

TRANSCRIPT OF PROCEEDINGS

8157 '00 FEB -8 P2:38

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

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE

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Pages 1 thru 179

Gaithersburg, Maryland
January 31, 2000

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FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE

Monday, January 31, 2000

9:23 a.m.

Gaithersburg Holiday Inn
Two Montgomery Village Avenue
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.
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PARTICIPANTS

Barbara Monsees, M.D., Chair
Charles Finder, M.D., Executive Secretary

MEMBERS

Kambiz Dowlath, M.D.
Laura Moore-Farrell, M.D.
Edward Sickles, M.D.
Robert Pizzutiello, M.S.
Kendra J. McCarthy
Patricia Wilson, R.T.

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P R O C E E D I N G S

1
2 DR. MONSEES: We are going to go ahead and get
3 started. We are missing one panel member, who I know is out
4 and about, Dr. Sickles, and he will be back.

5 This is the National Mammography Quality Assurance
6 Advisory Committee. Thank you for braving the storm and
7 being here, all of you who can be here.

8 We are going to start with Dr. Finder reading the
9 Conflict of Interest Statement.

10 DR. FINDER: The following announcement addresses
11 conflict of interest issues associated with this meeting and
12 is made a part of the record to preclude even the appearance
13 of any impropriety.

14 To determine if any conflict existed, the Agency
15 reviewed the submitted agenda and all financial interests
16 reported by the committee participants. The Conflict of
17 Interest Statutes prohibit special government employees from
18 participating in matters that could affect their or their
19 employer's financial interests. However, the Agency has
20 determined that participation of certain members and
21 consultants, the need for whose services outweighs the
22 potential conflict of interest involved, is in the best
23 interest of the government.

24 Out of abundance of caution, we have limited Dr.
25 Sickles, Dr. Dowlat, Dr. Nishikawa, and Mr. Pizzutiello's

1 participation in equipment standards because of their
2 involvement with mammography devices. They are allowed to
3 discuss mammography technologies including digital devices,
4 as well as talk about their observations and experiences
5 with these products, however, they will refrain from voting
6 on specific equipment standards.

7 Full waivers are in effect for 15 out of 17
8 participants because of their financial involvement with
9 facilities that will be subject to FDA's regulations on
10 mammography quality standards, with accrediting, certifying
11 or inspecting bodies, with manufacturers of mammography
12 equipment, or with their professional affiliations since
13 these organizations could be affected by the committee's
14 deliberations.

15 The participants include: Dr. Barbara Monsees, Dr.
16 Peter Dempsey, Dr. Laura Moore-Farrell, Ms. Patricia
17 Hawkins, Dr. Ellen Mendelson, Mr. Michael Mobley, Mr. Robert
18 Pizzutiello, Dr. Edward Sickles, Ms. Patricia Wilson, Ms.
19 Kendra McCarthy, Dr. Kambiz Dowlat, Dr. Robert Nishikawa,
20 Mr. Roland Fletcher, Dr. David Winchester, and Dr. Amy Lee.

21 Copies of these waivers may be obtained from the
22 Agency's Freedom of Information Office, Room 12A-15 of the
23 Parklawn Building.

24 Also, several of our members and consultants
25 reported that they receive compensation for lectures they

1 have given or will give on mammography related topics,
2 however, they have affirmed that these lectures were offered
3 because of their expertise in the subject matter, and not
4 because of their membership on the committee.

5 We would like to note for the record that if any
6 discussion of states or certifying bodies was to take place
7 in any meetings of the committee, it would be a general
8 discussion only, no vote would be taken and no consensus
9 sought. In the interest of getting as many viewpoints as
10 possible, all SGEs, including state employees, would be
11 allowed to participate in the general discussion, so that
12 all viewpoints could be heard.

13 In the event that the discussions involve any
14 other matters not already on the agenda in which an FDA
15 participant has a financial interest, the participant should
16 excuse him or herself from such involvement and the
17 exclusion will be noted for the record.

18 With respect to all other participants, we ask in
19 the interest of fairness that all persons making statements
20 or presentations disclose any current or previous financial
21 involvement with accreditation bodies, states doing
22 mammography inspections under contract to FDA, certifying
23 bodies, mobile units, breast implant imaging, consumer
24 complaints, and mammography equipment.

25 DR. MONSEES: Thank you.

1 I would like the panel members who are here to
2 introduce themselves, please, and to remind you that when we
3 have the committee discussion, please state your name prior
4 to making comments for the transcript.

5 DR. PIZZUTIELLO: Bob Pizzutiello, medical
6 physicist.

7 DR. MOORE-FARRELL: Dr. Laura Moore-Farrell,
8 radiologist.

9 MS. WILSON: Patricia Wilson, technologist.

10 DR. FINDER: Dr. Charles Finder, radiologist and
11 executive secretary of this committee.

12 DR. MONSEES: I am Barbara Monsees. I am a
13 radiologist and the chairperson of the committee.

14 DR. DOWLAT: I am Kambiz Dowlat, surgeon.

15 DR. MONSEES: Dr. Sickles, who will be seated next
16 to Mr. Pizzutiello, is here and he will be here shortly, I
17 believe.

18 We are going to move to the Alternative Standards
19 Requests. Dr. Finder.

20 DR. FINDER: I would like to announce that since
21 the last July meeting, the Division has evaluated several
22 requests for approval of alternative standards. One of
23 those requests has been approved. It involved a facility
24 that requested that they be allowed to perform an
25 alternative to the sensitometric/densitometric daily

1 processor QC test during those weeks when their sensitometer
2 was unavailable.

3 Their request was evaluated, an alternative
4 standard was granted. The standard reads: "The alternative
5 to sensitometric/densitometric testing of processor
6 performance can be used for a period of up to two weeks when
7 the facility sensitometer is unavailable. This alternative
8 is based on evaluating a phantom image through measurements
9 described in 21 CFR 900.12(e)(1) and (2)."

10 Then, we go in to explain what portions of the
11 tests have to be done. The alternative test must be
12 conducted each day clinical films are processed, but before
13 processing of clinical films, all the results must be
14 recorded and charted. If the processor performance fails to
15 meet any part of the alternative test, the problem must be
16 corrected before processing is resumed.

17 In order to make this known to the general public,
18 it actually appeared in the fall '99 edition of Mammography
19 Matters, in addition to being placed up on the web.

20 DR. MONSEES: Any comments from anybody on the
21 panel pertaining to this?

22 Okay. We will move on.

23 There are no public speakers that have made their
24 desire to speak known, and so we will just address this
25 letter that the panel members should have from the Institute

1 for Mammography Research. You have seen it before because
2 it was mailed in advance to you. I believe there are copies
3 out on the table out there.

4 Are there any comments pertaining to this letter
5 that you would like to make at this time, anybody on the
6 panel?

7 Would you like to make a comment? I didn't know
8 whether you were indicating yes or no.

9 DR. PIZZUTIELLO: Bob Pizzutiello. Having
10 reviewed this document, it seems to me that it is just an
11 indication that there is a study in process. I don't think
12 it is incumbent on the committee to take any action other
13 than to be aware that this is going on.

14 DR. MONSEES: Fine. It looks to me also, having
15 read this, that there are preliminary results, but they are
16 not described, so there is very little information really
17 available in the letter.

18 Any other comments?

19 Okay. We are going to move at this time to the
20 Inspection Demonstration Project. John McCrohan is going to
21 do a presentation for us.

22 Would you like to introduce yourself and tell us
23 what you are going to talk about?

24 MR. McCROHAN: Certainly. Good morning.

25 My name is John McCrohan. I am the Director of

1 the Division of Mammography Quality and Radiation Programs
2 in FDA, and we are going to be speaking this morning about
3 our plans for what we call an inspection demonstration
4 project which was required of us by the Mammography Quality
5 Standards Reauthorization Act, and we will go into some of
6 the background on what we intend to do and have a few
7 questions that we would like to get your input on.

8 Just for a little bit of background, let me remind
9 you that the MQSA was passed and became law in 1992, and it
10 was authorized at that point for five years. The
11 authorization was up in 1997, but we continued to have
12 authorization for expenditure of funds that year because we
13 got our annual appropriation during the summer of that year.

14 In fact, the act was not reauthorized until the
15 passage of MQSRA, the reauthorization act which occurred in
16 1998. It was that reauthorization act which created a
17 number of changes to MQSA.

18 It imposed some new requirements and some of these
19 have been discussed with you before, and probably the most
20 significant is the direct notification of patients of their
21 exam results, but it also created an obligation on the part
22 of the Agency to look into the issue of whether or not we
23 could amend the inspection frequency, currently annual
24 inspection frequency under MQSA.

25 There were a number of motivations, I think, for

1 Congress including this requirement in MQSRA, and there was,
2 in fact, testimony before the House Commerce Committee and
3 its Subcommittee on Health and Environment, and there were a
4 number of groups who came to testify before the committee.

5 Amongst the things that they pointed out were
6 their views that the annual inspection was a burdensome
7 requirement and particularly so for what they viewed as high
8 performance facilities, and they expressed the view, a
9 number of them, that biennial inspections might be
10 sufficient for such high performance facilities.

11 When the act was passed, it contained a number of
12 provisions, and in particular with respect to this
13 demonstration program, it called for that program to be
14 implemented, but not until April 1st--at the earliest, April
15 1st of 2001--and it further required that the facilities
16 that were selected for participation in the demonstration
17 project be given less than annual inspection, that the
18 facilities that we included in the project had to be
19 substantially free of noncompliances or significant
20 noncompliances, that the number of facilities be
21 statistically representative, we have a reasonable sample
22 size, and that we still, nevertheless, inspect at a
23 frequency which would assure compliance with the
24 requirements of the Public Law.

25 There was a bill report which came out in

1 conjunction with MQSRA, and that is fairly typical of the
2 legislation, that there is a report that allows the various
3 members of the committee that was involved in writing the
4 legislation to expound on their views in a little bit more
5 detail, and similar to the bill itself, the bill report
6 talked about decreasing the inspection frequency, limiting
7 this demonstration project to facilities with the highest
8 quality having a statistically representative sample size,
9 and a point which we will come back to later on, in the bill
10 report it indicated that we should limit this to three to
11 five states.

12 I emphasize that that is in the bill report, not
13 in the legislation, and so it doesn't have the force of law,
14 and I think one of the things we want to talk about is
15 whether we want this to be a national program or a program
16 limited to a few states, and that we should prepare well
17 before April of 2001, which is the statutory limit in terms
18 of our initiation of the program, and that is one of the
19 reasons we are here today.

20 If you can catch up with me, Charley, by going
21 forward a number of slides, I will tell you when to stop.

22 I don't think we were particularly surprised when
23 the legislation was proposed and when the Commerce Committee
24 had its hearings that a number of people testified with
25 respect to the issue of the inspection frequency.

1 One of the reasons I think that that seemed not
2 unreasonable as a point of discussion was that if you look
3 at the history of the inspections under MQSA, you will
4 notice, as indicated here, that the percentage of facilities
5 in a particular year that had no findings on their
6 inspections, it started out in the first year almost 32
7 percent, which frankly, at the time--and I think I may have
8 said this to the committee before--sort of surprised me
9 because it was a brand-new program with a lot of
10 requirements, and I thought it was quite remarkable and
11 commendable that a third of the facilities roughly had
12 inspections with no findings in that first year considering
13 all the things we were looking for.

14 That no findings number went up to almost 50
15 percent in the second year to close to 60 percent the next
16 year, and then 60 percent in the following year, and a
17 little over 60 percent, almost 62 percent, under the last
18 period when we were doing inspections under the interim
19 regulations.

20 Then, we switched over to the inspections under
21 the final regulations, and as you recall, there were a
22 number of new requirements imposed under the final
23 regulation, so again not surprisingly there was a bit of a
24 dropoff in the number of facilities, the proportion of
25 facilities that had no findings inspections, but still it

1 was nearly 50 percent of facilities had no findings
2 inspections so far under the final regulations in spite of
3 the new requirements that were being added, and so forth.

4 So, I think this lent some credibility to the
5 folks that were making the point that perhaps the annual
6 inspection frequency was more than necessary for some
7 facilities.

8 Certainly, the last pieces of data were not in
9 hand when they were making this point, but we certainly had
10 the first four pieces of data available, and I think it
11 bolstered the point that there were high performance
12 facilities out there as defined by no findings on the
13 inspection at least, and that perhaps these facilities, it
14 was worth discussing at least whether these facilities could
15 still perform equally well if they went to biennial as
16 opposed to annual inspections.

17 I think some of the counter-argument, of course,
18 is that there is a case to be made that the good
19 performance, in fact, is in part a result of anticipating
20 the annual inspection, and so on, but I think it certainly
21 seemed at least reasonable to look into the issue, and that
22 is what the demonstration program intends to do.

23 In addition to the proportion of facilities with
24 no findings that we showed earlier, I think it is
25 interesting to see that there are a fair number of

1 facilities who have had no findings inspections for, if you
2 read up from the bottom, for two, three, four, and five
3 consecutive inspections.

4 Again, I think that that suggests or adds, you
5 know, credibility to the notion that perhaps we can do less
6 frequent inspections and still--at least for selected
7 facilities--and still maintain the same assurance of
8 quality.

9 Clearly, there are facilities where we have, for
10 two or three or four or five times, simply validated the
11 findings on the first inspection, which was that they didn't
12 have any problems complying with the requirements of MQSA.

13 So, with that in mind, we want to talk about the
14 goals of the demonstration program. First, obviously, is to
15 comply with the requirements of MQSRA, and secondly, what we
16 want to do is to evaluate through this demonstration
17 program, a pilot, if we can, in fact, reduce the MQSA
18 inspection frequency for high performance facilities, and,
19 at the same time, maintain our current level of assurance of
20 quality.

21 I think that is a critical issue, and it seems to
22 me that no one would argue in principle that there aren't
23 facilities out there where we could go to a biennial
24 inspection and they would still do good work, and when we
25 went back the second year, we would find out there was no

1 problem.

2 I think the problem rather is how do we identify
3 those facilities or how do we have some confidence that we
4 have a schema for identifying those facilities in a
5 reasonable way, and that is I think really what is going to
6 be most of the point of the demonstration program.

7 We are going to take the approach of consulting
8 with a variety of groups, states, in the CRCPD, in
9 particular, with this committee, with our regional
10 radiological health representatives, with others in the
11 center who are more conversant with statistical methodology
12 than I am, with our own staff, of course, and then develop a
13 program plan and schedule for the demonstration program. We
14 begin to see that on the next slide.

15 We are anticipating that we would be involving in
16 this demonstration program a few hundred facilities
17 distributed nationwide, and we are going to come back to
18 that, that is the point of discussion, because as you
19 recall, the bill report, again not having the force of law,
20 but nevertheless, of interest, indicated that this ought to
21 be limited to three to five states.

22 My personal preference is to spread it more
23 broadly than that. That gives us a little bit better sense
24 of statistical representativeness even given a particular
25 size for the sample, but it also reduces whatever impacts

1 there may be, and we can discuss those on the states that
2 might be participating in the program.

3 We also want to make sure that we are selecting
4 these facilities on the basis of established criteria, and
5 we have some proposed criteria to talk about this morning.
6 There will also be a study and control group sort of
7 arrangement in the demonstration program, because we know
8 that we can identify facilities that can continue to receive
9 annual inspections, but essentially will be
10 indistinguishable from those facilities that will be in the
11 demonstration program and getting the presumed biennial
12 inspection. So, we do a biennial inspection in the study
13 group and annual inspections in the control group.

14 On the next slide we lay out the preliminary
15 schedule for the program, and, in fact, last year and what
16 you are seeing this morning is sort of the results of this
17 initial thinking about the program design which we need to
18 complete during this year.

19 One of the things I would point out is that the
20 statute said that we had to implement the program no earlier
21 than April 1st of 2002. If we can wait there for just a
22 second, there is some significance there because I think
23 that is the time when Congress anticipated, given the
24 effective date of the final regulations, was on or about the
25 time we might start inspections under the final regulation.

1 In fact, we started the inspections under the
2 final regs in July, and so at least in my mind, when I am
3 talking about these years here, I am really talking about
4 July 1st of that indicated calendar year, and, in fact, that
5 is about when we started the initial planning, and I would
6 think that by that time of this year, we can complete the
7 major elements of the program design, but we intend to
8 implement the program sometime in July perhaps of 2002, and
9 that would be the beginning of the 12-month period when the
10 selected facilities would not get an inspection.

11 That would give us the opportunity to assure that
12 all the facilities had had a couple of inspections under the
13 final regulations before we started the program, and we will
14 see the significance of that momentarily.

15 In 2004, July, let's say, we would have completed
16 not only the year when the selected facilities would not be
17 inspected, but we would have completed the following year
18 starting July 2003, ending July 2004, when they all would
19 have gotten annual inspections again.

20 So, we would have one complete set of data that
21 would allow us to determine whether the facilities that
22 didn't have the inspection, in fact, performed adequately in
23 the following annual inspection, or sort of for their
24 biennial inspection.

25 We would then be in position to do some analysis

1 and we have the potential to submit a report to Congress, a
2 preliminary report, in 2005.

3 Now, I point out--go back up a little bit in that
4 slide--that the next reauthorization of MQSA is in October
5 of 2002 if it occurs on the current schedule, and I point
6 that out because it is certainly clear that we won't have
7 any information from the demonstration program by the time
8 of the next reauthorization.

9 Following that, we would anticipate
10 reauthorization on the next occasion in October of 2007.
11 So, we do have a little bit of room to play with here sort
12 of at the end of the schedule, and one of the issues that I
13 want to come back to later is do we want to do another round
14 of, you know, no inspection for the people who are still in
15 the selected population and then another annual inspection,
16 so we could have essentially two complete rounds and still I
17 think have an opportunity to do some analysis before
18 Congress would begin or about the time Congress would begin
19 to consider the reauthorization of MQSA in 2007. So, we
20 will come back to that a little bit later.

21 So, to focus our attention a little bit, what we
22 see as the remaining questions and the questions over which
23 we would like to get your input, are issues related to the
24 criteria that would be used to select the facilities, and
25 one of the issues is are the criteria that we are about to

1 lay out here adequate for that purpose.

2 We also want to talk about the sample, should the
3 facilities be selected nationwide or limited to a certain
4 number of states. As I mentioned before, Congress in the
5 bill report said three to five states. My preference I
6 think is nationwide. It is probably going to be somewhere
7 in between for reasons which we will get into in a moment.

8 How long should the program run, should we do one
9 round of the study or should we try to do multiple rounds if
10 time permits, and then finally, what should be the period
11 inspected against when we go back to do the annual
12 inspection of a facility that had a pass, so to speak, a
13 year when they weren't inspected, when we go back, it is
14 part of the demonstration project at least, should we be
15 looking at the preceding 12 months or the preceding 24
16 months, and I have a strong personal view about that, too,
17 which I will get to in a little bit.

18 So, if we want to talk for a moment about the
19 selection criteria, I want to talk first about criteria that
20 are associated with states, and secondly, criteria
21 associated with facilities themselves.

22 From the perspective of the state, it is important
23 to understand that the states have laws which are
24 independent of MQSA, and certainly there are a number of
25 states where those laws and regulations under those laws

1 require annual inspection.

2 So, one of the things that we need in order for a
3 state, so to speak, to be included, be able to participate
4 or be able to have its facilities included in this
5 demonstration program is that the state have the legal
6 ability to modify laws or regulations or policies that
7 require yearly inspections of mammography facilities or, in
8 the alternative, be a state which does not have those kinds
9 of requirements.

10 Secondly, of course, they need to agree to make
11 those modifications if those are required, and to inspect
12 the participating facilities at the frequency designated by
13 FDA during the study period.

14 Again, one of the reasons that I am in favor of
15 broadening the participation as much as we can is that then
16 the number of facilities in any particular state that might
17 be in the study group, and therefore not inspected during a
18 particular year, would be as small as possible.

19 In addition, with respect to the states, they
20 would need to have the opportunity to modify the contract
21 that they have with us to do inspections based on the number
22 of facilities, be inspected during the demonstration
23 project, and that would be somewhat reduced presumably, and
24 then agree to notify us of any potential serious public
25 health risks that they perceive in the participating

1 facilities.

2 Presuming that a number of states are interested
3 and able to participate, then, we come to the issue of what
4 do we need to look at in order to include, and momentarily
5 to exclude, facilities from participation in the program.

6 Obviously, they need to be selected and we need to
7 have assurance that they are going to maintain full
8 certification during the program, and certainly if they
9 became uncertified, if they are closed, whatever, if they
10 became uncertified by suspension or revocation, that would
11 be a reason for removing them from the study.

12 Additionally, we would like to start with the
13 sense that they intend to provide mammography services
14 during the entire demonstration program. There is no reason
15 to include someone if they already know that they are going
16 to stop doing mammography at some point. We also want to
17 assure that they have had two annual inspections under the
18 final regulations.

19 Then, we have developed some exclusion criteria,
20 and this bears on the point that is made in the statute, and
21 that is, that we ought to be dealing with facilities that
22 are substantially free of noncompliances, and there is a
23 broad range over which one could interpret that phrase, and
24 what we have chosen to do so far is to say that we would
25 exclude facilities that had either a Level 1 or a Level 2

1 citation during inspections under the final regulations, and
2 remember, that will be two inspections under the final
3 regulations.

4 Secondly, we would exclude facilities that had had
5 even a Level 3 citation during their second year of
6 inspection under the final regulation.

7 So, in the presumed two inspections under the
8 final regulations, they could have, at worst, a Level 3
9 inspection followed by a no findings inspection. That would
10 be the worst case scenario.

11 In addition to that, we want to include a
12 criteria, an exclusion criteria, and exclude facilities that
13 had a Level 1 citation during the last two years of
14 inspection under the interim regulations, and also
15 facilities that have had a regulatory action taken or under
16 consideration.

17 So, if you put all that together, and you look at
18 the last four inspections that a facility would have had,
19 the worst that they could have had was a Level 2 finding
20 followed by a Level 2 finding in the last two years of the
21 interim regulations, we are excluding the Level 1's, and
22 then a Level 3 in their first final reg inspection followed
23 by a no finding inspection.

24 I would like to pause here for just a minute and
25 talk about that point a little bit. I think that the

1 selection criteria are clearly the critical part of the
2 study, and I think it is also clear that we could develop
3 selection criteria that were very restrictive.

4 I mean we could, for example, require that we
5 wouldn't include any facility that didn't have four no
6 findings inspections in a row or something like that, but I
7 think there are some reason at least to want to study the
8 question of whether or not facilities, such as the ones that
9 would be included by our criteria here, could still perform
10 adequately if they got biennial inspections.

11 Certainly, some of the study population--and we
12 can certainly design for this--may well be facilities that
13 have had four or five no findings inspections. If the study
14 population certainly has those kinds of facilities in it, it
15 might even be possible to differentiate between them and
16 other subparts of the population, and we might see that the
17 facilities that have had several, say, four or five no
18 findings inspections in a row did perfectly fine during the
19 demonstration program, but those that had only had, say, two
20 no findings inspections didn't do as well.

21 That would help us to better establish the
22 criteria that we might use were Congress to decide in the
23 reauthorization in 2007 to, in fact, change MQSA and allow
24 us to do a biennial inspection of a selected subset of the
25 population of mammography facilities.

1 So, one of the issues I think is going to be one
2 of the size of the sample versus the detail that we want to
3 study in terms of the behavior of facilities or the
4 performance of facilities and what is adequate performance
5 to quality for this presumed biennial inspection.

6 In terms of the sample size, back to the question
7 of whether or not the facilities ought to be selected
8 nationwide or from a limited number of states, as was
9 suggested but not required by the bill report for MQSRA, and
10 then also the question of whether or not the duration of the
11 program--and I have mentioned this already--we would be
12 exempting the facilities in the study group on the current
13 plan from inspections for the 12-month period beginning July
14 2002. July 2003 would begin the 12-month period when all
15 facilities would be inspected, and beginning July 2004, we
16 would be in a position to do some analysis and prepare a
17 report to Congress.

18 So, the question at that point is do you then
19 resume annual inspections of all facilities until Congress
20 has had a chance to act on that report, or is there time and
21 do you take the time to continue this cycle of biennial
22 inspections for the facilities in the study group who still
23 qualify, and it would seem that in 2004, if you wanted to,
24 one could not inspect the facilities in the study group, in
25 2005, beginning in July, you could give them an annual

1 inspection again. So, by July of 2006, you could have two
2 rounds of inspections, and then you would have not quite a
3 year to evaluate that material and write a report.

4 Probably Congress might begin considering the
5 reauthorization October 2007, the preceding spring of 2007.
6 So there is I think an opportunity timewise to get in a
7 second cycle in the demonstration program if that seemed
8 advisable.

9 Finally, is the question of when we do the
10 inspection, the annual inspection of a facility in the study
11 group, we won't have been there for two years, do we look
12 back 12 months, do we look back 24 months.

13 My strong personal preference is that we look back
14 12 months, that we simulate what would be done, presumably
15 done under a biennial inspection program, and that we look
16 back 12 months for those facilities, but we certainly have
17 the opportunity then, after we have done the inspection, so
18 to speak, that they would do it again on the biennial
19 schedule.

20 We certainly have the opportunity to look back at
21 records at least that would have been saved by the facility
22 for the 12 months preceding that to see if those records
23 suggest that there was anything that we missed by giving
24 them the exemption from that previous inspection.

25 So, there are a series of questions that we think

1 are worth some continued discussion, and we would certainly
2 be interested in the committee's thoughts on these, and if
3 it is convenient, and so forth, you can start with the issue
4 of the adequacy of the criteria that we have selected both
5 for the inclusion and exclusion of facilities.

6 I think the inclusion of states, and so forth, is
7 pretty much of a given in terms of state law, and there is
8 no real basis for us to--or opportunity, authority for us to
9 compel any state to make a change in any laws or regulations
10 they currently have that would require annual inspection.

11 So, I think we could focus our attention on the
12 issue of the inclusion and exclusion criteria for the
13 facilities, and then we can go to the remaining questions,
14 if that is convenient.

15 DR. MONSEES: You would like to hear from the
16 panel at this point.

17 Any comments on inclusion/exclusion criteria for
18 the facilities at this point? I would like to address
19 something on the states, as well, but you would also? Go
20 ahead.

21 DR. PIZZUTIELLO: A question, John. In the
22 facilities that are in the demonstration project, that get
23 inspected every two years, will the compliance be evaluated
24 as of the date of the inspection, in other words, one
25 snapshot for the two-year period, or they look back to see

1 if they have been in compliance, let's say, a year
2 previously and on the date of inspection?

3 MR. McCROHAN: Again, my preference would be for
4 us to have this inspection reflect what I take to be the
5 common-sensical meaning of biennial inspection, which is you
6 go in every two years, and you do what we now do, which is
7 to say you go and you look back a year, which is what we do
8 in our current inspections.

9 You are certainly look at some things as of the
10 date of the inspection, certainly the physical measurements,
11 and so forth, really only relate to the date of inspection,
12 but there are other things in the quality control area, for
13 example, where you are looking back over 12 months of the
14 facility's records to see whether they have done the tests
15 at the appropriate frequency and taken the appropriate
16 action, and so on, and so forth.

17 So, if I get the tenor of your question, my
18 preference I think would be--not a view shared by everybody
19 certainly--but my preference would be that we look, we do an
20 inspection and we look back 12 months when we do that
21 inspection.

22 DR. PIZZUTIELLO: That answers my question. The
23 thought that I had along those lines is the real question is
24 at the end of two years, has the facility been consistently
25 in compliance, because you could make the case that

1 facilities might not pay much attention for a year and then
2 get tuned up for the inspection, and to some extent that
3 happens, but because an inspection reviews all the records
4 since the last inspection, there is no gap.

5 What occurred to me, might be a possibility, would
6 be to use the normal inspection protocol, the software as it
7 is designed, for the past 12 months, but since this is a
8 demonstration project, perhaps to add a few screens, to do a
9 spot-check of, for example, were the personnel in compliance
10 at a period in between, and was the quality control
11 performed consistently over the two-year period, not a lot
12 of inspection time, but just to get a sense as to whether
13 the facilities were maintaining consistent compliance,
14 because that would nicely support the position of a biennial
15 inspection, I think.

16 MR. McCROHAN: And, in fact, that is I think one
17 of the later questions that we raise about, you know,
18 whether we ought to look back the 24 months or not, and I
19 think, you know, what you are suggesting is somewhat what I
20 was describing, which is you do the standard inspection, but
21 then certainly you have the opportunity at that time, at
22 least in the context of the demonstration project, to say,
23 okay, I have done my inspection, I have found what I found,
24 to some extent what would I have found had I been here a
25 year ago.

1 Certainly, in terms of the quality control records
2 in particular, it is fairly obvious that it would be
3 possible to do that.

4 I think there are certainly going to be some
5 issues about retention of records and what the requirements
6 are, what records are going to be available, and so on, but
7 for most of the quality control, I think that would be a
8 feasible thing to do, and it would certainly I think give
9 someone, even if you didn't intend to continue doing this
10 once Congress, presuming Congress does make a change in the
11 statute, even if you didn't intend to do that in the future,
12 it would give you some reassurance that, you know, you have
13 gone and you have looked at the periods you, quote, unquote,
14 "missed," and found that, in fact, there weren't any
15 problems there, and the fact that there were no problems on
16 their most recent inspection that you just did, you know, is
17 consistent with that as opposed to at least the hypothetical
18 that you could have a facility whose performance is cyclic,
19 and as you say, they are on their toes the year that you are
20 going to come to do the inspection, and not otherwise.

21 I think that is more, I hope that is more
22 hypothetical than real.

23 DR. PIZZUTIELLO: Along those lines, I think it
24 would be good to decide upfront if you are going to do that--
25 --which I think you should, I think the Division should--

1 then, anything that was found in the previous 12 months is
2 clearly going to be a citation. If you find something in
3 the period before that, is that going to be a citation or
4 not, I would suggest that it not be, but that it be a study
5 finding.

6 MR. McCROHAN: I think that is reasonable. I mean
7 I guess there is a more basic question, and that is, you
8 know, what was it Congress intended--and if nobody will
9 report me, let me say if Congress knew what it intended--in
10 this level of detail.

11 I mean when they said "biennial inspection," you
12 know, did they mean go every two years and look back two
13 years, or go every year and look back a year, and I don't
14 think that is clear, and certainly it is not irrational to
15 think that there would be some benefit from going every two
16 years and looking back two years.

17 Certainly, that is a longer inspection, but the
18 benefit to the facility of having an inspection every two
19 years as opposed to every year, I think still largely
20 accrues, but I think that common-sensically, I think what
21 Congress intended was, for high performance facilities, sort
22 of drop out consideration of every other year, but I agree
23 with you that certainly, there is an opportunity and reason
24 to take this extra step during the demonstration program
25 and, you know, go back to that missing year, so to speak,

1 and assure yourself that, in fact, having no findings in
2 this inspection is telling you something about performance
3 as opposed to hiding from you the fact that something is
4 going on during that missing year.

5 DR. MONSEES: Dr. Sickles.

6 DR. SICKLES: I would look on this as an
7 opportunity, not only to make findings during the study, but
8 also to develop the process the way it would be if Congress
9 reauthorizes it in a solid, established way, and that is,
10 set up a program, so that when it is finished, you know how
11 you are going to proceed with the final program.

12 The final program, to be realistically attractive
13 to facilities, would be what you describe, namely, doing a
14 one-year inspection, and I would develop policy, so that in
15 the demonstration project, you look previous, but that is
16 part of the project, not part of the plan.

17 The other thing that I would suggest is that
18 although you might not think it likely, it is certainly
19 possible that a facility other than just tuning up for the
20 second year inspection, could have been doing fine during
21 the first year and then fallen down in the second year, so I
22 would look just as carefully at the facilities that did well
23 on the second year's inspection as those which didn't do so
24 well on the second year of inspection, because you may find
25 it is completely random as opposed to facilities that are

1 really trying hard in the second year.

2 MR. McCROHAN: I think that is a good point. In
3 fact, there has been some considerable discussion of what
4 kind of episodes in a facility might lead to a change in
5 quality, and certainly, I think changes in personnel, which
6 are not necessarily predictable, could have a lot of impact
7 on quality either positive or negative, and that is one of
8 the things about trying to establish selection criteria.

9 I think you have to simply live with the fact that
10 if you are selecting facilities upfront, you are not going
11 to be able to anticipate all of the things that may happen
12 in a facility that might turn out to have an impact on
13 quality.

14 So, I think we are not--you know, we are in that
15 situation now with the annual inspection, things happen, you
16 know, we find out about them nine months later or 10 months
17 later when we do an inspection.

18 Certainly, we are going out a little more on a
19 limb with the biennial inspection, and part of the
20 demonstration project is to find how far out in the limb are
21 we and are we comfortable with that, and do we think this
22 all makes sense.

23 But I think some of the things we have talked
24 about are very focused changes in the facility, like a
25 change in the QC tech could make a major difference,

1 potentially a major negative difference in the quality in
2 the facility, and that is really not predictable, and past
3 performance isn't going to tell you much about that
4 probably.

5 DR. MONSEES: Are you going to, in fact, track the
6 personnel, and you will be able to analyze the data by
7 changes in personnel--that is one of my questions--the lead
8 interpreting physician and the QC technologist, even the
9 physicist, as well?

10 MR. McCROHAN: I think that is an important point
11 and at least from the perspective of the demonstration
12 program, when we go back to look, to the extent we can
13 effectively do so, when we go back to look at the missing 12
14 months, if you will, those are some of the issues that I
15 think we ought to get at, has there been a change in
16 personnel.

17 You know, you may know that from looking at the
18 last inspection plus this inspection, but I think it would
19 be worthwhile looking to see if there have been those kind
20 of changes in the meantime.

21 DR. MONSEES: Any other comments from the panel
22 regarding selection criteria?

23 [No response.]

24 DR. MONSEES: I have another comment regarding the
25 states, and that is, because the FDA is planning on

1 modifying the contract with the states regarding how many
2 facilities, is there a financial incentive on the part of
3 the state not to participate with this project because they
4 will have lost revenues that they are counting on.

5 In particular, they will lose the revenues for the
6 easy to inspect facilities, and the ones that are more time-
7 consuming and more labor-intensive, the ones that have
8 problems, they would get basically--they would lose money on
9 this deal, and therefore, they would be incented not to want
10 to participate with this program.

11 MR. McCROHAN: I think that is a good point. It
12 is certainly one we have talked about, and I think it is
13 real. I think one of the reasons why I was in favor of
14 selecting the sample nationally was to minimize the impacts
15 like that on any individual state.

16 I don't know what opportunities there are to look
17 for any kind of counter-incentives. Any of the sort of
18 resourcing of that obviously comes out of our appropriated
19 funds as opposed to out of our inspection fees since we
20 aren't going to be in a position to charge inspection fees
21 to the facilities that are not inspected.

22 So, part of the implication of your question, I
23 suppose, is something that we could look at, but we haven't
24 really, frankly, talked much about that at this point
25 because of the financial considerations on our part.

1 DR. MONSEES: Right. My guess is there will be
2 states that will not want to participate for this reason,
3 and that will have a negative impact on the facilities in
4 the state that obviously would be candidates for this
5 program, and I do think it is a good program.

6 I think that you want to not only make it less
7 burdensome for facilities that do a good job, but I think
8 this program would be incentive for them to even do a better
9 job because they know that if they do, they will not have to
10 be inspected as frequently, and that will be less burden, so
11 it would give them more incentive to do well.

12 So, I think it is a good program all around, and I
13 would like to see it be available in all the states, and I
14 would hate to see a state opt out of doing this because of
15 financial disincentive.

16 MR. McCROHAN: We are working with the CRCPD to
17 try to get at some of those issues, and they either are
18 surveying, or going to survey, or perhaps even have, the
19 states on some of these questions.

20 I think that certainly in a small state, the
21 impact proportionately could be greater, and one of the
22 other considerations is that in the smaller states, there
23 tend to be fewer inspectors who are supported by the
24 contract, and small changes in the contract can have the
25 effect of putting the state in a position where it can't any

1 longer cover the salary or the full salary of one of the
2 people that they have hired to do the work.

3 So, I think the impacts are likely to be less in
4 the larger states than the smaller states, and there may be,
5 I don't know, but there may be some differences in terms of
6 the content of the radiation control programs in the states
7 which have somewhat the same bias, if you will.

8 I mean I think the larger states tend to certainly
9 have bigger programs. Whether they are more focused on x-
10 ray than other things is a matter for the state and its
11 particular situation.

12 But I think there may be some bias introduced if
13 we find ourselves in a situation where we don't involve or
14 if the smaller states are disproportionately unwilling to be
15 involved.

16 DR. MONSEES: I agree. I think there is a
17 possibility for introduction of bias unless it is more
18 universal.

19 Yes, Dr. Sickles.

20 DR. SICKLES: I have a question to be followed by
21 a comment.

22 The question is how many states now require annual
23 inspections and therefore would not be considered as part of
24 this program?

25 MR. McCROHAN: The CRCPD is doing a survey to give

1 us that information. I don't have it right now.

2 DR. SICKLES: Just as a rough guess.

3 MR. McCROHAN: I really don't even have a broad
4 guess.

5 DR. SICKLES: The comment I was leading to is that
6 unless this number is really small, like two or three, in
7 which case it really doesn't matter, but if the number is
8 substantial, like 10 or 20, even though a state has current
9 regulations that require annual inspections, it doesn't mean
10 that they couldn't allow facilities within the state to
11 participate, just as the Federal Government is allowing
12 facilities to participate, so could a state if they made the
13 appropriate change in their regulations on an interim basis
14 just to participate in the program. So, you can encourage
15 them to do that.

16 MR. McCROHAN: I do think it is not two or three
17 states. I think it is more like the 10 or 20. I think it
18 also is a function of whether the requirement in the state
19 is statutory, regulatory, or by policy, progressively easier
20 to change.

21 If it is a statutory requirement, that is going to
22 be tough, and, in fact, we have a statutory requirement,
23 Congress passed a law to give us the opportunity to do this.
24 So, I think that if the requirement is statutory, it is
25 going to be difficult or at least time-consuming for a state

1 to make the requisite changes.

2 DR. PIZZUTIELLO: I want to also make a comment
3 about this choice of states. MQSA is obviously a national
4 program, but we have heard in the past that states differ in
5 their degree of connectedness with facilities. I remember
6 Don Flater making a nice point a few years back saying that
7 because they have a not very large number of facilities,
8 that their inspectors are very much in close connection with
9 their facilities, and that was one of the reasons why they
10 were a very good candidate for states to certify this
11 program.

12 I think that the more we distribute among states,
13 the better we are able to neutralize any bias in that
14 respect because it may very well be that in certain states,
15 because of the relationship and the number of facilities,
16 and so on, those states will have a higher proportion of
17 facilities where it would work and other states might not,
18 so if the number of states in this demonstration project is
19 limited, then, we could introduce a very significant bias in
20 that way.

21 MR. McCROHAN: By the way, I don't think there was
22 anything in the language of the bill report that shed any
23 light for me on why at least some member of the committee
24 suggested that the demonstration project be done in three to
25 five states as opposed to nationwide.

1 So, I don't know what the sort of internal
2 rationale for that was, but I tend to agree with you that
3 the more broadly we distribute it, the less bias we are
4 likely to have, and that more states are likely to be able
5 to participate certainly on the basis of the financial
6 issues.

7 DR. PIZZUTIELLO: One other simple comment. You
8 sort of alluded to it, but I wanted to remind the committee
9 that in terms of facilities that are in this demonstration
10 project, it probably would make sense to make sure that
11 there is an instruction packet that goes to facilities.

12 When I was reading through the guidance documents
13 over the last several months, I think that most of the words
14 say retain records since the last inspection, but it might
15 say since the last annual inspection.

16 So, if you are going to move forward in this,
17 someone probably needs to go back and look at the guidance
18 documents and make some adjustment appropriate to the
19 wording about records retention since the last inspection or
20 however you want to word it.

21 MR. McCROHAN: Good point. Thank you.

22 DR. MONSEES: Before we move on, I would like to
23 make another point. I do believe that the exclusion
24 criteria seem appropriate, and do I have consensus among the
25 panel that the inclusion criteria--

1 DR. DOWLAT: Yes.

2 DR. MONSEES: So, we agree that that is fine, the
3 exclusion criteria for facilities looks good.

4 The other thing, it is kind of a randomized trial,
5 it seems to me, correct, you are going to take appropriate
6 facilities and randomize them, a control group and study
7 group?

8 MR. McCROHAN: Right.

9 DR. MONSEES: Will the control groups be
10 identified, and will they know they are the control group,
11 or will you keep that a secret?

12 MR. McCROHAN: I don't know that we have talked
13 about that. I guess my instinct is to--

14 DR. SICKLES: No.

15 MR. McCROHAN: No?

16 DR. SICKLES: Why should they know?

17 MR. McCROHAN: That was my instinct was there
18 wasn't anything to tell them.

19 DR. MONSEES: They may ask you why they are not
20 identified. You are going to just pick out individuals, I
21 guess. Is the total group going to be everybody that meets
22 the inclusion criteria, or are you going to pick a subset of
23 those?

24 MR. McCROHAN: Right, a subset. What we feel we
25 need, we need to have a reasonable sample size. At the

1 moment I think we are talking in the range of, say, 3- to
2 500 facilities. That is the sum of the study and control
3 groups. In fact, when we look at the selection criteria at
4 the appropriate time, there may be more facilities that meet
5 those criteria, I suspect there might be, but I think we
6 wanted to have enough facilities in the study group to get
7 reasonable data, but not so many in the study group as to
8 have the demonstration project have so many adverse impacts
9 that it wasn't going to be feasible.

10 DR. MONSEES: Will the control group be a subset
11 of the total world of eligible, and will the FDA inspector
12 know that it is a control group, because I don't think you
13 should necessarily identify it to the FDA inspector either.

14 MR. McCROHAN: I agree.

15 DR. MONSEES: Okay.

16 MR. McCROHAN: Yes, and I agree.

17 DR. MONSEES: Yes?

18 DR. PIZZUTIELLO: One other comment. When you
19 were talking about the time line, somewhere in the midst of
20 all this, the October 2002 changes for equipment performance
21 become regulation, and I don't know exactly how this would
22 all work, but certainly facilities need to be made aware
23 that if they are not being inspected in 02--right, because
24 you are talking about a July time frame--the regs come into
25 effect in October of 02, that they are still held to that

1 requirement.

2 That may provide a little bit of a wrinkle because
3 I think we will find--in my experience, there is a pretty
4 good universe of x-ray equipment out there, that is going to
5 have great difficulty meeting the O2 requirements, it is
6 old, and I think it is due for replacement, but it is out
7 there in the universe.

8 So, there will be a blip, I think, for facilities
9 who will not meet this requirement, and that may introduce
10 just a particular variable in those spots. That is about
11 the only change in O2, when the data is analyzed, it might
12 be analyzed with and without those particular factors in
13 mind.

14 MR. McCROHAN: That is a good point. A particular
15 example of that is the AAC requirement, which I think is
16 probably the one you are thinking about.

17 DR. SICKLES: There is one other point which we
18 haven't touched on, and that was the duration of the
19 program. To me, as somebody who gets questions from
20 radiologists all over the country about this, when they are
21 made aware of the fact that the FDA is considering a pilot
22 of testing this, there is generally very positive response,
23 and I would think that if you want to get facilities that
24 will try to work hard on this, it would be best to have the
25 duration of the program go as long as it can rather than

1 just a one-year shot. If it is not going to cause a burden
2 to the FDA, and if you can just continue to do it for two
3 cycles instead of one cycle, I would go for it because it
4 will make it even more attractive to the facilities that are
5 participating if they know they have two chances to skip an
6 inspection as opposed to one.

7 DR. MONSEES: You may have skipped ahead because
8 he is giving us the questions a little bit at a time.

9 DR. SICKLES: Oh, I thought we were doing the
10 whole thing. I took it down.

11 DR. MONSEES: I think he wants to move on to the
12 other questions that he wants to ask of us, is that correct?

13 MR. McCROHAN: Yes, but, in fact, I think we have
14 kind of been moving around, and I have pretty much covered
15 all of the questions.

16 Just a point that I would make is that you remind
17 me, Bob, that there is also some personnel requirements that
18 will kick in, in I guess it's April of 2001, which are the
19 continuing experience requirements for the techs and for the
20 medical physicists, so those would be reflected in only the
21 last inspection that they would have under the final
22 regulations, but they would have an impact on their
23 selection. You would have to have no findings to those
24 before you would be included on the basis of the criteria we
25 have.

1 So, even though those changes are there, I think
2 we have got those covered, but you are right, that the
3 equipment ones in 2002 are kind of hanging out there.

4 I don't know that there is any--with all of the
5 changes coming along, I mean you have to start sometime, and
6 I think we just have to, as you suggest, live with that and
7 do the best we can to incorporate that in the analysis.

8 DR. MONSEES: Any other comments? Do you have any
9 other questions of the panel regarding this program?

10 MR. McCROHAN: I don't think so, because I think
11 we actually covered the four issues that I was interested
12 in.

13 DR. MONSEES: Thank you very much.

14 MR. McCROHAN: Thank you.

15 We will have a 10-minute break.

16 [Recess.]

17 Panel members, what we are going to do now is go
18 over the guidance documents that we are going to comment on,
19 and before we do, Dr. Finder is going to tell us about what
20 guidance is and what we are supposed to be doing here,
21 remember the directions that we usually get.

22 DR. FINDER: Before we begin our discussion of the
23 proposed final regulation guidance, I would like to briefly
24 explain the procedures that FDA is following as it develops
25 new guidance.

1 In response to public comment regarding the use of
2 guidance documents, FDA held an open public meeting on April
3 26, 1996, and on February 27th, 1997, they published a
4 Federal Register notice outlining the steps the Agency
5 needed to take prior to issuing guidance.

6 In brief, it stated the following: the guidance
7 had to be developed in an open manner that permitted input
8 from the general public and the regulated industry. In most
9 cases, new or controversial guidance had to allow for such
10 input prior to its implementation.

11 While statutes and their associated regulations
12 were binding and enforceable, guidance was to represent a
13 way or ways of meeting the regulations, but other ways would
14 be acceptable as long as they met the requirements of the
15 regulations or statutes.

16 Before we begin our discussions, I would like to
17 emphasize the following: We are here to discuss the
18 proposed guidance, not the underlying regulations. The
19 regulations have already gone through their own extensive
20 approval process, and while they are subject to future
21 change, the purpose of today's meeting is to address the
22 proposed guidance.

23 Documents we will be discussing today contain a
24 mixture of regulation and guidance. When you say the word
25 "shall require or must," they refer to the underlying

1 regulation, whereas, the word "should, may, or recommend"
2 refer to guidance.

3 The committee will be reviewing documents, some of
4 which have already been released to the public, and others
5 that will soon be released for public comment.

6 DR. MONSEES: Let's go over the documents that you
7 should have received in advance, and let's talk about what
8 they all are and which ones we are going to discuss today.

9 One of these says the Mammography Quality
10 Standards Act Final Regulations Quality Assurance
11 Documentation Issued on December 7, 1999. This is new final
12 guidance that has been previously discussed and finalized.

13 Hopefully, you have reviewed this. Are there any
14 additional comments that we need to have on the record at
15 this point? Hopefully, you have all reviewed this.

16 Yes.

17 DR. PIZZUTIELLO: I had one comment I just wanted
18 to bounce off the committee to see if my recollection was
19 perhaps not right.

20 Under Procedures for Infection Control--

21 DR. MONSEES: What page was that?

22 DR. PIZZUTIELLO: Let's see, I have a couple
23 versions--the very end--

24 DR. DOWLAT: Page 6.

25 DR. PIZZUTIELLO: Page 6.

1 DR. MONSEES: Yes, page 6 on that document,
2 Procedures for Infection Control. Go ahead.

3 DR. PIZZUTIELLO: This question came to me from
4 one of my clients, and, in fact, I sent an e-mail to Dr.
5 Finder, and he responded promptly and thoroughly.
6 Basically, what it says, the way I interpret this, the
7 question is what criteria would FDA use to see if facilities
8 meet these requirements for infection control.

9 My question is about Answer No. 2. It sounds like
10 facilities need to have logs or charts indicating that
11 infection control procedures were performed when the
12 mammography equipment came into contact with blood or other
13 potentially infectious materials.

14 My recollection was that in the past, the
15 guidance, as we had discussed it and understood it, was that
16 logs were not required, but that there needed to be a
17 procedure that said this is what is done routinely, and this
18 is what is done in the special case when there is fluid
19 contact.

20 I interpret this guidance document as having a new
21 requirement for facilities that says you need to have a
22 procedure, and you don't need to log every single cleaning
23 of every patient, but you do need to create a log whenever
24 there is fluid contact.

25 Is that the way you interpret it, Charley, and is

1 that the way we understood previous discussions?

2 DR. FINDER: Well, I wouldn't interpret it as a
3 new requirement. It is more that when we looked at the
4 regulation, the regulation actually says that the facility
5 shall do more than just establish the system. It's they
6 have got to comply with the system. Those words were added
7 into the regulation, and that's why as guidance, we added
8 the stipulation that when these events occur, that they
9 actually have to make a notation, it wasn't just enough to
10 have a written procedure that they were going to do this
11 when this rare event occurred, but that we felt that it was
12 important enough that when there was blood that came in
13 contact with the equipment, that there actually would be
14 some documentation that the action had been taken.

15 As for the previous guidance, that question
16 actually dealt with the question that we had at the time--I
17 believe it was guidance document 1 maybe, or 2, I think it
18 was probably 1-- in which we had gotten a question from a
19 facility and they had been wondering whether they had to
20 document cleaning between each patient, and the answer to
21 that basically was that they didn't have to have a log
22 between each patient because the regulation didn't require
23 that, and it didn't go into this other issue about what they
24 were supposed to do when blood did come in contact with the
25 equipment, so there isn't an inconsistency necessarily, but

1 I can certainly understand that people might have taken away
2 from that question and answer that there was no log needed
3 at all.

4 This is again what we feel is not a new
5 requirement, but merely an explanation of what the
6 underlying regulation called for. It's a way to explain it,
7 but I do understand why people might have some comments
8 about it and I would be happy to listen because again we are
9 talking about interpretation of regulation, and we do
10 appreciate the committee's thoughts on this matter.

11 DR. PIZZUTIELLO: I apologize for my poor choice
12 of words. I didn't mean to imply a new requirement, but I
13 know that those words have very specific meanings in this
14 context.

15 I don't have a problem with it. To me, it is a
16 relatively rare occasion. It's analogous to something we do
17 in radiation safety in our state, which is to document when
18 a person holding another individual for an exam. It is sort
19 of a rare case, and there might be, you know, a small number
20 per year.

21 I do think, though, that because this is a new
22 wrinkle on this question, that it would be helpful or
23 beneficial to publicize this perhaps in Mammography Matters
24 as a specific question, a little different interpretation, a
25 little bit further understanding of it, so that facilities

1 aren't caught off guard.

2 DR. FINDER: I agree with that, and I think Mammo
3 Matters is probably our single best way at this point
4 although I am hoping to make the web itself more of a
5 mechanism to inform facilities, so that when things go up,
6 more and more facilities will be aware, but we are going to
7 take every method that we have to try and address these
8 issues, not only this one, because infection control is just
9 one of the problematic areas, some of the recordkeeping for
10 some of the other things also is problematic, so we do want
11 to make sure that people are aware.

12 MS. WILSON: Patricia Wilson. I have a few
13 questions about this log. The Mammo Unit coming in contact
14 with blood is a fairly rare occurrence, but what does happen
15 more frequently is the non-intact skin under the breast, and
16 if you treat every patient as though it is potentially
17 infectious and you have a protocol for established cleaning
18 after every exam, why would you need to have a separate
19 protocol for blood that is going to occur much more rarely
20 than the non-intact skin when your standard operating
21 procedure says after every patient usage you clean and
22 disinfect your unit.

23 DR. MONSEES: I agree. We have a policy in place
24 and the policy and procedure manual states that the
25 equipment is cleaned after every patient. So, I am not sure

1 I understand this either, I think that it is not necessarily
2 logical and won't necessarily help, and it may be
3 burdensome. That's my opinion.

4 DR. SICKLES: If we take it as has been discussed,
5 it won't be burdensome because it will happen once a year or
6 very, very infrequently. If we try to expand it, or if you
7 are giving thought to expanding it to the more frequent
8 circumstance where the skin may not be intact, then, it
9 would become much more burdensome.

10 MS. WILSON: But asking your technologist to
11 remember this for the occurrence that happens once a year in
12 a facility, are they going to remember to document it?

13 DR. FINDER: I think we can take into account and
14 maybe look at the issue about what happens with the facility
15 that cleans between every single patient, and that again is,
16 as I love to say, every question and answer raises only new
17 questions.

18 That again was not something that was actually
19 addressed even in this guidance, and maybe we need another
20 question to deal with the issue about what happens if, as
21 part of your procedure, you clean between each patient, do
22 you have to have a separate kind of log for these episodes.

23 I don't know the answer to that. That is
24 something that we can certainly look at and talk with the
25 Division and also with our legal counsel as to how far we

1 can go based on what the regulation says, but it is
2 certainly something that we can take back with us and look
3 further into.

4 Again, this is some guidance on this issue. It
5 came after we had questions after the first guidance that we
6 issued. There is certainly going to be more guidance. That
7 is job security.

8 DR. MONSEES: Any other comments on this
9 particular document that we were just addressing?

10 DR. PIZZUTIELLO: No.

11 DR. MONSEES: I will give you a second to look
12 through for your annotations.

13 Nothing? Can I move on then?

14 The next one is the one that says Document 3.
15 This has been previously discussed by this panel. It is not
16 final. Are there any comments or changes that we want to
17 propose that we should discuss about this today?

18 This is Mammography Quality Standards Act Final
19 Regulations Document 3, Draft Released for Comment on
20 December 8th, 1999. Please look through and see if you made
21 any notations that you want to discuss.

22 Yes?

23 DR. PIZZUTIELLO: On page 9--

24 DR. FINDER: That's a different document.

25 DR. MONSEES: Which one is he looking at?

1 DR. PIZZUTIELLO: Document No. 3.

2 DR. FINDER: I am sorry. Okay.

3 DR. PIZZUTIELLO: Page 9. There is a question
4 about--it addresses degrees from non-U.S. institutions, and
5 this is under the medical physicist criteria.

6 Basically, the way I interpret this is that if
7 it's an FDA-approved certifying body sort of situation,
8 then, if the non-U.S. university is approved by that
9 certifying body, then, it would be considered acceptable.

10 I would like to draw the FDA's attention to an
11 organization called CAMPEP, and that is the Committee on
12 Accreditation of Medical Physics Programs, and that
13 committee accredits medical physics training programs of
14 which there are a relatively small number, maybe a dozen or
15 something like that.

16 That is not a professional certifying body, but it
17 is the organization that has been created by the three
18 medical physics societies specifically for the purpose of
19 evaluating medical physics training programs and also
20 medical physics continuing education programs.

21 So, I would like to see CAMPEP specifically listed
22 in here because I don't know that FDA-approved certifying
23 bodies would really want to get into the business of
24 deciding if programs were acceptable, especially if CAMPEP
25 has already done that.

1 I wouldn't say that we should exclude FDA-
2 approved, but since CAMPEP is the organization I think it
3 should be specifically mentioned.

4 DR. FINDER: What is the name of the organization?

5 DR. PIZZUTIELLO: The organization is called
6 CAMPEP.

7 DR. FINDER: And that stands for?

8 DR. PIZZUTIELLO: The Committee on Accreditation
9 of Medical Physics Education Programs.

10 DR. FINDER: Are you sure about that?

11 DR. PIZZUTIELLO: I am pretty sure.

12 DR. FINDER: If you were on I want to be a
13 Millionaire, is this your final answer?

14 DR. PIZZUTIELLO: Can I call my mother and ask
15 her?

16 [Laughter.]

17 DR. FINDER: If you get me that, the actual
18 information, I think that is something we can include
19 because again this is still in the draft form, we are still
20 waiting for public comment, and it certainly can be modified
21 to take that into account.

22 DR. PIZZUTIELLO: This actually happened to have
23 come up in my practice because one of the physicists that
24 recently joined my group came from McGill University where
25 he got a Ph.D. in medical physics, and the inspector said,

1 well, it is not acceptable because it is not a U.S.
2 university. So, then went the documentation from the CAMPEP
3 program, and they said, well, but it is not an FDA-approved
4 certifying body, and it took a little work to convince them
5 that this was okay.

6 DR. MONSEES: Good point. Any other comments from
7 this document? I have one that is somewhat picayune. On
8 page 12, equipment intended by manufacturer's design to not
9 be flat and parallel. In the guidance, the word "not," I
10 think needs to be moved to make it make sense.

11 The reg says, "Equipment intended by the
12 manufacturer's design to not be flat and parallel to the
13 breast support." The question says, "What documentation
14 should facilities have to show that their mammography
15 compression paddles were not designed to be flat and
16 parallel?" I think it should read the same, and it should
17 say, "Mammography compression paddles were designed to be
18 not flat and parallel." There is a difference in meaning, I
19 think, if you put the "not" in a different place.

20 Any other comments on this document? Yes.

21 DR. PIZZUTIELLO: Just back one page, on page 11,
22 under Equipment, this is the issue of the GE500T example, is
23 tapping the foot pedal considered fine adjustment of
24 compression?

25 DR. MONSEES: Yes.

1 DR. PIZZUTIELLO: I just need to say that my
2 experience with 500T's is that it really is not because it's
3 an air-driven compression system, and from the moment you
4 tap your foot on the pedal, there is a variable time delay
5 depending upon how each system is working, and then it makes
6 a certain amount of compression.

7 I find it very difficult to make fine compression.
8 Now, I don't position patients, so I can't speak for the
9 clinical application, but when I try to position test
10 equipment, and do fine adjustment, I have a great deal of
11 difficulty with that particular piece of equipment.

12 DR. MONSEES: You know that that was discussed
13 previously when we discussed this document, and a member of
14 the panel, Dr. Dempsey, I believe, said that he had several
15 units like this in his facility. He thought it was a matter
16 of technologist experience that made the difference.

17 Do you want to address what the FDA is doing about
18 that, Dr. Finder, regarding asking for additional public
19 comment?

20 DR. FINDER: Well, we have made it known, I
21 believe in Mammography Matters, where we specifically asked
22 this question, and we are waiting for public comment, and
23 this is one of those questions that we are really hoping to
24 hear from a large number of the facilities about what their
25 opinion is about this unit because the 500 and 600T's do

1 make up a significant portion of the base of equipment out
2 there, and we want to know whether the opinion is that this
3 does constitute fine adjustment or whether these units will
4 either have to be modified or taken out of service. It's a
5 big issue.

6 MS. WILSON: I have used the 600T, and while I
7 have no doubt that it's an easier exam to perform on models
8 that have the fine-tune manual compression, with experienced
9 technologists, I found that we had no difficulty obtaining
10 good compression.

11 I would support allowing this. Many facilities
12 have 600T units, 500T units, and they cannot, for one reason
13 or another, replace them at this point in time, and if the
14 radiologist looks at the films, and the ACR passes the
15 clinical images, you know, they are very particular when you
16 submit your clinical images for review, compression, motion,
17 I think that should be the guidance.

18 DR. FINDER: I just want to make one comment to
19 your comment about the ACR passing these films, there are
20 other accreditation bodies out there that look at films, so
21 it is not just the ACR that looks at them.

22 DR. MONSEES: Are there any other comments
23 pertaining to this particular document that we were just
24 discussing?

25 Okay, we will move on to the next one, which is--

1 okay, we will go back to that one. Take your time.

2 DR. PIZZUTIELLO: Page 22. This is a comment that
3 is under the topic of the weekly QC phantom, and there are
4 requirements in the regulation that if the parameters of
5 density or density difference varied beyond the permissible
6 amount, then, they need to stop doing mammography and
7 investigate the source of the problem.

8 I was unclear as to what was meant by the end of
9 the second paragraph, at the top of page 22. Essentially,
10 it is talking about if there is a variance in your data, and
11 the facility looks at the imaging change, and then it says,
12 "If no problems are detected, the facility may assume the
13 change is due to different film emulsions."

14 Then, it says, "They can then adjust their typical
15 clinical technique factors to meet the phantom optical
16 density requirements." I wasn't clear from that statement
17 are they required to do that, or they may. I am not sure
18 what the word "can" means in this context.

19 We are talking about variability from box to box
20 in films, but there is also variability sheet to sheet in
21 films, both of which have been documented, for example, in
22 the ACR-CDC document on recommendations for equipment for
23 mammography. Off the top of my head it is something 0.15 or
24 so density easily found between the beginning and the end of
25 a box of film, same box.

1 So, I am a little concerned that this might be
2 interpreted that facilities must adapt their clinical
3 technique factors, and I think that I would prefer to see it
4 that they may because there may be other reasons why the
5 facility has found some variability, and if the difference
6 is not clinically significant, I think that should be a
7 clinical decision.

8 MS. WILSON: I agree with this because constantly
9 adjusting your technical factors for clinical usage can be
10 very confusing for the Department especially a large volume.

11 DR. FINDER: Bob, your recommendation would be
12 that we change the word from "they can then adjust the
13 typical" to "they may then adjust"?

14 DR. PIZZUTIELLO: Yes.

15 DR. FINDER: I will certainly bring that back to
16 the group and see if they have any--"group" in terms of our
17 Division--

18 DR. PIZZUTIELLO: The reason why I bring that up
19 is that some inspectors have interpreted this as saying that
20 facilities must therefore go back and change all their
21 techniques by increasing to plus 1 for today, and I don't
22 know that that is something that we should put in the
23 guidance document. I think it should be a facility decision
24 for exactly the reasons that Patricia brought up.

25 DR. MONSEES: Dr. Sickles.

1 DR. SICKLES: I am not as troubled as you between
2 "can" and "may," but if you want to make it more clear,
3 then, you could make it even more clear in the text by
4 saying that it is optional.

5 That would overcome the semantic difficulty in
6 case there is an inspector who is over-interpreting the
7 regulations and say under some circumstances it may be
8 appropriate to do it, but it isn't required.

9 If you put in "but it isn't required," then, you
10 wouldn't get over-regulated.

11 DR. MONSEES: Any other comments on this document?

12 Then, let's move on to the one that has not been
13 previously discussed, and there are two copies for your
14 perusal, one was mailed to you in advance without the
15 numbers, and then Dr. Finder handed out one today with
16 numbers next to it, so that when we talk about it, we can
17 pull out the lines.

18 These are new questions for panel discussion, so I
19 would like to go through them question by question. If you
20 have no questions, that's fine.

21 DR. FINDER: I just want to make a point for the
22 public. These questions that are going to be discussed here
23 today in this document are being brought out for discussion
24 at the committee before they go into a proposed guidance
25 document, so even after they are discussed here, they are

1 going to go out for public comment before anything else
2 happens with them.

3 DR. MONSEES: And those will be available on the
4 web site when?

5 DR. FINDER: Well, what time is the meeting
6 supposed to be over? We will have to take the comments that
7 we hear today. It will then take some time to create the
8 document in the format that you have seen for the other
9 guidance documents, and then it has to go through a
10 clearance process.

11 Part of that is going to be dependent on whether,
12 after looking at all the questions, we believe this is Level
13 1 guidance or Level 2 guidance, there are different
14 clearance procedures they have to go through, I would expect
15 it to be up on the web probably sometime in the summer.

16 DR. MONSEES: Okay, just so that people know.

17 The first one: Is medical outcomes audit data
18 collected during facility inspections used in a national
19 database? The answer is no.

20 Do we have any comments or questions pertaining to
21 this item here? No. Okay.

22 The next question--and this would be line 8--What
23 type of lay summary should be sent to a patient who has a
24 normal mammogram, but an abnormal physical exam?

25 Any comments? Dr. Sickles.

1 DR. SICKLES: Yes, I do. I would propose a change
2 in the language on line 15, and that is, "the abnormal
3 physical exam" to be changed to "an abnormal physical exam."

4 What I see here is the opportunity for the
5 regulation to require a tailored patient letter, which I
6 think would be onerous. I think one can construct, very
7 appropriately, a generic patient letter that covers this
8 situation, where, you know, if you have a lump, then, so-
9 and-so, rather than to have wording that indicates you do
10 have a lump and therefore you should follow this course of
11 action.

12 By taking the "the" and changing it to "an," we
13 eliminate any--or at least eliminate some misinterpretation
14 of I think what the intent is, which is a good intent.

15 DR. MONSEES: I had also a concern about this
16 particular answer, and it pertained to the fact that I
17 didn't believe, and particularly for screening patients who
18 may not be admitting that they have an abnormal physical
19 exam or a self-breast exam, I want to make sure that the
20 radiology facility is not going to be responsible to know
21 for sure that that woman has an abnormal exam, therefore,
22 implying that they should have done a physical breast
23 examination to determine if she does or doesn't.

24 So, I think it needs to be constructed so that it
25 is clear that the facility is not responsible for doing

1 that, and checking that she has a negative physical exam.

2 DR. SICKLES: That is exactly why I wanted it to
3 be more generic and say "an" abnormal physical exam rather
4 than "the," because that removes from the facility the
5 responsibility to perform the clinical breast exam, which
6 traditionally is done by the primary provider.

7 DR. MONSEES: I agree.

8 DR. FINDER: I just want to raise a question of
9 perhaps the question should be reworded and while I was
10 listening to you, I came up with a little something. "What
11 type of lay summary should be sent to a patient who has a
12 normal mammogram, but where the facility is aware that the
13 patient has an abnormal physical exam?"

14 Would that help to address some of the issues?

15 DR. SICKLES: I don't know. I still would be in
16 favor of the generic statement in the lay summary, that
17 indicates not just to a woman who is aware that her
18 clinician felt something or may be aware that she felt
19 something, but just to every single woman who receives this
20 lay summary, she should know that mammography isn't perfect,
21 and if there is a lump, that she needs to consult her
22 physician, and I think it is much better to keep it generic,
23 which will inform all women, all the time, than to try to be
24 much more specific and identify this woman who does as
25 opposed to that woman who doesn't apply to this situation.

1 DR. MONSEES: I tend to agree, and the reason is
2 that there are many women that would like to deny that there
3 is something wrong, and they may not be admitting that they
4 have an abnormal physical exam, and I would hate to see them
5 use a normal lay letter as a reason not to go to their
6 physician.

7 So, the more you remind that mammography isn't
8 perfect, as Dr. Sickles said, I think the more helpful it
9 is. Anyway, that is my opinion on that.

10 Any other comments on that one? Okay, we will
11 move on the next question.

12 Must the compression paddle be placed in the x-ray
13 beam during half value layer measurements? Do we like the
14 wording of the answer here?

15 DR. PIZZUTIELLO: Yes.

16 DR. MONSEES: Okay. No comments on that? Okay.

17 Then next one, line 27. I have a
18 Master's/Bachelor's degree specifically in physics. Do I
19 still need to document my number of semester hours in
20 physics?

21 The answer to that, okay? Does anybody have any
22 comments on that?

23 Next question is line 41. What are the minimum
24 tests and/or review that the medical physicist must perform?
25 I won't read the whole question. Any questions or comments

1 on that one? Okay.

2 The table on the next page reads okay to you?

3 DR. PIZZUTIELLO: Yes.

4 DR. MONSEES: Next question. While performing a
5 physics survey, unit survey, or equipment evaluation--that
6 is line 2 on page 2--any comments or questions? Yes.

7 DR. PIZZUTIELLO: I think I follow the logic in
8 this answer, and the logic the way I understand it is that
9 there are certain requirements for essentially a mammography
10 equipment evaluation or if the machine fails, you need to
11 have immediate corrective action, those sorts of things.

12 However, I think it is important to realize that
13 it is often the case where a physicist finds a problem with
14 the machine. Heretofore, if we found a problem with a kVp
15 accuracy or the densities needed to be adjusted, we would
16 inform the facility that they need to do that, and then it
17 was sort of a professional judgment as to whether we felt we
18 needed to go back to verify that it was done again.

19 There is a cost associated with that repeat work
20 in a large number of facilities, and if we, as physicists,
21 had confidence in the service engineers, then, we would not
22 feel the need to go back and verify that it was done
23 correctly.

24 What I see here in the guidance is a change that
25 will impact facilities because it will require an additional

1 medical physicist visit afterwards if we say that any of the
2 enumerated items need to be adjusted.

3 DR. MONSEES: You are aware that there is a table
4 at the end that we are going to discuss.

5 DR. PIZZUTIELLO: I have some comments on that.

6 DR. MONSEES: Maybe we should hold the discussion
7 of which of those items when we review that table.

8 DR. PIZZUTIELLO: Sure.

9 DR. MONSEES: I would like to see, since it says
10 here, "Major repair," and it doesn't say what major repairs
11 are, I would like to see FDA put in there "See table such
12 and such," regarding what are the major repairs, at least in
13 the text of this answer here, because when I first read
14 this, not knowing there was an attached table, I wondered
15 what major repairs meant, and then later it says it, so I
16 think it should refer to that in the answer to the question
17 here.

18 DR. PIZZUTIELLO: I interpreted "major repair,"
19 because it's in quotes, the term "major repair" is used in
20 the regulation as defining the requirements for mammography
21 equipment evaluation, so if that is the case, you might also
22 just reference that citation.

23 DR. MONSEES: We are finished with this question,
24 the discussion of this one. Then, we will move to the next
25 one, which is page 2, line 17. "Our facility has

1 permanently glued the acrylic contrast disk to the phantom."

2 Do we have any comments on the Q and A here?

3 Somebody in the audience. Yes, would you please
4 come to the microphone and identify yourself even if we know
5 who you are.

6 MS. BUTLER: Penny Butler from ACR.

7 I just wanted to point out that the ACR's
8 procedure for evaluating phantom image quality has been
9 modified recently. We specifically state that the facility
10 should keep the disk on the phantom when they submit images.

11 A lot of facilities have glued the disk down on
12 the phantom, and there is concern that removing that disk
13 may cause artifacts that could interfere with evaluation
14 that we are doing at the ACR, particularly if our reviewers
15 don't know what those artifacts come from.

16 So, I would recommend not having language about
17 removing the disk in here.

18 DR. MONSEES: Have you got that, Charley?

19 DR. FINDER: Again, these questions have come
20 because facilities have asked us these questions, and we
21 have tried to go back and come up with answers to deal with
22 them, and if we take--I mean this was specifically addressed
23 because somebody asked us the question.

24 Do you think that we should just go back and say
25 don't remove the disk?

1 MS. BUTLER: Yes.

2 DR. MONSEES: She is suggesting that, or the other
3 thing you can do is that accreditation, you could say
4 accreditation bodies--

5 DR. FINDER: --no longer recommend removal of the
6 disk?

7 DR. MONSEES: Right, and that it could interfere
8 with the evaluation of the phantom image, right?

9 MS. BUTLER: Right, and I could submit language
10 for this, if you would like.

11 DR. FINDER: That would be fine.

12 MS. BUTLER: Okay.

13 DR. MONSEES: We will move on to the next question
14 on page 3.

15 "We use the same locum tenens interpreting
16 physician on a recurring basis," and then there is an answer
17 regarding that. Do we have any comments on that particular
18 one?

19 Okay. Line 30 on the same page, page 3. "We use
20 the same temporary radiologic technologist on a recurring
21 basis" and then there is a long answer to that one, similar
22 to the one before it. Any comments?

23 Okay. We will move on to page 4, line 7. "Under
24 what situations should facilities establish new processor
25 operating levels?" We have a comment on that one. Okay.

1 DR. PIZZUTIELLO: This is actually a fairly common
2 problem, and it is very common to be handled badly. The
3 problem is that facilities find that their sensitometric
4 values are varying, they come out of range, and the most
5 common thing that facilities do is to contact their provider
6 of films or chemistry, or the service person who services
7 the processor, and they say what should we do.

8 So, they ask a few questions, and the service
9 companies always say, well, just reestablish your baselines,
10 everything is really okay, I am sure of it, and there is
11 really no basis upon which to make that judgment.

12 What it does is it gets the person off the phone,
13 and it puts the service provider off the hook. What that
14 does is it says that even if the system is not operating
15 properly, and, in fact, the quality control data is alerting
16 us that something has changed and is potentially wrong, that
17 if we just restart a new value, then, the problem appears to
18 go away.

19 We have had experience with probably 15 or 20 in
20 the last couple of years, clients, where they have had this
21 happen, they call the service engineer. The service
22 engineer says just reevaluate, and they call us, and they
23 will say this doesn't really seem right, and when we worked
24 with them further and worked through, we found that there
25 were indeed problems, and they were able to correct the

1 problems, and then the numbers went back to within the
2 range.

3 If they had done what the service engineer
4 suggested, their problems would have been masked forever or
5 until there was some other big change.

6 So, I have an opinion that we should add to this
7 answer, the second paragraph, that the facility--this is
8 line 18--"that the facility should only reset or reestablish
9 their values after consultation with the medical physicist."

10 Now, maybe that is too strong, but that's my
11 opinion from what I see out there because I know that these
12 problems are getting buried.

13 DR. MONSEES: And when you say "after
14 consultation," this doesn't have to be in person?

15 DR. PIZZUTIELLO: Correct, does not need to be an
16 in-person visit.

17 DR. MONSEES: So, it is concordant with the way
18 the language is used for that table that is at the end, that
19 we will be getting to.

20 DR. PIZZUTIELLO: Yes.

21 DR. MONSEES: Yes.

22 MS. WILSON: Do you propose that facilities
23 receive written documentation of this conversation with the
24 medical physicist for their records?

25 DR. PIZZUTIELLO: I don't think so. I think that

1 there are lots of cases where facilities document on their
2 control charts when they find a problem and they investigate
3 it, and they write down what they did.

4 I think what they should do is write down the date
5 and say spoke with so-and-so, our medical physicist, who
6 advised us--whatever the advice was. I don't think that
7 they need to get a letter from a physicist or anything like
8 that. That is excessive.

9 DR. MONSEES: It sounds appropriate to me.

10 Any other comments on this one?

11 The same page 4--I sorry, I didn't see your hand.
12 Please come to the mike.

13 MS. BUTLER: Penny Butler, ACR. I would like to
14 point out that this guidance is in conflict with the
15 guidance that is in the ACR Quality Control Manual. There
16 is a section in there called "Reestablishing Processor
17 Quality Control Operating Levels."

18 There are some things that are consistent, but
19 there are a couple of additional situations that are
20 included in the manual, such as a change in film volume or a
21 change in replenishment rates, and I would like to point out
22 that when this section of the manual was written, we had
23 consulted with the film companies for guidance on when they
24 felt it was appropriate to reestablish QC operating levels.

25 So, I would recommend that FDA go back and look at

1 the QC manual, so we are not inconsistent.

2 DR. MONSEES: This answer, if you will note, says,
3 "The most warranted and common situations." I don't think
4 it is supposed to be inclusive here. Is it supposed to be
5 inclusive, Charley?

6 DR. FINDER: No, we did not want to go in and
7 explain or list all the possible reasons that we thought a
8 facility would come up with, because we didn't want to get
9 into the specifics of then, well, what happens in this
10 situation. So, we just tried to give what we thought were
11 the most common and then give just a few of those.

12 But it is not meant to be an all-inclusive type of
13 question.

14 MS. BUTLER: I guess what concerns me is the
15 second paragraph says, "should not use the"--I mean the
16 second paragraph comes out pretty strong, and facilities may
17 feel that the information provided in the first paragraph
18 would really be the only conditions that it would be
19 appropriate to do this kind of thing.

20 DR. MONSEES: It is easy to see how it might be
21 misconstrued, absolutely. So, how can we solve that? We
22 either include everything or suggest that they--make it more
23 clear that these are just the common ones, and that there
24 may be other ways, other times that they may need to do
25 that? How would we make that more clear, do you think we

1 should list everything?

2 DR. FINDER: The only problem with listing
3 everything is you can never always list everything in every
4 situation, and that is why we didn't try and do that. In
5 fact, we had long discussions about should we come up with
6 what we thought was a definitive list of the conditions, and
7 it quickly became apparent that we weren't going to be able
8 to because every situation can be different.

9 MS. BUTLER: May I make a suggestion?

10 DR. MONSEES: Yes.

11 MS. BUTLER: It might be useful to use the list
12 that's in the QC manual, so they are consistent, and then
13 come up with language to help facilities realize that the
14 door is still open for other types of situations.

15 DR. MONSEES: Yes.

16 DR. PIZZUTIELLO: This is exactly the reason why I
17 say that facilities need to consult with their medical
18 physicist because there are a wide variety of reasons why
19 these things happen, and sometimes facilities have done so
20 many things and changed so many factors that even though you
21 really don't like the idea of reestablishing the baselines,
22 it is just not possible to evaluate the data because there
23 is too many variables that have changed.

24 When you say that the medical physicists should be
25 involved, then, you are sort of adding this professional

1 judgment component, hopefully, the medical physicist is
2 aware of not only what is in the ACR manual, but we know
3 that the manuals get out of date. Maybe new film is
4 introduced with new characteristics that would become known
5 to the medical physicist, so I wouldn't want to limit it to
6 the manual, but I think that the items listed in the manual,
7 as Penny mentioned, would be an excellent reference.

8 Maybe it might be possible to just say there are a
9 number of references available, and you might mention this
10 particular reference in the manual, but to say that there
11 are other sources of good information.

12 DR. MONSEES: Do we have any other comments on
13 this? Yes.

14 MS. WILSON: I know of several facilities that are
15 routinely establishing new aims approximately every 18, 24
16 months, just because they have gone through so many
17 crossover procedures.

18 These are facilities that are performing
19 crossovers every two months, so during the course of a year,
20 they have six crossovers, and who is to say at the time that
21 you perform the crossover, that your processing that day is
22 optimized.

23 So, their feeling is that after a certain number
24 of crossovers, they benefit from establishing new aims, not
25 because they are out of limits with their current aims, but

1 just because they have had effects of multiple crossover
2 procedures.

3 DR. MONSEES: Did you have an answer to that, and
4 then we have a comment from the audience.

5 DR. PIZZUTIELLO: It is hard for me to imagine why
6 you would need to reestablish new aims. If the crossover
7 procedure is being done properly--and there are a number of
8 steps in that procedure, one of which is you should do it on
9 a day when the processor is in good control--so, if they are
10 following the appropriate steps, then, I don't see that they
11 should be reestablishing baselines.

12 One of the problems that I have found with some
13 frequency is that somebody makes a math error when they are
14 doing the crossover procedure, and then they think that
15 things are out of whack, and when you go back and look
16 carefully, you find that they inverted a sign or something,
17 and they made a mistake, then you understand where the data
18 is.

19 So, I really can't see any reason why you should
20 need to reestablish baselines. To me, that is a very big
21 flag.

22 MS. WILSON: Well, it's a tremendous amount of
23 work to reestablish aims if you go through the proper
24 procedure. I would assume that facilities would not take
25 lightly the reestablishment of aims, because of the amount

1 of time involved in it.

2 DR. MONSEES: Yes.

3 MR. SULIEMAN: Orhan Sulieman, FDA. I usually try
4 to keep as quiet as possible because Bob was really on the
5 right track.

6 We have been very frustrated by this whole
7 operation. I think the establish and review operating
8 limits, the reason we are addressing it in the guidance is
9 that facilities are using that.

10 There are inexperienced film or technical
11 representatives out in the field that give the facilities an
12 easy way out, so they don't have to address their
13 responsibility. With due respect to our medical physics
14 colleagues, some of them are not doing a good job themselves
15 and are referring to the technical reps.

16 So, there is a problem, and we are giving them an
17 easy way out by establishing new limits. They should
18 periodically double-check their limits, if they are doing a
19 whole bunch of other things correctly, but they shouldn't be
20 going to establishment of new limits to administratively
21 address the problem when fundamentally, the problem is still
22 there.

23 So, I think what I see, and I am concerned about,
24 is this breaking down where everybody is pointing fingers at
25 somebody else, that it is their responsibility. So, I think

1 the way this is written sort of raises a flag, says don't
2 reestablish operating limits serendipitously, you know, you
3 have got to make some extra effort before you look into
4 that.

5 How you get the appropriate professionals to
6 accept their responsibility is a different issue, and I
7 would throw that right back to you, what do we do about
8 that, but clearly, we get calls, and they get filtered
9 through to me sometimes, and I am hearing this theme over
10 and over again that the physicists told us to check with our
11 technical reps. The technical reps have told the facility
12 to reestablish their control limits.

13 I asked the facility how long have you been doing
14 this. Oh, I just started a month ago. So, clearly, even
15 the technologists in the facility are not up to speed.

16 So, we are trying to close a hole here, where
17 facilities are using to circumvent the intent of the
18 standards.

19 DR. MONSEES: Well, we have to trust that our
20 physicists are doing their job. I don't know that the panel
21 can address that, but certainly it helps to kick it back to
22 them, and the suggestion that you made sounds like the FDA
23 agrees with that.

24 DR. PIZZUTIELLO: I think that is a very important
25 point, and there has been some discussion. In fact, there

1 is a plan to produce a medical physics training program on
2 how to understand the subtle nuances of film and processing.
3 It was last done in about 1991 or so, and there is another
4 one in process, because none of this has been available for
5 a long time.

6 DR. MONSEES: Same page, line 20, has another
7 question here about new operating levels during the time a
8 facility is establishing operating levels, and then there is
9 a somewhat long answer to that I won't read.

10 Do you want to comment on that? It is okay with
11 you?

12 DR. PIZZUTIELLO: It's okay.

13 DR. MONSEES: On the same page, line 34. "What
14 constitutes an equipment evaluation," and then the answer to
15 that. Any questions on that? That is pretty clear, I
16 think. Okay.

17 At the bottom of the page, line 46. "Must the
18 equipment evaluation report be sent to the facility within
19 30 days?" And then the answer.

20 Any comments on that? I had a comment on that,
21 and that was the facility can't use the equipment until
22 documentation is received. Is a verbal okay saying the
23 report is to follow, so that it will decrease their down
24 time? Can I hear a comment from you on that?

25 DR. PIZZUTIELLO: I think there is too much

1 opportunity for a breakdown in communication with that
2 verbal report, but the preliminary report I think is the
3 appropriate thing to provide.

4 It exists in the ACR manual. It is essentially a
5 one-page check-off item where the physicist indicates that
6 everything passed, and then signs, and then says the full
7 report will follow.

8 DR. MONSEES: Can that be stipulated in here then
9 also?

10 DR. FINDER: One of the problems when we deal with
11 these questions as they appear is that they are left out of
12 context with all the other questions, and I believe we have
13 actually addressed that, I believe so in other guidance,
14 about the issue about these preliminary written reports,
15 that they would be acceptable.

16 So, I think that we have already addressed that.
17 If we haven't, we can certainly add a comment in here.

18 DR. MONSEES: I would. There is a lot of
19 redundancy in a lot of the questions that appear throughout
20 because the way the guidance is, nobody is going to read the
21 guidance cover to cover, and when they look something up on
22 those documents that are downloadable from the web, you
23 know, they want a particular answer, and they are going to
24 read part of that guidance. So, I would suggest that it be
25 in here.

1 Line 7 on page 5, "What assessment category should
2 be used for post-lumpectomy patients?" Yes.

3 DR. SICKLES: I have a comment on this one.
4 Basically, here you are describing how one might use the
5 assessment categories in a situation of a woman who has
6 already had breast-conserving treatment.

7 We give the example of how they might legitimately
8 use the category "benign." I think it also would be helpful
9 to put in here that it would be perfectly reasonable to use
10 the category "negative," specifically state that it would be
11 reasonable to use "negative."

12 It is not included, and I think it could be
13 without changing the meaning of it. One method would be to
14 read it as negative, another method would be to read it as
15 benign with a qualifying statement, and then the final
16 language.

17 The way it is worded here, you may be discouraging
18 people from using the word "negative," when indeed the
19 findings are negative.

20 DR. FINDER: I would just raise the issue if there
21 are post-surgical changes, would you call that negative?
22 Again, I would go back to the definition of negative, which
23 is there is nothing significant to report.

24 That is why we came up with using the benign.
25 Obviously, it's post-surgical, but if there are no changes,

1 certainly negative would be appropriate, but if there were
2 postoperative changes, would you still call it negative or
3 would you more likely use benign?

4 DR. SICKLES: I will relate back to the experience
5 that I have had being on the BIRADS Committee when these
6 various categories were developed many years ago. There was
7 a debate among the members of the committee at that time as
8 to whether one should even have two categories, negative and
9 benign, or whether one should simply have a single category,
10 call it what you will.

11 The consensus of the panel at that time was to
12 allow for both a negative and a benign for those
13 radiologists or those interpreting physicians, if we want to
14 use politically correct terminology, who wanted to make the
15 distinction between negative and benign, because some do,
16 but understand that there are also some who do not.

17 My particular preference is not to make the
18 distinction. I rarely use the term "benign." The vast
19 majority of my interpretations are negative even though
20 there are findings on the film, because I don't consider
21 them to be significant findings.

22 I don't comment on calcified fibroadenomas, I
23 don't comment on post-surgical scarring, I don't comment on
24 raised skin lesions, because it is a lot of effort, and it
25 doesn't help in the management of the patient.

1 So, anything that suggests to interpreting
2 physicians that they make their reports more complex, I
3 think could in some ways be detrimental to patient care, not
4 necessarily helpful, and I would encourage the use of--at
5 least not discourage the use of the category negative.

6 That is the only purpose of my comment.

7 DR. MONSEES: In this particular situation, I do
8 usually address the post-surgical change and call them
9 benign, but like Dr. Sickles, most things that are clearly
10 negative, I don't put in the report, and I just call them
11 negative, and I don't call them benign, vascular
12 calcifications, for example, BIRADS has a way that you can
13 comment on that, or secretory type calcifications, which are
14 clearly benign and characteristically so, and I don't
15 complicate the reports by putting those in the reports. I
16 just call them negative.

17 So, I think that it is probably a good point to
18 add that negative. It does clearly stipulate in here,
19 though, that the decision to which category to assign is
20 left to the interpreting physician, and I think that is the
21 way it should be.

22 DR. SICKLES: The only reason that I raised the
23 point was one might feel from reading this that that is the
24 recommended approach, and I think it is best to leave it to
25 the practitioner who is making the assessments as to whether

1 they are a lump or a splitter, do they want to put them all
2 as negative, or they want to split apart the ones that are
3 benign.

4 DR. DOWLAT: At the receiving end of that report,
5 and seeing the films and the report, I agree with you that
6 it is good to know that this is somewhat different from a
7 benign finding of microcalcifications or calcified
8 fibroadenoma. This is a patient who has had a lumpectomy
9 for cancer, now we are seeing the old non-cancers,
10 nevertheless, this is a scar that you want to be sure that
11 there is no malignant process growing in it, so both benign
12 and negative is fine with me, but is this also BIRADS
13 Category 2? Would you stipulate that, as well?

14 DR. SICKLES: The FDA so far does not discuss
15 using the numbers as opposed to the words, but benign is
16 what is commonly called Category 2, and negative is commonly
17 what is called Category 1.

18 As you are probably aware, there are patients
19 post-lumpectomy who have no findings at all. You can look
20 at the mammogram and wonder has this woman really had
21 breast-conserving surgery.

22 There are others where they are really very
23 striking findings. Sometimes they can be quite confusing.
24 The ones with more striking findings are more likely to be
25 put in the benign category, and the ones with the rather

1 inapparent findings are more likely to be put in the
2 negative.

3 DR. MONSEES: Probably benign is Category 3. The
4 FDA does not ask you to put the numbers in, but Dr. Sickles
5 is correct, benign means Category 2.

6 The next question, can we move on to that? On
7 page 5, line 16, "Our group practice interprets mammograms
8 sent to us by other facilities," and there is an answer to
9 that one, that basically says no. Any comments on that?

10 DR. SICKLES: Yes. It is a very long answer. It
11 doesn't really matter where this comment applies, but
12 basically, what you are talking about here is the fact that
13 it is possible for someone in the chain other than the
14 facility itself to actually go out and try to get the
15 process going, and you describe a mechanism by which the
16 radiologists involved, the interpreting physicians might
17 actually go and do all the paperwork, et cetera.

18 I wonder whether you shouldn't also put somewhere
19 in this fairly long answer the statement that ultimately,
20 the facility rather than the interpreting physician is the
21 one who is responsible to be sure that the whole process is
22 instituted, it is not the interpreting--although the
23 interpreting physician may choose to do it--it is the
24 responsibility of the facility to be sure it is done at the
25 facility which is cited, not the interpreting physician who

1 is cited.

2 I think that might be helpful somewhere in there,
3 probably near the end.

4 DR. MONSEES: I think it is there. Doesn't it say
5 the facility performing the mammography will be responsible
6 for obtaining a certificate?

7 DR. SICKLES: It is, but what you don't want to do
8 is you don't want to encourage--I don't think it is in the
9 best interests of patient care to encourage facilities to
10 try to get interpreting physicians to do this.

11 It would be much better--my feeling would be it
12 would be much better if the facilities do it than if the
13 interpreting physicians do it, especially if they are off-
14 site.

15 DR. MONSEES: There is a series of questions here
16 that basically get to the same thing. It does say later, I
17 think, in this document, that the radiologists can take the
18 lead and go and apply, but that it is the facility's
19 responsibility. I think it is fairly clear, but maybe you
20 should go over the wording again, understanding what his
21 concern is.

22 DR. FINDER: I believe anytime we have a chance to
23 make the question longer, we will look at it, yes.

24 [Laughter.]

25 DR. FINDER: No, actually, we are trying to make

1 it shorter, but it's an additional sentence, it shouldn't be
2 a big issue.

3 DR. MONSEES: There is a long answer here, isn't
4 there. Okay. In fact, which I thought were other questions
5 were actually just more paragraphs of the same answer.

6 DR. FINDER: It's all the same thing.

7 DR. MONSEES: Yes. On the next page, on page 6,
8 line 14, "The regulations at 900.12(e)" -- blah-blah-blah,
9 the people in the audience, Charley, do have copies of this,
10 right?

11 DR. FINDER: Yes.

12 DR. MONSEES: So, I don't have to read all of
13 this. Do we have any comments pertaining to the AEC
14 performance specification outside the 2 to 6 centimeter
15 range? Yes.

16 DR. PIZZUTIELLO: In the answer, line 24 and 25,
17 the gist of this is that the regulation says that the
18 machine has to meet the requirements over 2 to 6 centimeters
19 variable breast thickness, but that sometimes machines are
20 used for breasts that are outside that range.

21 In that sentence 25 and 26, it says, "the unit
22 also be tested at all clinically used thicknesses outside
23 this range and that the action limits specified in the
24 regulations be applied to the extended test."

25 I have a problem with that. I don't think it is

1 feasible, I don't think it's necessary, and I see that this
2 will cause tremendous problems. In my experience, when I
3 look at even the newest machines, they are able to perform
4 very well over the range of 2 to 6, and then for breasts
5 that are very thick, for example, at the 50 percent fatty,
6 50 percent glandular composition, which is the way we test
7 it, then, you have to make some allowances in technique for
8 the fact that this is a very thick breast, just like an exam
9 may be somewhat less optimal for a patient who is very large
10 for lots of reasons, just due to the patient's body habitus.

11 So, I am concerned that if we try to extend that
12 requirement of performance to the 8 centimeter breast, that
13 that would be difficult for many new machines and absolutely
14 impossible for older machines, especially considering that
15 in October of 2002, we considerably tighten the performance
16 requirements for automatic exposure control.

17 So, I have a concern about that. Similarly, in
18 the next paragraph, it talks about the AEC be tested under
19 all conditions of use, and I think there is a reflection
20 there on the technique chart.

21 I want to remind people that technique charts
22 generally specify different technique factors for breasts
23 that are largely fatty, largely dense, and half and half.
24 All the measurements that medical physicists routinely make
25 are made with phantoms that are half and half.

1 So, you actually make those measurements, and then
2 you generalize from your experience for breasts that are
3 fatty or breasts that are dense.

4 The implication in this paragraph to follow is
5 that all parameters need to be tested, and I think that that
6 would be very difficult, and I don't believe it would be
7 really beneficial. So, I have a concern with this whole
8 interpretation. I interpret it differently.

9 DR. MONSEES: I think it is especially important
10 because I probably can't conceive of a practice that does
11 not make exposures for women with breasts thicker than 6
12 centimeters.

13 It is very common to have--I mean probably there
14 is no practice that I can think of that would not have a
15 woman that would have an 8 centimeter breast somewhat in
16 that practice, and to confuse it even further, some of the
17 newer machines have different target and filter combinations
18 which may come into play with their automated exposures.
19 Basically, it makes a selection of the filter and target,
20 that will handle some of those thicker breasts, to handle
21 that kind of situation.

22 So I do not know how you would test for that and
23 control for that, and I would have to look to your judgment
24 on whether we should restrict it to the 2-to-6-centimeter
25 range or go beyond, but I see that it is problematic because

1 almost every facility is going to have thicker breasts.

2 Yes.

3 DR. SICKLES: As our population ages and as we
4 image older and older women, as we see this happening in our
5 practice, you also have it at the other end of the spectrum
6 with very thin breasts.

7 DR. MONSEES: Right.

8 DR. SICKLES: Older women tend to have the
9 half-centimeter breast which is really difficult to image,
10 difficult to position as well. It is also very hard to
11 establish a technique for that. You want the thing to give
12 you the 16 kvp, which, of course, it will not.

13 I think to strongly suggest--I forgot what the
14 language is--strongly recommend that testing go to the
15 entire range, you are going to be half-centimeter up to 10
16 centimeters. As you have heard, it is very hard to
17 establish good limits. I would stick with the 2-to-6.

18 DR. MONSEES: Yes.

19 MR. PIZZUTIELLO: Bob Pizzutiello.

20 There was a paper, I believe, at RSNA which
21 supports what we have done in our practice for a long time.
22 We test over the range of 2 to 8 centimeters, 2, 4, 6, and
23 8, and I think this is also recommended in the manual.
24 Maybe Penny can clarify that.

25 You apply the strict criteria to 2 to 6

1 centimeters, and then you apply a little judgment to looking
2 at what you can do with 8 centimeters. So that is, I think,
3 a reasonable approach. I am concerned that this
4 interpretation says you need to apply the strict criteria
5 out to the 8-centimeter breast, and potentially, if you
6 interpret it to the fatty and to the dense breast, I think
7 that is not reasonable and perhaps not helpful.

8 DR. MONSEES: Would you like to make a comment?

9 MS. BUTLER: In support of what was being said up
10 here, this guidance is actually in conflict with the
11 guidance in the QC manual regarding the outer limits there.

12 The QC manual ACR recommended action limit is to
13 say within plus or minus .3, as Bob pointed out was the
14 current limit, and this would apply to even when the new
15 limits kick in 2002. This also allows for the use of
16 density control adjustments for the extreme breast
17 thicknesses.

18 So I would recommend that. This is a practical
19 performance level, and FDA should have their guidance be
20 consistent with this.

21 DR. MONSEES: Thank you.

22 Any other comments about this?

23 [No response.]

24 DR. MONSEES: The next is at the bottom of page 6,
25 the last question, the Bucky assembly is being replaced on

1 our X-ray unit. Then, again, it alludes to major repair,
2 that it is not a major repair. You may want to reference
3 the table, whatever you have of major repairs.

4 Does anybody have any comments on the answer to
5 that one?

6 MR. PIZZUTIELLO: Barbara?

7 DR. MONSEES: Yes, please.

8 MR. PIZZUTIELLO: Bob Pizzutiello.

9 I do not know, Charlie, if this is a question of
10 what is in the regulation or not.

11 In my opinion, replacing a Bucky is rather
12 infrequent and pretty major because there are a lot of
13 things that can change when you replace the Bucky. So I do
14 not see that there is a great logic in excluding that from
15 having a medical physicist look at it because, when a new
16 Bucky comes in, there is a potential for things to go wrong.

17 I would prefer to see that included because it is
18 very rare.

19 DR. MONSEES: Any other comments on that?

20 [No response.]

21 DR. MONSEES: You can see when we get to that
22 table, we are going to have some editing to do here.

23 The next page, which is page 7, at the top, "We
24 are a mobile facility with a van that does not have on-board
25 processing," and there is a question.

1 The short answer there regarding the darkroom fog,
2 any questions or comments on that one from the panel?

3 [No response.]

4 DR. MONSEES: The last question on this page
5 regarding the ARRT(M) certificate, questions or comments on
6 that one?

7 [No response.]

8 DR. MONSEES: All right. Let's turn to the table
9 on the next page.

10 MR. PIZZUTIELLO: Excuse me. Dr. Monsees?

11 DR. MONSEES: Yes.

12 MR. PIZZUTIELLO: Just one comment on that
13 ARRT(M). Perhaps it might be useful somewhere in that
14 phraseology to include the way it is actually described. I
15 believe it is an advanced competency or something in
16 mammography. It is commonly called the ARRT(M) certificate,
17 but it might be good if we put in the actual wording so
18 that, if somebody is not familiar with this phrase, they
19 know exactly what it is.

20 DR. MONSEES: That is good. Why not? He is going
21 to win his million dollars yet.

22 DR. FINDER: Right.

23 Is that your final answer?

24 [Laughter.]

25 DR. FINDER: We certainly can, but, again, you

1 have to keep in mind that this phrase, this term, has been
2 used throughout the guidance already that has already been
3 issued, and we have used it hundreds of times already. So
4 we would have to describe it someplace, and we have not had
5 any problems yet.

6 DR. MONSEES: Let's see if we can go through this
7 first table on page 8, and then, because of people checking
8 out, we may need to break between this and the next page and
9 then continue that after lunch, but let's start with this
10 first table, "Required QC Tests for Facilities Using
11 Multiple Units & Screen-Film Combinations."

12 There is no lines on these. So, if you have any
13 comments on this, could you tell me which item you are
14 referencing?

15 Yes.

16 MR. PIZZUTIELLO: I would just have to say that I
17 was a little bit confused with the wording after "Phantom
18 Image" under "Units Tested."

19 DR. MONSEES: Thank you.

20 MR. PIZZUTIELLO: I read it about six times--

21 DR. MONSEES: It is very vague. Thank you.

22 MR. PIZZUTIELLO: --and I am still not really sure
23 what it means.

24 DR. MONSEES: Particularly the second one, "All
25 units that are used only for non-standard breasts...or

1 magnification work," I did not quite get that line.

2 Maybe you could comment on that, Dr. Finder.

3 DR. FINDER: Right. I can try and comment on
4 this, and I will certainly accept help from the audience in
5 terms of some of the physicists who are here from the
6 Division.

7 Basically, what we were trying to do here was
8 separate out the possibility of units that do not image the
9 standard breast because the requirement in the regulation
10 talks about that the phantom image is tested under those
11 conditions used for the typical standard breast, and we do
12 have at least--I am not sure if it was theoretical or
13 actual--units that are never used to image the standard
14 breast. They are only done for special diagnostic work, and
15 they do not "do the standard breast." So what are they
16 going to test? How often are they going to test? We did
17 not want to allow those units to go without any weekly
18 phantom testing. So that is what that is attempting to
19 answer, and if it is still unclear as to what I am talking
20 about, then I will gladly take help from the people from the
21 Division if anybody wants to talk about this further.

22 DR. MONSEES: When you say "using clinical
23 techniques that would be used for the standard breast,"
24 regarding the ones that are used only for non-standard
25 breasts--

1 DR. FINDER: Right.

2 DR. MONSEES: --you are saying using the
3 standard-view clinical techniques that would be used, not
4 the techniques that would be used in the non-standard way,
5 like magnification views. Is that what it meant?

6 DR. FINDER: Right. What we are saying is, for
7 example, let's say the unit is only used for magnification
8 work. What they would then have to do is come up with a
9 standard technique that they would have used for the cc of a
10 standard breast and shoot the phantom at those techniques.
11 Even though they clinically do not use it that way, they do
12 not use the unit that way, they would have to come up with
13 the techniques that they would have used for that type of
14 situation. Otherwise, we have a problem of what kind of
15 phantom test are they going to do or are they going to do a
16 phantom test. We did not want to allow them not to be doing
17 some type of phantom test on those units.

18 MR. PIZZUTIELLO: If you have a machine that is
19 not used to image a standard breast, I am not sure how a
20 machine like that could be accredited because if a machine,
21 for example, were used only for magnification work, how
22 could you submit images for accreditation? You could not.

23 DR. MONSEES: You could not.

24 MR. PIZZUTIELLO: It could not be accredited.

25 Therefore, it could not be--

1 DR. FINDER: Right. The question is what do we
2 mean by use for the standard breast. If it is used once
3 every 3 years for a standard breast or just to become
4 accredited, that is what we are trying to basically get at.
5 You would use those techniques, but these are the questions
6 that come into us. We have had the question: "We do not
7 use this unit for standard breast. We only use it for
8 magnification. What do we do? What type of test?" That is
9 what this was supposed to address.

10 DR. MONSEES: Can I say something about this?
11 Then I will let Dr. Sickles.

12 Are we sure we are not confusing this with
13 facilities saying they only do diagnostic work on that unit
14 and not screening patients? Because when you have to submit
15 your images, you have to submit normal images to the ACR,
16 for example, or to the accrediting body. Therefore, they
17 have a hard time, maybe, finding patients that have benign
18 breast changes because they are all abnormal. Maybe that is
19 what they are asking rather than that they only do mag views
20 and no non-mag views, but I do not know what the questions
21 were specifically.

22 Dr. Sickles wanted to make a comment.

23 DR. SICKLES: I am not sure what the people who
24 are writing in are asking, but I am aware of the occasional
25 facility which sets apart a particular unit for

1 magnification work or for the spot compression-type views.

2 They are not just talking about diagnostic
3 mammography. They are talking about the real problem cases
4 where they have a special unit set aside and maybe even a
5 special technologists who is comfortable with all of these
6 additional views to do the fancy stuff.

7 If they do that, I think it would be less
8 confusing in this chart if, as a footnote, you more
9 specifically indicated what you meant here, which is the
10 equipment that is designed for a small subset of diagnostic
11 mammography patients that required special views, and then
12 you simply indicate that what needs to be done is that the
13 testing that needs to be done needs to be done in the same
14 type of situations, what they have to go through when they
15 get accredited. That should cover it because they have to
16 go through the same thing when they get those units
17 accredited.

18 DR. MONSEES: Right.

19 DR. SICKLES: They have to use it on a standard
20 breast or they are not going to get it accredited.

21 DR. MONSEES: Yes.

22 MR. PIZZUTIELLO: I just thought of one occasion
23 which I have heard from a few folks where they have mobile
24 units that, for example, only do nursing home patients, and
25 they say that all their patients are fatty, that we never

1 have dense breasts and we do not have the 50/50 mix.

2 That might be a case where since you defined the
3 standard breast as 50-percent fatty and 50-percent
4 glandular, that patient population would not fit. So, if I
5 use that as an example in my mind, then I think this sort of
6 makes sense. It is just that the words are a little bit
7 tricky.

8 If you have a population which there is not
9 normally people in that category, you would use the
10 techniques that you would use if you were to image a patient
11 in that category.

12 DR. FINDER: Right. That is what we were trying
13 to get across. Now, whether we accomplished it in the
14 manner that is totally clear, we certainly can take a look
15 at the wording. If you have suggestions about what wording
16 you would like to put in, we would be happy to take a look
17 at them.

18 DR. MONSEES: I would just like to make note that
19 we have a panel member who has just joined us.

20 Ms. McCarthy, thank you very much for making your
21 way here. You probably have stories to tell afterwards
22 about the weather.

23 MS. MCCARTHY: Sorry for the delay.

24 DR. SICKLES: Again, in the situation that Bob
25 raised, to get passed through the accreditation process, you