18 the student? Either/or? Can both get credit? So this is
19 an important question.

20 Then what if there's more than one student? What
21 if you have a teacher and, say, two or three techs in the
22 room? Can they all derive credit from that, or should it be
23 only the people whose hands are on here?

24 Let's start with that question. Who should get
25 credit? Can the teacher get credit and the student get

1 credit? And the reason it's important--it sounds absurd.
2 Why should the teacher be looking for credit? Because there
3 are some people that don't have jobs as technologists and
4 yet they're experts and they teach. And they're going to
5 need to accrue credit as well to stay certified or
6 accredited.

7 So why, you say?

8 DR. SICKLES: Ed Sickles. If they're not doing
9 clinical mammography, why do they need to stay accredited?

10 CHAIRPERSON MONSEES: It may be pertaining to
11 whether they're allowed to teach. Is that right, Charlie?
12 They can't teach unless they are?

13 DR. FINDER: Well, people like to leave their
14 options open.

15 CHAIRPERSON MONSEES: To leave their options open.

16 DR. SICKLES: Oh, okay. I suppose so.

17 CHAIRPERSON MONSEES: I'm not sure if they're
18 required to be in order to teach.

19 DR. SICKLES: Well, Barbara--Ed Sickles--from my
20 vantage point, anybody who's teaching and is doing hands-on
21 during the teaching should be able to get credit for what
22 they're doing in addition to the student who is being
23 taught.

24 CHAIRPERSON MONSEES: As long as an image is
25 generated.

1 DR. SICKLES: As long as an image is generated.

2 Now, if this is meant to count as the clinical
3 experience part, which is really what you're talking about--

4 CHAIRPERSON MONSEES: That's what we're talking
5 about, clinical experience.

6 DR. SICKLES: Somebody who's in the room observing
7 this really isn't getting the clinical experience. So I
8 know that this imposes problems on inspectors trying to
9 verify these things. I mean, it is going to create problems
10 for the inspectors. But if there's a teacher who's teaching
11 six students in a room and there's a total of 12 patients,
12 then legitimately, if they divide it up equally,
13 legitimately each student would get two-patients credit and
14 the instructor would get 12.

15 CHAIRPERSON MONSEES: Okay.

16 DR. SICKLES: That would be my answer to your
17 question.

18 CHAIRPERSON MONSEES: I would agree with you.

19 Does anybody else on the panel have--yes?

20 DR. DOWLATSHAHI: Dowlat. A question of Dr.
21 Sickles. Does that teaching include the phantoms?

22 CHAIRPERSON MONSEES: No. No, we're talking about
23 a live patient having an image, not a phantom.

24 Yes?

25 MR. PIZZUTIELLO: Bob Pizzutiello. In our state,

1 and I imagine in most states, there are specific definitions
2 of what a technologist can do, what constitutes the taking
3 of an image. And generally speaking, it has to do with
4 positioning the patient, making the exposure. That's part
5 of the practice of X-ray technology.

6 I think anybody who's doing that is fulfilling
7 their requirements, and from a practical point of view, I
8 think two people can do one patient. I don't see how more
9 than two people can do one patient. So it would seem to be
10 reasonable to say that for any given time, any given
11 patient, no more than two people can get credit, whether
12 they be an instructor or two people individually.

13 DR FINDER: All right. Let me just bring a little
14 nuance into this. What about one person doing one breast--

15 [Laughter.]

16 DR. FINDER: And I raise this question because we
17 get asked this, and if we say that you have to do two
18 breasts, then what about the mastectomy patient? And how
19 does that count? I hate to bring it up, but these are the
20 questions that we get asked, and we want your advice on how
21 to deal with some of these things. Can someone who's
22 learning do one breast and then another, you know, a
23 training technologist come in and do the other breast and
24 count it as one for each of them?

25 It raises all sorts of issues.

1 CHAIRPERSON MONSEES: I've heard of splitting
2 hairs, but--okay. Ms. McCarthy--

3 DR. FINDER: Well, we're splitting people, is what
4 we're doing.

5 CHAIRPERSON MONSEES: Right.

6 MS. MCCARTHY: It seems to me if we're focusing on
7 the images, you know, and not the patients, we're focusing
8 on the output, that one breast equals one image, and that
9 would be credited to that particular technician. And that
10 also takes care of your mastectomy patient.

11 DR. FINDER: Well--

12 CHAIRPERSON MONSEES: Yes?

13 DR. FINDER: I just raised this other issue. If
14 we go with that, then all of a sudden we've halved the
15 requirement that we started with.

16 CHAIRPERSON MONSEES: And I think the reason to
17 address this is for low-volume facilities. So I think that
18 my feeling is that if it's a large-volume facility, this
19 should not be allowed. But if it's a low-volume facility
20 where there aren't ample patients to meet the need, that
21 maybe there needs to be some sharing, or somebody who's
22 training and may be doing more patients but not actually
23 taking the images--I'm talking about the teacher.

24 We have two comments here. Yes, first Sickles,
25 and then we'll go to Pizzutiello.

1 DR. SICKLES: Ed Sickles. I would make the
2 proposal--you can take this to the extreme and say that, you
3 know, each person can do one view of one breast, which is
4 even more ridiculous. I would allow for a maximum of two
5 individuals to be credited with experience for a given woman
6 at a given time.

7 CHAIRPERSON MONSEES: Okay. Yes?

8 MR. PIZZUTIELLO: Bob Pizzutiello. Since most
9 women don't have mastectomies, I think that the intent was
10 that when a technologist does a mammogram, she's doing a
11 four-view mammogram. I don't think we need to worry about
12 the fact that some patients in any population may have only
13 one breast.

14 In the big view, if the experience has said we've
15 done a mammogram, it's four views. So I would agree with
16 Dr. Sickles that two people can get credit for one patient.
17 It doesn't matter anything further, and that the bookkeeping
18 would get really ridiculous.

19 CHAIRPERSON MONSEES: I think that's probably
20 reasonable.

21 Any other guidance here from the panel?

22 [No response.]

23 CHAIRPERSON MONSEES: Okay. Now, we've talked
24 about the continuing experience. Now we're asked to give
25 guidance on how we count this for their CME hours. Am I

1 understanding this appropriately? Correct me if I'm wrong.

2 So, for example, if they're in there learning
3 hands-on, and there's 10 technologists with a model getting
4 CME, they can be there for an awfully long time. How should
5 we count the hours? If they're not actually doing hands-on
6 the entire time but they're in the room, should we count the
7 entire time they're in the room or only the time they're
8 doing the hands-on? That's the way I understood the
9 question. Am I right?

10 MR. MOURAD: The question is, teaching sometimes
11 varies. Sometimes it takes 10 minutes, sometimes 15,
12 sometimes 20. Should we even consider this at all as an
13 option or should we just forget about it? Should we set a
14 time limit for--

15 DR. FINDER: Let me just try and put this into
16 perspective. What we've had are the following questions to
17 us: There's a certain amount of training that they have to
18 do, 40 hours, and now we're saying that they have to do 25
19 exams, presumably, and it can be part of that 40 hours.

20 Now, as strange as it may seem, some people have
21 made mention that they may want to claim as much as an hour
22 or two hours for each of these exams and end up with, you
23 know, all their training as just doing the exams. And what
24 we're asking from the committee is their estimate as to what
25 upper range should we consider to be acceptable as time

1 spent to do an exam, and above that amount, we should begin
2 to question what's really going on. That's what we're
3 asking.

4 CHAIRPERSON MONSEES: I see. So it's not--can all
5 of it count as--can all of the experience being taught how
6 to take mammograms count, but whether an hour per exam would
7 be considered excessive?

8 DR. FINDER: Right. There is the requirement for
9 40 hours.

10 DR. SICKLES: I have a question.

11 DR. FINDER: Yes?'

12 DR. SICKLES: This is not CEU hours. This is just
13 informal education hours?

14 DR. FINDER: This is part of the initial training,
15 the 40 hours, so it's formal training.

16 DR. SICKLES: Is it CEU hours?

17 DR. FINDER: It can be training in a program. It
18 wouldn't be continuing education units.

19 DR. SICKLES: In a formal education program?

20 DR. FINDER: Right.

21 DR. SICKLES: Why not let the formal education
22 program define the hours as you do in other situations?

23 DR. FINDER: Well, they're asking us.

24 DR. SICKLES: Oh, the education programs are
25 asking you.

1 DR. FINDER: How much would we, you know,
2 basically allow and how much they're talking about, because
3 some of these programs will come and say that we spend a
4 long amount of time with each of these examinations. And we
5 have to in some sense have a judgment as to what would be
6 reasonable. That's why we bring up the issue.

7 DR. SICKLES: This is Ed Sickles. I don't feel
8 competent to answer that question because I've not observed
9 any of these training sessions. Maybe you could answer that
10 because you've got experience with it.

11 MS. WILSON: Patricia Wilson. I think that 12 and
12 a half hours would be an adequate amount of time. That
13 would give 30 minutes per exam, which is basically about
14 double what we schedule for a screening mammogram, and
15 particularly since this initial training does not have to be
16 a formal program, it can be program developed in your own
17 facility. I would be very happy with that, and basically
18 that is what we are doing now.

19 CHAIRPERSON MONSEES: Thank you very much. Very
20 helpful.

21 Any other comments on this particular issue? Yes?

22 DR. DOWLATSHAHI: Could I ask--this is Dowlat--
23 Patricia whether at the end of that session on an average
24 you feel that that person is trained? You should have some
25 kind of an idea whether when she does or he does the number

1 12 or number 13 she can do it adequately to your
2 satisfaction?

3 MS. WILSON: I think that after this initial
4 training of only 25 exams the technologist still requires a
5 lot of input and guidance from her peers and the
6 radiologist. No, I don't think that a technologist that's
7 only done 25 exams is as competent as somebody who has
8 worked for several years on the film. It's a starting
9 point.

10 CHAIRPERSON MONSEES: I would agree with that.
11 It's a starting point. At this point, they should know when
12 to ask for help, and it's like being launched on anything.
13 You have to take it very seriously, and you have to know
14 when to ask for help. By that point they should know enough
15 to be able to be on autopilot to know when to ask for help.

16 Yes?

17 MS. FISCHER: Ruth Fischer, FDA. Just as a point
18 of background, the interim regulations had no requirement,
19 no experience requirement at all for technologists, and so
20 this was added to the final regulations. So we're going
21 from people who even could receive their ARRT certificate in
22 mammography conceivably could have that and not even
23 performed an exam. So the addition of the 25 was an
24 improvement in the final regs.

25 CHAIRPERSON MONSEES: Thank you.

1 I think that answers the list of questions that I
2 was asked to address by FDA. I'm going to give the FDA an
3 opportunity to add any others at this point. Do you need
4 any guidance on any other issues?

5 DR. FINDER: No, but we'd like to hear if anybody
6 had any specific issues they'd like to bring up, and I would
7 like to remind everybody that we are anxiously awaiting to
8 get your comments on the documents that we sent you. I'll
9 be happy to pick them up as I leave at the end of this
10 meeting--

11 [Laughter.]

12 DR. FINDER: --since I'm sure they're all written
13 out and nicely collimated and everything else. But if you
14 don't happen to have them with you, we'll still be happy to
15 accept them in the next few days.

16 CHAIRPERSON MONSEES: In particular, you're
17 talking about the guidance, the draft guidance document.

18 DR. FINDER: Right, that document that we had sent
19 you. If you have comments about it, questions, if you've
20 got any right now, we'd be happy to listen to them. If you
21 don't, as I say, we'll certainly take your written comments.

22 CHAIRPERSON MONSEES: In particular, that
23 document's important because it was not discussed as it
24 existed, you know, point by point, but there are other
25 things--

1 DR. FINDER: Right.

2 CHAIRPERSON MONSEES: Yes, there are other things
3 that were discussed that if there's anything additional that
4 you have, any thoughts that you have, I'm sure Dr. Finder
5 would like to hear about that as well.

6 Okay. Are there any other issues that are of
7 concern to panel members or the FDA that we need to discuss?
8 Yes, sir?

9 DR. NISHIKAWA: This is Bob Nishikawa. It's not a
10 new point, but I just thought about it over the break in
11 regards to collimation. For a digital image that's
12 displayed on soft copy, you don't have to worry about
13 whether there's a white area or not because you can blank
14 that out. Actually, Ed Hendrick, I think, specified contact
15 mammography, if you put maybe contact film screen
16 mammography, that would give a little more leeway when
17 people--

18 DR. FINDER: Right, we have thought about that
19 issue, and we'll take that under advisement and see what
20 kind of adjustments we can make.

21 CHAIRPERSON MONSEES: An important point.

22 All right. I'd like to thank all of the panel
23 members and I would like to thank those of you in the
24 audience who are very knowledgeable and who were willing to
25 give your time and your input. Sorry? Did you have

1 something else to say, Charlie?

2 DR. FINDER: No.

3 CHAIRPERSON MONSEES: We're getting to closing
4 down this meeting, so I'm about to do that.

5 I'd like to thank those people in the audience,
6 too, in addition to the people on this panel that gave of
7 their time and their expertise, because I think that we
8 really gave some valuable input collectively as a group to
9 the FDA. So thank you very much.

10 With that, we will adjourn. We're adjourned.

11 [Whereupon, at 10:56 a.m., the meeting was
12 adjourned.]

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C E R T I F I C A T E

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

A handwritten signature in black ink, appearing to read 'T. C. Bitsko', is written above a horizontal line.

THOMAS C. BITSKO