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

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE

Monday, November 2, 1998

9:00 a.m.

Gaithersburg Hilton
620 Perry Parkway
Gaithersburg, Maryland

PARTICIPANTS

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

MEMBERS

Patricia Wilson, R.T.
Carolyn Brown-Davis
Edward Sickles, M.D.
Robert Pizzutiello, M.S.
Peter Dempsey, M.D.
Michael Mobley, M.S., M.P.A.
Patricia Hawkins, M.P.H.
Ellen Mendelson, M.D.
Robert Nishikawa

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1 participating in matters that could affect their or their
2 employer's financial interests. However, the Agency has
3 determined that participation of certain members and
4 consultants, the need for whose services outweighs the
5 potential conflict of interest involved, is in the best
6 interest of the government.

7 Full waivers are in effect for 13 out of 15
8 participants because of their financial involvement with
9 facilities that will be subject to FDA 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 Laurel Moore-Farrell, Ms. Patricia Hawkins, Dr. Ellen
17 Mendelson, Mr. Michael Mobley, Mr. Robert Pizzutiello, Dr.
18 Edward Sickles, Ms. Patricia Wilson, Ms. Kendra McCarthy,
19 Dr. Kambiz Dowlatshahi, Dr. Robert Nishikawa, Mr. Roland
20 Fletcher, and Dr. David Winchester.

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 We would like to note for the record that if any
25 discussion of states or certifying bodies was to take place

1 in any meetings of the committee, it would be a general
2 discussion only, no vote would be taken and no consensus
3 sought. In the interest of getting as many viewpoints as
4 possible, all SGEs, including state employees, would be
5 allowed to participate in the general discussion, so that
6 all viewpoints could be heard.

7 Also, several of our members and consultants
8 reported that they received compensation for lectures they
9 have given or will give on mammography related topics,
10 however they have affirmed that these lectures were offered
11 because of their expertise in the subject matter, and not
12 because of their membership on the committee.

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 participants
16 should excuse him or herself from such involvement and their
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 If anybody has any questions?

1 [No response.]

2 DR. MONSEES: We are ahead of schedule. Is there
3 anybody in the audience who objects to beginning the public
4 hearing early? We are going to do Dr. Finder first and then
5 let's go right to that. It will still be early.

6 **Alternative Standards Requests**

7 DR. FINDER: I want to go and talk about approval
8 of alternative standard requests. In the past, the
9 committee has asked that they be updated on any requests for
10 alternative standards to the regulations that we have
11 approved, and since the last meeting, there has been one,
12 and I want to just briefly go over it.

13 As the committee is aware, at the May meeting,
14 General Electric made a presentation at the open public
15 session explaining the problems and associated costs
16 involved in having their equipment meet the collimation
17 requirement of the final regulations. They also discussed
18 the benefits to the film quality of allowing the x-ray field
19 to be collimated to an area within the image receptor.

20 Shortly after the meeting, General Electric
21 submitted a formal request for an alternative standard.
22 They supplied additional information to that already
23 presented at the meeting, some of which is proprietary and
24 therefore must remain confidential.

25 On June 19, 1998, after reviewing the data and

1 conducting experiments of our own, approval of the
2 alternative standard regarding General Electric mammography
3 equipment was granted.

4 The alternative reads as follows: The beam
5 limiting devices of all systems shall allow the x-ray field
6 at the plane of the image receptor to extend to the entire
7 chest wall edge of the receptor, and may, but are not
8 required to, allow the x-ray field to extend beyond any edge
9 of the image receptor. Such extension shall not exceed 2
10 percent of the perpendicular distance from the image
11 receptor plane to the position of the focal spot and the
12 primary x-ray beam shall not extend beyond the edge of the
13 image receptor support except for the chest wall side.

14 Since that time, we have received additional
15 requests for similar alternative standards. These are
16 currently being evaluated, and I can't go into any details
17 about which companies put in those requests.

18 The other thing that I can tell you is as of late
19 last week, a proposed change to the performance standard
20 regarding collimation was published, and there will be a
21 similar publication probably in the next day or two
22 regarding the MQSA regulations regarding collimation to be
23 consistent with this approval.

24 Any questions?

25 [No response.]

1 Science and Technology and have been involved with
2 coordinating the CDRH response to this issue.

3 [Slide.]

4 I am sure by now most people have heard about the
5 doomsday that we face. It has been described lots of
6 different ways. It certainly is a medical device problem
7 for some products, and it is certainly a problem for the
8 health care community as facilities take the actions
9 necessary to prepare to deal with this issue.

10 One term I like, which was coined by a physician
11 in the Department of Veterans Affairs, Health
12 Administration, the "millennium bug syndrome." It is
13 something that apparently affects some medical devices.

14 [Slide.]

15 The problem, of course, is when two digits only
16 were used in representing dates, and the potential for
17 confusion, error, other problems that this introduces, any
18 anytime the computation, comparison, sorting that uses
19 dates. For instance, if the date reads 00 for the year, one
20 is not sure which year is meant. If this is only being used
21 for interpretation by a human observer, i.e., you are just
22 reading a printed date or you are reading a displayed date,
23 it doesn't present too much of a problem in that there
24 weren't too many computer records being generated in 1900
25 with the 00 printed on them.

1 So, that is not such a major problem although it
2 is technically in noncompliance with the definition that we
3 have put forward, but the problem arises when comparisons or
4 calculations are used and the system doesn't know what to do
5 with 00.

6 [Slide.]

7 A couple of years ago this was a comment that was
8 in one of the trade press trying to point out the issue
9 here, and that is that up until just a year or so ago,
10 probably many PCs, even currently on the market, had
11 problems dealing with the date. This is because of the way
12 their real-time clocks or their basic input/output system
13 was designed, and that leads to concerns because there are
14 many medical devices which utilize PCs or microprocessors in
15 their operation, their control, or their monitoring.

16 I have listed here just a couple of examples. It
17 is quite clear that pacemakers themselves will not stop at
18 midnight in the Year 2000 on January 1. They will continue
19 to function just fine. There are, however, some older
20 models of pacemaker controllers that the physicians use to
21 monitor and interrogate pacemakers that will need some
22 software upgrade or changeover.

23 The same kind of problem may exist in other types
24 of products where PCs are used, such as in a clinical
25 central monitoring station perhaps, where information from a

1 lot of different monitoring devices are consolidated and
2 displayed and recorded perhaps.

3 The same thing with clinical laboratory
4 instruments that are providing information to a central
5 database collection facility or even the individual lab
6 instruments may be operated and controlled by PCs.

7 [Slide.]

8 A couple other quotes that we are trying to point
9 out the magnitude of this problem. I think people have
10 realized this and are working on it, but in 1996, people
11 were saying, you know, this is the biggest job we have ever
12 faced and the deadline won't give, there is no flexibility
13 here it is coming and we have to deal with it.

14 The comment about health care systems was focusing
15 primarily on the hospital records and information systems as
16 opposed to the medical devices, but the idea there was that
17 there were still many software applications that needed to
18 be upgraded, many lines of code needed to be examined and
19 tested before people could be sure that the systems are
20 going to function properly.

21 [Slide.]

22 There are a number of different medical devices
23 that can have problems - microprocessors, as I mentioned, or
24 PC controlled products. There are medical devices that are
25 just strictly software applications. The best example

1 probably is a radiation treatment planning system used to do
2 treatment planning for brachytherapy or teletherapy, and if
3 that system only used two digits to represent the year, the
4 calculation of source strength could be in error.

5 There are, in fact, software applications that had
6 that problem and are having to be upgraded by their
7 manufacturers. Any kind of device interface, the databases
8 or recordkeeping systems are a potential source of problem,
9 and there are many kinds of products that have some kind of
10 embedded chip, real-time clock for either date display, date
11 printing on records, many of these, the actual date has
12 nothing to do with the actual function of the device, but it
13 does have something to do with the recording of what the
14 device has done, and the seriousness of these kinds of
15 problems is variable, so one has to do a careful analysis of
16 each product to see what the impact is going to be.

17 [Slide.]

18 I just put this up to let you know that we have
19 come up with a definition of what we mean for a product to
20 be compliant. This is based on the federal acquisition
21 regulation requirements for products that the Federal
22 Government purchases. It is slightly modified. I am not
23 going to go through and read it all. It is in the handout.
24 I will mention that the committee received two handouts,
25 one, a copy of these slides, and another, a copy of a letter

1 that we are giving to all the advisory panels, which
2 contains as an attachment, a brief summary of all the
3 activities that we have been involved with, with regard to
4 the Year 2000 problem, so you can take a look at that later
5 if you would like.

6 [Slide.]

7 Our requests for the panel, as I mentioned, is to
8 give you an update on what is happening with regard to this
9 problem, to give you a chance to provide us advice on
10 problematic devices or products from your domain of
11 experience, particularly, I think the areas that this
12 committee might be concerned about are definitely the
13 mammography x-ray systems, if they are microprocessor
14 controlled, such things as the patient identification
15 apparatus associated with these for putting on the
16 demographic information, perhaps the software that is used
17 to track and monitor patients to do the quality assurance
18 activities within a facility. There are any number of kinds
19 of areas where dates are used and could be a potential
20 problem.

21 For the device panels, we have also been asking
22 them to identify any particular devices that they would have
23 a concern about, the way the device operates and how the
24 date might be a critical aspect of that product's operation.

25 We are open to suggestions to other actions that

1 we at CDRH and FDA need to be taking. One of the things we
2 have done primarily is to try to get the word out is set up
3 a World Wide Web site where information from manufacturers
4 on the status of their products is presented to the public.

5 [Slide.]

6 This is the web address for the FDA home page.

7 When you get to that site, you can select the Year 2000
8 item.

9 [Slide.]

10 This is just a brief shot of what the first page
11 looks like that comes up there. The second item there is a
12 place one can click on and then be able to search this
13 database based on manufacturer's name and find out what that
14 manufacturer has reported about their product.

15 We currently have over 3,000 manufacturers of
16 medical devices represented in this database and are
17 continuing to update it as manufacturers provide us
18 information. There is also a lot of information here on the
19 letters we sent to manufacturers, our guidance document that
20 we put out in June for manufacturers that describe our
21 expectations of what their responsibilities are to deal with
22 this problem, and other information from congressional
23 testimony and other sources of information on the Year 2000
24 problem.

25 [Slide.]

1 We have done, in a brief nutshell, these kinds of
2 things. We have sent letters to manufacturers, we have
3 provided guidance to manufacturers. We have established
4 this database where product information can be obtained.

5 We continue to monitor the situation, reports of
6 products with problems, actively involved with several
7 groups including manufacturers, professional associations to
8 look at ways to make sure the right people are aware of the
9 actions they need to be taking, and we will be looking at
10 some additional educational activities to make clinicians
11 and the public more aware of this issue with respect to
12 particular problems or issues that need attention. So, we
13 expect to continue to do some of those kinds of things as we
14 get closer to the Year 2000.

15 [Slide.]

16 As a closing comment, I would welcome any comments
17 or suggestions the members of the panel may have or even
18 members of the public. My contact information is here.
19 You could also, as well, contact Dr. Finder, the Executive
20 Secretary, and I am sure he would be glad to pass on any
21 ideas, comments, or suggestions you might have for us.

22 I would be glad to answer any questions if the
23 panel has any on this issue, but it was just meant to give
24 you a brief indication of what our activities in this area
25 have been.

1 Thank you.

2 DR. MONSEES: Thank you.

3 Do any of the panel members have a question?

4 MR. MOBLEY: Tom, are there any products out there
5 that you know about that are fatally flawed, such that they
6 can't be fixed or jury-rigged or whatever?

7 MR. SHOPE: I think there are products that the
8 manufacturers have said we don't think it is economic to
9 repair these, they are old, we think you would do a much
10 better job at buying something new and modern with all the
11 new bells and whistles on it, so there are a lot of products
12 that manufacturers have indicated they don't plan to fix.

13 The problems with these usually are in the date
14 display or date printing regime rather than a functionality
15 problem. There are some products that because they are used
16 by a PC, if that PC is not taken care of, and the PC doesn't
17 work, the product doesn't work and you lose the
18 functionality totally of the product, so there are a few of
19 those kinds of issues.

20 One of the concerns is some of the older medical
21 imaging systems as an example where they have a feature
22 where they sort past images and present to the physician to
23 do the interpretation, images in the chronological order in
24 which they were taken. If that sorting mechanism goes
25 astray, you won't get the Year 2000 images first, and, if

1 fact, there are systems with those kind of problems, so
2 either software upgrades are going to have to be done to fix
3 that sorting problem, or some other mechanism in place for
4 the facility to realize and deal with that, but there are
5 those kinds of issues.

6 They are not major catastrophic for health kinds
7 of things where pacemakers are going to fail or
8 defibrillators won't work that we are aware of, we aren't
9 aware of those kinds of problems, but there are the
10 potential there. We haven't done the complete inventory
11 from every manufacturer. We have right now almost 500
12 products listed on the web site as definitely having
13 problems of some sort. Most of them are very minor. That
14 doesn't include 170 or so manufacturers that have put the
15 information up on their web site and we just have a link to
16 that web site, where there they may have again a large
17 number of products with these minor problems described, but
18 I think all the problems are of a nature that the hospital
19 needs to know about it and needs to know what action they
20 need to take to deal with that problem, so they aren't
21 surprised January 1.

22 MR. MOBLEY: I guess fatally flawed, my question
23 was fatally flawed, and that would be one that is not going
24 to work or can't be jury-rigged or whatever.

25 MR. SHOPE: And there are some of those.

1 MR. MOBLEY: Is there a potential, then, that FDA
2 would do a recall or something to this effect regarding
3 those?

4 MR. SHOPE: Well, we, in our guidance document,
5 talked about what our authorities and responsibilities are,
6 and we certainly for any product that rises to the threshold
7 of a potential significant risk to public health, which is
8 roughly the criteria in the Act for a recall, and if the
9 manufacturer is not taking care of that problem voluntarily,
10 we will certainly follow up with those.

11 One of the problems here is this is a problem that
12 doesn't happen until after some date, so we can't take
13 action before that. It is an unusual problem for us from a
14 compliance enforcement sense. We have said in our guidance
15 document to manufacturers that we encourage you to fix these
16 problems, to find the solution and make it available, if you
17 find a solution that only involves fixing a date problem, we
18 don't consider that a modification that triggers a new
19 premarket submission, just fix the date problem. If you add
20 some functionality, if you change something that affects
21 safety or effectiveness of the product, then, you need to
22 submit a report to us, but if it is just fixing the date
23 problem to make the thing work the way it was intended to
24 work except it won't do that after the Year 2000, the
25 manufacturers don't have to submit information to us on

1 that.

2 As well, we have said any of those fixes they do
3 prior to the Year 2000, we aren't going to call them
4 recalls. We want to have an incentive for the manufacturers
5 to deal with these problems, however, we do have a new reg
6 called the regulation on corrections and removals, which
7 requires a manufacturer to report to us any action they take
8 to either correct or remove a product which that correction
9 is done to address a risk to public health or a failure to
10 comply with the regulation or the law.

11 So, there are some of these more serious kinds of
12 problems that the manufacturers will be required to report
13 to us under the correction and removals, but we are not
14 going to call those recalls until they are, in fact, the
15 problem exists. The preventive action, we aren't going to
16 cast in a bad light and put the manufacturer on the recall
17 list basically for doing what they need to do.

18 DR. MONSEES: Thank you. If there are no other
19 questions from the panel, we will move on to the next
20 speaker. Thank you very much.

21 Our next speaker is Mark Guenin -- I am not sure
22 if I am pronouncing that right, excuse me -- M.D.

23 Dr. Guenin, you have 10 minutes, please.

24 DR. GUENIN: Oh, boy.

25 DR. MONSEES: Will you identify yourself.

1 DR. GUENIN: I will have to move quickly then, and
2 I will try to. My name is Mark Guenin, and I am a
3 diagnostic radiologist, board certified, from Pennsylvania.
4 I have no conflict of interest that I know about other than
5 performing stereotactic biopsies, which is the subject of my
6 address today.

7 I am the medical director of a fairly busy women's
8 imaging center where we perform approximately 25,000
9 diagnostic mammograms each year. I am the primary reader on
10 roughly 10 percent of those, namely, 2,500 mammograms.
11 Naturally, I am MQSA qualified.

12 I have been performing minimally invasive breast
13 biopsy for the past four and a half years. I have performed
14 approximately 1,100 such procedures, roughly two-thirds
15 under stereotactic guidance and one-third under ultrasound
16 guidance.

17 I would like to raise an issue that you folks
18 probably wish would just disappear, namely, that of
19 physician qualifications for stereotactic biopsy. This is a
20 very contentious issue, and I am going to wade right in
21 here.

22 [Slide.]

23 It is my firm belief that a physician performing
24 stereotactic biopsy should be MQSA qualified, that the
25 physician requirements for stereotactic biopsy be a superset

1 of MQSA qualifications. We are all aware, of course, of the
2 joint agreement between the American College of Radiology
3 and surgeons regarding such requirements. Initially, the
4 ACR developed a very nice voluntary accreditation program
5 modeled on their praiseworthy mammography effort.

6 After many meeting with the American College of
7 Surgeons, it turns out that the already less stringent
8 requirements for a nonradiologist were further watered down.
9 I am not going to go over this entirely too busy slide, but
10 I have listed the areas where the qualifications for
11 radiologists and nonradiologists differ. You will notice
12 that in every instance, the qualifications demanded of a
13 radiologist are significantly more stringent than those
14 imposed upon nonradiologists. This makes no sense.

15 I would like to remind the FDA that they are under
16 no obligation to honor this agreement. I believe that this
17 agreement was politically motivated, does not serve the best
18 interests of the patient, and should be ignored.

19 I have no direct incentive to be here today. I am
20 performing as many stereotactic biopsies as I would care to.
21 I have many incentives not to be here today. First and
22 foremost, I count as personal friends several surgeons who
23 do stereotactic biopsies, and they might find my comments
24 here this morning offensive. I am going to have to live
25 with that.

1 Second, like many radiologists in private
2 practice, I am dependent, not only on providing excellent
3 care for my patients, but also in maintaining relationships
4 with my referring physicians, some of whom are these very
5 surgeons.

6 Like most radiologists, I am not particularly
7 inclined to rock the boat, but this is an issue that I feel
8 quite strongly about and I cannot be silent about it. There
9 are many of my friends in radiology practices across the
10 country who would like to make similar comments, but
11 political considerations prevent them from doing so.

12 We seem to have forgotten that stereotactic biopsy
13 is, first and foremost, an imaging guided procedure. You
14 ask anybody who does stereotactic biopsy, they will tell you
15 that the trivial part of the job is pushing the button. The
16 real work comes in accurate targeting, choosing the right
17 lesion, verifying that it has gone away, which sometimes it
18 does on the stereo table, and choosing the safest approach
19 to the lesion based on the diagnostic mammogram.

20 Such skills are exercised in everyday practice in
21 performing diagnostic problem-solving mammography.
22 Reviewing previously read mammograms is a poor substitute
23 for that experience. Those previously read mammograms
24 arrive at the surgeon's office, nicely marked with red wax
25 pencil marks indicating the area of interest.

1 Reviewing these films is an inherently passive
2 activity. It goes without saying that the digital images
3 that appear on your monitor during the scout phase of a
4 stereotactic biopsy are not nicely marked with red wax
5 pencil marks saying biopsy here.

6 There are many instances when, in the course of
7 doing a difficult stereotactic biopsy I have found myself
8 drawing on every bit of experience I have accumulated being
9 the primary reader on approximately 20,000 mammograms in my
10 professional lifetime.

11 Sure, there are very easy stereotactic biopsies,
12 just as there are easy appendectomies, but you can't go into
13 a procedure banking that it is going to be a straightforward
14 procedure. Anybody doing a medical procedure had better be
15 able to handle the difficult, as well as the
16 straightforward.

17 [Slide.]

18 As an example, this is a young, 41-year-old woman,
19 asymptomatic. She came in for her routine mammogram. Her
20 finding, a very subtle one, is limited to an area of
21 architectural distortion in the upper outer quadrant of the
22 left breast.

23 [Slide.]

24 Confirmed with spot impression magnification
25 filming doesn't appear well on a slide, very difficult to

1 see, not present on the CC view, not present on the true
2 lateral view. This was a subtle finding. Stereotactic
3 biopsy was the only way to get a tissue diagnosis which was
4 necessary in this case.

5 [Slide.]

6 I performed a stereotactic biopsy. I will tell
7 you it was subtle on the screen-film mammogram, it was even
8 more subtle on the digital scout image. There is no
9 question in my mind that a non-MQSA person would have failed
10 to do this stereotactic biopsy.

11 [Slide.]

12 The stereotactic biopsy was accomplished, and it
13 revealed a low-grade DCIS.

14 There are tricks involved in problem-solving
15 diagnostic mammography that get learned and reinforced in
16 everyday practice. Such tricks include tangential views,
17 rolled views, magnification, ultrasound, you name it. These
18 tricks cannot become second nature, which they need to, by
19 taking a weekend course.

20 In the course of performing problem-solving
21 mammography, I will often request that a technologist return
22 to get a spot impression film. When she comes back to the
23 reading room armed with that film showing no abnormality, I
24 have got a decision to make. Either that tech missed the
25 area and she has got to go in and find it again or the

1 lesion truly disappeared, indicating that it was a benign
2 summation shadow. That is a pretty critical distinction.
3 That is something that we do every day in diagnostic problem
4 solving mammography. That is a skill that you need to have
5 doing a stereotactic biopsy because that occasionally
6 happens. No amount of passive review of already read films
7 will give you that experience.

8 Now, I have a great deal of respect for the
9 arduous training and daily workload of a busy surgeon. They
10 need to master a large number of skills including operative
11 technique, hemostasis, wound healing, nutrition, medical
12 care of the surgical patient. Unfortunately, none of those
13 skills has any bearing whatsoever on image-guided breast
14 biopsy.

15 In addition to experience in being the primary
16 reader on a problem-solving mammogram, experience with other
17 imaging guided interventional techniques is very useful in
18 the more intangible sense. Being familiar with handling a
19 needle and correcting trajectories based on images is
20 invaluable in difficult cases.

21 Direct experience with radiology-pathology
22 correlation is invaluable. That is something that
23 radiologists do on an everyday basis in their practice, in
24 addition, during training, the Armed Forces Institute of
25 Pathology, right down the road here, which is the mecca for

1 rad-path correlation, serves as host to 95 percent of the
2 radiology residents in this country for an intense, six-week
3 course in rad-path correlation. It is an eye-opening
4 experience. I know of no parallels in the surgical world.

5 In addition, the radiology literature is full of
6 articles describing the radiology-pathology correlation of a
7 wide variety of breast lesions. Such articles in the
8 surgical literature are scarce.

9 Furthermore, being interested in the procedure is
10 vitally important. Now, it is impossible to make a blanket
11 statement about the interests of any given individual in a
12 procedure, but it is useful to look at the articles
13 concerning stereotactic biopsy in the radiology and surgical
14 literature as a useful surrogate for measuring the interest
15 of these specialties in this procedure.

16 [Slide.]

17 No other specialty fought the widespread adoption
18 of a minimally invasive breast biopsy as did the general
19 surgery community, and that is reflected in their
20 literature.

21 This is an article which would have been a
22 landmark article had it appeared in 1990 or 1991. It is
23 entitled, "Stereotactic core needle biopsy of nonpalpable
24 breast lesions, initial experience with a promising
25 technique." There is a problem.. This was from the Archives

1 of Surgery in April of 1998. This isn't news. This is the
2 type of article that appears all too frequently. But should
3 the FDA reward radiology simply for having pioneered the
4 procedure and push for its early widespread adoption? Of
5 course not. The procedure ought to be performed by those
6 most qualified to do that, and in my opinion, most qualified
7 is best reflected, the best surrogate measurement of most
8 qualified is MQSA qualifications.

9 [Slide.]

10 Well, what can go wrong when a non-MQSA person
11 performs a biopsy? Let's take a look at a couple of
12 examples. This is a mammogram, a CCV I have just abstracted
13 here. Obviously, a calcified fibroadenoma of no consequence
14 whatsoever. You will have to take my word that circled in
15 wax is a group of cluster calcifications, pleomorphic. Spot
16 compression magnification films were performed. This was
17 deemed worthy of biopsy.

18 This patient was sent to a surgeon who does
19 stereotactic biopsy. That surgeon performed a stereotactic
20 biopsy, was evidently satisfied with the course of that
21 biopsy and the pathology results that came out of it,
22 because she returned at the usual six-month follow-up
23 interval after her stereotactic biopsy, and again you will
24 have to take my word that these calcifications are still
25 sitting here, actually circled with wax pencil, and the clip

1 marking the spot where the biopsy was performed is way out
2 in left field here. Mammographically, this is miles away.
3 I have no explanation for how a biopsy could have been
4 performed, deemed satisfactory, and that large a miss.

5 [Slide.]

6 Sometimes surgeons are unable or unwilling to
7 perform radiology-pathology correlation. This is an example
8 of a 68-year-old woman who underwent a right mastectomy.
9 Nine years later she was asymptomatic coming in for her
10 routine mammograms.

11 [Slide.]

12 One of my partners -- this really doesn't project
13 -- but there is an irregular nodule in the medial aspect of
14 that breast. Spot compression filming confirmed it, not
15 present on the oblique or true lateral views, they are not
16 localizable in three dimensions, although he suspected it
17 was in the upper inner quadrant.

18 [Slide.]

19 Did an ultrasound, which shows up not at all here
20 on the screen, but came across a vague area of decrease of
21 sound absorption in the upper inner quadrant. He felt two
22 things. He felt that this was a more mammographically
23 striking problem, and he stated in his report that this was
24 nonpalpable. He recommended a stereotactic biopsy.

25 Instead, the patient was sent to a surgeon who, on

1 physical exam, felt he could feel something here, and he
2 went about cutting out something out of her upper inner
3 quadrant, and this was the resultant pathology report.

4 [Slide.]

5 The pathologist is fairly shouting out here that
6 you got all fat. In the gross description, there is a
7 discrete nodule in the largely fatty tissue,
8 microscopically, a few bands of fibrous tissue traversing
9 the largely fatty tissue, normal fat versus lipoma.

10 Evidently, the surgeon was satisfied with the
11 conduct of this biopsy, felt that he had removed the nodule,
12 so the pathologist wouldn't lie, would he, and the patient
13 didn't return for another mammogram for over a year.

14 [Slide.]

15 The original mammogram is this black area here. I
16 apologize for that. The CC view post-biopsy, the wire
17 marking the scar, and this irregular nodule is still
18 present.

19 [Slide.]

20 Under ultrasound, she now has a 9.5 mm hypoechoic
21 sound absorbing mass. At needle biopsy, this was an
22 infiltrating lobular carcinoma. There is no question in my
23 mind that this lesion was present at the time of the
24 mammogram, and it was a miss.

25 DR. MONSEES: Can you sum up?

1 DR. GUENIN: Boy, that is hard. There is so much
2 I could say here. We have non-MQSA persons doing diagnostic
3 mammography here.

4 [Slide.]

5 This is an example of a letter from a surgeon back
6 to the referring doctor describing how the lesion
7 disappeared, and in his opinion, then, that proved that this
8 was benign fibrous tissue.

9 We have non-MQSA persons performing diagnostic
10 mammography whether the FDA likes it or not.

11 I do want to take issue with a statement that was
12 made during last fall's hearing. At that hearing, there was
13 testimony by a Dr. Kravitz, who said it should be public
14 policy to steer women to have stereotactic biopsies
15 performed as opposed to an open procedure. Great. I
16 couldn't agree more. He then goes on to say, "Logically" --
17 and that is his word -- "Logically, a surgeon who is not
18 allowed to perform stereotactic biopsies will be more likely
19 to recommend that a patient get a wire localization biopsy,"
20 in other words, an open surgical procedure, which by the
21 way, pays much better than the stereotactic procedure.

22 Well, he may call that logical, but I call that
23 obscene. Think of the implications of that statement.
24 Loosely translated, that is saying when the patient's best
25 interests and my own self-interest differ, I will follow my

1 own self-interests.

2 Nobody on this committee took him to task for
3 saying that, and none of the surgeons who testified later
4 made any effort to distance themselves from that outlook.

5 If I stood here before you and told you that that
6 attitude was out there in the surgical community, you could
7 be forgiven for not believing me, but those are words from
8 the mouth of a surgeon himself, and there was no effort made
9 to chastise him.

10 In the final analysis, stereotactic biopsy is
11 problem-solving mammography armed with a needle. The same
12 skills that are necessary to perform diagnostic problem-
13 solving mammography are those required to perform high
14 quality stereotactic biopsy, and MQSA qualification should
15 be the basis of a foundation for stereotactic
16 qualifications.

17 Thank you.

18 DR. MONSEES: Do we have any comments from the
19 panel members? Dr. Finder, will you make a comment, please.

20 DR. FINDER: I just want to make mention that the
21 issue of interventional mammography is not on the agenda,
22 not up for discussion at this meeting. It has been
23 discussed at other meetings, and it will be discussed in the
24 future.

25 The other thing I just wanted to make mention of

1 is that our two surgical representatives are not here today
2 to comment.

3 The last thing I want to mention is that tomorrow
4 morning we will have an update on the voluntary stereotactic
5 accreditation programs.

6 DR. MONSEES: Thank you. Another comment?

7 MR. MOBLEY: Dr. Finder, that is where we stand
8 right now relative to the proposals of requirements is that
9 it has been left up for a period of time for the different
10 colleges to come up with a voluntary program.

11 DR. FINDER: That is correct.

12 DR. MONSEES: Thank you very much, sir.

13 Our next speaker is Eleanor Sherman. Is Ms.
14 Sherman here? Thank you.

15 You have 10 minutes, Ms. Sherman. Would you
16 identify yourself and who you represent, please.

17 MS. SHERMAN: My name is Eleanor Sherman. I am
18 the President of Technowipe, lint-free wipes. I am a
19 licensed x-ray technologist with many years of mammography
20 experience, and I also have a patent on a mammography
21 disposable shield, and have 510(k) clearance, as well, on
22 that device. It is not made and it is not in the
23 marketplace.

24 [Slide.]

25 I am here to discuss the compliance guidance on

1 the Mammography Quality Standards Act final regulations, and
2 I wanted to discuss the problems associated with 21 CFR
3 900.12(d)(2), which holds the QC technologists responsible
4 for procedures for safety and protection of patients and
5 personnel, and discuss 21 CFR 900.12(e)(13), requiring the
6 quality control technologist to comply with manufacturers'
7 recommended procedures for cleaning mammography equipment
8 and if adequate manufacturers' recommendations are not
9 available, to comply with generally accepted guidance on
10 infection control.

11 I would like to present what three technologists
12 had mailed to me from the manuals of three different
13 manufacturers, and what the current manufacturers are
14 providing the technologists.

15 Dr. Elizabeth Jacobson in the past has said that
16 contaminated mammography equipment does pose a threat for
17 cross-contamination of the AIDS and hepatitis virus and
18 bloodborne pathogens, and that she was holding both the
19 manufacturers and the end user responsible for correcting
20 this. This was a long time ago, this was a couple years
21 ago, and this statement continues to be in MQSA, but I would
22 like, as a technologist, to discuss the problems associated
23 with the responsibilities that they will have.

24 Manufacturer 1 says, "Disconnect the equipment
25 from the circuit breaker prior to cleaning, and do not allow

1 water or liquids to enter equipment as they may cause short
2 circuits and corrosion."

3 I believe this is excellent advice because there
4 are electrical hazards, as well as corrosion potential if
5 liquids enter the equipment. My recommendation for the
6 technologist was to ask for additional instructions how not
7 to let the liquids enter the equipment. What method does
8 the manufacturer want us to use to assure that it is not wet
9 and that it is safe for the technologist to resume using it?

10 The other problem that, as a technologist, I
11 foresee, is this is very time-consuming, that the circuit
12 breaker is not usually right next to the equipment, and I
13 believe that there is electrical potential for hazards.

14 [Slide.]

15 Manufacturer 1 continues, saying, "Painted plastic
16 parts and aluminum surfaces should be wiped with a dry
17 woolen cloth," and warns against use of abrasive detergents
18 or polishes, and continues to say how you are supposed to
19 wipe it with a woolen cloth only. I am not sure where you
20 get the woolen cloth.

21 Again, my comments, what kind of plastic are they
22 discussing, because the difference between polyethylene and
23 polycarbonate is dramatic, you cannot look at the plastic
24 and determine what chemical to use on it. For instance,
25 polycarbonate with repeated use of alcohol will crack and

1 break your equipment, however, polyethylene will cause
2 another problem and that will distort your image under
3 radiation. You cannot tell by looking at a plastic part
4 what to clean it with, and I think that is why the
5 manufacturer should be held responsible.

6 I also believe they have an obligation to the FDA
7 for the safety and compliance for providing cleaning
8 instructions, as well as disinfecting instructions using
9 tested cleaners.

10 The manufacturer then cautions the technologists
11 that they apply a small sample of cleaner to out of view
12 location on the compression paddles to check for
13 compatibility prior to applying on entire surface.

14 This appears that Manufacturer 1 had not tested
15 the chemical, and has not told the technologist what
16 chemical to use.

17 [Slide.]

18 Manufacturer 1 continues and goes on to say rinse
19 well with clear water, dry thoroughly with a chamois or
20 moist cellulose sponge to prevent water spots. Then, they
21 go on to say a warm final wash should be made using a mild
22 soap or detergent solution and ending with a thorough
23 rinsing with clean water.

24 Anyone who knows the construction of a bucky
25 understands that you cannot rinse a bucky, nor could you

1 bathe it with anything, so although they talk about the
2 hazards of chemicals getting into the housing, their
3 instructions clearly tell you to rinse with water twice,
4 which would ruin the equipment since there are all sorts of
5 wires in the bucky.

6 [Slide.]

7 This manufacturer then goes on to talk about
8 different kinds of chemicals to use on the paddles and face
9 shields. No warnings or special instructions are given
10 using these chemicals. I believe that the manufacturer of
11 the mammography equipment, if they are telling technologists
12 to use a specific chemical, should include Material Safety
13 Data Sheets, that the technologist should file these sheets
14 with their infection control protocols.

15 For instance, they talk about using Naphtha, which
16 is a cleaning fluid, has very bad odors. Bleach has
17 inhalation warnings associated with it, the technologist
18 using it may have asthma, which may trigger a asthma attack.

19 They mentioned M Spray 2000, which requires 10
20 minute wet contact and is corrosive. It requires the use of
21 goggles, face shield, and rubber gloves when using it.

22 [Slide.]

23 Manufacturer 1 continued, "Fine hairline scratches
24 and minor abrasions can be removed or minimized by using
25 mild automobile polish."

1 They then go on to recommend three automobile
2 polishes, Johnson & Johnson paste wax, Novus Plastic Polish
3 1 and 2, and Mirror Glaze Plastic. It is suggested that a
4 test be made, again leaving the responsibility to the
5 technologist. This is a very scary thought that an x-ray
6 technologist would use automobile polish on any equipment
7 for patient contact.

8 I am not sure who is developing these
9 instructions, but it does appear that they are a used car
10 dealer because it has nothing to do with infection control.

11 [Slide.]

12 Now we go on to Manufacturer 2. They go on to
13 provide, "Patient contact surfaces should be washed with
14 mild soap in lukewarm water." They do not say what kind of
15 soap should be used, and they do warn, "Removable parts that
16 do not contain electrical components such as the compression
17 paddles may be removed from the equipment and immersed if
18 needed. Equipment parts such as the bucky/cassette holder
19 that enclose electrical components must not be immersed but
20 rather cleaned with a soft dampened cloth," again warning
21 not to get liquids into the equipment.

22 [Slide.]

23 Surfaces, then, they go on to say, should be
24 scrubbed with a soft bristle brush, such as a toothbrush,
25 which is necessary to reach corners or remove material that

1 has dried onto the surface. They go on to say, "Subsequent
2 disinfection may not be effective if the surfaces are not
3 thoroughly clean.

4 Manufacturer 2 continues, "Rinse all surfaces with
5 clean water to remove visible residue," again warning not to
6 get any liquid into the internal mechanisms. They go on to
7 say dry surfaces with soft cloth to remove any visible
8 residue.

9 They just said not to immerse the bucky, but now
10 they are saying to rinse all surfaces. This is very
11 confusing.

12 [Slide.]

13 They give low level, intermediate disinfection
14 instructions.

15 DR. MONSEES: Will you sum up, please.

16 [Slide.]

17 MS. SHERMAN: Anyway, they go on then to recommend
18 the use for high level disinfection the following chemical.

19 Next.

20 [Slide.]

21 And that is Cidex. Next.

22 [Slide.]

23 Cidex now has -- this is the materials. They have
24 a data sheet which talks that Cidex may cause possible
25 corneal injury, skin irritation, direct contact is

1 irritating to respiratory tract, may cause stinging in the
2 nose and throat, discharge, or possibly bleeding from the
3 nose, coughing symptoms, et cetera, et cetera, and this is
4 for the technologist, and it requires protective clothing.

5 [Slide.]

6 I am concluding with Manufacturer No. 3. They go
7 on to say what not to do, but they do not say anything what
8 to do. Now, the quality assurance technologist is
9 responsible and liable under MQSA for following the
10 manufacturer's instructions.

11 Now, the manufacturers have not, in my opinion,
12 given adequate manufacturers' instructions. I am not sure
13 how it has passed the FDA or whether the FDA has ever seen
14 this, but the way that the law is written now, it is going
15 to be the physicians and the hospitals and the technologists
16 that will be liable for following these instructions, and if
17 they don't, they will be fined, and the manufacturers have
18 not met their obligation to the FDA for providing safe,
19 tested use of chemicals to use on their equipment, and I am
20 very concerned that if a technologist does use this, there
21 will be health hazards presented to themselves, as well as
22 the patient.

23 DR. MONSEES: May we have the lights, please.

24 Thank you. Do we have any questions or comments
25 from the panel?

1 [No response.]

2 DR. MONSEES: Thank you, Ms. Sherman.

3 Our next public speaker is Charles Showalter. You
4 have 10 minutes. Will you identify yourself, please.

5 MR. SHOWALTER: Thank you, Dr. Monsees. I am
6 Charles Showalter. I represent the American College of
7 Radiology. I have no conflicts of interest that I am aware
8 of other than my employment with the ACR.

9 I want to mention three areas that we are
10 concerned about in terms of our transition to the final
11 regulations and how the FDA may intend to interpret the
12 guidance in these three areas. The three areas are the
13 requalification for physicians and radiologic technologists
14 in particular, the interpretation of continuing education
15 requirements, and, thirdly, the test for screen speed
16 uniformity. So, those are the three areas I wish to briefly
17 call your attention to mainly for the discussion purposes
18 later in the day.

19 Requalification in the regulation reads to me that
20 if one goes through whatever procedure is spelled out in the
21 regulation, that one is indeed requalified. That is what
22 the term means to me, the term I would think means to most
23 people. And yet for physicians, they have to read 240
24 mammograms or the number that would get them up to 960 over
25 the past two years.

1 In the case where they read 240, but not enough to
2 get them up to the 960 over the past two years, and they are
3 requalified, and according to regulation able to continue to
4 now interpret independently, I understand that if indeed
5 they did not get their number up to 960 over the past two
6 years, and they are inspected at a facility, perhaps a
7 different facility because many physicians work at more than
8 one facility, they will indeed be cited for failure to meet
9 continuing experience requirements, and this would be the
10 same for the technologists if they did not get their numbers
11 up to 200 over the past two years, they did 25 exams under
12 supervision, therefore, requalified, and are able to
13 practice independently, they still are not free from
14 citation if they are inspected at another facility.

15 Now, the reason for that is, as I understand it,
16 that there is concern that people, physicians,
17 technologists, physicists perhaps, would use requalification
18 as a mechanism for never meeting the continuing experience
19 requirement. That is a valid concern. We would not, at the
20 College, want to see that happen.

21 However, what we are concerned about is what
22 appears to be a broad shotgun sort of approach applying to
23 everyone just to try to catch people who might use the
24 regulation in this way, and we believe that the regulation
25 perhaps needs to be clarified to catch those who might

1 repeatedly fail to meet the continuing experience
2 requirement and therefore requalify year after year, in
3 contrast to those who might find themselves, as many will,
4 in an unusual situation due to an illness or other reason
5 for being absent from practice and suddenly find that they
6 don't have the numbers up and they have to requalify.

7 We would recommend in this area and in the
8 continuing education area the approach that has been taken
9 under the interim regulations, that is, if an individual
10 physician goes through requalification, they are given a
11 six-month period where, if they are inspected at a different
12 facility, they will not be cited for failure to meet the
13 continuing experience requirement.

14 We are told this can't be continued under the
15 final regulations. We believe that is a mistake, and we
16 believe that some means should be found to continue it. A
17 similar argument can be made for continuing education. We
18 believe that no one should repeatedly fail to get their
19 continuing education over a three-year period, their 15
20 credits as required, whether they be a technologist, a
21 physicist, or a physician.

22 However, the first time somebody fails to meet
23 this, through whatever mechanism, it seems to me that
24 barring them from practice immediately is a rather extreme
25 penalty. Any penalty under a regulation ought to be

1 somewhat related to what one thinks the problem is, and to
2 me, one does not suddenly become unqualified to practice
3 because they have 14 credits instead of 15 credits over the
4 past three years of continuing education.

5 Now, again, under the interim regs, we provided a
6 three-month grace period, the FDA did, for allowing
7 individuals who didn't meet their continuing education
8 period to acquire those, and after that three-month period,
9 if they still didn't have their continuing education, they
10 had to stop practicing.

11 Again, we would not see, at the College, this as
12 something anybody ought to repeat, but some will
13 legitimately find, due to course cancellation or whatever
14 reason, themselves lacking the required credits at the end
15 of a three-year period. Maybe they had every good
16 intention, but they just didn't get it for whatever reason.

17 We believe immediate bar of practice is an
18 extreme, an unnecessarily extreme penalty and that there
19 ought to be some provision, such as under the interim regs,
20 of the three-month period where they are able to continue
21 practice.

22 Those two issues are addressed to one extent or
23 another in the guidance that you will be discussing later on
24 when you get to personnel, and we would like to call your
25 attention to those.

1 The third issue is in the equipment area relating
2 to screen-film, screen speed uniformity. The way the
3 regulation is currently written and being interpreted, as we
4 understand it, all cassettes in a facility need to be lumped
5 together to meet the 0.3 density requirement.

6 It seems to me, and to us at the College, that
7 there may be legitimate reasons, although they may be rare,
8 they still may be legitimate for having, for example, you
9 large cassettes being different intrinsically than the
10 smaller cassettes.

11 There may be differences in manufacturer, you may
12 elect for whatever reason to use different film in the
13 different cassettes, that it seems inappropriate to require
14 lumping, as we believe the regulation reads now, the lumping
15 of the 18 by 24, and the 24 by 30 cassettes into one
16 population. We believe they should be tested separately.

17 We don't believe that within the population of 18
18 to 24, or 24 by 30, that there ought to be variance beyond
19 the 0.3 as the regulation requires. We just object to the
20 lumping them together.

21 So, those are the three issues we wanted to call
22 your attention to. I would be happy to answer any questions
23 at this point. I and other members of the College will be
24 around when the discussion occurs later on.

25 That is all I have.

1 DR. MONSEES: Thank you. Do we have any questions
2 and comments from the panel at this time? Yes, please.

3 MR. MOBLEY: In terms of the three-month grace
4 period in the standard, and I don't off the top of my head
5 remember exactly how the standard is worded, but could it be
6 established that the three-month grace period begin three
7 months before the standard said you had to have the credits?

8 MR. SHOWALTER: I apologize, Mike. I don't
9 understand the question yet.

10 MR. MOBLEY: Sorry. You mentioned the continuing
11 education requirement, and I think in somebody's brain, they
12 went brain dead on a certain date just because they didn't
13 have one CEU or whatever, and I was hearing you say we used
14 the three-month grace period during the interim standards,
15 and I am sitting here thinking there are several ways to use
16 grace periods. One can be a grace period that you recognize
17 explicitly I guess and say here is a period that you have
18 got to have the credits within this period of time, it is
19 better to have them within another period of time, but we
20 are going to give you a grace period, and if there is three
21 years to get these CEUs, well, in the last three months of
22 that three years, you know, we are going to start pointing
23 out to you that, hey, you are not within your time line.

24 MR. SHOWALTER: You are absolutely right, that
25 there are different ways to use grace periods. We would not

1 like to see the grace period result in a three-year accrete,
2 that is, that the period becomes three years and three
3 months, that it is really three years, if you run over this
4 year, you ought to get it early next year, because your
5 three years ends at the same time next time that it ended
6 this time.

7 We would not like to see people use this
8 repeatedly. You know, we don't think that it is a good
9 reason, you know, it is unlikely that a course gets canceled
10 in the last month of the three-year period every three
11 years, but we are simply arguing that it may be extreme to
12 disbar due to unusual circumstances one time.

13 DR. MONSEES: Any other questions or comments from
14 the panel? Thank you very much.

15 The next speaker, Bob Uzenoff from Fuji. You have
16 10 minutes, sir.

17 MR. UZENOFF: Thank you.

18 DR. MONSEES: Will you identify who you are. You
19 are from Fuji.

20 MR. UZENOFF: Yes. Good morning. I am Robert
21 Uzenoff, Executive Assistant to the President for Corporate
22 Development at Fuji Medical Systems, U.S.A. I appear before
23 you this morning to request a change in FDA's draft
24 compliance guidance released August 27, 1998 for the
25 Mammography Quality Standards Act final regulations.

1 My comments relate to 21 CFR 900.12(e)(5)(viii),
2 specifically, the title and sentence that reads:
3 "Uniformity of screen speed. Uniformity of screen speed of
4 all the cassettes in the facility shall be tested and the
5 difference between the maximum and minimum optical densities
6 shall not exceed 0.30."

7 Fuji requests that the draft guidance (1) be
8 changed to more appropriately designate the attribute as the
9 uniformity of density of the image receptor and support, and
10 (2) be amended to explicitly permit, as conforming,
11 exposures that are clinically used.

12 The former standard, the FDA-recognized American
13 College of Radiology Mammography Quality Control Manual
14 instructed the evaluation of each receptor size or each
15 receptor type individually at the clinically appropriate
16 exposure. The final regulations neither permit nor prohibit
17 such grouping and evaluation at clinically relevant levels.
18 Unfortunately, the current draft guidance is also silent on
19 this issue.

20 The adoption of Fuji's requested amendment would
21 eliminate what is at best an ambiguity in the regulations.
22 FDA makes no uniformity requirement for the other image
23 receptor associated elements of the patient support, bucky,
24 film, and cassette. With adoption of the proposed
25 amendment, FDA will be able to uniformly interpret and

1 fairly and, in our view appropriately, this final rule.

2 If FDA interprets the final regulations as
3 prohibiting grouping, as we believe they now read, FDA will
4 discourage improvements and innovations in devices and limit
5 choices in clinical practice.

6 For instance, Fuji developed and marketed a
7 mammography cassette with improved screen-film contact. The
8 improved cassette has a thicker back a manufacturing change
9 that was incorporated in Fuji's 18 cm x 24 cm EC-MA
10 cassette, but for practical reasons could not be implemented
11 in the 24 cm x 30 cm EC-MA cassette.

12 These cassettes are in widespread clinical use
13 today with no reported problems of size-to-size density
14 difference. Depending on the conditions at each facility,
15 the cassette back attenuation difference is either
16 clinically insignificant or accommodated by AEC settings for
17 each size. However, without permitting grouping in the
18 annual test, a large fraction of the 24 x 30 cm cassettes,
19 when compared to the 18 x 24 cassettes will not meet the
20 0.30 optical density difference criteria.

21 This proposed clarification, if adopted in the
22 final guidance, would (1) acknowledge and account for the
23 fact that the "screen speed uniformity test" includes
24 effects of size-to-size, that is, batch-to-batch, variations
25 in film sensitivity, and the consequences of employing a

1 different size bucky, patient support, grid, and scatter
2 conditions due to field size with their inherent
3 contributions to density variability further; and (2) permit
4 the practice of mammography with multiple types of image
5 receptors in a facility, tailed to clinical needs. For
6 example, new, more efficient grids could be employed on a
7 single size, if desired, and facilities wishing to upgrade
8 their screen-film combinations unit-by-unit would not be
9 penalized.

10 Unless the clinically relevant exposure is
11 permitted as conforming, the final regulations may not
12 produce the desired results and impose unnecessarily
13 restrictive criteria.

14 Thank you for your attention.

15 DR. MONSEES: Thank you.

16 Do we have any comments from people on the panel
17 here? Do you have any comments? You are shaking your head.

18 MR. PIZZUTIELLO: I think you have stated it very
19 well. We are going to have a lot of discussion about this
20 later, I suspect.

21 DR. MONSEES: Thank you.

22 Our last speaker this morning is James Princehorn
23 from Lorad. You have 10 minutes, sir.

24 MR. PRINCEHORN: Good morning. I am Jim
25 Princehorn from Trex Medical, Lorad Division. I know of no

1 conflict of interest.

2 I would like to address two topics today, the
3 first being a general request with regards to the guidance
4 document, and second, a specific topic regarding the Motion
5 of the Tube-Image Receptor Assembly.

6 On the first topic, I would strongly suggest that
7 a recommendation be given to the authors of the guidance
8 document to include an Intent statement for each of the new
9 regulations, where appropriate. I feel this statement would
10 highly reduce the misinterpretations of the regulations and
11 result in better achieving the goals of the MQSA program.

12 As an example, what is the intent of the
13 compression paddle deflection requirement? The regulation
14 just states that the paddle must not deflect from parallel
15 by more than 1 cm at any point on the surface of the
16 compression paddle when compression is applied.

17 My conversations with different people have
18 suggested two possible intents. One possible interpretation
19 suggests that proper compression is achieved only with
20 flatness of compression of 1 cm or less.

21 The other suggests that the intent is to assure
22 that deflection over the life of the use of the paddle does
23 not increase by more than 1 cm from its initial "base"
24 deflection value.

25 This second interpretation suggests that this is

1 really a QC requirement and is intended to be a check to
2 assure consistent compression over time. I believe I could
3 argue that this would have more value, that is, the intent
4 is to maintain consistency over the life of the unit, not to
5 assure an absolute value.

6 However, if the first interpretation is what is
7 meant, then, as a manufacturer, I must consider redesign of
8 existing product as every reasonable compression paddle
9 today deflects upon application of compression to some
10 degree. Also, there is no measurement criteria offered in
11 the regulation. This would probably result in a given
12 paddle being accepted by one physicist and rejected by
13 another just due to different means of measuring the
14 deflection, and/or different interpretations of the
15 requirements.

16 Another example of the value of knowing the intent
17 of the new regulations involves the Motion of the Tube-Image
18 Receptor Assembly movement and its requirement to remain in
19 its fixed position in the event of power interruption. We
20 believe the intent is to provide safe removal of the patient
21 in such an event. Knowing this intent would highly assist
22 us in the development of retrofit kits for existing
23 installed equipment so that they may become compliant with
24 the new regulations.

25 This brings me to the second topic. We have an

1 installed base of mobile mammographic units that have an
2 onboard battery to provide powered transportation. I could
3 easily design a battery back-up scheme using this existing
4 battery to retain the tube-image receptor assembly locked n
5 its position in the event of power interruption. However, I
6 would have to limit this operation to a given period of
7 time, five minutes, for instance. This would easily permit
8 the safe removal of the patient. However, the regulations
9 might be interpreted that the tube-image receptor assembly
10 must remain in a locked position for the entire duration
11 when the power is not applied.

12 I would like to make a request that the panel
13 provide the FDA with guidance on this particular regulation,
14 so that we may proceed to design this type of battery
15 backed-up retrofit kit which we feel meets the full intent
16 of the regulation. Our alternate approach would be a much
17 more complex solution which would carry a much higher cost
18 to the owners to these units.

19 Thank you.

20 DR. MONSEES: Thank you.

21 Do we have any comments or questions from the
22 panel?

23 [No response.]

24 DR. MONSEES: Thank you very much.

25 I believe this concludes the public hearing

1 portion of our schedule here. We will go to break early.
2 We will have a 20-minute break, and we will reassemble here
3 at around 10:33, something like that. Thank you.

4 [Recess.]

5 DR. MONSEES: Before we begin a discussion of the
6 proposed guidance documents, we are going to hear from Dr.
7 Finder pertaining to good guidance practices and our
8 directions.

9 **Good Guidance Practices and Directions for**
10 **Discussion of the Proposed MQSA Guidance**
11 **Under the Final Regulations**

12 DR. FINDER: Before we begin our discussion of the
13 proposed final regulation guidance, I would like to briefly
14 explain the new procedures that FDA is following as it
15 develops new guidance.

16 In response to public comment regarding the use of
17 guidance documents, FDA held an open public meeting on April
18 26, 1996, and again on February 27, 1997, they published a
19 Federal Register notice outlining the steps the Agency
20 needed to take prior to issuing guidance. In brief, it
21 stated the following:

22 1. Guidance had to be developed in an open manner
23 that permitted input from the general public and the
24 regulated industry. In most cases, new or controversial
25 guidance had to allow for such input prior to its

1 implementation. While statutes and their associated
2 regulations were binding and enforceable, guidance was to
3 represent a way or ways of meeting the regulations, but
4 other ways would be acceptable as long as they met the
5 requirements of the regulations or statute.

6 Before we begin our discussions today, I would
7 like to emphasize the following. We are here to discuss the
8 proposed guidance, not the underlying regulations. The
9 regulations have already gone through their own extensive
10 approval process and while they are subject to future
11 change, the purpose of today's meeting is to address the
12 proposed guidance.

13 The documents we will be discussing today contain
14 a mixture of regulation and guidance. When you see the
15 words "shall require or must," they refer to the underlying
16 regulation, whereas, the words "should, may, or recommend,"
17 refers to guidance.

18 For example, in the question how does a facility
19 demonstrate satisfactory performance for mobile units after
20 they are moved to a new location, the answer states that
21 each unit must be tested prior to its use on patients. Now,
22 that is a regulation. Then, it goes on to recommend
23 examples of tests that could fulfill the requirement, which
24 would be the guidance.

25 In the draft compliance guidance document, you

1 will notice that there are some modifications to the
2 regulations. These represent technical amendments which
3 correct mistakes or omissions that occurred mainly during
4 the printing process. Also the committee will be reviewing
5 documents, some of which have already been released to the
6 public, and others which will soon be released for public
7 comment.

8 DR. MONSEES: Thank you.

9 Those of you who received this material, and the
10 panel members here, there is that little sheet that Dr.
11 Finder has handed out pertaining to the subjects of what I
12 did to make it easy, because there seemed to be so many
13 documents that we have to look at, at the same time.

14 I made a listing and then I have noted draft A,
15 draft B, and then the Small Entity Compliance Guide, and
16 those will be the pages of the corresponding discussion
17 points for comments, draft guidance, et cetera.

18 Please feel free to comment on anything whether or
19 not it is something that we discussed ahead of time that you
20 should prepare some comments on. We are going to go down
21 the list from the top to the bottom on this sheet, so we are
22 going to be starting with Personnel Issues. We have general
23 issues, retention of personnel records, and then we are
24 going to get to interpreting physician, radiologic
25 technologist, and physicist.

1 First, with general issues, which Draft A is the
2 bigger of the two drafts, the longer of the two, and then
3 Draft B is the other one, the smaller one, and then I have
4 the page of the Small Entity Compliance Guide. I did not
5 put the federal regs page in there. We can look those up if
6 we need to. So, general personnel issues, which would be
7 page 3 of the larger of the drafts, starting on there, which
8 are the guidance advice here that we have got.

9 **Proposed MQSA Guidance - Personnel**

10 DR. MONSEES: Does anybody have any comments on
11 this for the general personnel? I had a question. Is this
12 right, this CFR 900.20? I think it is the wrong number.

13 DR. FINDER: It is in the Definition Section, so
14 it is .2, and it's O, for the letter O, not zero, but I can
15 check.

16 DR. MONSEES: Oh, it is in the Definition Section.

17 DR. FINDER: Yes.

18 DR. MONSEES: Any other comments? Yes, sir.

19 MR. PIZZUTIELLO: In this section that talks about
20 the dates when the continuing education, and so on,
21 requirements need to be met for inspection, I would like to
22 just pass on a comment from a number of my clients where
23 there are radiologists who have multiple facilities, a very
24 common situation, and some of them have facilities that are
25 inspected all throughout the year, and they just found it

1 difficult to know exactly when the dates for their 36 months
2 should commence and end, and essentially, it has become a de
3 facto of 24 month requirement for them because some
4 facilities are inspected in January all the way through
5 December. So, I wanted to just mention that as an issue
6 which would be I think in the interests of the community to
7 try to come up with a better resolution for that.

8 DR. MONSEES: Any discussion on that? Yes.

9 DR. DEMPSEY: I would like to second what Bob said
10 in regard to physicians. Again, I have had comments from
11 many radiologists who are in groups that cover different
12 sites, that are accredited at different times frames, and if
13 you notice in the regulations, they have to keep different
14 records for each site at the time of the inspection, and it
15 is very difficult for them to go through these manipulations
16 of calendar quarters or which day and everything, and if
17 there was a way to simplify that somehow, some way, it would
18 make it easier for those people covering multiple sites with
19 different inspection times.

20 DR. MONSEES: Any way there could be a database
21 that would maintain names of individuals, so that when an
22 inspector came, he would just be able to check that somebody
23 was already meeting the requirements, and not have to go
24 back through that again?

25 DR. FINDER: This was an issue that was brought up

1 with your predecessors on this committee, and there are a
2 number of issues that we had to deal with, and this may
3 sound very complex, but it is actually a simple method that
4 came up.

5 There are a couple of things that we have to
6 address. One is that the law itself gives us authority over
7 facilities. It does not give us authority over individuals.
8 The only person that we can hold responsible is the
9 facility, so that is one of the reasons that people who work
10 at multiple facilities may be in effect responsible for
11 meeting the requirement or showing that they demonstrate
12 that they meet the requirement several times, but there is
13 no requirement on the individual per se. It is just to make
14 sure that the facility, make sure that these people meet the
15 requirement.

16 The other was the business about establishing a
17 national database on physicians or technologists or medical
18 physicists. While there is some advantage to that, the
19 comments that we had received was that, one, since we don't
20 regulate the individuals, there is a question of
21 confidentiality issues that could arise.

22 The second is that they would still have to update
23 us in some manner nationally rather than locally at the time
24 of the inspection. So, we basically came down to the fact
25 that between the law and the logistics, and the

1 confidentiality issues, that the best way to do it would be
2 to check at the time of the inspection at each facility, and
3 that is how it came up.

4 DR. SICKLES: Is it, in the FDA's opinion, totally
5 unworkable to establish a policy, for example, of using
6 calendar years except for facilities which are just
7 beginning to appear, and then phase them into calendar years
8 over the course of the next one year? That would alleviate
9 a good deal of this problem.

10 DR. FINDER: Again, what we would then be talking
11 about is a change to the regulation, and that is something
12 that we can consider. Again, that is something that we had
13 looked at, and it becomes an issue about the following
14 situation. In effect, you could have a facility or a person
15 not meeting it for as long as four years.

16 The other issue is what are you going to do with
17 somebody who doesn't meet it at the beginning of the year,
18 your January 1st deadline, but by the time that you walk in,
19 he actually does, are you going to cite them anyhow, even
20 though they now currently meet the requirement? It didn't
21 make any sense to do that, so we were trying to set it up on
22 the date of the inspection, if you don't meet it at this
23 time, then, we cite you, but not at some point in the past.

24 So, there are pluses and minuses to all of it.

25 DR. MONSEES: Dr. Mendelson.

1 DR. MENDELSON: One of things that perhaps could
2 be done on a state-by-state basis is a request by someone
3 representing multiple facilities to cycle the facilities'
4 inspection times together, and it is perhaps something that
5 would be less formal than establishing calendar year,
6 although I think that would help a whole lot, but just some
7 nod paid to getting things together for the sake of
8 efficiency and all of that should help somewhat.

9 DR. FINDER: We do have some policies that we have
10 sent out to the inspectors and maybe we can do a better job
11 of getting out to facilities in the sense of trying to do a
12 paperwork reduction, so that it is possible for somebody who
13 works at multiple facilities within the same corporation,
14 let's say, to have one set of records that floats around,
15 because all the facilities are given notice ahead of time,
16 so if there is one centralized set for the group of
17 facilities, they can just move that around and save a lot of
18 paperwork.

19 There is no perfect way to deal with this,
20 unfortunately, but we are open to suggestions.

21 MR. MOBLEY: I just wanted to comment that from
22 the state inspector's perspective, that this is a difficulty
23 in terms of many times they will go into a facility -- you
24 know, I have had this feedback from our inspectors -- they
25 will go into a facility and they will know that the

1 individual -- usually it's the physician, sometimes it is
2 the physicist, rarely is it the tech -- but they will know
3 that the person in question is qualified because they have
4 been to another facility or maybe many facilities, but it is
5 just at this one facility, and it is the facility's
6 responsibility to demonstrate that, but at the same time,
7 the inspector knows that this person does qualify just based
8 on their history, but they are constrained to some extent
9 that, well, this facility can't demonstrate that.

10 So, it does seem like there should be some
11 mechanism, but given the constraints you mentioned about the
12 database concerns, et cetera, I don't know how you do it,
13 but it would seem there are ways of doing it more
14 efficiently than this.

15 DR. DEMPSEY: Just for the record, because I think
16 it has been alluded to already, and it is probably going to
17 come up again, but just for the record, I would like, Dr.
18 Finder, the comment has already been made, we are talking
19 about guidance and not regulations here, but just for the
20 record, suppose it became apparent that a regulation, final
21 reg, would have to be changed, what would the procedure be
22 to get a final regulation changed, et cetera, just so that
23 we have it understood?

24 DR. FINDER: Basically, what we would have to go
25 through is the notice and comment process, and involved in

1 that would be a proposal of a regulation, which would then
2 be discussed, it would go out for public comment, usually
3 with a 90-day comment period.

4 We would then have to look at the comments, we
5 would then revise, if necessary, and then go out with a
6 final version of the regulation, the change. It can be
7 done, it is being done, in fact, we are going to be
8 discussing some of the changes, in fact, some of the changes
9 that you see are changes to the regulations.

10 They are technical amendments which go through
11 easier in the sense that they are usually typos, and even
12 that takes time. We are going to be dealing with some
13 substantive changes in the sense -- and we will hear about
14 this tomorrow -- with the reauthorization of MQSA, that
15 there are going to have to be changes to the regulations and
16 the guidance, some of which you have got in here already,
17 which will have to be changed. So, that is going to be a
18 process that goes through.

19 Yes, it can be done, but it is not an easy
20 process.

21 DR. MONSEES: Any other comments on this, the
22 general personnel draft guidance document?

23 MR. NISHIKAWA: It is a question for the FDA in
24 general on new modalities, in particular, digital
25 mammography. For example, there is a section on physicists

1 must receive at least eight hours of training and surveying
2 units of new mammography modality.

3 Is the FDA proposing that the regs for screen-film
4 systems applied to digital without any modification?

5 DR. FINDER: No, and the regulations themselves
6 have a section that say, like for the QC, where it is pretty
7 well established in terms of film-screen mammography and
8 laid out in the regulations, there is a little section in
9 there that says that for new mammographic modalities -- and
10 you are basically talking about digital -- they would follow
11 the manufacturer's recommendations.

12 MR. NISHIKAWA: Then, I see a difficulty here.
13 Unless the physicists doing the inspection go to training
14 courses offered by the manufacturer, because each
15 manufacturer will have a different QC, you can go to a
16 national meeting, for example, and get training. You would
17 have to go specifically to a training course from the
18 manufacturer.

19 DR. FINDER: There are a number of options that
20 are allowed in here. One of them is to get the training
21 directly from the manufacturer, and we expect a lot of
22 people would in a sense that in the beginning, there
23 probably won't be a lot of courses that would be applicable,
24 but eventually, that will be the case, and it certainly is
25 allowed that they can get this training from other sources.

1 MR. NISHIKAWA: But that would mean someone who
2 wanted to inspect, say, a system from GE and a system from
3 Fisher, would have to go to two separate training courses.

4 DR. FINDER: Not according to the regulations per
5 se. They would have to get training in digital. Now, one
6 would expect that if there are major differences between the
7 systems, that they would get appropriate training in both.

8 MR. NISHIKAWA: I think that, then, is a flaw in
9 how this is interpreted, because the systems are quite
10 different, and I think they require different expertise to
11 properly survey them.

12 DR. MONSEES: Any other comments on that?

13 We will then address personnel retention,
14 personnel records. It is page 9 of the Draft A document.
15 It is in the Small Entity Compliance Guide, 22.

16 Does anybody have any comments about that? It is
17 rather short. No questions, no comments? Okay.

18 Let's move to the interpreting physician,
19 personnel - interpreting physician. That has some
20 information on this on page 4, 10 through 15, then, guidance
21 document B is 6 to 8, in the Small Entity Compliance Guide,
22 page 17. This, I am sure there will be some comments.

23 Dr. Dempsey.

24 DR. DEMPSEY: I would like Dr. Finder to comment
25 about interpreting three months of training in terms of

1 residencies, how does that apply, because many residency
2 programs are currently two months of mammography, not three
3 months, and do then, if it is going to stay two months, do
4 you have to document 420 hours? I would just like
5 clarification on that.

6 DR. MONSEES: The alternative pathway says that if
7 you are not board certified, you need three months, but if
8 you are board certified, you don't have to have three
9 months. Is that correct?

10 DR. FINDER: That's correct.

11 DR. DEMPSEY: That's right. Okay. I just wanted
12 to be sure of that, because there are certain residency
13 chiefs that are reading this, that are misinterpreting that
14 they are going to have to revamp their programs.

15 DR. FINDER: Let's say this. First of all, all
16 the residency programs receive letters, template letters, of
17 what they are supposed to sign to document the requirements.
18 The issue, though, is if the resident doesn't pass the
19 boards, and they don't have the three months, then, they
20 won't be allowed to practice, so it is a question of do they
21 feel lucky. If they don't, then, they have to show the
22 three months if they don't pass.

23 MR. MOBLEY: I have had people in our institution
24 asking me, well, if they condition something else on the
25 boards, in other words, they condition GI or something like

1 that, can't they still read mammograms, and I am telling
2 them no, it is very clear you have to pass the entire board
3 exam. Isn't that correct?

4 DR. FINDER: That is correct, and I believe there
5 is a question in here, in the guidance, that specifically
6 addresses that.

7 DR. DEMPSEY: Yes, there is, right.

8 DR. MONSEES: Any other? Yes.

9 MR. MOBLEY: On page 10, the first item there, the
10 question is or one of the questions, "Does the supervising
11 physician have to sit next to the physician being supervised
12 when he or she reads and interprets the film?"

13 The answer is, "Direct supervision for an
14 interpreting physician means that during a joint
15 interpretation of the mammograms, the supervising
16 physician," et cetera, et cetera.

17 It wasn't really clear in my mind exactly what the
18 joint interpretation meant. It appears that what it is
19 saying is that the physician, the reader can read and make
20 an interpretation, but then that reader has to sit down with
21 the supervising physician and go back through it or go back
22 through with the supervising physician, making a separate
23 reading, and then discussing it. I just wanted to make sure
24 that was really clear, because it wasn't clear in my mind.

25 DR. FINDER: Yes. I think that is exactly what it

1 means, in the sense that the physician being supervised
2 could go through the initial reading of that mammogram
3 without the supervisor present, however, before they come up
4 with a final assessment, they would have to get together and
5 agree that that was the correct assessment on that film.

6 MR. MOBLEY: Is there action that would take place
7 on the initial reading? When does this joint interpretation
8 reading occur, are there actions that would occur at the
9 clinical level or whatever prior to the joint interpretation
10 occurring or whatever? How does that work out?

11 DR. FINDER: Well, in terms of the joint
12 interpretation has to occur before the patient is informed
13 of the results, so the idea was that before any action would
14 be taken, direct supervision would have taken place. So, it
15 wouldn't be a situation where somebody unqualified could
16 read the film, send out a report, and then sometime
17 afterwards have this joint interpretation or joint
18 supervision.

19 DR. SICKLES: I think later, in a different part
20 of this -- and there is so much of it, it is really hard to
21 refer to exactly which part -- it is clear, not in this
22 section, but in another section, it is clear that when you
23 are doing this kind of supervision, that it is the
24 supervising radiologist who is responsible for the
25 interpretation, and therefore, that is the one that counts,

1 and therefore, in terms of anything that the "training"
2 radiologist or whatever you want to call him is doing, that
3 is not an official interpretation. It is pretty clear on
4 that.

5 MR. MOBLEY: I did see that later on. I was just
6 wondering -- and I don't work in a radiologist operation, so
7 I don't know -- but I was just wondering, when a film is
8 originally made, are there some circumstances in which an
9 initial cut decision is made -- bad choice of words there --
10 initial decision is made in terms of going forward or not
11 going forward, releasing the patient or just film is made,
12 the patient is released, and films are viewed later on?

13 DR. SICKLES: Yes, that does happen at times
14 Usually, in diagnostic mammography rather than screening, or
15 in screening which is monitored before the patient leaves
16 the department, I could foresee a circumstance. I don't
17 know that the FDA wants to regulate it, but I could foresee
18 a circumstance where somebody who doesn't have his numbers
19 up there, was in a chair doing this kind of triage, then,
20 the review came later after the patient left.

21 What that would do would be to require the patient
22 to be recalled, where otherwise she might not have had to be
23 recalled. I don't know that the FDA wants to micromanage it
24 quite to that extent. I can tell you that in a realistic
25 way, this kind of double reading might take place using a

1 scenario where the qualified radiologist doesn't necessarily
2 review all the cases specifically with the first
3 radiologist, but rather reviews only the ones where there is
4 a disagreement.

5 We went through this procedure once for one of our
6 radiologists who had low numbers, and the way that we worked
7 it out, and we worked it out with the local inspector, so
8 they were quite comfortable with it, was the cases were
9 actually read by the official radiologist first, and that
10 was all finished, and then the radiologist "in training,"
11 reviewed the cases, wrote down what they would have done,
12 and we discussed only the ones where there was disagreement.
13 We didn't discuss the ones where there was agreement, but
14 they didn't know what we had written down. That is another
15 way to do the same thing.

16 DR. MONSEES: In that situation, were both names
17 on the report?

18 DR. SICKLES: No.

19 DR. MONSEES: Will that suffice, if somebody's
20 name is not on the report?

21 DR. SICKLES: It did in our local situation.

22 DR. MONSEES: Let's comment on that because I
23 think that is kind of still up in the air here.

24 DR. FINDER: Well, basically, what the
25 requirements are is that there has to be the qualified

1 person who interpreted those films. There only has to be
2 one name. If you want to include other people who were
3 being directly supervised, that is up to the institution,
4 but you don't have to. The only person's name that has to
5 go on there is the one that official read the report and is
6 qualified.

7 DR. MONSEES: How, when somebody is trying to
8 obtain the continuing education experience, do they have to
9 produce a document or do they have to have their name on
10 those reports, or can they have just been there to see those
11 and track themselves?

12 DR. FINDER: There is guidance in here that
13 addresses that, and the fact is that they don't have to have
14 their name on the report. There are other ways to document
15 those. One of the measures that we have talked about is to
16 get a letter from the facility saying Dr. so-and-so read X
17 number of mammograms under the direct supervision of the
18 qualified interpreting physician, who they list, and sign
19 off on that, and that would be sufficient. You don't have
20 to have a name on the official medical report.

21 DR. SICKLES: And that is exactly the way we did
22 it, and we actually supported it. They didn't look at it,
23 but we had the documentation of names of the cases if they
24 needed it.

25 DR. MENDELSON: That was what I was going to bring

1 up, but I think it perhaps should be made more explicit in
2 the guidance, because it does talk about the name of the
3 supervising physician being on the report, and by
4 implication you are assuming that the radiologist who is
5 reading with supervision also has his or her name on the
6 report, but that is not the case and when you have visiting
7 fellows and other CME experience, so perhaps it should be
8 stated more explicitly. I think that would be helpful.

9 DR. MONSEES: Yes.

10 DR. SICKLES: I actually have comments on two
11 specific guidance statements. If you want to, we will do
12 them. The first one is in the big one, which I think we are
13 calling A.

14 DR. MONSEES: Yes, page 1.

15 DR. SICKLES: And if you go to page 13, the
16 question on the bottom, which begins, "A radiology resident
17 had" -- did you find that?

18 DR. MONSEES: Yes.

19 DR. SICKLES: Just to avoid any confusion, and
20 this is nitpicking in terms of words, it talks about had a
21 rotation more than a year prior to graduation. It really
22 should say, "more than a year, but less than two years."
23 Otherwise, it wouldn't fit this definition.

24 DR. MONSEES: Okay.

25 DR. SICKLES: And as a minor point, but you may

1 want to just add that terminology.

2 The second one relates to the document B, and if
3 you go to page 6, the top question and its answer. This
4 relates to how one counts time in a combined rotation. This
5 would obviously only be for somebody who is using the
6 alternate pathway to do their documentation, but, you know,
7 he said he had a rotation where there was part chest, part
8 mammography, and how to divide it up, and I think although
9 the answer says that you would have to divide it up, it
10 doesn't provide any guidance as to how to do that.

11 You might add to it an example, you know, one way
12 to do this would be that you could count the number of
13 examinations done of both types. Another way would be to
14 count the amount of time spent on the combined rotation, for
15 example, if you did mornings on chest and afternoons on
16 mammography, you might just provide an example which would
17 give a little bit more discrete guidance in this regard just
18 to be a little more specific.

19 DR. MONSEES: I think this was brought up the last
20 time when we discussed this, and we were alluding to a
21 percentage of time, and, of course, this is subjective,
22 isn't it? Perhaps we should be a little more specific.

23 DR. SICKLES: I just think it would be useful as a
24 guidance if we had an example.

25 DR. MONSEES: Okay.

1 MR. PIZZUTIELLO: In your example, might you also
2 include some of the hours relating to the physics that are
3 addressed in the section of the code including physics
4 specific to mammography, radiation effects, and radiation
5 protection, so if you are going to be divvying up your
6 example to say I spent mornings on chest and afternoons on
7 mammography, but we spent 100 hours doing physics of imaging
8 on these issues, how might you include the physics in your
9 example?

10 DR. FINDER: We do have another guidance question
11 that does deal with that, and the limit that we have
12 accepted in the guidance is 90 hours, so there is a
13 specific, but that is the other thing, is we have got all
14 these different documents, hopefully at some point in the
15 not too distant future we will put it all together into one,
16 so that you will see a list of questions about the same
17 topic, and hopefully it will have addressed all the answers.

18 DR. MONSEES: But in the same place instead of in
19 three different documents.

20 Yes.

21 DR. DEMPSEY: Document A, page 12, I just wanted
22 to make a specific comment based on conversations I have had
23 with Bob Kristofko at our place at UAV, who is in the ACCME,
24 and that is, that if you look at the question about CME
25 toward the top of the page, and answer, "Any CME credits

1 earned prior to '99, may be either one or two, and then
2 after April '99, must be Category 1."

3 Because many physicians these days are getting
4 away from the traditional meeting CME, and are doing it with
5 it CD-ROMs, and whatever, the only thing I would say is that
6 that section in some way should be highlighted, because it
7 may very well catch a lot of physicians unaware that that is
8 a requirement, so I agree with what is there, I am just
9 saying that needs to be highlighted because that would go
10 against what a lot of physicians are -- the trend is
11 currently not the traditional meetings, to the tune that
12 about across the board, according to Bob Kristofko, meeting
13 attendance is down in the past year 23 percent across the
14 board, all medical specialties.

15 DR. MONSEES: That might be a good item for the
16 mammography matters.

17 I had a question pertaining to document A, page 8,
18 the experience with digital mammography. We use digital on
19 stereo units now. Does CME pertaining to stereo unit
20 digital, which is small field of view, count? Can we
21 specifically talk about that? How will that be?

22 DR. FINDER: What do you think, should it?

23 DR. MONSEES: Well, I don't think it should when
24 it comes to full field of view, I certainly don't think so,
25 but I would like to hear from our physicists perhaps what

1 they think, but people might count it that way, may
2 interpret it that way, because it is digital, it is a
3 digital receptor.

4 MR. NISHIKAWA: I think a radiologist should
5 comment on it. I don't think it should count, it is
6 completely different, if nothing else, different purpose for
7 doing the examination.

8 DR. SICKLES: The FDA doesn't regulate
9 stereotactic units with digital, and I don't think that any
10 experience with that should count to full field digital,
11 which is being defined as a different modality.

12 DR. MONSEES: I didn't know if somebody would try
13 and count that CME towards their digital experience.

14 DR. SICKLES: They might try, but I would not
15 allow it, and you might want to even make a question and
16 answer to make that very specific. You could work that in.

17 DR. MONSEES: Do you think that is a problem, Dr.
18 Finder?

19 DR. SICKLES: It's a potential misunderstanding,
20 which could be corrected with a question and answer.

21 DR. FINDER: That actually raises another issue
22 that I think we should address in terms of how specific we
23 want to get with our inspectors going in and looking at this
24 material. I know we want certain things to happen, but we
25 also have to take a look at the other issue, and I think

1 this is a good place to discuss it, about how intrusive and
2 how detail oriented we want to be in some of these things
3 and how we are going to separate out some of the -- it is
4 going to be hard enough with the general issues in terms of
5 mammographic modalities or CME in general, but we will
6 certainly take the advice.

7 I mean if you think that it should be excluded,
8 then, we are going to have to take a look at it individually
9 and say if this is digital mammography, but it is digital
10 stereotactic mammography, then, we won't -- you know, it is
11 up to you guys.

12 DR. MONSEES: I just don't want people to be
13 misinformed where they think that that counts, not
14 necessarily that the inspector needs to go down the list and
15 look at the topics of every single CME hour that they have
16 attended.

17 DR. SICKLES: In the beginning, I don't think it
18 is going to be a very big problem because in the beginning,
19 there are not going to be that many facilities which will
20 have full field digital, so that people will have to get the
21 CMEs. It will work in very gradually, slowly, and as long
22 as the guidance is clear as to what people need, I think
23 that the end users will understand what they have to get.

24 It is already in the guidance that for people who
25 are trying to document modality-specific hours, that they

1 are going to have to do more than simply say I went to a
2 course. They are going to have to maintain the agenda of
3 the course, so they can show the inspector, yes, this was
4 digital mammography. It would be a stretch for an inspector
5 to be asked to believe that a lecture that said stereotactic
6 mammography counted as digital, because somewhere in that
7 lecture somebody talked about using a stereotactic unit that
8 had digital in it. You would want digital in the title, and
9 you don't find digital in the title of stereotactic
10 lectures.

11 DR. FINDER: Not yet.

12 DR. SICKLES: Not yet.

13 DR. FINDER: Of course, after this discussion, it
14 may start to show up a lot.

15 DR. SICKLES: I don't think so.

16 MR. PIZZUTIELLO: I would like to present the
17 other side, and that is that there are a number of physics
18 lectures that are being given primarily to medical
19 physicists, which deal with the physics of digital and
20 stereotactic and for a medical physicist as opposed to a
21 radiologist, it is more technology based, and there are
22 similarities although there are certainly differences in
23 terms of the approach.

24 So, I guess I would want to say that if a
25 physician were to sit in on a course where the physics of

1 digital imaging was presented, and stereotactic was used as
2 an example, I am not sure that it would be totally
3 irrelevant.

4 DR. MONSEES: That is why I brought it to begin
5 with.

6 MR. PIZZUTIELLO: Let's be careful about not being
7 too specific.

8 DR. MONSEES: That is why I brought it up to begin
9 with, because really, there are similarities, understanding
10 the physics of it.

11 MR. NISHIKAWA: I have a comment on that. I agree
12 with Bob's comment although if someone exclusively had eight
13 hours of training only on stereotactic digital devices, I
14 don't think that would be acceptable as training on digital
15 per se.

16 DR. MONSEES: Any other comments on physician
17 issues, personnel issues - physician? I had a question that
18 maybe I just don't understand this one. On page 6 of A
19 document, in the middle it says, "If an individual publishes
20 a paper in mammography, is it acceptable to use that paper
21 for continuing medical education, how many units may the
22 individual obtain," and it said, "Credit can be obtained if
23 an organization grants CME to an individual for
24 publication." Is there such a thing?

25 DR. FINDER: Right, the CME granting organizations

1 give Category 2 credit for papers and publications, whether
2 they want to give Category 1, I guess would be up to them if
3 they want to, but this policy could also extend to the other
4 personnel categories, so it would still hold, because the
5 only group that has to have Category 1 is the physicians
6 after implementation.

7 This was a policy that we have had under the
8 interim regulations. People have come up to us and said I
9 have published this paper, I have given this presentation, I
10 want to get some credit for it, and we said that's fine, but
11 we don't know how much credit to give you. You go to a
12 organization, a CME-granting organization, and if they grant
13 you X number of credits, we will accept it.

14 So, this is just a continuation of that interim
15 reg policy into the final. If an organization says that a
16 paper is not Category 1 credit, they won't be able to count
17 it, but if they do, then, they will.

18 DR. SICKLES: Barbara, in truth, organizations
19 like the AMA and the CMA do give Category 2 hours for
20 writing papers, and some of them give up to 8 hours for a
21 paper, some give up to 10.

22 MR. NISHIKAWA: I have a follow-up question on
23 that. Does each author receive credit or just the first
24 author?

25 DR. FINDER: Again, that would be up to the

1 organization.

2 DR. MONSEES: Any other issues pertain to
3 personnel issues for the interpreting physician?

4 Okay. Let's move on to the Radiologic
5 Technologist issues. This is Draft A, 16 to 19; Draft B, 11
6 to 14; and in the Small Entity Compliance Guide, it is page
7 20. I said it wrong? Again, for the technologist, 16 to 19
8 in Draft A, and in B it is 9 to 10, and the Small Entity
9 Compliance Guide, page 19. Thank you very much.

10 Comments? Yes, please.

11 MS. WILSON: Patricia Wilson. Page 19, Draft A, I
12 would like to see a six-month grace period for a
13 technologist that failed to meet the requirement of
14 continuing experience. It is really not addressed in here,
15 how to reestablish your requirements. This pertains again
16 to what was discussed during the session this morning.

17 DR. FINDER: Right, and just to reiterate that,
18 under the interim regulation policies, it is not in the
19 interim regs, but under policy, what we would do for the
20 physicians -- it didn't apply to the technologists or the
21 medical physicists because they did not have a continuing
22 experience requirement -- they would be given a period of
23 time, six months after they requalified, and during that
24 time they would not be cited, their facilities would not be
25 cited in case they happened to be inspected if they had not

1 gotten their numbers back up to that required by the
2 continuing experience requirement.

3 We had received advice that that policy should
4 end, and we did put that in the guidance that that would
5 terminate as of the implementation of the final regs, but we
6 would like to hear your opinion on that. Obviously, we
7 heard from the ACR representative and Patricia Wilson.

8 DR. MONSEES: Let's open this discussion then to
9 the physician also, the issues that were brought up this
10 morning by Mr. Showalter.

11 Does anybody on the panel want to comment?

12 DR. FINDER: I just want to bring up another
13 point, that it only applies to the physicians and the
14 technologists, it does not apply to the physicists. It is
15 not that we don't like the physicists, it is the fact that
16 the requirements that they have to requalify automatically
17 get them back up to their continuing experience requirement,
18 whereas, for the technologists and the physician, they don't
19 have to necessarily.

20 For example, the physician can read 240
21 examinations under direct supervision. It doesn't get them
22 up to the 960 for the previous two years. Similarly, for
23 the technologist, they only have to do 25 exams. It doesn't
24 get them up to the 200 for the previous two years.

25 For the medical physicist, however, their

1 requalification process gets them up to the requirements, so
2 they don't have to deal with this.

3 DR. MONSEES: So, let's address this. You have
4 heard it brought up twice now, once by Ms. Wilson and once
5 by Mr. Showalter.

6 Does anybody have any feelings about this? Do you
7 understand the issue? Should there be a drop-dead deadline?

8 DR. FINDER: Let me also explain one of the
9 reasons that we had this policy under the interim
10 regulations for the interpreting physician, and I think it
11 will apply also, if not more so, for the technologist, was
12 the situation where a physician was working at multiple
13 facilities.

14 If he only works in a single facility and he gets
15 cited, he requalifies, he will not be reinspected for a
16 year, so he basically has a certain amount of time in which
17 to get his numbers back up. That may not be the case with a
18 physician that interprets at multiple facilities.

19 What could happen, and why we established the
20 policy was a situation of an interpreting physician who
21 requalified by reading 240, was requalified so he could
22 interpret independently, and since he happens to work at
23 another facility that just happens to get inspected the day
24 after he finishes requalification, he would re-cited again
25 because he didn't have the 960.

1 He would then have to go under direct supervision
2 again for another 240. That was the purpose of the policy,
3 to allow people the time to get up to the 960, and, in
4 effect, it basically gives them the same amount of time as
5 somebody who was interpreting at a single facility would
6 have. That was the purpose of it, the rationale behind it.

7 DR. MONSEES: Did you have a comment?

8 DR. SICKLES: The only thing that I am
9 uncomfortable with -- and I don't know the right way around
10 it in terms of regulation -- is the person who attempts to
11 abuse the situation by purposely requalifying instead of
12 maintaining their hours, and I don't know whether you can do
13 this in a regulatory way by not allowing one to do it in
14 successive years or I don't know how you can handle that,
15 but that is the only thing that really bothers me about the
16 situation.

17 DR. FINDER: Well, we do have a mechanism. It is
18 not perfect, but it is a mechanism, and that is that
19 facilities that repeat the same noncompliance, have that
20 noncompliance kicked up to a higher level.

21 So, if it was a level 2 -- actually it is a lower
22 level -- it was a level 2 one year, and they repeated it, it
23 would be a level 1 the next year. So, there is a mechanism,
24 it is not perfect.

25 DR. MONSEES: Can grace periods be allowed in the

1 guidance or does it have to be in the regs?

2 DR. FINDER: For the continuing experience
3 requirement, we have gotten legal advice that we could
4 include it in the guidance, the way the reg is written,
5 however, for the continuing education requirement, that is a
6 much touchier issue because it specifically states in the
7 regulation that you will stop performing the service.

8 So, I think that we can do it under the continuing
9 experience requirement, which for most people is the big
10 issue. I am not so sure we can do anything with the
11 regulation as it stands for the continuing education, i.e.,
12 the 90 day or three-month "grace" period.

13 DR. MONSEES: Yes.

14 DR. MENDELSON: I do think that if we can do it
15 under the guidance for the continuing experience, it should
16 be included certainly as we transition from the interim to
17 the final regulations, and I think that that would help
18 those people would find themselves having to deal with
19 multiple inspections because they are involved in
20 interpreting at multiple sites.

21 The continuing education requirements are much
22 easier to fulfill, 15 credits can be obtained really in a
23 day and a half at a weekend course, and I think that that
24 would be -- it is less of an issue -- but I do think if we
25 can in the guidance incorporate the grace period, it would

1 be helpful, and I think most people would not abuse it, but
2 would appreciate it.

3 DR. MONSEES: What Mr. Showalter was asking was
4 the last minute course cancellation, et cetera. I have to
5 say that I share your opinion in that I have little sympathy
6 for somebody that is waiting for the last month to get their
7 CME, but it doesn't sound like there is much leeway here
8 anyway.

9 DR. SICKLES: I just had a question. To what
10 extent now, since we do have a grace period, is it utilized?

11 DR. MONSEES: Do we track it?

12 DR. FINDER: Actually, I can't give you a specific
13 number, but we can probably find out. Basically, it would
14 be a situation of determining how many people were cited for
15 it.

16 DR. SICKLES: Well, no, it is how many people are
17 not being cited because they are being allowed the grace
18 period or are these the people that are being cited and --

19 DR. FINDER: No, no.

20 DR. MONSEES: They get a level 3?

21 DR. FINDER: No, these are level 2's, and they are
22 all cited. If you don't meet the requirement, you get
23 cited. Well, I shouldn't say you, the facility gets cited.
24 It is only a question of what they have to do or what they
25 are allowed to do afterwards, but the citation goes in, so

1 we do have a tracking of the number of citations, and
2 presumably, these people are then going to use it in some
3 manner.

4 DR. SICKLES: Be definition, a level 2 citation
5 gives you 30 days to respond, so you automatically have a
6 30-day grace period just because you are going to respond
7 within 30 days, and you will say I already got it in those
8 30 days. I mean there is a de facto 30 days right there,
9 right?

10 DR. FINDER: That is another issue. I mean once
11 you are cited and you are told that you are not supposed to
12 do something, and if you do something, and you are found out
13 later, you can get into a lot of trouble. So, I don't know
14 that that helps that much.

15 The other issue that I don't have any tracking of
16 is we know how many people, let's say, get cited, how many
17 facilities get cited for continuing experience, but I can't
18 tell you how many of those people, when they requalify, get
19 back up to the 960 versus using the 240 route, and those
20 that requalify by getting up to 960 don't need a grace
21 period, it's the other ones.

22 DR. MONSEES: If it is going to be written into
23 the guidance, then, I suggest that it be discussed that they
24 would still be cited, and what would be the implications if
25 they would read mammograms without somebody who is

1 supervising, who is an interpreting physician, a qualified
2 interpreting physician, so that it is unambiguous?

3 MS. HAWKINS: Patricia Hawkins. I would just like
4 to say, you know, in looking in terms of level 2 citings,
5 and so forth, and how this is being looked at, is that it is
6 not as significant as level 1, but it does compromise
7 quality mammography, and when I look in terms of what was
8 sent to us, looking at a breakdown of inspection findings,
9 is that in level 2, we still have a very high number of
10 personnel qualifications being the issue there, so I think
11 that that should be addressed, you know, that we should look
12 at that very seriously before thinking in terms of allowing
13 additional grace periods.

14 DR. MONSEES: Okay.

15 MS. WILSON: Dr. Finder, if you had a situation
16 where a technologist has left her field for a year or 18
17 months, comes back into mammography, and reestablishes her
18 qualifications by performing 25 mammograms under direct
19 supervision, and then the facility has their inspection the
20 next week, will they be cited for this technologist not
21 meeting her continuing experience?

22 DR. FINDER: If there is no grace period, yes,
23 they will be cited, because the inspector will be looking
24 back from the date of that inspection two years to see if
25 she has got 200 mammograms performed. If she doesn't, then,

1 the facility will be cited. So, without a grace period,
2 that is what will happen.

3 MS. WILSON: I could see this happening, and I am
4 very much in favor of the grace period.

5 DR. MONSEES: I hear you.

6 MR. MOBLEY: I guess I am hearing a lot of things
7 bandied around here, and it is not clear to me how the grace
8 period works with the citation, et cetera. I believe in the
9 past, and I think what you said was that even though there
10 was a grace period, a citation was issued if somebody didn't
11 meet the standard, and it was a grace period that allowed
12 them to continue doing what they do and then work during
13 that period to bring themselves into compliance, so that
14 they would be cited, they would have 30 days to respond to
15 the citation, and the response could be during the next six
16 months this tech, this physician will get this training,
17 this experience, et cetera.

18 That would have been the status previously, so the
19 grace period doesn't buy you anything in terms of being
20 cited, you are still cited, the grace period only allow you
21 to continue to operate while you bring yourself into
22 compliance, is that correct?

23 DR. FINDER: Right. The example that was brought
24 up is a little bit different than the one that we usually
25 come across. Usually, at the inspection, a person is found

1 to not meet the qualifications, at that time they are cited,
2 then, they requalify.

3 This is a little bit different in the sense that
4 this person in effect requalified before any citation ever
5 went in, so that is the difference in the situation, but
6 that, at least to my way of thinking, the minor in terms of
7 number of cases where people automatically are requalifying
8 ahead of time.

9 MR. MOBLEY: I think from my perspective, that if
10 the system works that way, that that seems reasonable and
11 also from a regulatory perspective, you are dealing with a
12 situation and that you are putting the facility on notice
13 that the personnel have to meet the standard, but you are
14 not shutting the facility in effect, in some cases, maybe
15 you are shutting the facility down. I mean we don't believe
16 people go brain dead on day 91 or whatever it is, three
17 years and a day.

18 But you are citing the facility, you are putting
19 them on notice, then, they have a period of time, the grace
20 period we are referring to here, for those personnel to
21 bring themselves into compliance and thus the facility into
22 compliance with the standard.

23 DR. FINDER: Well, it is a little bit different in
24 the sense that we are talking about two different
25 requirements, one of which -- well, under the present system

1 we have two different grace periods, and the question is
2 what to do with them under the final regs for the continuing
3 experience. The situation would be as follows: an
4 inspector would go in, a person would be cited for not
5 having 960 mammograms. They would have to stop interpreting
6 mammograms and go under direct supervision at that point and
7 either read enough films to get them up to 960 or at least
8 240.

9 The grace period that we are talking about would
10 only apply after they completed that process, and its only
11 purpose would be to prevent them from being re-cited if they
12 are inspected at a different facility in effect. That is
13 its purpose.

14 The other grace period that is working right now
15 is a 90-day grace period for continuing education. That
16 applies to all three personnel categories right now, and
17 what it says is if we come in, the inspector finds that you
18 don't have the 15 CMEs, your facility gets cited, but you
19 have 90 days, at which time you could continue to provide
20 services, but you would have that 90 days to get your 15
21 CMEs back up. If at the end of the 90 days, you haven't
22 done that, then, you have to stop.

23 What we are talking about here, at least in the
24 current guidance, is to get rid of both of those. Now we
25 are hearing some suggestions to reinstitute the one for the

1 continuing experience, which is the six-month "grace"
2 period. The other thing is should there be a "grace" period
3 just like there is right now for continuing education, and
4 as I was saying, under the regulations, the way that they
5 are written, that one would be more difficult to deal with.
6 I don't know if we could do that under guidance. We might
7 have to propose a change in the regulation, but we are
8 certainly interested in hearing what you have to say about
9 it.

10 DR. MONSEES: I have just a question pertaining to
11 what you just described before we take the comments. Excuse
12 me. So, if a radiologist who had not met the continuing
13 experience requirement were reading at two facilities, the
14 first facility would be cited that was inspected, the second
15 facility, just because it was inspected second, wouldn't be
16 cited even though they are two separate facilities? That is
17 what I am hearing him say.

18 DR. FINDER: Well, it depends on certain
19 situations. If the physician went under direct supervision
20 at the second facility at the time of the inspection, they
21 would not be cited. The issue that comes up is how is the
22 second facility supposed to know that this guy is under
23 direct supervision, and the only way that they would know is
24 if the physician tells them.

25 Part of the guidance would be to explain to the

1 physicians that if you become cited at one facility, to
2 notify all the others that you are under direct supervision,
3 so they don't get cited. Otherwise, what would happen is
4 the inspector would come in and he wouldn't know any
5 different. That facility would get cited.

6 The way that that would get taken care of,
7 hopefully, would be when they send in their response to the
8 30-day requirement, and they would basically say, well, we
9 put this guy under direct supervision. So, that is how they
10 would eventually deal with it, but unless the physicians
11 notify their various facilities of what is going on, the
12 inspector won't know about it either, and they will be
13 cited.

14 DR. SICKLES: It seems to me that in terms of the
15 longer grace period for continuing experience, the value of
16 that, if I understand it correctly, is to protect a second
17 facility from getting cited when the individual involved has
18 already begun to remedy a situation that was identified at a
19 previous inspection.

20 To my mind, in terms of protecting patients and
21 guaranteeing good quality mammography, it is reasonable to
22 retain that kind of a grace period, because this person is
23 remedying the situation, has already gotten up to the 240
24 hours, which we judge to be reasonable in order not to
25 require direct supervision, so I don't see that we are

1 jeopardizing public health in any way in that situation.

2 What we are doing is we are trying to reduce the
3 number of citations that are technical.

4 DR. FINDER: Right, and the reason that the 240
5 was picked, because that is the initial requirement, and we
6 allow people who have read the 240 to read independently,
7 the same thing.

8 DR. DEMPSEY: A comment on continuing medical
9 education. I think it has been alluded to several times
10 this morning that you have to look at this, 15 CMEs in three
11 years is not much, and most people can get that at one
12 meeting. I think to require that within a three-year period
13 is pretty minimal actually.

14 DR. MONSEES: Yes.

15 MR. PIZZUTIELLO: I also support the grace period
16 because think about what happens if there is no grace
17 period.

18 DR. MONSEES: For which one?

19 MR. PIZZUTIELLO: For the continuing experience,
20 because if you don't allow the grace period, then, you
21 essentially invalidate the whole requalification procedure
22 for any subsequent facilities, and there shouldn't be any
23 penalty for a professional working at multiple facilities.

24 So, based on sort of looking at the negative side,
25 it makes perfect sense to retain the six-month grace period.

1 DR. MONSEES: Did you want to make a comment about
2 for the technologist?

3 MR. PIZZUTIELLO: It applies equally well to
4 technologists and to physicians.

5 DR. MONSEES: Any other comments on this issue?
6 Anything else?

7 MS. HAWKINS: Let me just ask a question here, and
8 I am perhaps furthest from this, you know, as far as what
9 happens.

10 DR. MONSEES: Pat Hawkins.

11 MS. HAWKINS: Patricia Hawkins. Now, you take,
12 for instance, in some areas you may have personnel that
13 actually is going to be working in numerous facilities, and
14 so if that person has not met the requirements, is that you
15 not only affect facility number one, but facility number
16 two, three, four, five. So, you could have a whole area
17 where you are compromising the possible compromise of
18 quality in mammography.

19 DR. MONSEES: I am not sure, in what issue, are
20 you talking about the continuing experience of the
21 radiologist and the technologist?

22 MS. HAWKINS: Yes.

23 DR. MONSEES: Would you like to restate why you
24 think perhaps to the contrary?

25 DR. SICKLES: The issue of the grace period

1 relates to what I would like to consider a technical
2 citation of a second facility. When a first facility
3 already was cited, the person involved in the citation from
4 the first facility already has remedied the situation for
5 the first facility, but because there are two different
6 rules for experience requirement, the second facility is
7 technically out of compliance although the first facility is
8 technically in compliance.

9 I don't see that as a threat to the public health
10 for the second facility, because this individual has already
11 achieved enough continuing experience to be safe for the
12 first facility, that person really is also safe for the
13 second facility. It is a technical reason why they get
14 cited for the second facility.

15 That is why the grace period makes sense to me.
16 It wouldn't make sense to me if I thought that there really
17 was a substantial danger to the public health. I see it
18 more as a technical citation than as a meaningful citation.

19 MS. BROWN-DAVIS: Carolyn Brown-Davis. Now, my
20 understanding is that the person, once cited, is going to be
21 under supervision provided -- to get out of the first. So,
22 that, in turn, I think, kind of nullifies perhaps the
23 concern about those people who are going to receive
24 mammography services during that six-month period. My
25 antenna went up for that, too, I think that the grace period

1 actually is a good thing, I mean a good thing from the point
2 of view of the consumer, because the physician or the person
3 who has been cited would have to be under supervision for a
4 six-month period or else that second mammography site would
5 be open for citation. Is this correct? Okay.

6 DR. FINDER: Well, it is not six months, but they
7 would have to read the correct number of mammograms under
8 direct supervision, and the idea behind this is that they
9 would not be allowed to do the following: they wouldn't be
10 allowed to read under direct supervision at one facility
11 while they are doing this requalification process and read
12 independently at another facility. If they read at facility
13 B, they would have to be under direct supervision there
14 also. So, I think that is hopefully where the safety comes
15 in.

16 DR. MONSEES: Does that clarify things for you?

17 MS. HAWKINS: It does.

18 DR. SICKLES: This is an extremely confusing
19 subject, and I think it would be -- once you make the
20 decision on the grace period, I think you are going to have
21 to write a really carefully worded guidance, because
22 everybody is going to get confused about this

23 DR. MONSEES: Plus you want to avoid abusers of
24 the system as was brought up by Mr. Showalter earlier, and
25 that should probably be worked into that, as well, if the

1 grace period is going to be accepted.

2 DR. FINDER: The other thing I think we have to
3 keep in mind is the number of people that might be in a
4 situation where they would have to use this grace period.
5 First of all, we don't want them to get into a situation
6 where they are going to be cited in the first place.

7 Second of all, it is only going to apply to those
8 that, in the requalification, don't get up to the required
9 number, it's the lower number, you know, the alternative in
10 effect. So hopefully, that number will be relatively small.

11 For physicians, it should be vanishingly small,
12 because we have already got their situation going on right
13 now. For technologists, I can see a situation where it is a
14 new requirement, we are going to have a fair number of
15 people get caught by that.

16 DR. MONSEES: Did you have a comment.

17 DR. MENDELSON: I just wanted to reiterate the
18 importance, I think, of ascertaining how many facilities are
19 one of multiples, and in those instances, to try to combine
20 the inspections and at least put them in some sort of
21 synchronization, so that all of this really, after some
22 years, will become a very small problem.

23 I think it is crucial to do that, and I think that
24 that is an amenity that states should provide as enacting
25 for the inspections.

1 DR. MONSEES: So, that is guidance for the state.

2 DR. MENDELSON: That is guidance for the state,
3 but it should go into the guidance document here as a way of
4 dealing with the problem that we can all see and that is
5 quite complex.

6 DR. MONSEES: Can that suggestion be put in the
7 guidance document for the states, that they might consider
8 that?

9 DR. FINDER: I don't see why we couldn't. It is
10 certainly something to consider.

11 MR. MOBLEY: Just go to inspection planning. I
12 mean it doesn't necessarily belong in here, but it can just
13 be part of your inspection planning activities, it would
14 seem to me.

15 DR. MONSEES: Any last comments on this issue
16 before we break for lunch? I think we are scheduled to do
17 our break. Do you have any comments on this issue? We have
18 not finished yet, the personnel issues for the technologist,
19 but we have some time after lunch to do that, yes.

20 MR. PIZZUTIELLO: One thing on this last item that
21 Mike brought up. If you don't put it in the facility
22 guidance document, and it only goes out to the inspectors,
23 then, facilities won't know that they can request it.

24 So, if you put a little line item in the guidance
25 document that says if you have multiple facilities, you can

1 request to your inspectors to try to group the inspections,
2 then, you will get the word out to the people who need to
3 make the request. If all you do is you let the inspectors
4 know, then, you are not quite informing the right
5 population.

6 MR. MOBLEY: That is good. I think that is
7 better. I think the thing you have to realize, though, is
8 that you do have operations. I mean, for example, in
9 Tennessee, in Memphis, we have a number of people who
10 operate in Arkansas and Mississippi, and obviously, the
11 State of Tennessee does not control the inspections out of
12 those areas, and we also have facilities that operate in
13 areas of Tennessee where they cross our inspectional
14 boundaries.

15 The reality of it in my mind is, though, between
16 the facilities wanting to coordinate inspections and our
17 perspective, that makes sense to us, too, because it makes
18 it easier to do all those types of inspections within
19 reason. I don't see why it couldn't be worked out.

20 DR. FINDER: I would suggest that before we put
21 any guidance, we would have to talk with the states to find
22 out. I think it would be terrible to put in guidance, oh,
23 yes, you can request this, and find out that 49 states won't
24 accept it, won't deal with it, so we would have to do some
25 work before we put it out as guidance.

1 DR. SICKLES: I would also point out to you that
2 it will be a lot easier to achieve this kind of grouping in
3 terms of radiologists, because radiologists and facilities
4 tend to stay together, where technologists often will just
5 by getting some extra hours of work, cross over to a
6 competing facility rather than to a cooperating facility.
7 Technologists frequently work for competing radiology
8 groups, where radiologists don't.

9 DR. FINDER: I just want to bring up the example
10 of the locum tenens who reads cross-country, and if he calls
11 up and wants to have all his facilities done at once, I
12 think there might be a little trouble there.

13 DR. MONSEES: Any other comments on this issue
14 before we break for lunch?

15 When we reconvene, we are going to still talk
16 about personnel issues pertaining to the technologists
17 before we go on to the physicist. We will reconvene at 1
18 o'clock. It is now quarter to 12:00. Thank you.

19 [Whereupon, at 11:45 a.m., the proceedings were
20 recessed, to be resumed at 1:00 p.m.]

AFTERNOON PROCEEDINGS

[1:00 p.m.]

1
2
3 DR. MONSEES: We are going to pick up where we
4 left off. We are going to begin with radiologic
5 technologists again, pages 16 to 19 in Draft A, in B it is 9
6 to 10, and 19 in the Small Entity Compliance Guide, and we
7 are going to pick up where we left off.

8 Are there any other issues pertaining to those
9 pages, that part of the draft compliance guide that we need
10 to talk about?

11 MS. HAWKINS: I do.

12 DR. MONSEES: Any others from the panel?

13 Go ahead, Ms. Hawkins.

14 MS. HAWKINS: I have a question in the larger
15 draft on page 18, in reponse to the question at the top of
16 the page, and the answer, and it talks in terms about
17 training requirements. Is that the training requirements,
18 the very last sentence or the very last phrase of it,
19 "includes instructions in areas not normally covered during
20 the performance of the examination," and I wanted to know
21 what types of trainings that this might encounter, and so
22 forth.

23 DR. MONSEES: Would you like to answer that?

24 MS. WILSON: Quality control tests, instruction
25 about the anatomy of the breast.

1 MS. HAWKINS: And the reason I am asking this
2 question is because in this whole process of screening for
3 breast cancer, and so forth, and the process of mammography,
4 the technologist is perhaps the only individual that the
5 consumer has contact with, and so I am just concerned that
6 as we look in terms of some of the disparities that we see
7 out there as they relate to health care, you know that the
8 President has recently announced an initiative to address
9 those disparities, and I believe that cancer is one of those
10 four areas that he is targeting, is that in terms of going
11 back to culturally competency in the process, dealing with
12 clients, and so forth, like that, making certain that, you
13 know, because I think you are going to need for an effective
14 mammogram, you are going to need the participation of the
15 consumer, you know, the cooperation of the consumer in
16 getting that type of relaxed atmosphere at that point of
17 examination, I think is very important.

18 DR. MONSEES: Okay. I saw a question in the
19 audience that I will entertain, one of the former members of
20 NMQAAC.

21 Identify yourself, please.

22 MS. HEINLEIN: Rita Heinlein. I have no
23 affiliation.

24 I have two questions. Question No. 1, relating to
25 the discussion that you all had this morning about the grace

1 period. My question to the committee is if a technologist
2 has not completed 200 exams on the date that they are
3 inspected, then, they would have to do 25 exams under direct
4 supervision in order to requalify, correct? And they would
5 have a six-month period in order to bring their total number
6 of exams up to 200.

7 Now, what if, at the end of the six months, they
8 have not brought the total number of exams up to 200? That
9 means they have to stop doing mammography, correct? Until
10 they do 25 exams under direct supervision, then, they have
11 requalified again, is that correct? And then they get
12 another six months to bring their total number up to 200.

13 So, they could feasibly just continue this pattern
14 of doing 25 every six months and continue to requalify, is
15 that correct?

16 DR. MONSEES: This pertains to possible abuses as
17 was mentioned this morning by Mr. Showalter pertaining to
18 radiologists that could essentially do the same thing, so we
19 should talk about maybe the guidance document contains
20 something that says, for example, you know, limit one per
21 customer per time or whatever, something so that we don't
22 have repeat offenders or have somebody use this as a do loop
23 type of way to avoid confronting, really fulfilling the
24 requirements.

25 Can that be considered if this type of thing was

1 to be included in the guidance document, could there be some
2 way that it could be limited, so that abuses wouldn't occur?

3 MR. MOBLEY: Wouldn't that be just taken care of
4 by the fact that the enforcement process would bump up the
5 citation at the facility, and then the citation itself would
6 go from -- I can't remember, I think it is an L2 to an L1 --
7 so the citation becomes more serious, and Dr. Finder will
8 have to answer this because I don't know about FDA's
9 program, but in our program, this would be considered from
10 our perspective a willful violation which rolls it over into
11 another round.

12 DR. FINDER: In terms of the escalation of the
13 level of citation, we mentioned that earlier, and yes, that
14 is what would happen. The issue about putting it in
15 guidance is something that we obviously can consider, but I
16 just want to remind people what guidance is. It is not
17 binding. The question is what we could do under the
18 regulations, not so much under the guidance.

19 I mean the guidance obviously for everything is
20 you should do what the regulations say to do, good quality
21 mammography, and you shouldn't do bad things. We can put
22 things like that in there, but I am not so sure that that is
23 going to change anybody's idea if somebody wants to go ahead
24 and do something that like that, if a few words in guidance
25 is going to make any difference.

1 I think that the way to approach it is through the
2 compliance actions that we may be able to take against that
3 facility per se.

4 MS. HEINLEIN: One other question, and I apologize
5 to the committee, I was here late this morning, and if this
6 has already been addressed, then, please let me know that.

7 The question on page 18 concerning the distinction
8 between Category 1 and 2, CMEs for physicians, and there is
9 Category A and B for technologists, will there be this same
10 distinction in the final regs, that technologists would only
11 have to have Category A, like the physicians only have to
12 have Category 1?

13 The answer is no, that there is no distinction,
14 and I wanted to know why that is, because Category B for
15 technologists, it does not have to be preapproved, and it
16 can them reading anything, that they just pick up any
17 article and read that, and they can document that they have
18 read that article, and then count that as their Category B
19 credits.

20 DR. FINDER: Basically, this is a policy that is
21 actually in place right now, and the only distinction here
22 is the fact that physicians now have to do Category 1. For
23 technologists, it has always been this way.

24 The answer to your question basically is the
25 documentation, and in effect, technologists already are only

1 submitting Category A, because that is the only one that
2 they can get documentation for, so that is all we have been
3 accepting.

4 MS. HEINLEIN: All right. But now it says here
5 that since either is accepted, but must be appropriately
6 documented.

7 DR. FINDER: Right.

8 MS. HEINLEIN: So, appropriate documentation,
9 could that be that if someone picks up an article and
10 decides to read an article in Ladies Home Journal about
11 breast cancer, and they document the title being Breast
12 Cancer Statistics or whatever, and they documented that, and
13 then they go to their supervisor and say I read this article
14 in the Ladies Home Journal, and I can count this as Category
15 B, and the supervisor signs off that they read that, would
16 that be appropriate documentation to the inspector?

17 DR. FINDER: In terms of the documentation that we
18 are looking for, it has to be appropriate to the subject.
19 We have gone through the acceptable areas, I don't know if
20 we have gone through the actual guidance here in terms of
21 what are acceptable areas for continuing education, but
22 there are certain requirements that that has to meet, and
23 then there are requirements of documentation.

24 In the scenario that you have described, I don't
25 think it would meet it would meet the standard to say that

1 this would be acceptable CME.

2 MS. HEINLEIN: The "I don't think" is my concern.

3 DR. FINDER: Right, and as you well remember at
4 the discussions that we had at this committee, there was the
5 issue about Category 1 credit for physicians, and if it was
6 supposed to be Category A credit for technologists, I don't
7 remember if that specifically was brought up or wasn't.

8 MS. HEINLEIN: I don't remember either.

9 DR. FINDER: If you felt at that point, that that
10 was necessary, then, that is where it should have been
11 brought up, but at this point, I don't think that we can,
12 through guidance, require that it be Category A for
13 technologists if it isn't in the regulations.

14 MS. HEINLEIN: No, but I guess it could certainly
15 say that under Category A has more appropriate documentation
16 or something like that. I mean again, I guess I am just
17 looking to see if there is a potential loophole for someone
18 who has said I don't have any money to go to a class, I am
19 not going to go to any courses, all I really have to do is
20 just read 15 articles. So, that is my concern.

21 DR. MONSEES: Thank you. Yes.

22 MR. PIZZUTIELLO: The issue might be one of
23 documentation. When you submit to an organization like
24 ASRT, they determine how many credit hours are approved, and
25 in a situation that Rita just explained, no one can decide.

1 What if the technologist says it took me 15 hours to read
2 this article, I am a slow reader, so in that case, since it
3 hasn't been objectively determined what number of hours go
4 with it, that might be the basis for the division to say we
5 cannot accept credits for which there has been no
6 determination of how many hours are appropriate.

7 DR. FINDER: Basically, what we have said in terms
8 of the documentation is that we are requiring or asking for
9 some CME-granting organization to stipulate how much they
10 are going to give for these things, and that was brought up
11 a little bit earlier in terms of writing articles, giving
12 presentations, things like that.

13 So, it is a combination of what are acceptable
14 areas and what is acceptable documentation, and I don't
15 think that the situation that was brought up will come up
16 very often in terms of a difficult situation to deal with,
17 but you never know.

18 DR. MONSEES: Yes.

19 DR. SICKLES: I just have a question because I am
20 not familiar with Category B hours as earned by
21 technologists. What continuing education agencies award
22 Category B hours and what are their requirements for doing
23 that, does anybody know here?

24 MS. WILSON: I have no idea. All our
25 technologists always get Category A, and we have many, many

1 technologists to keep track of.

2 DR. FINDER: Category A is very similar to
3 Category 1. In terms of the difference basically, it is
4 kind of like the difference between -- Rita?

5 MS. HEINLEIN: The distinction between A and B?
6 As far as ASRT is concerned, Category A has to be
7 preapproved, so they have to submit objectives, outlines, as
8 you know, faculty, credentials, et cetera, et cetera.

9 If all of those meet the criteria established by
10 the ASRT, then, they will award a Category A credit. If
11 someone reads an article or something that is not
12 preapproved, then, because they did read it, the ASRT will
13 recognize that as Category B. However, ASRT limits the
14 number of Category B credits that you can get to comply with
15 the 24 credit requirement for your AART.

16 DR. SICKLES: Does ASRT award the Category B hours
17 or who does the awarding of the hours, what organization
18 does?

19 MS. HEINLEIN: I don't know that ASRT -- I don't
20 know that answer.

21 DR. SICKLES: Because the scenario that you posed
22 was a technologist reads an article, goes to her supervisor,
23 who obviously has nothing to do with the ASRT, and then the
24 supervisor somehow magically awards her the hours, and I
25 would think it is more formal than that, I would hope.

1 MS. HEINLEIN: I don't know that it is. I think
2 that it is just a matter of it's either Category A or if
3 they can show that they did some other reading, then, they
4 would be granted, given credit for that time if it was like
5 done, approved by some type of a supervisor, they could
6 count that as not a Category A, but the ASRT allows a
7 certain number of hours for that, and so they call it
8 Category B.

9 DR. SICKLES: The only suggestion that I would
10 give, if it is really that loose, then, I think the FDA
11 might consider commenting on this in the guidance in terms
12 of what documentation they would require above simple
13 recording of I read an article and my supervisor signed off
14 on it. I would hope there would be more than that, because
15 that does not imply much in the way of education.

16 DR. MONSEES: Important point. Anybody else,
17 comments? Yes.

18 MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla,
19 American College of Radiology. Going back to the continuing
20 experience for technologists, I wanted to bring up another
21 issue. In deference to Rita, yes, I think we all agree we
22 are concerned about people who try to gain the system or
23 repeatedly have the same offense.

24 On the other hand, the way the guidance is
25 currently written, the potential exists that if a

1 technologist were to take an extended period of time off,
2 say, two years for maternity leave, and returns, because the
3 clock started ticking on the date that they initially became
4 qualified, in a small or rural facility where the volume of
5 patients is very small, the potential exists they could be
6 cited as much as two more times once they come back to work
7 even if the requalify by having 25 done under supervision.

8 So, I have looked at a scenario, we will provide
9 that in writing to the FDA, but I think one of the things
10 that is of great concern to me is that in a rural community
11 where it is hard to recruit technologists, to begin with, we
12 may find that we are actually limiting access because
13 technologists may not be able to requalify without the
14 facility being cited.

15 So, I think it is a very serious issue that needs
16 to be reevaluated, and go just the grace period is not going
17 to address that issue. Thank you.

18 DR. MONSEES: Thank you.

19 Any other comments on that? Okay. Any other
20 comments pertaining to the radiologic technologist and the
21 guidance documents? Okay.

22 We will move then to Personnel Issues, the Medical
23 Physicist. This is Draft A, which is the bigger one, pages
24 20 to 24; B, 11 to 14, and the Small Entity Compliance
25 Guide, page 20.

1 Who would like to begin? Yes, sir.

2 MR. PIZZUTIELLO: This is the smaller document,
3 line 471. There is a discussion about medical physicists.
4 What it says here is that FDA believes that two medical
5 physicists cannot jointly, simultaneously perform a survey
6 on a mammography unit. I have to disagree with that.

7 I think that there are many examples where medical
8 physicists work in collaboration. You certainly can't have
9 five or 10, but it is very common for two medical physicists
10 to work together, and that is not only in a training
11 situation, and I have personally been involved in training
12 situations, one just recently, but also in the situation
13 where two medical physicists sometimes work quicker
14 together, so they decide to work together, or there may be
15 other reasons to work together.

16 I don't see any reason why the FDA should exclude
17 the opportunity for two physicists to jointly work together.

18 DR. MONSEES: We have radiologists working
19 together, both getting credit for exams. We have
20 technologists who are training, both of them can get credit
21 for the exams. I don't see any reason why it is different.

22 Dr. Nishikawa, do you have any comments on that?

23 MR. NISHIKAWA: I agree.

24 DR. FINDER: Not wishing to be one to bring up
25 some issues, but we had to struggle with this ourselves, and

1 the questions that I would raise to you, and ask the
2 committee to think about, what the requirement actually is
3 that we are talking about, and for the continuing, it's I
4 believe it's two facilities and six units for two years,
5 something like that, which isn't a great number of units to
6 do, and what we are asking is if two or more physicists are
7 doing a test, how many hands can be in there at any one
8 time?

9 It is a different issue if they are going to do it
10 sequentially and that they do all the tests, but if you have
11 got two physicists splitting up the QC tests that they have
12 to do, each one we would say is doing five, is that meeting
13 the experience requirement if you have three in there, and
14 they each do three, is that enough? That is the issue that
15 we were struggling with.

16 The other issue is if we try and put that an
17 arbitrary number of two or three or four, where do we draw
18 the line and what rationale do we use to draw that line?
19 Those are the issues that we were dealing with, and we felt
20 that the original proposed requirements, the number of
21 facilities and units was much higher, and we dropped it.

22 We felt that if we were going to do that, then, we
23 should at least have these people doing the actual survey
24 themselves, but I would be interested to hear what people
25 say.

1 The other thing is for the technologist and the
2 interpreting physician, we are dealing with somewhat
3 different situations. For example, for the interpreting
4 physician, it really makes no difference whether one person
5 has looked at the same mammogram or 400 have looked at it,
6 they still get the same or can still get the same
7 experience.

8 For the technologist, it is harder. I think they
9 have the toughest one, because they are dealing with live
10 people, and there are a limited number of technologists that
11 can actually work on one person, and for there, I think we
12 are proposing that no more than two, and that basically
13 comes down to the fact, some of the guidance that we had
14 talked about at the last meeting, that you felt that two
15 people could get a reasonable experience out of that, and we
16 had to deal with the fact that in some low volume
17 facilities, we had to establish some kind of mechanism for
18 them to do it.

19 With the physicist, we are talking about a
20 relatively small number of facilities and units to begin
21 with, and do you feel that it is appropriate for them to do
22 only half the tests on the equipment, because that is what
23 we are talking about.

24 DR. MONSEES: As long as they are there, and at
25 least it is more objective in that you get data from it from

1 most of these tests as opposed to a technologist where you
2 are positioning and really hands-on is even more important,
3 but I am not physicist, but I have watched physicists do it.
4 Do you think that you have to actually do these tests?

5 MR. PIZZUTIELLO: I think that Dr. Finder raises a
6 good point. The requirements are awfully easy, to begin
7 with, but I really think that just as two technologists --
8 and we had this discussion last meeting -- two, but clearly
9 no more than two can be reasonably involved in "hands-on"
10 performing of a mammography procedure.

11 I think that two medical physicists can work
12 together. Now, I would not see that as one physicist doing
13 some of the tests, and another physicist doing another
14 batch. I would see that the tests are performed
15 collaboratively, and that was the circumstance I was
16 thinking about.

17 DR. SICKLES: My understanding is that what
18 defines this is who signs off on the report, is that
19 correct?

20 DR. FINDER: Not necessarily, because, you know,
21 we are talking about two different things. We are talking
22 about somebody trying to get additional experience, and
23 wouldn't necessarily have to be the person that signs off on
24 the survey. You would have to be identified.

25 DR. SICKLES: You would have to be identified in

1 the survey.

2 DR. FINDER: All the people who are involved with
3 this would have to be identified, but it wouldn't be the one
4 actually signing off, the qualified one necessarily.

5 DR. SICKLES: How will the person who is gathering
6 the experience be able to document that they have gathered
7 it?

8 DR. FINDER: Again, it would be the same kind of
9 documentation we have talked about for the others. It might
10 be letters from the facility or from some organization,
11 whatever, that showed that they were being done under the
12 direct supervision.

13 What we were trying to do is extend the situation
14 where we know we have to do it, which is a trainee, where
15 you have one person supervising the other, but the other
16 situation was two qualified physicists, is it appropriate
17 that they can split a unit, is that okay, and the other
18 issue is how do you determine whether each one of them did
19 each of the tests, or whether they were working
20 collaboratively or sequentially.

21 Again, the way I thought of it was they split up
22 the tests, because it is kind of hard to be doing the same
23 tests together.

24 MR. NISHIKAWA: Actually, from my experience,
25 although I have never formally done a QC test, it is faster

1 for two people to do it together than one person doing it
2 alone. However, if the split was the first person would do
3 the first half, and the second person would do the second
4 half, that would be not an acceptable situation, but two
5 people doing them simultaneously, I think both derive
6 benefit from doing it, but I don't know how to prevent the
7 splitting of chores.

8 DR. MONSEES: Yes.

9 MS. BUTLER: Penny Butler. I am currently with
10 the American College of Radiology, but that is fairly
11 recent. As one who has had a lot of experience doing
12 mammography surveys, I can easily say the benefit that you
13 gain from doing a survey, the educational and experience
14 benefit is not from physically going through the motions of
15 setting up test equipment and doing the test, but it is the
16 consultative and interactive, if are working in a pair,
17 discussing the results.

18 One person may do the test, but when you get the
19 results, and you discuss it and you share that information,
20 I think it is of equal benefits to the individual, so I
21 would agree with Bob and Robert about two physicists, for
22 example, getting full credit for the survey.

23 It is the intellectual process, not the physical
24 process.

25 DR. FINDER: So, could three do it?

1 MS. BUTLER: My personal opinion, I would think
2 you would have to put a cut somewhere, and I would say two,
3 a pair.

4 DR. MONSEES: The same with the technologists, we
5 put a cut someplace. Any other comments on this?

6 Continuing with physicist issues, did you have any
7 other comments? Anybody else on the panel? We are speaking
8 to guidance on physicists, personnel issues.

9 Okay. We are going to move to equipment issues.

10 DR. FINDER: You didn't leave anything out, but I
11 just wanted to ask a question or bring up a point that I
12 think was alluded to earlier, and I just want to make sure
13 that everybody agreed to it or thought that it was
14 reasonable.

15 For some of the experience, the physicist may be
16 in a somewhat different position than either of the other
17 two categories in that some of the topics that they may deal
18 with in terms of getting continuing medical education may
19 extend more widely than, let's say, for a technologist or an
20 interpreting physician.

21 Let me give you an example. We would be looking
22 for continuing education in areas of physics related to
23 mammography, but "related to mammography for physicists,"
24 might extend over a larger area. One could say that general
25 x-ray production might be an important topic, it wouldn't

1 necessarily say mammography, but it would still be
2 applicable, whereas, for the interpreting physician, or the
3 radiologic technologist, it might not be as extensive an
4 area.

5 One could say that positioning for the
6 technologist obviously is important, but there are some
7 areas that probably, you know, general radiographic
8 positioning wouldn't be appropriate.

9 For the medical physicist, however, some of the
10 information they would learn from general mammography
11 equipment might still be applicable, because it is all
12 physics in that sense.

13 Would you agree with the assumption that we might
14 have to give more latitude to the areas that would be
15 acceptable for physicists than maybe for the other two or
16 not?

17 MR. NISHIKAWA: I understand all the words you
18 said, I am not sure exactly what that means, give more
19 latitude.

20 DR. FINDER: It wouldn't be the first time people
21 didn't understand.

22 MR. NISHIKAWA: So, the example you gave, I didn't
23 understand, was that a concrete example that would be
24 allowed or are you asking should that be allowed?

25 DR. FINDER: I want to know your opinion on the

1 fact that for interpreting physicians and technologists, we
2 are basically looking for something that says mammography or
3 breast disease or something in the CME, whereas, for
4 physicists, do you think that should still hold? Should a
5 physics course, say, mammography, or should we accept more
6 for that?

7 DR. MONSEES: It could be advanced film-screen
8 combinations or something like that.

9 MR. PIZZUTIELLO: I think that when you are not a
10 medical physicist, it probably all seems like it is physics
11 and it is all the same, but I would say that from my
12 perspective, almost everything relating to the physics of
13 mammography is at least significantly different from the
14 physics of general radiography.

15 The only exception I would say to that would be
16 film processing. Film processing is critical and it is very
17 compatible with general radiographic stuff, but anything
18 else relating to imaging, there is not a whole lot of hours
19 that a medical physicist needs to have, and I would favor
20 not being very, very flexible with that. It really ought to
21 say x-ray tubes or image producing of the x-ray beam blend
22 to mammography in order to be really relevant to this issue.

23 MR. NISHIKAWA: I agree with Bob. Most of the
24 equipment is fairly specialized and quite different from
25 other general radiographic procedures, so I think you would

1 need some education on specific mammography equipment.

2 DR. MONSEES: Did you have a comment?

3 MR. MOBLEY: Bob may have just covered it, but I
4 was thinking that, to me, that is an important consideration
5 and one where sometimes you see a failure is that people
6 want to overextend themselves because they are very
7 knowledgeable of the basics, and may be very knowledgeable
8 of a specific technology or whatever, but I think somehow
9 there needs to be -- and it may be addressed in here by this
10 last statement -- that there needs to be assurance that the
11 physicists have the training appropriate for the specific
12 technology and/or device it is that they are looking at.

13 I guess the obvious one today is the one that just
14 flew out of my mind -- digital, that's it, digital.

15 DR. FINDER: One just quick last question. The
16 issue about counting equipment surveys done at non-certified
17 facilities, not acceptable. Is that okay with everybody?
18 Yes.

19 **Proposed MQSA Guidance - Equipment**

20 DR. MONSEES: Now we are going to move on
21 equipment. We have Draft A, pages 25 to 35. That is the
22 bigger draft. The smaller draft, 15 to 19. In your
23 Compliance Guidance, page 22.

24 Specifically, I think we should mention something
25 that was brought up, the compression paddle discussion was

1 brought up in the public session, and any other issues that
2 are important.

3 Yes, Dr. Dempsey.

4 DR. DEMPSEY: Before we get to that, and I didn't
5 know exactly where to make this comment, but it probably
6 applies to training, as well as equipment. Throughout the
7 guidance book, this comes up about a modality, and I think
8 that it is potentially going to be very confusing, and
9 basically, the gist is we are all using the same modality
10 right now.

11 The only new modality that would come in the near
12 future would be digital, but the way the guidance is worded,
13 you are going to be fielding a lot of queries about does
14 ultrasound count as a modality, does MR count as a modality,
15 and I think in the guidance, if there was a way to, at the
16 very beginning, even put down terms and terminology, what
17 counts as a modality or, more specifically, what doesn't
18 count as a modality would be very helpful and I think would
19 decrease the phone traffic to the FDA.

20 DR. MONSEES: You plan to put that in there? It's
21 in there.

22 DR. DEMPSEY: I know it is in there, but it is one
23 of those things that needs to be really highlighted.

24 DR. MONSEES: We will call Dr. Dempsey the William
25 Safire of the panel.

1 DR. FINDER: We tried to deal with that, and I
2 agree with you we have been getting a lot of questions about
3 it. We have tried to handle it in a couple of ways. One is
4 through this guidance where we specifically say, but you are
5 right, you have to read it.

6 The other thing is we have tried to make it
7 universal that whenever we use the term "modality," we call
8 it a mammographic modality, and maybe eventually, people
9 will understand that ultrasound and MR are not, but until
10 that happens, we are going to continue to be fielding these
11 questions. So, if you can come up a way to highlight it, I
12 agree, because we have gotten a lot of questions on it.

13 DR. DEMPSEY: I think one of the things that many
14 of us who participate in courses could do a favor, by
15 bringing it up ahead of time.

16 DR. SICKLES: Just to follow up on Pete's comment,
17 if you look on page 4 of D, where this question is actually
18 asked and answered, since apparently there may be some
19 confusion about ultrasound or MR, you may want to add them
20 into the answer for this and just say that they don't fall
21 under MQSA, so they wouldn't be counted as modalities, but
22 you may want to just expand the answer to include it.

23 DR. MENDELSON: Just to move, it is answered on
24 page 8, but it comes up on page 4 before that. On page 8,
25 it does say that the term "mammographic modality" refers to

1 a technology for radiography of the breast. That is under
2 that first question/answer sequence there.

3 Examples are screen-film mammography and
4 xeromammography. If that is just moved forward, so that it
5 is answered before the question gets asked, I think that
6 that will take care of it.

7 DR. MONSEES: She is talking about in the first
8 document on page 8.

9 DR. MENDELSON: It is radiography. Mammography is
10 a generalized term.

11 DR. MONSEES: Document A. This obviously will be
12 reformatted into one, more intelligible document, and we are
13 recommending that it be up front in the original document
14 that comes out, in the guidance document.

15 Moving on to equipment then. Comments pertaining
16 to equipment. Who wants to start?

17 MR. PIZZUTIELLO: I will start an opening bid on
18 the compression paddle issue. The issue that was brought up
19 earlier in one of the open session discussions about
20 compression paddles is one that I have concern about.

21 In general, the regulations were focused on not
22 being prescriptive, but were focused on end results,
23 however, in the issue of compression paddles, I think there
24 needs to be some indication of what kinds of test conditions
25 would be used to evaluate whether a compression paddle

1 deflects by more than 1 cm.

2 I can easily envision the circumstance where
3 physicists may get a reputation for being easy, not that
4 physicists are ever easy, but because one physicist gets
5 known as passing compression paddles because they just
6 barely apply any pressure on the paddle, and they use a real
7 soft foam test device to see if it deflects by 1 cm, and
8 then you might get the less happy physicist who likes to
9 test compression devices with a golf ball to see if the
10 compression goes up to maximum 60 pounds on the machine.

11 One of the easy answers that came to my mind --
12 and I am not sure it's the best -- but just someplace to
13 start might be to say if the accreditation phantom is used,
14 that is something that pretty much everybody has, and if a
15 typical pressure that everybody has to have, let's say 25
16 pounds, that might be a standard operating condition that at
17 least we could uniformly apply. It might not be the best,
18 but maybe I would throw that on the table for some thought.

19 DR. MONSEES: This looks like it is on page 30 of
20 document A, pertaining to the paddle? It doesn't say
21 anything about using the phantom, but at least that is where
22 some of the guidance is offered.

23 MR. MOBLEY: I just had a general question there
24 about that, because I guess when I looked at that, I thought
25 that there was little or no specificity as to how you would

1 do this, and based on your comments, Bob, I guess there is
2 little or no specificity about how you do this test, so it
3 seems that he is right, you know, some specificity to be
4 input. The question is when the standard was written, what
5 was the intent, because I heard, and not being privy to the
6 development of the standard, I heard that maybe there is two
7 interpretations to the standard based on the comments that
8 were made this morning.

9 DR. MONSEES: Anybody remembers, even somebody
10 from the audience perhaps, maybe Mr. Showalter --

11 MR. PIZZUTIELLO: I can answer the question. The
12 two points that Jim Princehorn raised this morning were is
13 this an initial standard that the machine should meet when
14 it is first designed or installed, or is it a continuing
15 standard to see that the machine continues to meet those
16 requirements.

17 DR. MONSEES: That was the point that was made by
18 our speaker.

19 MR. PIZZUTIELLO: I think that is something other
20 committee members might not be aware of, is that there has
21 been a significant evolution in the design of paddles over
22 the last, say, 10, 12 years. The early paddles were much
23 more flexible in particular on the large compression device.

24 They would tend to bow significantly in the
25 middle. Almost any paddle, if the mount gets worn over

1 time, will have slop in the chest wall, nipple, and
2 direction over time, so those are two different issues.

3 The newer paddle designs were made to be much more
4 rigid and as a rule, don't have much of a problem with this.
5 There is a large bulk of existing equipment out there which
6 will not meet this requirement if it is pretty strictly
7 interpreted.

8 I don't know, I can't remember at the previous
9 committee meetings what the intent was, but maybe that is
10 something we need to discuss.

11 MR. SHOWALTER: Charles Showalter, ACR, formerly
12 with FDA. This is a requirement that like many of the
13 equipment requirements, underwent evolution with time, and
14 when it was initially proposed, as I recall, there was a
15 specific test method also proposed.

16 Given the rush of getting the final standards out,
17 we really didn't have time to verify the test method. There
18 were a lot of questions about whether it was a valid test
19 method, and rather than finalize an unproven test method, we
20 simply took it out. That certainly leaves open the
21 questions of how you go about testing, and I think your
22 concerns are valid, that physicists might get various
23 reputations depending on how they pass or don't pass various
24 pieces of equipment, but anyway, that is how we got to where
25 we are, as I recall it.

1 The initial test method, as I recall, involved a
2 disk and X number of pounds of compression. Perhaps Charley
3 Gunzberg can remember better than I do the details.
4 Whatever the details were, though, they were unproven. They
5 seemed reasonable, but we certainly did not have the
6 opportunity to go out and test the method on a bunch of
7 different equipment as one would like to have done.

8 DR. MONSEES: Is this particular issue going to be
9 addressed in the ACR new manuals that are being worked on
10 now, this particular test?

11 MS. BUTLER: A procedure for this test is not in
12 the Quality Control Manual draft because it was not one of
13 the quality control tests specified by MQSA for medical
14 physicists or anybody for that matter. It is addressed as
15 an equipment checklist. There is a checklist in this draft
16 that says FDA requires these specifications be present on
17 equipment. That is where we are now.

18 DR. MONSEES: So, whether you check it or not,
19 nobody is going to know what the criteria are to check it.
20 You basically can look at it, but you don't know whether you
21 will meet whatever requirements there are because we are not
22 really sure, it is very ambiguous, is that correct?

23 MR. MOBLEY: The AAPM doesn't have a methodology
24 developed for it or suggested methodology?

25 MR. PIZZUTIELLO: There is no standard that I know

1 of that defines how this measurement would be made. Let me
2 just remind folks that I am sort of assuming that the
3 medical physicists will be doing this. That is a whole
4 other question of who is going to assess these equipment
5 performance characteristics, but it might also well be that
6 inspectors will do it, and then you can get into arguments
7 between inspectors and medical physicists, so it can get
8 more complicated.

9 MS. BUTLER: The question was where did this test
10 methodology come from, and Charley Gunzberg could probably
11 correct me if I am wrong, but I believe it came from the
12 ACR-CDC document that came out a few years ago for new x-ray
13 equipment. There was a test methodology in that document
14 with these specifications on it.

15 MR. PIZZUTIELLO: I know the document. I don't
16 recall that there was a test methodology in there. John
17 Sandrik is nodding his head that that is correct. It was
18 mentioned as a performance characteristic, but I don't
19 believe there was any way of evaluating their
20 characteristics.

21 MS. BUTLER: I believe there was a description in
22 there about the infamous disk that Charley was referring to.

23 MR. MOBLEY: I am going to take a step further
24 back. I guess we have this requirement that is here, we
25 don't have a methodology for testing for it.

1 One mechanism in my mind for determining how good
2 our test method is, is for somebody to tell me how critical
3 this 1 cm deflection -- I think that is the requirement --
4 how critical this 1 cm deflection is.

5 DR. DEMPSEY: I am answer that. In terms of
6 having gone out on site visits, I can distinctly recall one
7 site that had the older type paddle where on all the
8 clinical films, we had one area of apparent unsharpness in
9 the geometric center of the film that we couldn't figure out
10 until we went in and looked at the machine and just put your
11 hand under it, and the whole center of the paddle bowed up,
12 so it is quite critical and it was obvious on clinical films
13 that there was an area of unsharpness.

14 So, in its most egregious areas of not meeting
15 specs, if you will, it can show on clinical films.

16 DR. SICKLES: Is it reasonable -- I am asking this
17 question not know the answer -- but is it reasonable in the
18 time period between now and when this might be implemented
19 to develop a specification that might be agreed upon by
20 reasonable individuals as working? We seem to be faced with
21 an impossible situation of deciding our specification for
22 which there is no good test.

23 I think it is imperative that we have a good test,
24 and I think we just have to develop one quickly and field
25 test it quickly, and then that is what will be used.

1 DR. MONSEES: I think the important thing is that
2 whatever it is, it has to have clinical implications because
3 if it doesn't, it is a test that really has no purpose. So,
4 something needs to be developed before the inspectors go out
5 in the field and start trying to interpret this on an ad-hoc
6 basis, I think.

7 DR. FINDER: Let me address a couple of issues
8 that have been brought up. The first refers to the
9 regulation, and there is a requirement that the paddle not
10 deflect more than 1 cm in those situations in which it was
11 not designed to do that. There is another requirement that
12 talks about if the paddle itself was designed to act
13 differently than it is supposed to.

14 Basically, it comes down to the very
15 commonsensical requirement of if it is supposed to do
16 something, it was designed to do something, it should do it.
17 The 1 cm was discussed in the previous committee, and that
18 is the requirement.

19 The issue that comes up is how do you test against
20 it, and in the original proposal, there was a test method
21 that was put forth, it was removed in the final regulations
22 for the reasons that were described. We are dealing with
23 some organizations to come up with an acceptable or
24 reasonable test that we can put in guidance to allow people
25 to understand what we mean by this and how to meet it, but

1 again, it is only going to be guidance, it will one way that
2 you can meet this test.

3 As with many of the tests that are required in the
4 regulations, there is no specific formula on how to do it
5 because we were advised to give flexibility, so that people
6 could do other things. That is why it is not in the
7 regulations. That is why we took it out.

8 It allows people more flexibility, it makes life
9 harder in the sense of, well, if somebody comes up with
10 something new and different, is it acceptable, but we felt
11 that in order to give facilities flexibility to innovate, we
12 would have to deal with that.

13 DR. MONSEES: Now, pertaining to the time line
14 here, I don't know how important this is, but if the
15 manufacturers feel that in view of the fact that this is
16 ambiguous and that it may change whether or not the existent
17 paddles would end up meeting these inspection requirements,
18 that could be a problem out in the field come April 1999,
19 maybe we would have to go back to what we discussed last
20 time, and that is maybe not inspect for it until the
21 manufacturers would have a chance to retrofit the units. I
22 don't know whether we should discuss that or not.

23 DR. SICKLES: Absolutely, you don't want to be
24 inspecting for something where 50 percent of the equipment
25 out in practice would have to be thrown out, because then

1 you would be shutting down facilities, but I think what we
2 should try to achieve, as quickly as possible, is -- and it
3 doesn't have to be written in stone -- I think all we need
4 is one acceptable method in a guidance document to show what
5 might work.

6 That should not limit other possible methods, but
7 the difficulty here that I am concerned about is the person
8 who is being too strict in applying these rules, not the one
9 who is being too lenient, but too strict in applying the
10 rules, who is going to cause facilities unnecessarily to
11 replace very usable equipment.

12 If there is one acceptable method that you have
13 validated, so that, you know, if you got back a report from
14 your physicist or whoever is doing the testing this doesn't
15 work, at least you could try that method and see whether it
16 did work.

17 DR. FINDER: That approach is exactly what we are
18 taking. I don't want to get into too big a detail, but this
19 meeting is ending Tuesday, we are having a meeting on
20 Wednesday to discuss this exact issue with various groups,
21 so I believe that we will be able to put out some guidance.

22 Actually, while the test method originally
23 proposed was not necessarily validated, it at least can give
24 people some idea of the thinking that was involved in this,
25 so they do have something, but I agree with you. The idea

1 of having some more guidance on this is appropriate.

2 DR. MONSEES: Any other comments on this issue?

3 Do the manufacturers have any concerns that they need to
4 vocalize at this point pertaining to these compression
5 paddles and some of this rule which seems to be -- pardon me
6 -- use the word flexible or ambiguous or wobbly?

7 MR. SANDRIK: Given the opportunity, I will take
8 it. John Sandrik, GE Medical Systems.

9 One thing in particular that I noticed in the
10 guidance document that was brought up was something that was
11 totally unexpected from previous documents. It talks about
12 going to a maximum system force when doing this test.

13 The proposed regulations talked about going to the
14 maximum power-driven compression. The final regulations did
15 not say to any level of force, and the guidance went to a
16 maximum system force which could be certainly a worst case
17 possibility than anything we have even considered before, so
18 this is news to the manufacturers that only came out a
19 couple of months ago compared to what we have seen before.

20 Certainly, the ambiguity here of what the intent
21 is, is a major problem. We are trying to react to design
22 paddles or upgrades that will suit the purpose when we don't
23 know what the purpose is, because we have looked at various
24 tests. Essentially, we shrink-wrap a paddle around some
25 sort of test object, and I don't know if that is what you

1 want, or you are talking about really mechanical looseness
2 of the attachment of the paddle to an arm or to the gantry
3 or whatever as far as this limitation in motion.

4 We have issues where if the paddles are too stiff,
5 they are uncomfortable, if they are too thick, they are too
6 attenuating, if they are too thin, they will tend to deform
7 around some object, particularly if that object is a golf
8 ball versus a sponge, and there is absolutely no definition
9 of how this test be done, and until we get some definition,
10 we can't design a test, and certainly we don't want to have
11 to design to every physicist's individual test on how this
12 should be done. We will never manage that. Thank you.

13 DR. MONSEES: Thank you. I think the FDA has
14 probably heard enough on this, do you think? Okay.

15 Other equipment issues? Yes.

16 MR. PIZZUTIELLO: I have a small related issue on
17 compression paddles, a different issue, and that is the
18 requirement that there be a separate compression paddle
19 sized to each image receptor and bucky, and I think it might
20 be helpful to clarify in the guidance document that -- let
21 me back up.

22 There are many machines that were originally
23 equipped with a single compression device or two buckies.
24 It was larger than the small bucky and smaller than the
25 larger bucky. I think it might be helpful to clarify that

1 facilities in that situation would need to get two new
2 compression paddles, so that each one close approximates the
3 size of the bucky rather than the one that the middle is
4 okay for one, and then buying a second one.

5 Does anybody have any different thoughts on that?

6 DR. MONSEES: Go on.

7 MR. PIZZUTIELLO: The next issue is the
8 decompression during power cutoff, which is 912(b)(3), and
9 the comment was raised earlier in the public comment section
10 is uninterruptable power supply acceptable to meet this
11 requirement. I think in one of the later documents, it
12 talked about one minute, which I thought was very sensible.
13 Was that in the newer document? Okay. It's on line 553 of
14 the B document. So, I personally think that is very
15 sensible.

16 DR. MONSEES: It is at page 16 of the B document.

17 MR. PIZZUTIELLO: I was thinking it is sensible.

18 DR. MONSEES: Right.

19 DR. SICKLES: Just one additional point. There
20 was a question in the presentation as to what the intent
21 was. I believe the intent here is just to make sure that
22 the machine won't injure the patient.

23 DR. MONSEES: Yes.

24 DR. SICKLES: And not to have some kind of a
25 system which prevents the machine from moving for the next

1 24 hours, which wouldn't cause any noticeable harm to
2 anything. So, I am very comfortable with the way you have
3 it right now, although if there is a driving need to
4 describe the intent as meaning patient injury, you could add
5 a phrase to clarify that.

6 DR. MONSEES: Does that clarify things for the
7 manufacturers in the audience who had a question about this?
8 Yes? Thank you.

9 DR. FINDER: I think we did, however, no
10 clarification goes without new questions, so now I have five
11 new questions based on this that we received, and given all
12 that we have said already, someone asked what about if you
13 turn off the switch intentionally, shut off the power
14 intentionally, should that -- because even with the power
15 back up, I believe it would necessitate how they hook up
16 that power backup to make sure that the unit doesn't move
17 when it isn't supposed to.

18 So, there are a series of questions. What about
19 if you just turn off the power switch, would you allow the
20 gantry to move in that situation? You hit the off switch.
21 Is that acceptable to have the gantry start to move?

22 The next one is if the user intentionally releases
23 the brakes, is that okay?

24 The third one is if the user presses the emergency
25 off button, is it okay if the unit starts to move?

1 The next one is if a failure occurs in the system
2 circuitry up to and including the brake assembly itself, is
3 that okay? And if there is just a power failure in the
4 room?

5 So, those are the five conditions they wanted
6 specific answers to their questions on. So, is it okay if
7 somebody turns off the on/off switch and the gantry moves by
8 itself, is that acceptable?

9 DR. MONSEES: Go ahead, Dr. Sickles.

10 DR. SICKLES: I am not going to be able to handle
11 this one too well, but I hope Patricia Wilson can help us
12 with this. The intent here is to avoid patient injury.

13 DR. FINDER: I would agree with that, and I think
14 that should be the guiding force.

15 DR. SICKLES: Therefore, in each of these
16 circumstances, why would somebody turn off the power? If,
17 in A, B, C, D, and E, the patient is in the machine when
18 those things occur, then, the patient should be protected.

19 If, in any of A, B, C, D, and E, there is really
20 no meaningful way that the patient would be in the machine,
21 then, I don't think it needs to apply.

22 DR. FINDER: I think the other thing to keep in
23 mind is the idea of intentionally. What was the person
24 intending who was taking the action? I think those two
25 things should be the guiding thoughts. So, now we have got

1 five questions.

2 DR. MONSEES: Yes, sir.

3 MR. PIZZUTIELLO: Two things. As a medical
4 physicist, I work on lots of different machines, some of
5 them I am really familiar with, some of them, I am a little
6 less familiar with, and there have been times when I have
7 gone, one of these machines that don't have any English
8 words, you know, everything has got symbols, and I once hit
9 the button that I thought was going to do one thing, and I
10 turned the power off to the machine.

11 Now, I am pretty dumb when it comes to those
12 things, but maybe other people might make that same mistake,
13 and if you had a patient who was under compression and you
14 had a technologist who wasn't familiar with that machine,
15 and she hit any one of the buttons that interrupted power,
16 you could be in a situation where the patient could be at
17 risk.

18 The second issue is how are you going to test this
19 sort of thing, and the easiest way to say it is when power
20 is interrupted, everything has to stay in the same place, so
21 that means whether you turn the switch off, whether you hit
22 the emergency off button, whether you yank the cord out of
23 the wall, that is how you test it, so I would favor the
24 simple approach.

25 MS. WILSON: I agree with Bob. I think that makes

1 no difference if the power is interrupted for whatever
2 reason, I think it needs to remain stable.

3 DR. MONSEES: Any other opinions on this one way
4 or another?

5 DR. FINDER: Let me just ask this situation
6 because as far as I understand it, there are machines out
7 there that when you shut off all the power, the gantry will
8 move. Now, from what I understood, that you would then be
9 saying that if you shut off the power, how long would it
10 have to stay unmoving?

11 DR. SICKLES: One minute.

12 DR. FINDER: One minute. So, if somebody hit the
13 off button by accident, you would still want it to stay
14 without movement for at least a minute. Okay.

15 DR. MONSEES: Does that address all five
16 questions?

17 DR. FINDER: Let's see. Emergency off button, you
18 would still want it to not move. Intentionally releases the
19 brake release mechanism for the gantry, would you tell him
20 that he has to wait a minute before -- that is an
21 intentional use.

22 DR. SICKLES: It doesn't have anything to do with
23 power

24 DR. FINDER: Those are the questions he asked.

25 Failure occurs in the system circuitry up to and

1 including the brake assembly itself, so I guess that is some
2 kind of malfunction. Can you force a machine to perform
3 adequately under all circumstances? So, you think that that
4 wouldn't be part of -- or do you, the requirement?

5 DR. MONSEES: Who is to say how it is going to
6 behave when it malfunctions?

7 DR. FINDER: Right.

8 MR. PIZZUTIELLO: You can go nuts on that,
9 uninterruptable power supply could also fail

10 DR. FINDER: Exactly. So, basically, as far as I
11 get the committee's thoughts, if you hit the on/off switch,
12 you hit the emergency off or if there is a power failure,
13 under those three conditions, it should stay at least for a
14 minute.

15 MR. MOBLEY: Repeat your last one there, before
16 you gave us the list of the ones that you thought we had
17 agreed on. What was your comment on --

18 DR. FINDER: The power failure or the assembly --
19 excuse me -- the system circuitry or the intentional release
20 of the brake?

21 MR. MOBLEY: No, the intentional release of the
22 brake, what was right after that? You mentioned something,
23 you had a litany of things.

24 DR. FINDER: Well, it is intentional release of
25 the brake, you hit the on/of switch, you hit the emergency

1 off switch, a failure occurs in the system circuitry up to
2 and including the brake assembly itself, or there is a real
3 power failure to the room. Those are the five.

4 MR. MOBLEY: No comment.

5 MR. NISHIKAWA: Are you talking about changing the
6 regs or is this in the guidelines?

7 DR. FINDER: This would be guidance because it
8 says in the regs that the gantry shouldn't move. The
9 question is for how long and under what conditions, so it
10 would be guidance basically.

11 DR. MONSEES: Any other comments on this issue?
12 Let's move on. Any other equipment issues? Yes.

13 MR. PIZZUTIELLO: The next equipment issue is on
14 page 16 and 17 of the B document. This relates to
15 measurement of the light field, and I think there needs to
16 be again some way of determining how that measurement is
17 going to be made.

18 If you make a measurement of a light field in the
19 full room light, you are measuring the room plus the light
20 field of the collimator, that doesn't seem to be very
21 sensible. I think what you are looking for is the light
22 level that is specified 15-foot candles above the background
23 light level, and I think that the guidance should suggest
24 that that be the way it be tested.

25 Another item that is on line 616 of the light

1 field is it is recommended that the facility add this to the
2 list of items to be examined by the physicist during the
3 survey. I think that is really a general issue that relates
4 to all the equipment requirements. Who is going to assess
5 these, whether it be the compression paddle, the light
6 field, some of the other things?

7 I think that there needs to be some communication
8 to the facilities to say make sure these are evaluated and
9 perhaps you should have your physicist evaluate them. It
10 goes again to the question I raised just before lunch.

11 You need to communicate to the facilities who have
12 responsibility for compliance that they need to make sure
13 that they assess compliance, and then the question is when
14 the inspectors come around, are they going to just look for
15 a physicist assessment that it has met requirements, or the
16 inspector is going to go then and reassess compliance with
17 their own test and duplicate the work of the medical
18 physicist, which I would say would be redundant.

19 DR. MONSEES: Any other comments? Do you have any
20 other issues pertaining to equipment? Anybody else on the
21 panel have any issues while he is thinking of that? Yes.

22 MR. NISHIKAWA: Document B, page 16, line 533-534.
23 The term image receptor refers to the film. As a physicist,
24 image receptor means to me the screen and the film. I don't
25 know why this question is in here, but to me I find it --

1 DR. FINDER: The reason it is in here is because
2 people have asked what do you mean by image receptor, so we
3 have given the definition. The definition is not from MQSA.
4 It turns out that it is in the performance standard already.
5 It has been defined this way for 20-plus years. So, we are
6 just taking that definition, so that people understand what
7 we mean by it.

8 MR. NISHIKAWA: Okay. Also, in Document A,
9 sometimes there is a reference specifically to screen-film
10 systems and sometimes there is no reference to any type of
11 detector at all.

12 If there is a reference to film-screen system, I
13 don't have a problem. If there is no reference to any type
14 of detector, does that mean it applies to all imaging
15 methods or just filter screen-film systems?

16 DR. FINDER: In fact, if I am not mistaken, there
17 is an overall statement for these things that these apply to
18 film-screen systems, and then again there is a separate
19 section that talks about the fact that if it is non-film-
20 screen, you have to follow the manufacturer's tests.

21 MR. NISHIKAWA: There is one spot in here, I have
22 to find it, where it specifically talks about films from a
23 digital system. I can't find it. Anyway, on page 34, they
24 talk about film processing right at the very bottom.

25 DR. FINDER: In the second document?

1 MR. NISHIKAWA: Document A, page 34.

2 DR. MONSEES: Are you talking about chemical
3 solutions?

4 MR. NISHIKAWA: I probably misinterpret this, but
5 my point is that for films produced from a digital system,
6 hardcopy of the digital image, they may be using film that
7 uses a different chemistry than the main processor of the
8 mammography area. I just point that out, that you would
9 need a separate processor.

10 DR. MONSEES: Yes.

11 MR. PIZZUTIELLO: On that same item, on page 35 of
12 the A document, the question is film processing solutions
13 must be essentially equivalent to what the manufacturer's
14 specification is. I think that that is going to be
15 extremely difficult to obtain that information from the
16 manufacturers.

17 We have been trying for years to get x-ray film
18 manufacturers to specify conditions, and they have been very
19 reticent to do that. This would be ideal. Another way
20 perhaps to consider assessing the equivalence would be to
21 look at the characteristics that we can measure.

22 For example, if we know that the dose to a phantom
23 under certain conditions is a certain number, and then you
24 replace it with a different chemistry, and the dose is very
25 similar, then, you might say that the speed is comparable.

1 If you could measure the contrast, whether it be with a
2 simple measuring of the difference in the disk on the
3 phantom, or a better way would be to use a gamma plot
4 measurement, if you find out that characteristic of a film,
5 measured in the field, then, you change something like the
6 chemistry, and you obtain similar data, and I would say you
7 would have established equivalence.

8 So, I would like to see the guidance document
9 reflect not only data from the manufacturer, but also field
10 measurements that could be made to demonstrate equivalence.

11 DR. FINDER: Would you like to give some examples
12 later, you know, just hand me some.

13 MR. PIZZUTIELLO: Sure.

14 DR. MONSEES: Yes.

15 MR. MOBLEY: While we are there, I want to comment
16 on a number of the answers there, and I guess this is
17 somewhat in support of what Bob was saying. It bothered me
18 that the best answer we have is that one mechanism to
19 establish compliance would be to have documentation from the
20 manufacturer, such as advertising material.

21 I guess my experience in matching equipment or
22 protection needs or these kinds of things in a technical
23 arena is that advertising material is usually not very
24 beneficial. It is going to do all things for all people,
25 just buy it and try it, but then when you buy it and try it,

1 you find that, oh, yeah, for this energy I have got to do
2 these things or I have got to make this adjustment or
3 whatever, it is not just as simple as just looking at what
4 the advertising material is.

5 I was looking for something I guess along the
6 lines of what Bob is saying they have been asking for. It
7 just seems like to me there needs to be very specific
8 requirement of you have got to use the developing solution
9 or the developing technique or process that that film is
10 designed for.

11 I don't know how you get away from that. It
12 bothered me to see that, and it is repeated down in there a
13 number of times, and at one point there is a suggestion that
14 maybe they should contact their medical physicist for advice
15 and assistance, and I just think that is -- it just seemed
16 like that we were just kind of, you know, you ought to use
17 something that is good for the film that you are using.

18 It wasn't really as critically handle as I think
19 the issue is.

20 DR. FINDER: I think one of the issues we were
21 trying to deal with is the situation where a manufacturer
22 says that only their solution or their film, or whatever, is
23 the applicable one, in which case you have locke somebody
24 into just using that one manufacturer, and we tried to give
25 some flexibility here because we know that facilities using

1 different processing chemicals and different films, and
2 mixing and matching, and what we were trying to do is get
3 some kind of system where if they were going to do that,
4 that they would at least look to make sure that what they
5 were doing was appropriate.

6 Now, if the guidance doesn't make that clear
7 enough or there could be better ways to say that, we are
8 certainly open to any suggestions.

9 MR. MOBLEY: I think that what you just said was
10 better than what is said here, and that is, I mean that if
11 you go with a film and you don't want to go with that film
12 manufacturer's specific material, then, you have got to have
13 somebody come in or you have got to have somebody on staff
14 that can do this to determine that what you do do is as good
15 or better than going with the manufacturer's solutions or
16 whatever.

17 MS. WILSON: I have a question for Bob. What
18 would think about documenting the average gradient and
19 background density to address this issue?

20 MR. PIZZUTIELLO: I think that average gradient is
21 really not a very sensitive indicator. It is only two
22 points on the curve, and they don't really represent two
23 points that are used all that much in the clinical
24 mammography area. They are really a little bit too light.
25 So, I think that that is the crudest way, but it would not

1 be my preferred way to do it.

2 At least if you are measuring density difference
3 across the contrast disk, that is in the region of the way
4 mammography film is used, and that is easy to do, but the
5 best way to do it would be to do a gamma plot which looks at
6 how the contrast changes in the film. That might be a
7 little sophisticated to require, but it could be in the
8 guidance document, it would get people to do that.

9 DR. MONSEES: It certainly wouldn't be too
10 sophisticated for the physicist to do.

11 MR. PIZZUTIELLO: Absolutely not.

12 DR. MONSEES: Do we have comments in the audience?
13 Yes.

14 MR. UZENOFF: Bob Uzenoff, Fuji Medical Systems
15 and also I am an expert on the Isotechnical Committee 42
16 Photography Working Group 3, Sensitometry. TC-42 Working
17 Group 3 has this summer adopted as an item of work looking
18 into a standard sensitometer for assessing the performance
19 of processing of medical radiographic films.

20 The issue is an important one, and one that we
21 realize for commercially available sensitometers now you can
22 get quite different results in average gradient. They are
23 not all matched together for speed, and for average gradient
24 you can get quite different results from one brand of
25 sensitometer or model of sensitometer within one brand.

1 So, I don't know that it has been so much of a
2 problem with the physicists' help in assessing what
3 performance is like, what the manufacturer intended, but I
4 would be careful at this point about getting too
5 quantitative about measurements on commercially available
6 sensitometers. It is not quite there yet.

7 DR. MONSEES: Thank you. Yes.

8 MR. PIZZUTIELLO: That is one of the benefits of
9 the gamma plot, is it is relatively insensitive to the
10 sensitometer, but Bob Uzenoff makes a good point.

11 DR. MONSEES: Was there another comment? Yes.

12 DR. DEMPSEY: Just one more comment. This whole
13 area is a bigger can of worms, I think, than a lot of people
14 realize. The physics people at our place finished a series
15 of experiments, and I don't know whether it is published
16 yet, which they took all the available mammography films,
17 but processed them using I think it was upwards of 20
18 different manufacturers of chemistry.

19 The results were rather astounding, and so this is
20 a much thornier issue, again to start putting numbers on it
21 might be more than what the FDA wants to do.

22 DR. MONSEES: Do you want to continue with
23 equipment issues?

24 MR. PIZZUTIELLO: I have nothing further.

25 DR. MONSEES: Any other equipment issues from the

1 panel, please?

2 MR. MOBLEY: I have several. We are on 34, and
3 some of these questions, maybe not so much guidance, it is
4 just seeing that maybe there is a problem with the standard.
5 The A document, page 34, the first question, "How much
6 variability from normal optical density setting must the
7 system provide," and the answer is, "The regulations do not
8 specify the range of variability that must be provided, only
9 that some variability be available."

10 If it is that broad, that just does not seem to be
11 some variability, that is an amazing thing. I will just
12 leave it at that comment.

13 Page 33, I answered that one. Page 28, the answer
14 at the top of the page there, the answer is or the last
15 statement of the answer is, "The decision on whether to use
16 the magnification still rests with the facility." Are we
17 talking about the facility making that decision, or does the
18 operator make that decision?

19 DR. FINDER: I think the term "facility" was a
20 global process. It is not the operator necessarily, it may
21 be in most cases, one would hope it was the interpreting
22 physician who decided to ask for magnification. So, rather
23 than specify individuals, we just said the facility.

24 DR. MONSEES: It is a group decision.

25 DR. FINDER: A democratic decision.

1 DR. MONSEES: The other one is actually kind of
2 comical, the one that you brought up, that don't specify the
3 range of variability, so in other words, if you go to a plus
4 density setting, and it gives you a minus, that is
5 variability, but would be in the wrong direction. It is
6 kind of laughable, isn't it.

7 DR. FINDER: I think it came down to the fact that
8 there was no easy way to define a reasonable amount of
9 variability.

10 MR. MOBLEY: It just seems there should be some
11 range that you can say here is the number, otherwise, the
12 number may be plus or minus, it may be --

13 DR. MONSEES: At least that it should be
14 stipulated that -- perhaps it is enumerated that it
15 increases your exposure time by such amount or whatever, I
16 don't know, but at least it should be stipulated what the
17 specs are. Don't all the manufacturers have specs that say
18 if you go to a different density setting, what happens with
19 the exposure time?

20 MR. PIZZUTIELLO: They don't do that because it
21 depends a lot on the film-screen combination that you have.
22 You have a higher contrast film, then, one step will make
23 more of a difference in the density.

24 DR. MONSEES: But is there a range?

25 MR. PIZZUTIELLO: But they generally specify the

1 MAS variability and it is generally in the 10 to 15 percent
2 range per step.

3 MR. MOBLEY: Page 27, the answer at the top of the
4 page, the last two items in the answer, in particular, the
5 last sentence says, "A medical physicist may be consulted
6 regarding the appropriateness of the technique to the x-ray
7 unit."

8 As I read that requirement, it just seemed like to
9 me that it wasn't something where they may be consulted, but
10 it just seemed like to me that they shall be consulted or
11 whatever. I mean as I see it, you are asking for some real
12 critical decisions there that I think the physicist ought to
13 be the one or should be certainly one of the ones involved
14 in making that decision.

15 DR. MONSEES: Does anybody have any comments on
16 that? I saw a hand up in the audience.

17 MS. HEINLEIN: A question, the wording in the
18 final regs states that, "Systems used to perform non-
19 interventional problem-solving procedures shall have
20 radiographic magnification capability."

21 Now, my question is when they are talking about
22 non-interventional problem-solving procedures, does that
23 mean if someone is called in to a facility for, say, a
24 diagnostic workup, or perhaps the diagnostic workup is doing
25 a 90-degree lateral projection or maybe a roll view or

1 something like that, that is actually not magnification, but
2 they are doing that, would they be able then to schedule
3 that as diagnostic mammograms as problem-solving procedures?
4 I am trying to get the distinction between is problem
5 solving only tied in with magnification, in other words, the
6 unit that they have there, if they called them back to do
7 90-degree laterals or roll film, would they have to have the
8 ability to have a 0.1 focal spot?

9 DR. MONSEES: From my point of view as a
10 radiologist, it is hard to know what you are going to need
11 when you are doing that problem solving, and if you call a
12 patient back -- I am sorry? We will Dr. Sickles answer
13 that.

14 DR. SICKLES: I think we can answer your question
15 because it is actually in this draft which you probably
16 don't have.

17 MS. HEINLEIN: I have A.

18 DR. SICKLES: Then, look on page 27, the last
19 question right at the bottom.

20 DR. FINDER: She doesn't have B.

21 MS. HEINLEIN: I have this one. It says --

22 DR. SICKLES: But I think your question is
23 answered in that response, and what they are saying is that
24 it has to be available, but it doesn't have to be used in a
25 given circumstance, and the radiologist-technologist

1 combination of them can decide for which patients you need
2 to use the magnification and for which you don't.

3 MS. HEINLEIN: So, therefore, anyone that does any
4 type of problem-solving mammography, must have magnification
5 available.

6 DR. SICKLES: That is written for the regs.

7 MS. HEINLEIN: The reason I bring that up is I
8 have had a few places say, well, we call them back to do
9 problem solving, but we don't do mags, so therefore, do we
10 have to have a 0.1 focal spot, if we know we are not going
11 to do mags, obviously, because you don't have a 0.1 focal
12 spot, but I mean if we are calling them back, if we are
13 scheduling to come in for a diagnostic mammogram because we
14 see something and we are going to do additional views, do I
15 have to have magnification capabilities?

16 DR. SICKLES: The regulations say that you must,
17 and for that facility to want to do problem solving without
18 it, they would have to seek redress in a change in the
19 regulations, not in the guidance, because the regulations
20 state that you must.

21 MS. HEINLEIN: I am just getting clarification on
22 that.

23 DR. MONSEES: As a radiologist, I would like to
24 say that I think that that is important because when you are
25 calling a patient back for problem-solving mammography, you

1 don't know what views you are going to need, and you don't
2 want to call a patient back and not have that capability
3 available in the evaluation of the patient, so I think it is
4 in the best interests of the patient that it be available
5 when they return.

6 MS. HEINLEIN: And I agree. I wanted to make sure
7 that the FDA was giving that same feedback because there was
8 a distinction on their definition of problem solving.

9 DR. MONSEES: Thank you for pointing that out.

10 DR. SICKLES: Just to further what Barbara says, a
11 facility that is posing that question to you, which you
12 posed to us, I would suggest should rethink their practices
13 and maybe not do mammography, because they ought to know
14 better.

15 DR. FINDER: Let me just be clear. Now we have
16 guidance and we have in the second guidance on page 17 and
17 18, let's address that question, and it says at the bottom
18 of the page, line 630, "Screening facility schedules only
19 asymptomatic patients for mammography, our equipment cannot
20 perform magnification, are we permitted to perform
21 additional views on patients who report an abnormality or
22 area of concern at the time of the study, or who have an
23 abnormality detected on screening mammogram, what do they
24 do?" Is everybody okay with the answer that we have given
25 here?

1 DR. SICKLES: I think you gave a very good answer
2 to that question. It does come up. I think your response
3 is very good in that regard because it gives the facilities
4 who want to be able to basically convert a screening into a
5 diagnostic exam, the ability to do that according to this,
6 but it doesn't require people to do it if they choose not
7 to.

8 DR. FINDER: I know that you don't have this, so,
9 Rita, you don't know what we are talking about.

10 MS. HEINLEIN: I just borrowed it from the person
11 next to me. So, does this not just contradict what we just
12 said?

13 DR. FINDER: Wait a minute. Who gave it to you?
14 [Laughter.]

15 MS. HEINLEIN: Actually, I looked over their
16 shoulder, no one gave it to me. Pick any of these empty
17 seats, all these people, I am sitting next to one of those
18 people that has an empty seat next to them.

19 So, does that not contradict, that is what I am
20 saying, someone, of they call them back to do this workup?

21 DR. FINDER: This doesn't call back. That is the
22 issue.

23 MS. HEINLEIN: That is the issue. Okay.

24 DR. FINDER: That is the difference, and let me
25 just for the people in the audience, what we are talking

1 about is a situation where a patient shows up, is found to
2 have an unsuspected abnormality, can they do something at
3 that point, or do they have to send them to a different
4 facility to get a "diagnostic" workup, and the answer that
5 is given is if they believe that they can work this up
6 without magnification at that time, they should go ahead and
7 try and do that.

8 However, it also says that this is not the usual
9 case, you should not be scheduling these people, you should
10 not schedule a person for a diagnostic study unless you have
11 magnification capabilities.

12 MS. HEINLEIN: Then, I would suggest that in this
13 question, as it is worded on line 632, I would put the
14 question mark at the end of "at the time of the study," and
15 take out the, "or who have an abnormality detected during
16 the screening mammogram," because someone may have an
17 abnormality detected during the screening mammogram after it
18 was read that afternoon, and then called back. Do you see
19 the distinction?

20 DR. FINDER: I think it is fairly clear -- and
21 maybe we can make it clearer in the answer -- that we are
22 not talking about calling anybody back to do diagnostic
23 studies without magnification. It is not a call-back
24 situation, it is at that time, and I think we haven't made
25 that clear.

1 DR. MONSEES: Medicare has recently addressed this
2 issue, as a matter of fact, pertaining to patients who have
3 screens, and then an abnormality is detected at the time,
4 and then they are converted to diagnostics, and they are
5 asking that facilities track the number that are converted
6 in that way, so that there is no abuse.

7 MS. HEINLEIN: But still the concern I have is
8 with this wording, "or have an abnormality detected during
9 screening." Many people have screening mammograms that, as
10 you know, that then are batch read later on at the end of
11 the day. So, this was detected on the screening mammogram,
12 you see what I am saying?

13 DR. MONSEES: I understand your point, and I agree
14 with you.

15 MS. HEINLEIN: I just think that that has to be
16 clarified that the patient is not called back, but, you
17 know, I think the wording of "detected during the screening
18 mammogram," I think it would be better just to have the
19 actual question mark come right after, "at the time of the
20 study."

21 DR. MONSEES: I agree with Rita. Do you have a
22 comment to that?

23 DR. SICKLES: I was just going to agree with that.

24 MS. HEINLEIN: Is there a guidance document to the
25 guidance document, like Guidance A, Guidance B, Guidance C

1 document?

2 DR. MONSEES: That is the page that I handed out
3 to the people. I didn't give a copy to you either.

4 You don't have Guidance Document B yet. When is
5 that going to be on the web, by the way?

6 DR. FINDER: As soon as we finish this meeting, we
7 will take your comments into consideration and then go
8 through the process. It is going to take a little bit of
9 time to go out, but we wanted to get your opinion on
10 Guidance Document B before it actually goes out.

11 DR. MONSEES: So A is on the web, B is going to be
12 on the web soon, and then there is another smaller document.

13 DR. FINDER: So, that will be C, and then there
14 will probably be a D, and as we come up with more guidance,
15 we are going to try and get this out as fast as possible,
16 but we have to make cutoffs in terms of how many questions
17 we can answer. We can't keep delaying it because April is
18 coming around fairly quickly and we have got to get this
19 information out, but as we get new questions, there will be
20 more guidance issued.

21 DR. MONSEES: But eventually, it will be folded
22 into a single document that has an intelligible order, maybe
23 even a web site that you can interrogate with key words,
24 something really modern.

25 DR. FINDER: As it looks right now, the guidance

1 is of such voluminous quantity that a paper document really
2 is not going to be the most effective way to get this out.

3 DR. MONSEES: Pertaining to equipment issues.
4 Yes.

5 MR. PIZZUTIELLO: On page 28 of the big document,
6 there is a comment there about the magnification factors and
7 the way the equipment is used, and I think that needs to be
8 addressed relating to the performance testing when medical
9 physicists test their line-pair resolution of mammography
10 units. Many units have more than one magnification ratio
11 available, and we have found that in many cases, if you use
12 the largest degree of magnification, then, the unit fails to
13 provide the 11 and 13 line-pairs minimum requirement.

14 I would like to see the guidance documents specify
15 that the equipment needs to meet that requirement in the
16 normal mode of use, in other words, if a machine has, let's
17 say, a 1.8 and a 1.5 magnification capability, and the
18 physicist has come in and said we recommend that you use
19 this machine at 1.5, because that is where it meets the
20 requirements, and a facility does that, then, the machine
21 should be compliant.

22 Even though the machine is capable of being used
23 at a higher magnification ratio, as long as the facility has
24 decided not to use it that way, then, I think it should be
25 okay. I would like to see some guidance in that area.

1 DR. MONSEES: Any comments on that?

2 MR. MOBLEY: Let me understand exactly what you
3 are saying. Are you saying the machine would not have to
4 meet the criteria just because a facility chose not to use
5 it that way, but the machine has to be designed to operate
6 in a certain manner, so at another facility it would have to
7 meet the standard because they choose to use it differently?
8 Help me.

9 MR. PIZZUTIELLO: Sure. For example, the other
10 example is not only magnification ratio, but some machines
11 have more than one MA station for the small spot and more
12 than one for the large spot, so if you use the machine on
13 the small spot with the big MA, then, that focal spot is
14 usually bigger, so it may fail the line-pair resolution if
15 you crank up the MA all the way. So, just because the
16 machine has the capability to provide that, doesn't mean
17 that the facility has to use it that way.

18 So, if the facility has said we will not use it
19 this way, but it complies with the resolution requirements,
20 then, that should be acceptable. So, it should be up to
21 each facility to decide how to use its equipment in order
22 that it provides a reasonable image and also that it meets
23 the qualification.

24 DR. MONSEES: So, it would be very easy for them
25 to put in their policy and procedure manual that this is

1 what they are going to use, and then to provide
2 documentation pertaining to the line-pair resolution for
3 that particular method.

4 MR. PIZZUTIELLO: Yes.

5 DR. SICKLES: I have no problem with this, as a
6 matter of fact, I agree with that, but it does run contrary
7 to another issue which I would have to search for in here,
8 but somewhere in here, there is a question related to where
9 equipment has the capability to be used for magnification,
10 then, it has to meet certain standards even if the facility
11 states in its procedure manual that it won't use it for
12 magnification.

13 There is such a question in the guidance
14 someplace, I just forgot where it was, but basically, the
15 response to that was we don't care whether the facility says
16 they won't use it, if the equipment is designed to be used
17 in that way, it has got to pass the test. If you are going
18 to say that for one method, shouldn't you be consistent for
19 another, or should you drop the statement that is the
20 guidance that counters it?

21 Do you know this section I am talking about?
22 There is one somewhere. I will have to go look for it.

23 MR. MOBLEY: I will just take your comment, Ed,
24 and go back to Bob. Maybe I am having a conceptual
25 difficulty, I think I am, but you are saying that the

1 machine should only meet -- I guess what I am hearing is
2 what you are saying means the machine has to meet the
3 standard at all the different uses because any facility
4 might choose to use a machine in any number of different
5 manners?

6 MR. PIZZUTIELLO: No, I think I am saying the
7 opposite. I am saying that as long as a facility has a
8 clear policy that says we will not use the machine in this
9 mode, because the results aren't so good, then, that is
10 acceptable, as long as they can do magnification in a mode
11 that meets the requirements, and their procedures say this
12 is how we are going to do magnification, I think that would
13 be acceptable.

14 MR. MOBLEY: Facility X might use it one way, and
15 Facility Y might use it another way, and -- I am just trying
16 to think how does the manufacturer or how does anybody
17 understand how this machine is supposed to operate other
18 than going into the facility and looking at how they say it
19 is supposed to operate, and that is the way it operates.

20 MR. PIZZUTIELLO: The difference is that there are
21 two things. One is how the machine is designed, and the
22 other is how the machine is performing. So, when a
23 physicist goes into the field and makes a measurement, you
24 are measuring the focal spot as you have got on that
25 particular tube, at that age, and so on, and it may be when

1 the machine was brand-new it was okay to be used in all
2 these modes, but after three or four years, maybe the higher
3 MA focal spot no longer meets the requirements, so if the
4 lower MA focal spot meets the requirements, and the facility
5 says this is the way we will use it, then, they have made a
6 decision as to appropriately use the equipment.

7 MR. MOBLEY: Maybe I am getting confused with the
8 equipment standard now, but aren't most of the requirements
9 there required to be met over the lifetime of the unit?

10 DR. MONSEES: The lifetime of the unit or your
11 money back.

12 [Laughter.]

13 MR. PIZZUTIELLO: The question is does every
14 feature on the machine, the machine has more than one way of
15 meeting the requirement. As long as it can meet the
16 requirement one way, is that enough? Does it have to meet
17 the requirement under every possible way? We talked about
18 this earlier, I think, about the collimation when you
19 mentioned the collimation issue from GE's alternative
20 proposed standard.

21 You can't meet the collimation requirement under
22 every possible mode because nobody can do 24 x 30 field of
23 view in a mag mode. So, the clear sense was that when we
24 say that the equipment needs to meet a performance
25 requirement, it is the way it was supposed to be used.

1 DR. MONSEES: Do you want to tell us where it is?
2 Which document is it in?

3 DR. SICKLES: I found the thing I was talking
4 about. Go to page 32 on A, on the bottom. This is a
5 question that deals with AEC. Basically, the question talks
6 about a facility that performs only screening, and does the
7 AEC have to function in every mode in which the machine is
8 capable of operating even though the procedure manual would
9 say that it is only being used for screening, therefore, no
10 magnification, and the answer is yes, it still has to meet
11 the -- AEC has to work for magnification even though you are
12 saying you are not going to use it.

13 That flies in the face of the other
14 recommendation, and I think we ought to be consistent. If
15 we are going to be consistent with Bob's recommendation,
16 which I agree with, then, I think we might want to consider
17 changing the answer to this question, because I mean we are
18 basically then applying a double standard, we are saying you
19 can adjust it in this circumstance, but you can't adjust it
20 in that circumstance, and that does not make sense.

21 DR. MONSEES: Do you have a comment on this?

22 MR. PIZZUTIELLO: I agree with Dr. Sickles very
23 clearly. We need to make a decision as to how we are
24 interpreting it. Are we saying under all conditions
25 everything has to work, or under the clinical conditions?

1 DR. MONSEES: What is important is the clinical
2 conditions obviously.

3 MR. MOBLEY: I agree with that from an operations
4 perspective, that you want to assure this working in the
5 clinical conditions, but I still have problems from two
6 different directions.

7 One is how do I manufacture them -- and I am not
8 manufacturing machines -- but how do I manufacture a machine
9 so that it meets the standards under clinical conditions
10 when I don't necessarily know what those may be, because I
11 manufacture a machine that meet certain criteria as
12 developed as FDA or whoever, and there it is.

13 Then, from an inspection perspective regarding it,
14 then, how do I look to see whether this machine meets the
15 specifications that it is manufactured to or designed to
16 operate under if in every facility it can be different.
17 That is really difficult.

18 DR. SICKLES: I think I can answer both. The
19 first one is manufacturers obviously will have to produce
20 equipment that meets specifications with any possible use,
21 and if they are selling with magnification capability, then,
22 obviously, the AEC or focal spot size or anything else will
23 have to work according to specifications, so for the
24 manufacturer, it should be clear.

25 For the inspector, if we are going to allow

1 clinically relevant testing rather than just general
2 testing, but just clinically relevant testing, the inspector
3 can look to the procedures manual of the facility, and if
4 the procedures manual says this equipment will be used for
5 screening only, then, they will apply screening only tests
6 to that equipment, and I think that is very straightforward,
7 and an inspector shouldn't have trouble being pointed to,
8 you know, screening-only machine, look in our policy manual,
9 and therefore, you shouldn't be doing all these extra tests
10 on this machine.

11 DR. MONSEES: Then, perhaps there should be a
12 label on the machine that says "for screening purposes
13 only," just like there is a label that says that the unit is
14 accredited, maybe there should be specific labels that say
15 meets certain requirements if they are different then.

16 MR. PIZZUTIELLO: The other issue regarding
17 manufacturers is that we are talking about standard that is
18 being applied retroactively to equipment that was designed
19 before these ideas ever came to light, so that is why I
20 think we are looking really at the clinical implications.

21 With new equipment, when it comes out, every
22 manufacturer that I know of is now producing new equipment
23 that meets these standards under all conditions. Add that
24 to the fact that when the equipment is acceptance tested by
25 the medical physicist, it is going to be acceptance tested

1 according to these standards.

2 So, we are really looking at the specific case of
3 the universe of equipment that is out there, that is old,
4 that we are now trying to fit into comparable performance
5 standards as to new stuff, so I think it is reasonable to do
6 it in this circumstance.

7 MR. MOBLEY: That equipment is grandfathered, is
8 it not?

9 MR. PIZZUTIELLO: No, it has to meet these
10 standards, all equipment does.

11 DR. FINDER: There is no grandfathering of
12 equipment.

13 MR. MOBLEY: Aren't we by guidance changing the
14 regulation then?

15 DR. MONSEES: Can this be handled in a guidance
16 document?

17 DR. FINDER: To which regulation are you talking
18 about?

19 MR. MOBLEY: The one that Bob is addressing.

20 DR. SICKLES: I think, by guidance, you can allow
21 a facility to define specific uses for its equipment, and
22 require it to meet regulations only for those designated
23 uses, if the FDA chooses to allow this to happen, and it is
24 an FDA decision, but we can advise the FDA as to whether
25 this is advisable or not.

1 DR. FINDER: It depends on how the regulation is
2 written, what it says. If the regulation says all
3 equipment, under all conditions, that is what it says. If
4 it says under clinical conditions, it is under clinical
5 conditions. If it doesn't say, then, we have some leeway in
6 interpreting things, but there is not a lot.

7 Once it is down on paper, we don't have that much
8 say either, and that is why the process that was involved in
9 writing these regulations was so long and involved, and got
10 as much input as we could, because all these are
11 compromises, so, you know, you can look at it each time and
12 come up with another reason and say I don't like this
13 portion of the regulation, are we going to redo it, but it
14 went through its own process.

15 DR. SICKLES: What is the answer to the question
16 of flexibility here for the facility in terms of these regs,
17 specific regulations? Is there flexibility in the
18 regulations to allow it or not?

19 DR. FINDER: I would say depending on which
20 regulation you are talking about. If you are talking about
21 the AEC question, I think it is fairly clear that it refers
22 to various configurations. It is not under all clinical
23 conditions, but it has a different term in there, the
24 configuration. So, it talks about magnification, non-
25 magnification, it doesn't say under all conditions of

1 magnification, it just says under magnification, so it is a
2 little bit different than what we are talking about here,
3 under the focal spot for magnification and the resolution
4 requirements there.

5 I have some questions that when we finish this
6 discussion may not be answered, and we are going to have to
7 bring those up anyhow. I was hoping to get at least a few
8 things settled before I throw in a couple of zingers here
9 that came to us.

10 I just want to bring up a certain point that was
11 mentioned to me. In the proposal for the system resolution
12 under the mag mode system, there was a specification of 1.5
13 times magnification to be used or the closest value to that.
14 That was dropped in the final regs. So, we have people that
15 are asking several questions referable to this, at what
16 various magnifications do I measure this at, what is
17 appropriate, and where does the 11 and 13 line-pairs come
18 in, and they specifically asked in the magnification mode,
19 what is the justification for those, those values.

20 MR. PIZZUTIELLO: It's in the regs. You just said
21 that.

22 DR. FINDER: I know. That is an answer that I
23 give when I am very desperate. I hate to give an answer
24 that it is in the regs, and that is why it is, but they
25 asked what was the scientific justification for that 11 and

1 13 line-pairs when applied to various different
2 magnification modes.

3 DR. MONSEES: And that is in the QC tests, right?

4 DR. FINDER: The annual QC tests.

5 DR. MONSEES: We are still in equipment.

6 DR. FINDER: But they brought it up.

7 DR. MONSEES: We aren't there yet.

8 DR. SICKLES: There are articles in the literature
9 indicating line-pairs that can be achieved with
10 magnification, and 11 and 13 are lower than what is usually
11 in the literature. I mean they are lower than that. I can
12 think two publications -- they are old now -- by Art Haas,
13 demonstrating what one can achieve, but beyond that I don't
14 think you have a good answer.

15 DR. MONSEES: Any more equipment issues? Yes.

16 MR. PIZZUTIELLO: I have one other one. This is
17 not addressed in the guidance that I noticed. In the
18 section 912(b)10(2)(a), I will just explain it. It says,
19 "The size and available position and selected position of
20 the AEC detector shall be clearly indicated."

21 Now, on a lot of the older units that I see --
22 well, the new units, they all tell you very nicely on top
23 what the position is, there is LEDs, and so on, but on some
24 of the older machines, the way you tell is you reach under
25 with your hand, you slide the AEC detector back and forth,

1 there are three positions, and then you find the position
2 that you want. So, my question is, does that qualify as the
3 detector shall be clearly indicated, the position of the
4 detector? Is hunkering down or feeling with your hand
5 clearly indicated, does it need to be visually indicated?

6 DR. MONSEES: Go for it.

7 MR. MOBLEY: Having no knowledge whatsoever of
8 this issue, it would seem like to me that it would be
9 appropriate for it to be visually indicated, because aren't
10 they asking you to be able to visualize where that detector
11 is from above the plane? I mean you are saying you position
12 -- I mean I understand if you position that detector, then,
13 you know where it is when you position it, but what about
14 the next patient or the next --

15 DR. MONSEES: The next view.

16 MR. MOBLEY: That is the word, the next view. I
17 am having trouble with words today. How do you know where
18 it is without thinking back, well, I just set it here.

19 DR. MONSEES: In fact, that is an important thing,
20 that the technologist needs to do every single time they
21 make an exposure is to pick the proper photo timer position.

22 DR. SICKLES: Here, I would ask the question to
23 the technologists in the room, the intent, of course, is to
24 make sure that the technologist is setting it correctly, so
25 it is not being exposed by air or whatever.

1 If you were working with a machine that had such a
2 device where you could only tell photo cell location by feel
3 underneath, would you view that as being unacceptable, now,
4 in 1998?

5 MS. WILSON: Yes, I would. I would prefer to have
6 it visible from the top.

7 DR. SICKLES: Rita, do you have any thoughts on
8 that?

9 DR. MONSEES: Any comments from the audience?
10 Rita.

11 MS. HEINLEIN: I have to say that for me, feeling
12 underneath of it, you can feel the clicks, and so I am
13 comfortable in knowing whether that is in number one, number
14 two, or number three. So, I don't have a problem with that.
15 I think to support what Mike said, you know, there is really
16 two issues. One is the size and available position clearly
17 indicated at the x-ray input surface of the breast on the
18 compression paddle, and with that issue, yes, I think that
19 that is critical and you need to have the available
20 positions up there, and then the selected position clearly
21 indicated. It is not really clearly indicated by having
22 this little clicker underneath. I guess it is more of a
23 feel thing where you can feel the indentations.

24 It is better to have something at least on the
25 side that you can have a little mark that you know whether

1 you are in position one, two, or three, but I mean you can
2 tell by the indents. I feel comfortable with that, but I
3 think if I was new technologist coming into it, I would
4 probably have more difficulty and want to have a more clear
5 indication along the side or on the top.

6 DR. SICKLES: To the extent that an experienced
7 technologist might be able to do this especially having
8 worked with that particular machine for many years, no
9 problem, on the other hand, that same facility working with
10 this unit could easily hire a new person who had no such
11 experience, and therefore might be making mistakes right and
12 left.

13 MS. HEINLEIN: Correct.

14 DR. MONSEES: Yes.

15 MR. PIZZUTIELLO: I would agree with the latter
16 comments. I think that if you are really good and you are
17 really accustomed to a machine, feeling is just as good, but
18 we are really concerned about patient safety, repeats,
19 unnecessary exposure, and today, in 1998, I think it is not
20 standard for technologists to reach under and feel. Some
21 sort of visual reminder, sometimes it is just a reminder,
22 you say, oh, did I position the photo timer in the right
23 location. So, I would agree.

24 DR. MONSEES: Yes.

25 DR. DEMPSEY: I would agree with Bob's comments

1 because it is one of these out of sight, out of mind, and
2 even an experienced technologist may have had the photo cell
3 out to the furthest position, then, the very next patient is
4 a small-breasted patient, and the photo cell may be out over
5 air, unless they are visually reminded, because, you know,
6 you get busy and you forget that that last patient was all
7 the way out. I just think that it is a safety issue for the
8 patient that will prevent repeats.

9 DR. MONSEES: Yes.

10 MS. HEINLEIN: Just to add to that, it would be
11 interesting to get a feel from the manufacturers as to how
12 many, if this went into guidance, how many pieces of
13 equipment out there would then not fulfill that guidance
14 issue. I think there is a number of them.

15 DR. MONSEES: Are there any manufacturers in the
16 audience who are aware of a common piece of equipment that
17 is out that will not fulfill this requirement?

18 DR. FINDER: You don't have to mention names.

19 MR. PIZZUTIELLO: There are a couple of
20 manufacturers with equipment that was designed, I would say,
21 in the latter part of the '80s, early '90s, not significant
22 in terms of numbers, but there are a number out there.

23 DR. MONSEES: Do you have any other equipment
24 issues? We are going to go to break soon. Something that
25 we can discuss before we do?

1 DR. FINDER: No.

2 DR. MONSEES: Yes.

3 MS. BROWN-DAVIS: How do we address this issue --
4 don't have her name -- but the issue that the woman brought
5 to our attention about the cleaning of the equipment? How
6 does that get addressed?

7 DR. MONSEES: There is part of the guidance
8 document that should control, and we will be doing that. It
9 is coming up.

10 We have some available time tomorrow, you know,
11 and I imagine that we will be using that being that we are
12 only partway through the discussion of the draft document
13 today.

14 Are we done with equipment? Are there any other
15 equipment issues that we want to address when we come back
16 from break? Anybody else here have any equipment issues in
17 the guidance document that we should be talking about after
18 break?

19 Okay. So, we are going to go and we are going to
20 reconvene at 3:15, and when we do, we are going to be moving
21 to Quality Assurance, and General, and then Records, and
22 then will be moving to Quality Control.

23 See you at 3:15.

24 [Recess.]

25 **Quality Assurance and Quality Control Issues**

1 DR. MONSEES: Quality Assurance and then Quality
2 Control Issues. At the request of Eleanor Sherman, we are
3 going to look at facility cleanliness and infection control,
4 which is on page 56 of the Draft Guidance Document A, and
5 then the Small Entity Compliance Guide, pages 33 and 35
6 first, and then we are going to move to other quality
7 assurance issues, general, and then records next.

8 Let me have you turn to that, page 56 of the first
9 one. At the top of that page is facility cleanliness, and
10 then infection control, the second part. In your Small
11 Entity Compliance Guide, pages 33 and 35.

12 Does anybody have any comments about the guidance
13 document? "Facilities shall establish and comply with the
14 system specifying procedures to be followed by the facility
15 for cleaning and disinfecting mammography equipment after
16 contact with blood or other potentially infectious
17 materials. This system shall specify the methods for
18 documenting facility compliance with the infection control
19 procedures established and shall comply with all applicable
20 federal, state, and local regs, comply with manufacturers'
21 recommended procedures. If adequate manufacturers'
22 recommendations are not available, comply with generally
23 accepted guidance on infection control until such
24 recommendations become available."

25 Yes, Ms. Hawkins.

1 MS. HAWKINS: I would just like to ask for FDA's
2 response to the information that was presented this morning
3 from Ms. Sherman related to manufacturers, you know, their
4 guidance, and so forth, as far as equipment is concerned.

5 DR. FINDER: In terms of the material that was
6 presented today, I cannot speak to the individual items as
7 to what the manufacturers had in their manuals. Some of the
8 things that were presented seem not to apply to what we are
9 requiring here in the sense that they would not fulfill, to
10 my way of thinking, an adequate cleaning. But I can't
11 address the individual specific things because I haven't
12 seen the entire documents that are referenced in that
13 presentation.

14 I think it is important to point out the fact, the
15 third clause here, that if adequate manufacturers'
16 recommendations are not available, that there are other
17 methods that the facility is supposed to follow in terms of
18 the guidance that is available out there from other sources.

19 DR. MONSEES: This is also, if you will notice in
20 the answer to the question, it says, "Disinfecting
21 mammography equipment that has come in contact with blood or
22 other body fluids." In having an extensive conversation
23 with Infection Control individuals at our hospital and our
24 medical school, they looked into this and consider this a
25 very low risk situation. We are not talking about high risk

1 situation here. We therefore have to, I think, be very
2 careful about how we dictate what is going on here.

3 I think since this is low risk, and since most
4 facilities know how to deal with standard low risk
5 procedures, and there are OSHA regs pertaining for
6 bloodborne pathogens, but most of the time we are not
7 talking about bloodborne pathogens, because there is no
8 blood, there is no body fluids.

9 MS. SHERMAN: Doctor, that is absolutely untrue,
10 and I am going to take exception to it.

11 DR. MONSEES: I think that we would like to hear
12 from the panel on that. Thank you.

13 Anyway, I think it is a fairly low risk situation.
14 Yes, it can happen, but it is fairly low risk.

15 Yes, sir.

16 DR. DEMPSEY: I would like to ask Dr. Finder, in
17 the FDA's role as probably hearing a lot of perhaps
18 anecdotal reports one way or the other, is there anything
19 officially on record of transmission of HIV or hepatitis
20 through mammography procedures that you are aware of?

21 DR. FINDER: That I am aware of, no.

22 DR. MONSEES: I would like to ask some of the
23 other practicing radiologists to make comment, whether they
24 think is a high risk situation.

25 DR. SICKLES: I, too, have asked our Infection

1 Control people about the issue, and I basically got the same
2 response that you did, that in a situation where you can
3 identify an individual where body fluids reach the machine
4 or where there is a chance that they might reach the
5 machine, then, obviously, you would want to go through the
6 appropriate steps, but in most circumstances, the great
7 majority of patients, that would not occur.

8 Now, that does not relieve the facility from the
9 obligation to keep the equipment clean, which is different,
10 that is a different situation, but it is not a high risk
11 situation where 80 percent of the women going through the
12 equipment are going to get infected by the equipment, no,
13 that is not happening. If it were, we would know about it,
14 because there would be a clinical problem that would have
15 surfaced, and it hasn't.

16 DR. MONSEES: Yes.

17 DR. MENDELSON: From my own experience, I would
18 concur with Dr. Monsees' and Dr. Sickles' opinion, and it
19 does come up in other areas of imaging, as well, in
20 ultrasound, for example, where the transducer contacts
21 patient's body and skin, there may be further opportunities,
22 and that also is considered low risk.

23 In terms of body fluids, I think that the
24 regulations are specific in the disinfection of whatever
25 comes in contact through the OSHA regulations, and for

1 mammography, it might be ulcerated skin where there is some
2 bleeding, it might be nipple discharge that is elicited
3 through compression, and there, I think extra precautions
4 are taken according to the manufacturer's recommendations
5 for cleansing the unit.

6 MS. BROWN-DAVIS: But we saw this morning that the
7 manufacturers' recommendations for cleaning seemed to be
8 little better than what I do -- I probably would do more for
9 a household bathroom. This concerns. I mean I am not an
10 expert, but it certainly does sound like there needs to be
11 something a little bit more. I don't know, aren't there
12 levels of cleaning that go in hospitals?

13 DR. MONSEES: Yes, and there are chemicals that
14 are used that are recommended in individual facilities. One
15 of them that we have used was commented on, that is causes
16 asthmatic attacks, and things like this, but to my
17 knowledge, we have never had anybody with upper airway
18 difficulties after that is used. I mean if you sprayed it
19 in their face, I suppose, but it is very effective, it is a
20 very effective cleanser.

21 Yes.

22 DR. DEMPSEY: I am sure Ellen and Ed would concur,
23 but at each institution you have an Infection Control
24 Division that comes around, looks at the situation, and
25 approves the methods, and proves that the methods you are

1 using are effective methods to take care of cleaning and
2 disinfecting, and that has to go across the board with all
3 sections, not just mammography.

4 DR. MONSEES: That would pertain to hospitals.

5 DR. DEMPSEY: Sure.

6 DR. MONSEES: But it does not necessarily pertain
7 to office practices.

8 DR. DEMPSEY: I understand that.

9 DR. MONSEES: Which should have their own policy.

10 DR. DEMPSEY: But I am saying that an office
11 practice could go to a recognized institution and find out
12 what procedures they use and such, and do those, but again,
13 the ones that we use are verified by the Infection Control
14 team that inspects us on a regular basis.

15 DR. MONSEES: To answer your question
16 specifically, after looking and speaking with our Infection
17 Control people and some of the chemicals that are used,
18 sprays that are put both on the receptor plate and on the
19 compression plate, they are very effective, highly
20 recognized as being bactericidal, and I am not sure that
21 there is as much concern out there as was voiced this
22 morning. I will give Ms. Sherman a chance to speak again.
23 Do you have another comment?

24 MS. HAWKINS: I just want to this, for some
25 interpretation here. As I am looking at the breakdown of

1 inspection findings, and is this one that would fall under
2 the annual physicist survey or the processor QC?

3 DR. MONSEES: No.

4 DR. SICKLES: This is the technologists.

5 DR. MONSEES: This is something that needs to be
6 in the policy and procedure manuals that are apply to
7 facility, but it is not inspected by the actual process of
8 doing it is not inspected by the inspector. He will look at
9 the policy and procedure manual, and the physicist will not
10 inspect that.

11 MS. HAWKINS: So, under the process of QC, if
12 there were deficiencies, it would be under that category, is
13 that correct?

14 DR. MONSEES: I am not sure. How would it be
15 cited under what process, but if you don't have a procedure,
16 you will be cited.

17 DR. SICKLES: If it is not in your procedure
18 manual, you should be cited. In terms of how it might come
19 up if there were noncompliance, certainly, if a patient, as
20 a consumer, didn't have it done when it should have been
21 done, then, that would generate a complaint, which if she
22 had an open sore, would be a serious complaint, and then
23 there is this whole serious complaint mechanism that would
24 have to get worked into. So, that is certainly one way that
25 it might surface.

1 But this is an issue that the technologist is
2 supposed to be doing on an ongoing basis, and if it is in
3 the policy and procedures manual, the technologist should be
4 doing it. I am not sure -- and you can address this -- but
5 I am not sure how the inspector validates something like
6 this.

7 DR. FINDER: Well, there is a question or at least
8 a proposed question for the inspection where they would
9 check to see if there is the SOP for infection control.

10 MS. HAWKINS: See, I am just looking at this as
11 the level of findings, because under the process of QC, the
12 fiscal year for FY '98, and we are just going up through
13 March 31st, what you are looking at, almost 6 percent of the
14 findings, you know, being in that category. These are level
15 1, serious findings. I am just wondering if that is some
16 sort of an indicator that there may be problems in
17 facilities.

18 DR. FINDER: No, those results are not based on
19 this question, because this question doesn't exist in the
20 interim regs at this point, so you can't use those numbers
21 to judge the future.

22 MS. WILSON: I just would like to add that from my
23 experience, technologists are very eager to do everything
24 they can to protect the patients, which, in turn, protects
25 themselves from contracting anything.

1 DR. MONSEES: I agree with that, yes.

2 MR. PIZZUTIELLO: Another issue that was raised
3 this morning in the first presentation was that the cleaning
4 chemicals that are used may affect the integrity, the long-
5 term integrity of the compression paddle. That is a
6 different issue from infection control. It is an important
7 issue in terms of the performance of the paddle and whether
8 it cracks or not, but it is a different issue from
9 infection.

10 So, the first issue is do you do some kind of
11 cleaning that takes care of the infection issue, and then
12 the second is whatever chemical you use, is it going to
13 compromise the performance of the equipment in other ways.
14 It seems to me that since these regulations regulate
15 facilities, and not manufacturers, that it is difficult, and
16 the ideal situation would be to say manufacturers must
17 provide this information, but the regulations can't do that,
18 because the regulations are for facilities.

19 So, what it says is either you get recommendations
20 from the manufacturer or you come up with something on your
21 own. I think that is very reasonable.

22 DR. MONSEES: I will give you two minutes to make
23 your point, Ms. Sherman.

24 MS. SHERMAN: I don't know why I have two minutes
25 and the other people had unlimited amounts of time. I find

1 that interesting.

2 My name is Eleanor Sherman, and I have been here
3 since 1991. It is no longer an option. It has been
4 documented. The FDA has a policy. I really don't care what
5 some third-party person said their opinion is. The fact is
6 Dr. Jacobson, who is the head of CDRH, has acknowledged this
7 is a serious risk, and to make light of it, I think is
8 unfair to 25 million women who are exposed. Women discharge
9 on the equipment. I am an x-ray technologist. I can
10 testify to that, and I have documented it.

11 Women have irradiated breasts. That is
12 compromised skin. The CDC has written a letter saying there
13 is a risk for these women coming in contact with
14 contaminated equipment. Women, 90 percent of the women will
15 shave under their arms, that is compromised skin. It is not
16 a choice to clean or not clean the piece of equipment.

17 The FDA has already determined that it is to be
18 cleaned and disinfected, and it is a policy already of the
19 FDA after each patient, and women deserve to have a clean,
20 sanitary surface. So, to make your opinion about it is very
21 low risk, you know, that is like saying, well, you shouldn't
22 wear a condom because there is not a big risk.

23 DR. MONSEES: Let me clarify something.

24 MS. SHERMAN: I find it insulting.

25 DR. MONSEES: Let me clarify something. I never

1 said that the equipment should not be cleaned between each
2 patient. I absolutely agree it should be cleaned between
3 each patient.

4 MS. SHERMAN: And disinfected.

5 DR. MONSEES: And disinfected.

6 MS. SHERMAN: Right.

7 DR. MONSEES: Between each patient.

8 MS. SHERMAN: Right.

9 DR. MONSEES: Absolutely, and we have our
10 technologists wash their hands between patients.

11 MS. SHERMAN: But that is not protecting your
12 technologists because you cannot wash your hands after you
13 have been contaminated. You are supposed to use universal
14 precautions, and that has said you protect the patient and
15 yourself before you come near the next patient, so you don't
16 understand. I have been arguing this since 1991, and now I
17 have a new panel, and nobody has heard what the old panel
18 has heard, and I start all over again with the same
19 argument.

20 The fact is that women deserve a clean, sanitary
21 environment, and the other fact is once that equipment is
22 contaminated with bloodborne pathogens, which is a nipple
23 discharge, anybody's nipple discharge, that equipment stays
24 contaminated for over two weeks, and you must be able to
25 disinfectant. This has been documented.

1 DR. MONSEES: Well, I think it is disinfected.

2 MS. SHERMAN: No, don't understand. This is again
3 where I started. You don't understand the level of
4 disinfecting, and in order to appropriately disinfect
5 bloodborne pathogen, you need at least as 45-minute
6 immersion of your equipment like Cidex was recommended. You
7 cannot disinfect the bucky.

8 The fact is the FDA has already written a policy,
9 and they said, well, if you cannot use the chemical
10 disinfectant, then, you should use a barrier that is
11 acceptable to the FDA, that has 510(k) clearance, and that
12 would be acceptable. But nobody has made it available to
13 the 25 million women, and they go and tell me to manufacture
14 it when they have an obligation to the technologists to
15 provide either appropriate disinfecting instructions or a
16 barrier that could be purchased.

17 So, to start this argument with your opinions, it
18 is very nice to hear, but it is not fact, and it is not
19 based on infection control policy. I have been dealing with
20 this since 1991, and I find it very insulting to me, as a
21 technologist, to hear your opinions about how light-
22 heartedly whether it is a low risk, you don't tell a boy to
23 go have sex without a condom even though his risk may be
24 low.

25 DR. MONSEES: I find that, itself, insulting in

1 response to what I commented on. I am saying that I take
2 this seriously --

3 MS. SHERMAN: How do you know that the risk is
4 low? You have never done, nobody has ever looked at it.

5 DR. MONSEES: I am not saying that the risk is
6 zero.

7 MS. SHERMAN: You said low.

8 DR. MONSEES: It is low according to Infection
9 Disease Control individuals who deal in this day in and day
10 out.

11 MS. SHERMAN: Well, I have written articles, and
12 it has been reviewed by --

13 DR. MONSEES: We are going to end this here.
14 Thank you, Ms. Sherman, for your comments.

15 MS. SHERMAN: Well, you don't like to hear what I
16 have to say, but you know what --

17 DR. MONSEES: We are done. Done.

18 MS. SHERMAN: You may be thinking you are done,
19 but I am not done. Okay?

20 DR. MONSEES: Fine. Go ahead and submit what you
21 would like to in writing.

22 MS. SHERMAN: I have submitted, but I ask you that
23 you withdraw your statement. You can bang all you want.

24 DR. MONSEES: Will you please be seated.

25 MS. SHERMAN: No.

1 DR. MONSEES: We are finished.

2 MS. SHERMAN: You may be finished, but I find this
3 extremely offensive, and I think women --

4 DR. MONSEES: What would you like us to do?

5 MS. SHERMAN: I think it is about time you did
6 something.

7 DR. MONSEES: Thank you for your comments.

8 MS. SHERMAN: You are welcome.

9 DR. MONSEES: Would anybody on the panel like to
10 respond to that?

11 [No response.]

12 DR. MONSEES: Let's move on. Does anybody have
13 any issues pertaining to cleanliness of the facility in
14 addition to the infection control portion of this? Okay.

15 We are going to move on then to Quality Assurance,
16 General, Draft A, pages 40 to 41, B, 25, Small Entity
17 Compliance Guide 27. Page 40 to 41 on the initial document.
18 Draft A. Does anybody have any comments?

19 Page 25 of the second document. You don't have
20 that? Maybe we can get you copies of that, and then you can
21 take a look through that, and we will give you opportunity
22 to --

23 DR. FINDER: There is one on 26, but we are not up
24 to it yet.

25 DR. MONSEES: And Quality Assurance, Records part,

1 was also on page 25 of that second document, was on page 42
2 of the initial document. What quality assurance records
3 must be maintained, where and for how long, and then on page
4 25 there is what looks like some wording changes. It is in
5 the second document.

6 Can we move on? You can read these and then if
7 you need specific time to look at them, we will revisit
8 those.

9 Does anybody have any comments on the General or
10 the Records part of the Quality Assurance? Pages, I am just
11 going to go over this again, 40 to 41 and 42, and then 25 of
12 B -- okay. Quality controls tests other than annual, and
13 then we will move on to, pages 43 to 47 of Draft A, 26 to 29
14 of Document B. It's on 29 of the Small Entity Compliance
15 Guide. So, other than annual QC tests? Yes.

16 MR. PIZZUTIELLO: I have a comment. On the bottom
17 of page 26, on B, in the 1970 region, in performing a
18 physics survey, what tests, and so on, should be performed,
19 and it then lists a series of tests of five bullets. It
20 says, "For unit with multiple target filter combinations,
21 the following tests must be performed for each clinical use
22 target filter combination," and the focal spot condition,
23 the first bullet, and the second bullet, x-ray field, light
24 field, image receptor, compression paddle alignment are not
25 affected by the filter. It may be affected by the target,

1 but not by the filter.

2 So, under this guidance, you would need to repeat
3 the tests under a circumstance where you gain no useful
4 information, and it takes time, and I think that should be
5 changed. So, I would like to see it say, "The focal spot
6 condition and x-ray field," et cetera, "shall be evaluated
7 for each x-ray target," and then the remaining ones, beam
8 quality and half value layer, which is the same thing,
9 automatic exposure control and system artifacts shall be
10 evaluated for each target filter combination.

11 DR. MONSEES: Okay. Any other comments on that?
12 Go ahead.

13 MS. WILSON: I had a comment, but on another
14 question, if I may.

15 DR. MONSEES: All right.

16 MS. WILSON: On page 45, the backup processor for
17 mammography indicates that facilities do not need to perform
18 daily QC. As I interpret this, it says that would establish
19 your operating aim on your backup processor, and then you
20 would stop and do nothing until the time arose where your
21 mammography processor was out of limits or down, and then
22 you would run another strip and test this processor to see
23 if it was within limits.

24 So, how do you do this, if you take your initial
25 box of film and have it in the dark room, and it sits there

1 for six months or a year, and you run strips out of that,
2 your values may decrease because of the length of time the
3 film has been open. If you do not use this method, and you
4 just use another box of film, you are going to get very
5 different results, because there is a wide variation from
6 emulsion to emulsion with your contrast levels.

7 I would suggest that either we ask facilities to
8 perform daily processor QC on their backup processor or we
9 ask them to perform a phantom, and score the phantom for
10 passing results and also evaluate it for background density
11 to see where it lies in relationship to the primary
12 processor.

13 There may be a need to adjust your steps, your
14 density steps when converting from one processor to another.

15 DR. MONSEES: Okay. Let's hear some comments on
16 that.

17 DR. SICKLES: This actually also relates to a
18 comment that I have about a different section. It is sort
19 of an alternate way to check your processor. We might as
20 well discuss them both at the same time because it's the
21 same issue.

22 Go to page 26, line 968 to 970 is the whole
23 sentence. It talks about an alternate method to do daily
24 processor QC when there is no sensitometer, densitometer
25 available. It is the same concept, you know, what is the

1 alternate method. The alternate method is not specified
2 here, there is no guidance about it, and as a radiologist
3 who is reasonably knowledgeable about this, I just talked to
4 Bob Pizzutiello about it, you know, what is an acceptable
5 method. He raised a few options, but I think they should be
6 spelled out in guidance. Perhaps Bob could explain to us
7 what they might be.

8 DR. MONSEES: I would imagine also that this area
9 is going to be covered in the new ACR manual. Is this
10 covered in the ACR manual, as well? Cross-over?

11 MS. BUTLER: No, this isn't cross-over.

12 DR. MONSEES: I am sorry, not cross-over,
13 sensitometer, backup processor, and then using the film
14 batch, et cetera, is that in there? Okay. Let's hear about
15 it. Maybe it should be.

16 MR. PIZZUTIELLO: The issue, the way Patricia and
17 Dr. Sickles raise it is exactly right. You can't really set
18 up a baseline value on a box of film and put it away for a
19 long period of time, because as the aging of film occurs,
20 the characteristics change.

21 So, if you try to set it up, in fact, if you do
22 what this implies, you will have probably have a difficult
23 time getting data that fits the criteria even if everything
24 is okay, so I think we need to clarify what it means to
25 establish a baseline.

1 We have had this situation with facilities that we
2 serve when they only have one sensitometer and it breaks.
3 They have to get it fixed. What we have had them do is to
4 shoot a phantom every day to measure the optical density off
5 the phantom image and to track that daily.

6 That gives a reasonable estimate of what the
7 system speed is, and then we have them measure the density
8 difference in the contrast disk in the phantom. It gives a
9 reasonable estimate of the contrast characteristic. It is,
10 I think, practical because most facilities can't afford to
11 buy a backup sensitometer/densitometer.

12 It would make sense to do that here. There is a
13 research project that we performed with FDA, which has been
14 submitted for publication, which talks about an alternative
15 method to doing daily film processor QC, and it is based on
16 this principle.

17 So, sometime, hopefully in the near future, there
18 will be something published on it, but in the meantime, I
19 think if we talked about -- if the guidance document talked
20 about using phantom imaging and optical density and density
21 difference on the phantom as a measure of speed and
22 contrast, that would be the best way to compare the
23 processor that you would use for backup with your other
24 processor. This will now work since phantom imaging is
25 required once a week, so you will be able to compare it with

1 a relatively recent phantom.

2 DR. MONSEES: But with the same box of film that
3 you are normally using rather than some other box of film
4 that you were talking about in a different processor.

5 MR. PIZZUTIELLO: That's right.

6 DR. MONSEES: So, that answers the question about
7 this other box of film, which has aged.

8 DR. SICKLES: Yes. It also answers the question
9 about the thing on page 26, because that is an alternate
10 method of doing your daily regular processor QC if for some
11 reason you don't have access to a sensitometer or
12 densitometer on that day.

13 MS. WILSON: I also would like to comment on that.
14 I question, if you were lucky enough to obtain a backup
15 sensitometer and densitometer, how those values would
16 compare to what you were getting off of your unit, if there
17 would be such a difference between them that the films would
18 still be out of limits.

19 MR. PIZZUTIELLO: The densitometer, as long as you
20 have a calibration strip, should not affect it, but the
21 sensitometer would indeed affect it, because the brightness
22 of individual sensitometers varies quite a bit, so that is a
23 problem using backup sensitometers. Backup densitometers is
24 not a big problem.

25 DR. MONSEES: But you could go back and you could

1 compare your old strips to the newly obtained strip and see
2 perhaps how they --

3 MR. PIZZUTIELLO: With the densitometer.

4 DR. MONSEES: Right.

5 MR. PIZZUTIELLO: But the sensitometer, it is more
6 difficult.

7 DR. MONSEES: What I am saying is you could
8 compare with the new system, with the densitometer, which is
9 a standard, and see if there is a variance, right, between
10 the new and the old sensitometer, between your old strips
11 that you ran, and the new strips, couldn't you?

12 MR. PIZZUTIELLO: You would have to be able to
13 make --

14 DR. MONSEES: Not at the same time, but go back
15 historically.

16 MR. PIZZUTIELLO: If you did it periodically, if
17 you were going to do this as a backup system and on day one,
18 you tested sensitometer A and sensitometer B, yes, that
19 would work, if people thought ahead of enough to do that,
20 that would be an idea situation.

21 DR. MONSEES: Any other solutions that you didn't
22 think or, or any other comments on this? Yes.

23 MR. MOBLEY: This might just be for my own
24 education, but help me just a second here. The testing that
25 is required of the processor for mammography, is mammography

1 so very different from routine radiography that that testing
2 is something that shouldn't just be required across the
3 board, so that your backup processor in effect should have
4 these tests being made every day for its routine use? I am
5 assuming it is used for something else other than
6 mammography.

7 MR. PIZZUTIELLO: I think you have asked two sort
8 of separate questions. Is the processing in mammography
9 critical? Absolutely. The second question is so then why
10 shouldn't we be doing sensitometry on our back processor
11 every day?

12 MR. MOBLEY: No, that is not what I asked.

13 MR. PIZZUTIELLO: Okay. What is the second one?

14 MR. MOBLEY: In my mind, I am thinking why are we
15 not doing these same kind of tests on all processors that we
16 require processors for mammography, is it just that we
17 haven't gotten to the point of doing that because we are not
18 interested in that yet?

19 MR. PIZZUTIELLO: You are talking about other
20 modality processors?

21 MR. MOBLEY: Yes.

22 MR. PIZZUTIELLO: Yes. In screen-film imaging, in
23 the state I live in, you have to do it every day, so that is
24 an issue that varies among the states. There has been no
25 real opposition to the fact that in mammography, where it is

1 more critical, it needs to be done every day. Some states
2 have not required that radiographic processor QC be
3 performed every day.

4 MR. MOBLEY: Okay.

5 MS. WILSON: In North Carolina, we also are
6 required to do it on the standard processor every day with
7 the film used clinically for diagnostic, but there is
8 nothing that says you cannot also do a mammo film QC on that
9 processor, which is what we do at our facility, we run Q
10 strips every day. It takes much longer to see a change on
11 double emulsion film as opposed to single emulsion film QC.

12 DR. MONSEES: Yes.

13 MR. NISHIKAWA: A comment on the same section
14 here. It says that the device and method for performing QC
15 without a sensitometer or a densitometer. I can't imagine
16 checking a processor without a densitometer. I think that
17 "or densitometer" should be struck from there.

18 DR. MONSEES: That is line 970?

19 MR. NISHIKAWA: 970.

20 MR. PIZZUTIELLO: Just to add to that, that makes
21 good sense. That means that what we are saying is that if a
22 facility has no densitometer available, they have to stop
23 processing mammograms. If they have no sensitometer
24 available, they can go to an alternate means.

25 DR. MONSEES: So if a densitometer breaks, they

1 have to get one pretty quick, but once they get one, since
2 you said they are exact and reliable, they can start up.

3 MR. PIZZUTIELLO: Yes.

4 MR. MOBLEY: Let me ask Bob, we have talked about
5 the fact that there needs to be a procedure regarding
6 utilization of a backup processor, and this question here
7 talks about how to deal with densitometer/sensitometer
8 availability, and everything, and you mentioned this
9 research project.

10 Is the stage such that someone can sit down and,
11 in FDA or wherever, and write these procedures, these
12 optional guidance procedures, or is there further work to be
13 done?

14 MR. PIZZUTIELLO: I would say that there is no
15 reason why these procedures couldn't be written out, so that
16 people understood exactly how to do them. It is relatively
17 new, hopefully, they will get published soon, but the
18 procedure is valid for backup purposes independent of the
19 rest of the research.

20 DR. MONSEES: Is there any such guidance planned
21 for the QC manuals from the ACR on these issues for backup
22 situations where things fail? Ms. Butler.

23 MS. BUTLER: It is my recollection that the
24 information that is in the draft of the '98 QC manual is
25 basically the same that was in the '94 manual with an

1 elaboration on cross-over, and I will have to go back and
2 look at it and see specifically what was in there.

3 DR. MONSEES: Thank you. Any other QC other than
4 annual issues that we want to discuss here?

5 MR. MOBLEY: Page 46 of A, the last question. It
6 is not really clear to me. It appears that a test is
7 required.

8 DR. MONSEES: For film-screen contact, is that
9 what you are talking about?

10 MR. MOBLEY: No.

11 DR. MONSEES: What page are we on?

12 MR. MOBLEY: Yes, that is the one. What optical
13 density or range should the facility use for the screen-film
14 contact test, and what is the criteria for determining pass
15 or fail for a cassette? The answer is there is none, as I
16 read it.

17 DR. MONSEES: Right, and as best I know, there is
18 no exact answer to that. You know it when you see it kind
19 of thing.

20 MR. MOBLEY: Well, I might see it differently than
21 Bob might see it. When I read that, I thought, well, this
22 is interesting, but how do we know when you are in
23 compliance or not in compliance.

24 MR. PIZZUTIELLO: There are two issues raised in
25 this paragraph. The less important of the two is how dark

1 is the film, how dark is your test film. Originally, there
2 was some suggestion of 0.7 to 0.8. Some people like it
3 darker, I like it darker, but that is not the real critical
4 issue. The real critical issue is how big an area of non-
5 contact, and where does it occur, and how severe.

6 At this point, there has been nothing definitive
7 published or generally agreed upon except that if it is
8 really bad, as Dr. Monsees says, you know it, so it's a
9 suboptimal situation. If we had more definitive data, we
10 would be able to use it. In the absence of that, this is
11 about all we can do as far as I know.

12 DR. MONSEES: Comment from Ms. Butler?

13 MS. BUTLER: With my ACR hat on, in the revision
14 of the manual and also in the '94 manual, we have 0.7 to 0.8
15 as far as optical density for this test. Putting my former
16 NMQAAC member hat on, I seem to remember a discussion
17 regarding the quality control tests during the early days of
18 getting away from specificity for the performance of these
19 tests, and just focusing in on the performance themselves.
20 Perhaps members from FDA could talk more on that, but a lot
21 of this stuff was in the original proposals, but it was
22 pulled out during the final rules.

23 DR. MONSEES: Do you want to comment on that?

24 DR. FINDER: Well, that is exactly right, and
25 again it goes down to flexibility for the facilities to do

1 things. We could have been very prescriptive and put in a
2 test procedure, but that would have meant that people would
3 have had to follow it, and they couldn't have deviated from
4 it if it went into the regulations.

5 So, if we don't do that, then, the rest of is
6 guidance, whatever we say is guidance, they can't or don't
7 have to follow. So, you gain in one area and you lose in
8 another. That was what we were advised to do.

9 MR. MOBLEY: But in this case, we have a
10 requirement, but there is no pass or fail criteria for that
11 requirement.

12 DR. FINDER: Right, and when that pass/fail
13 criteria becomes available, when there is a consensus, then,
14 I think that we can put out guidance that would be more
15 specific, but until that happens, we can say a lot of things
16 here, but there is no justification for it, there is no
17 consensus on what the criteria should be.

18 DR. MONSEES: So, the facility should track it,
19 but there are no criteria for when they should discard a
20 cassette. Right?

21 MS. WILSON: Well, actually, there is, I believe,
22 for areas of poor contrast over 1 cm in size, that would
23 fail the film-screen contact test. Is that correct, Bob?

24 DR. MONSEES: Bob.

25 MR. PIZZUTIELLO: Excuse me?

1 DR. MONSEES: If an area is more than a centimeter
2 in size, does it fail the test?

3 MR. PIZZUTIELLO: I have been trying to avoid
4 that. In the initial suggestion of this test, it was
5 suggested that areas of more than 1 cm within the central
6 area of the cassette where the breast would be, might pose
7 an area of concern. It is common to have multiple small
8 areas around the periphery. Those are generally considered
9 not to be an area of concern, but all we have is a general
10 guidance, if you will, on what the requirement is.

11 That what we, as facilities, do when we evaluate
12 cassettes to see if they meet the requirement, but it is not
13 a hard and fast requirement, and it has never been compared
14 to the scientific scrutiny of some other tests, so that is
15 what we have to work with, but you can't really say for sure
16 that that absolutely is okay and that if you fail, it is
17 absolutely bad.

18 What we have found is that if you use that
19 criteria, then, nearly all good cassettes can pass that
20 criteria if they are functioning properly, and if they fail
21 the criteria, cassettes can be replaced, and the criteria is
22 met again. So, that is a little different way of thinking
23 than saying that this is what science says we should do. We
24 know that this works. Does that answer your question?

25 MS. WILSON: I thought the ACR manual gave that,

1 that it would fail for areas over a 1 cm, is that correct?

2 MS. BUTLER: You are correct that there is
3 guidance, which was adopted under the interim rules as
4 basically regulation, that if it exceeds 1 cm and also I
5 think five in number, so there is general guidance out there
6 for this, and it works.

7 MR. MOBLEY: It would seem then to me that we can
8 put that guidance in here and maybe it will work toward
9 helping develop the consensus. Some of my comments
10 obviously today are just -- I mean this is an outlier kind
11 of thing. You see there is a requirement for something, and
12 there is no criteria for it, I mean that is obviously an
13 outlier in my mind, and at a minimum we could provide some
14 guidance, and as I hear it, that is what we are here to do,
15 provide guidance, and as I heard Dr. Finder say, our
16 guidance is not the regulation, it is just guidance, and I
17 would suggest that we put that guidance in here.

18 DR. FINDER: Well, I think we have guidance here.
19 It says, "If you follow the same conditions as under the
20 interim regs," and it gives a range of density, and it talks
21 about a poor contact area exceeding 1 cm. I mean the
22 guidance is in here. The question is do you want to get
23 more specific than that, and the consensus I have gotten is
24 that there is no consensus any more specific than what is
25 right here.

1 MR. MOBLEY: Okay. You want to go back to the
2 interim regulations, I guess. No further.

3 DR. MONSEES: Any other QC test issues, other than
4 annual QC tests? Yes.

5 DR. SICKLES: Could you go, please, to page 29 on
6 B. This relates to a question right up at the top of the
7 page about subtracting artifacts in the weekly phantom QC
8 test. There is a very brief answer that says, "Follow the
9 criteria established by the accreditation body."

10 I happen to feel that it would be helpful here to
11 provide a bit more guidance than that. Specifically, the
12 ACR and its approach, and I am not sure about the individual
13 states -- I know what California does, but I am not sure
14 about the other two states -- do have policies on
15 subtraction on artifacts, but I think it would be helpful to
16 facilities to have it spelled out a little bit more clearly
17 than just follow what the accreditation body says, by
18 indicating the degree to which subtraction occurs.

19 There is a good deal of confusion among users
20 about how to work with this, and I have talked to the
21 inspectors about it, and the inspectors are clear on what
22 the rules are, but they tell me the facilities are not at
23 all that clear about what it is.

24 So, I think it would be helpful to be a little
25 more specific in the guidance document as to what these

1 policies are. You don't have a three-page long thing, but
2 you can just give a rough outline. You can subtract a half
3 a point. I mean there are rules, and they can be summarized
4 in three sentences.

5 DR. MONSEES: Do you want to comment on what is
6 going to be in the new manual?

7 MS. BUTLER: That issue is recognized in the
8 revisions of the new manuals, and there are going to be very
9 specific guidance complete with pictures on how to subtract
10 for artifacts verbatim. It might be difficult to extract
11 that and put into FDA guidance.

12 DR. SICKLES: If there will be such specific
13 indicators in the ACR manual, then, maybe you would want to
14 reference that page in the ACR manual, so that people have a
15 better shot at it than just this one sentence, which really
16 isn't very directive.

17 DR. MONSEES: Just like you referenced OSHA
18 guidelines for the bloodborne pathogens, maybe you could
19 reference this, although this may be published before the
20 ACR manual.

21 Other QC tests other than annual? Yes.

22 MR. PIZZUTIELLO: On the B document, page 28, at
23 the bottom, under Weekly Quality Control Tests, Roman
24 Numeral II, "The OD of the film at the center of the image
25 shall not change by more than plus or minus 0.2 from the

1 established operating level," we know that there is batch-
2 to-batch, emulsion-batched variability of film that exceeds
3 that.

4 We have had experience with many facilities who
5 have had that circumstance, so I guess my question is if a
6 facility has a batch of film, and these values change by,
7 let's say, 0.3, then, we will have exceeded this, does that
8 simply mean that the facility is free to reestablish their
9 operating level, and if that is the case, is there any
10 benefit to clarifying that, because I can see facilities
11 jumping up and down with their film manufacturers saying
12 that we are failing to meet this criteria, and perhaps we
13 could clarify it in the guidance that that is reasonable
14 cause to reestablish your operating baselines.

15 DR. SICKLES: Actually, this problem comes up
16 frequently. We have had the same situation, and our first
17 go-through with it, did amount to a lot of yelling and
18 screaming at the film manufacturers, and then as we came to
19 realize this was a more pervasive problem, we simply now do
20 what Bob suggests, we just reestablished a new baseline, and
21 I think it would be very helpful to spell it out.

22 DR. MONSEES: Any other comments on this? Yes.

23 MS. WILSON: In lieu of establishing a new
24 baseline, could you post a new technique chart to reflect
25 speed of the new baseline film, because if your film is

1 going to be changing back and forth from batch to batch,
2 which we have found quite often, it is so simple to say
3 while you have this emulsion number in stock, you need to go
4 to minus one.

5 MR. PIZZUTIELLO: That is commonly done. In fact,
6 one machine that is out there automatically will do it for
7 you. You can sort of input the QC values. Yes, I think
8 that is clearly the way to go. You don't want to have a new
9 batch of film that is slower or faster and keep everything
10 the same, because then your films will be either too light
11 or too dark.

12 DR. MONSEES: Did you have a comment?

13 MS. BUTLER: Recognizing this, in the next
14 revision of the QC manual, there is a process in place to
15 deal with this by establishing essentially new technique
16 charts or adjusting techniques, and changing the plus or
17 minus density used for the phantom quality control chart.

18 DR. MONSEES: Did you have a comment?

19 MR. UZENOFF: I would agree with the suggestion
20 that some change in technique is appropriate. The idea
21 shouldn't be to make a new baseline because the idea for the
22 clinical image is to keep the density within a certain
23 range, and, in fact, this is one of the components of the
24 uniformity of screen speed test, the same thing can happen
25 in the screens because that is buckies, and in this case we

1 happen to be talking about another item here, but wording
2 like an appropriate clinical exposure, what you would want
3 to see the facility do is if they are getting higher or
4 lower densities than their guideline, they should adjust for
5 it, for whatever the reason, or be allowed to adjust for it.

6 DR. MONSEES: That sounds reasonable. Any other
7 comments on this issue? We will go on then to the next
8 issue.

9 MR. PIZZUTIELLO: This actually belongs in the
10 annual test, but there is a section on page 27 that talks
11 about grouping of cassettes, and I don't want us to meet
12 that. It is on about line 1020. This goes to the issue of
13 how do we group cassettes when we do screen speed
14 uniformity, but it is discussed in this section of the
15 guide.

16 To summarize what was said earlier, there is very
17 good reason to not group all the cassettes together, first
18 of all, large and small cassettes, different film batches,
19 design of different cassettes, and so on. Secondly,
20 facilities sometimes have higher speed screen-film
21 combinations available within a given size, 18 x 24's, that
22 they might use for max.

23 So, if you group all the cassettes together, you
24 will make that procedure unworkable. So, I think that the
25 cassettes, when you do this test, need to be grouped, not

1 only by size, but also by function, so that if you have a
2 specific use cassette, then, those cassettes shall be self-
3 consistent, but need not be consistent with other cassettes
4 used for other purposes.

5 DR. MONSEES: It makes sense, and, in fact, many
6 of the manufacturers have different choices that you can
7 make depending on whether you are using screen-film
8 combination A or B. Yes.

9 DR. DEMPSEY: I would like to second what Bob just
10 said because our facility is an example where we have about
11 six or eight cassettes that are used only for magnification
12 that are different screens, so I would agree. We would be
13 out of compliance immediately if they grouped them all
14 together.

15 DR. MONSEES: Any other comments on this?

16 MS. WILSON: I just would like to say I also agree
17 we would be out of compliance.

18 DR. MONSEES: There is some work to do, Dr.
19 Finder.

20 DR. FINDER: Let me just ask in terms of the
21 groupings, a couple of examples. Suppose you have got film-
22 screen cassettes that are supposedly the same speed,
23 different sizes, but you find out that they are not, is that
24 acceptable, or do they have to be specified as different
25 speeds, designed for different speeds?

1 DR. MONSEES: So, small receptor, large, 18 x 24,
2 24 x 30?

3 DR. FINDER: I would say, to me, if you are
4 talking about things like this, it might be unimportant as
5 to the size of the cassette, except that it is easy to
6 figure out which one you are dealing with just on the basis
7 of the size, but if they are supposed to be the same speed,
8 should they, or could we just say that you could take a
9 whole manufacturer's set of cassettes and do your test on
10 them and divide them up into the various film-screen speeds
11 even if they weren't supposed to be different speeds, is
12 that acceptable?

13 MR. PIZZUTIELLO: I don't think that that is very
14 good because as I think somebody mentioned earlier, when you
15 do the screen speed test, you are really looking at two
16 different things. You are looking at the amount of light
17 coming off the screen, but you are also looking at the
18 attenuation, the absorption of the whole film cassette
19 package, which is the automatic exposure controls behind.
20 Some manufacturers have come up with different materials for
21 the front and the back, and different thicknesses of that
22 material, so there may be a difference.

23 It would be, for example, reasonable -- and I have
24 seen at some facilities -- where they go to plus 1 density
25 for the large cassettes, so all of them are just taken on

1 the large size cassette or plus 1 density on the small zero
2 density.

3 If you group them all together, then, that would
4 invalidate that whole cassette formulation, and I don't see
5 that there is any reason necessarily to do that. So, if you
6 would test the screen speed under the clinical conditions,
7 which we have alluded to earlier, then, if your technique
8 chart says go to plus 1 for the large cassettes, for
9 example, then, that would be acceptable, and once you have
10 done that, then, you can compare the plus or minus 0.3, or
11 the other way to describe it would be to just segregate
12 them.

13 DR. FINDER: Right, but what I am asking is what
14 should be the criteria for that, is it based on the size, is
15 it based on what the manufacturer says is the speed of the
16 screen, because I can imagine a situation where a facility
17 would say, oh, we have got all these cassettes, and they are
18 different speeds, but they are all separate, and we know
19 which ones they are, we just change our techniques to deal
20 with that. That is my question.

21 DR. MONSEES: But they are going to be
22 discernible, they are going to either an 8 x 10 or 18 x 24
23 size all falls in one category unless it is a high speed
24 system for mag, right, then, that would fall out into a
25 different way to do it.

1 MR. PIZZUTIELLO: All cassettes that have the same
2 size should meet the same criteria unless they are of
3 different speed.

4 DR. MONSEES: Right.

5 MR. PIZZUTIELLO: That would be a simple way to
6 describe it. That allows you to separate different sizes.

7 DR. FINDER: So you would have at a minimum at
8 least two different sets, and depending on your designs --
9 the issue that I have, though, is what are you going to do
10 with the situation where, because the manufacturers tend to
11 not give a speed, but give a name to a cassette, you know,
12 high speed, low speed, whatever. If they all said high
13 speed, and they were from different manufacturers, should
14 they mean the same thing?

15 DR. MONSEES: Gosh, how could you possibly mix --

16 DR. FINDER: That is what I am asking about. The
17 reason I bring this up is because at the last committee the
18 idea of uniformity was stressed fairly strongly, and the
19 feeling was that 0.3 would be large enough to account for
20 the issues. Now, maybe that is not true, but that is again
21 where we came up with these numbers.

22 In fact, there was a suggestion to reduce it from
23 0.3 down to 0.15.

24 DR. MONSEES: Yes.

25 DR. DEMPSEY: By Barbara's reaction, I know she

1 was thinking the same thing I am. Most facilities would
2 have the same manufacturer's speed screens in, and would not
3 be mixing manufacturer's screens. My only point was if you
4 have, say, six or eight designated cassettes only used for
5 mags, and we have external designations on them, so we know
6 that they are faster screens, they should be treated
7 separately from the others, obviously, but I can't think --
8 does anybody on the panel mix manufacturers' screens? I
9 don't think anybody does.

10 DR. MONSEES: Do you know if people are doing that
11 in practice?

12 MR. PIZZUTIELLO: What do you mean by mix
13 manufacturers' screens?

14 DR. MONSEES: Different vendors' screens.

15 MR. PIZZUTIELLO: I think if you specified the
16 manufacturer and the model screen, that would be a better
17 way perhaps than to describe the speed, but clearly, you
18 don't want to have a facility with different cassettes.
19 They would say, well, we use plus 1 for this cassette and
20 zero for that cassette. That would be bad.

21 DR. MONSEES: I think we all have the same
22 understanding here. Any other comments on this issue?
23 Okay, let's move on. Any other QC non-annual tests that you
24 want to discuss?

25 MR. PIZZUTIELLO: I have one more, and I need some

1 help on this. I was going to do my homework, but I forgot
2 this one. On the B document, line number 1095 or
3 thereabouts, it talks about, on Roman Numeral II, repeat
4 analysis. "If the total repeat or reject rate changes than
5 the previously determined rate by more than 2 percent," the
6 way I recall -- and, Patricia, maybe you can help me with
7 this -- the difference between repeat and reject rate, the
8 reject includes QC films. When you do the numbers, the
9 repeat essentially is the clinical films, and the reject
10 includes QC films.

11 Maybe I am wrong on that. Maybe Penny can help
12 refresh my memory, but if that is true, I don't understand
13 how it is meaningful if you use more QC films one period or
14 another, and what does that regulation imply, and could we
15 clarify that in the guidance?

16 DR. MONSEES: I thought the repeat pertained to if
17 you are taking additional films, say, for example, you are
18 taking, instead of four standard views, maybe you are taking
19 six views, to take the front of the breast, for example,
20 that that would be included as a repeat, but it is not
21 rejected, it is not thrown in the film bin. Am I right?

22 DR. FINDER: My understanding is we are talking
23 about clinical films here.

24 DR. MONSEES: Right, for the repeats. They may
25 not be pitched, they may be films that are still used, but

1 sometimes you take additional images for the radiologist
2 other than the four standard views, but you want to track
3 how many patients for whom you are doing that.

4 Am I misunderstanding this?

5 MS. WILSON: I may be wrong, but that is not the
6 way I understand it. On the repeat analysis form, it has
7 two sections, one for reject and one for repeat, and the
8 reject rate, if my memory serves me, includes things such as
9 clear film, QC films, things like that, and that is always
10 going to be a higher number than your actual repeat rate,
11 because it has more films included in it.

12 But what the FDA inspectors track when they come
13 to our office is that we maintain a repeat rate of between 2
14 and 5 percent, and that it does not change from one month to
15 another by more than 2 percent.

16 In other words, if we had a 2 percent one month,
17 and we had a 4 percent the next month, we would have to show
18 that we had done a corrective action to find out what was
19 causing the increase in the repeat rate.

20 DR. MONSEES: We need some history, a history
21 lesson here, I think. Yes. Excuse me a second here. We
22 are going to do historical perspective here.

23 MS. HEINLEIN: You are correct when you say the
24 reject does include clear film, green film, black film, QC
25 film, where repeat is those when you repeat a position or a

1 view that has already been done. So, if you were doing any
2 interior view for better compression, because you asked for
3 that film, that would be a repeat. If, however, you are
4 doing like, say, you do a CC, and you do an exaggerated CC,
5 that is not a repeat. That is an additional film. So, that
6 is number one. So, there is a distinction between repeats
7 and rejects.

8 Rejects are not just those repeated films that are
9 thrown in the box, that includes those repeated films that
10 also go in with the patient's jacket. But the key is that
11 you are repeating the exact same position. That is when it
12 would be a repeat.

13 The other issue is one of, right, the concern is
14 the number of repeats, not the number of rejects, and so to
15 the way it is worded in Document B -- I don't know that that
16 is addressed in A -- but in B, it would be just to take that
17 2 percent, apply that to the repeat rate, not necessarily to
18 the reject rate unless it is in the regs that way.

19 DR. MONSEES: Actually, there is no question and
20 answer, interestingly, in Document B. Do you have it?

21 MR. PIZZUTIELLO: Here is what I found. It is as
22 Trisha and I recall. The way the repeat analysis is
23 structured in the ACR manuals, historically and in the draft
24 manual, the clinical causes for repeat, positioning, too
25 light, motion, and so on, that all gets totaled up in the

1 repeat rate. The reject rate, you add QC, wire-loc, clear
2 films, and that's it. So, the reject rate is the clinical
3 rate, which is the repeat rate, plus other stuff that is
4 non-clinical, and that can vary widely depending on which QC
5 you do.

6 In the regulation, it says, "If the total repeat
7 or reject rate changes from the previously determined rate
8 by more than 2 percent, the reasons for the change shall be
9 determined." So, what I am saying is if a facility has a
10 busy QC month and they do a lot of QC, does that mean that
11 we are expecting facilities to comment on that, and if we
12 are, I think we should say that in the guidance. I
13 personally don't like having reject rate in the reg, but we
14 are not really here to discuss that, given that the reg is
15 what we are stuck with at the moment.

16 I would like to try to minimize the impact of this
17 reject rate.

18 DR. MONSEES: You are right. The reject rate, why
19 is it even applicable here?

20 DR. FINDER: I think that it is in there because
21 in previous discussions, repeat and reject, I believe were
22 considered in terms of their clinical use, and dealing with
23 the difference between the film that was kept in the jacket
24 versus the one that was thrown away, and I would have to
25 check on this, and we can look into it, but I am not sure

1 that it supposedly applies to the reject that you are
2 talking about, but we will look into it, and I agree with
3 you, if it is that much of an issue, we have to come out
4 with guidance to clarify exactly what we mean.

5 MR. PIZZUTIELLO: We are just talking about the
6 semantics of what the word reject means.

7 DR. MONSEES: Right.

8 MR. PIZZUTIELLO: We all agree that what we are
9 interested in is the clinical rate and that the other stuff
10 is not important, we can work out the details.

11 DR. MONSEES: Right. Any other comments
12 pertaining to this? Any other QC non-annual tests that we
13 want to talk about?

14 MS. WILSON: Page 52, on mobile units, I have a
15 question. If you are at a site, and do your mobile exams,
16 you come back and your phantom scores below the 0.20 limits,
17 what should you do? Would it be better to run those films
18 through another processor or to take your processor that you
19 normally use for mammography and run an exam, evaluate those
20 clinical images to determine if you can proceed with the
21 entire batch of mobile films?

22 DR. MONSEES: So, if you are batch processing, and
23 you come back. You want to tackle this?

24 DR. SICKLES: I can tell you what we do. First of
25 all, this happens almost never, but if this were to happen,

1 what our people are instructed to do is to go to a backup
2 processor that is in compliance, and since we don't have
3 another phantom to run through, because we have only got one
4 phantom and it has been used, the phantom image had been
5 used, we take the first two images of the first case, run
6 them through, look at them, and make a determination of
7 whether they are readable.

8 I think this has happened twice in our whole
9 experience of 12 years, so it is not a common occurrence,
10 but in those circumstances it was readable, and we just ran
11 all the films, and we felt very comfortable with it. I
12 think that is a reasonable approach.

13 Using the same processor that you have already
14 demonstrated -- not using the same processor -- using the
15 phantom image on that processor where you have demonstrated
16 that it is really out of compliance, rather than going to
17 another one, I think is a little bit less secure than using
18 a backup one, but if you didn't have a backup processor for
19 some reason, I think that is your only choice. It is either
20 that or get the processor fixed extremely promptly, so you
21 can process the images without waiting for two days before
22 the processor is fixed.

23 Usually, in a batch processing mode, people are
24 batch processing at the end of the day, which is too late to
25 get processor people in to fix the processor. They have to

1 wait until the next morning, and most facilities don't want
2 to wait until the next morning to run their batch processed
3 films.

4 DR. MONSEES: Plus also usually they are using the
5 processor during the day, and they know if it is in or out
6 of compliance, so they would have the opportunity to stop
7 the van from taking films if the processor were going to be
8 out, that they were going to use at day's end were out of
9 compliance. I mean they might be able to do something about
10 it unless they have a backup.

11 Do you have any other annual ones, Ms. Wilson?

12 MS. WILSON: No.

13 DR. MONSEES: Rita.

14 MS. HEINLEIN: Again, just to go back to the
15 repeat rate question, again, this isn't addressed in A, so I
16 am sort of guessing what might be in the mystery document B.
17 Does it say that if there is a change of more than 2
18 percent, that then they have to identify the cause?

19 DR. MONSEES: Yes.

20 DR. FINDER: That's in the regulation.

21 MS. HEINLEIN: In the guidance document, it can be
22 interpreted to say that if they have a repeat rate of 5
23 percent, and then the repeat rate dropped to 2 1/2 percent,
24 that then they would have to identify the reason for that,
25 even though they have less repeats, is that correct?

1 DR. FINDER: That is correct.

2 MS. HEINLEIN: Thank you.

3 DR. FINDER: The reason being is that that drop
4 may not be a good sign.

5 DR. MONSEES: It may or may not be a good sign.

6 DR. FINDER: Right, it may or may not.

7 DR. MONSEES: It is very definitely not definite.

8 DR. FINDER: Exactly.

9 DR. MONSEES: Now, mobile units. Let's finish
10 this part on mobile units as long as we are talking about
11 them, and then we will go back to the annual tests.

12 Page 52, Draft A, 33, Small Entity Compliance
13 Guide. This is the facility shall verify that mammography
14 units used to produce mammograms at more than one location
15 meet the requirements. Do you see that, the middle of page
16 52, mobile units? How does the facility demonstrate
17 satisfactory performance for mobile units after they move to
18 a new location? You are looking in Draft B, and it's in A.

19 Do we have any comments or is there anything to
20 discuss here? Does anybody have any comments about this?
21 It seems okay to me. So, we are done with that part.

22 Let's move on to Quality Control Test, Annual,
23 which are a few pages back from that. 48 to 51 in Draft A,
24 30 to 33 in Draft B, and we are talking page 30 of the Small
25 Entity Compliance Guide. So, annual tests. Do we have any

1 issues here?

2 MR. PIZZUTIELLO: I have two items. One is on
3 Draft B, line 1227 on page 32, and it is also on page 53 in
4 the big document. It states it nice and clearly, I think,
5 that this is an issue for facilities and medical physicists
6 to deal with. Historically physicists were required to get
7 their reports to a facility within 30 days.

8 Under the new requirements, facilities need to
9 evaluate any issues raised in the physicist survey, and find
10 out the source of the problem and implement corrective
11 action within 30 days. So, obviously, you can't give your
12 physicist report in 30 days, and the facility meet that
13 requirement.

14 So, the answer that is on the bottom of page 53 is
15 very good and direct, but I think this is a significant
16 change in practice from the interim regulations, and while
17 we are trying to address it within the physics community, I
18 would like to ask that the division think about putting a
19 special note in Mammography Matters and communicate that any
20 way they can to try to alert medical physicists of the fact
21 that they have to change their practice, and it is two
22 things.

23 You have to let facilities know on the spot if
24 they fail either phantom image or dose, and then you have to
25 let them know soon enough with anything else that they can

1 find the problem and correct it within 30 days.

2 DR. MONSEES: So, the communication issue here for
3 those of you that might be confused, this is between the
4 physicist and the facility.

5 MR. PIZZUTIELLO: Correct.

6 DR. MONSEES: To be done in a very timely fashion,
7 so that they can correct what they need to. It makes sense
8 to me. Does anybody have any questions about that?

9 DR. SICKLES: Is there a way to get that message
10 out to physicists through an AAPM publication or something
11 like that?

12 MR. PIZZUTIELLO: As soon as this meeting is done,
13 I have to write an article for the AAPM Newsletter, which
14 will go out to people, but I would like to have it be
15 parallel by something more official from FDA.

16 DR. MONSEES: Yes.

17 MS. BUTLER: This is an important issue, and in
18 the revision of the QC manual, there is a form for the
19 physicist to leave on site prior to leaving, indicating what
20 tests pass or fail, and corrective action they recommend at
21 the time.

22 DR. MONSEES: That's great, so we are all on the
23 same page. Any other annual tests?

24 MR. PIZZUTIELLO: One more. On page 33 of the B
25 document, the last paragraph before that says medical

1 physicist annual survey, I think we just need to clarify the
2 line on 1269, that says, "When placing the bar pattern with
3 its length perpendicular to the chest wall, the high
4 frequency end should be close to the chest wall," I think
5 that is not clear. What does it mean to say the "length of
6 the bar pattern?" I think we had better just say, "the
7 bars," because the patterns don't always a clearly defined
8 length and width. So, we can get at that detail.

9 DR. MONSEES: The lines or whatever, okay, the
10 bars.

11 DR. FINDER: Let me just say that this individual
12 section has been rewritten I don't know how many times,
13 because every time we write it, somebody else has another
14 question about how are you placing this bar, and I think the
15 only way we are going to be able to do this is a picture. I
16 don't know if we can do that, but all I can say I think I
17 have come to that conclusion already, draw pictures.

18 DR. MONSEES: Okay. Any other comments? Yes.

19 MS. WILSON: On page 31, line 1184, the x-ray beam
20 limitation device. Is the misalignment total 2 percent from
21 the right and left side, and an additional 2 percent from
22 the chest wall and nipple edge of the film?

23 DR. MONSEES: I thought it was summed up. Isn't
24 it added together?

25 DR. FINDER: If that is not clear, I think we can

1 put in some guidance.

2 MR. PIZZUTIELLO: It is not clear. I was talking
3 with someone from FDA about that earlier, and I think that
4 should be clarified. The way I would interpret this, it
5 says along either the length or the width. That would mean
6 you get 2 percent for the length and 2 percent for the
7 width.

8 MS. WILSON: That is the way we are inspected
9 currently, and there has been a lot of confusion about this,
10 so I think if we can have clarification on this, it would
11 make it much more simple for all of us.

12 DR. MONSEES: Good. I didn't understand it that
13 way, so you taught me something.

14 Any other annual tests?

15 DR. FINDER: The question that I brought up
16 before, about the magnification and the 13 and 11 line-
17 pairs, is that settled? We are going to say that if you are
18 going to measure it, it has to meet those requirements in
19 all the mag modes? Was that the consensus?

20 MR. PIZZUTIELLO: I thought what we said was that
21 it would have to meet the requirement in the clinically used
22 mode.

23 DR. FINDER: In the clinically used, that is what
24 I wanted to check, that's the consensus here.

25 DR. MONSEES: That is page 30.

1 DR. FINDER: Page 30 in the B document.

2 MR. MOBLEY: Is that what the regulation requires?

3 DR. FINDER: That is a good question. The
4 question was is that what the regulation requires, and we
5 are going to have to look at this because in the focal spot
6 condition, it doesn't specifically talk about magnification,
7 the word isn't there.

8 MR. PIZZUTIELLO: In fact, there has been
9 discussion on the web among medical physicists, some who
10 said, well, I don't think any of these resolution things
11 apply to magnification because it doesn't specifically say.
12 I don't agree with that, but one interpretation.

13 DR. FINDER: We are going to have to look at what
14 the options are here in terms of that. Again, this had been
15 rewritten from the proposal where there was a specific
16 magnification requirement for 1.5 mag. When that was
17 dropped out, it became a little more confusing. It was --
18 well, I won't go into that. But the consensus here would be
19 that if you are going to use a clinical mag mode, it should
20 meet these requirements. That is the consensus. Okay.

21 DR. MONSEES: Before we move on to Physics Survey,
22 which is going to be next, I just want to give these people
23 who were missing pages an opportunity. Did you get a chance
24 to read it? Otherwise, we can revisit it tomorrow. Do you
25 want to make any comments about the missing pages, the

1 quality assurance, and the records, general, and records
2 that you were missing in Document B? If you haven't had a
3 chance to read it, we can do it tomorrow. I will call for
4 that tomorrow. Do me a favor and if you have any questions,
5 make sure to bring that to my attention tomorrow.

6 Physics Survey

7 DR. MONSEES: We will move on to Physics Survey,
8 pages, in the A Document, 54 through 56, in the B document,
9 33 to 34, and page 33 of the Small Entity Compliance Guide.
10 I think we are going to look primarily to our physicists and
11 to Ms. Wilson.

12 MR. PIZZUTIELLO: I have one item. On page 55 of
13 the middle of the page, they are talking about the equipment
14 evaluation, the mammography equipment evaluation. This is
15 an issue where, in addition to the annual survey, there are
16 major changes to the system that a medical physicist needs
17 to do a subset, an appropriate subset, of the tests during
18 the annual survey.

19 Examples of major changes that would call for an
20 equipment evaluation are: replacement of an X-ray tube,
21 collimator, AEC, AEC sensor and filter. I think that is all
22 very good. Also, for the processor, a total overhaul, pump
23 replacement, which I have a problem with, replacement of
24 developer and fixer racks, which I also have a problem with,
25 or the control board.

at

1 A pump replacement happens relatively frequently
2 and if the processor sensitometry is good, then I am not
3 really sure what the medical physicist would add to that
4 circumstance. Replacement of the developer and fixer racks,
5 that, also, happens relatively frequently and I would say
6 that the technologists, in most facilities, are pretty well
7 able to assess artifacts.

8 So I would like to see those two taken out of the
9 list of things that require and equipment evaluation.

10 DR. MONSEES: I would tend to agree with that. Do
11 you?

12 MS. WILSON: Those are exactly the same items that
13 I had concern over.

14 DR. MONSEES: Any other comments on that?

15 MR. PIZZUTIELLO: No.

16 DR. MONSEES: Ms. Butler, would you care to
17 comment on whether the ACR manuals are going to address in
18 more detail what we should stipulate to get a equipment
19 evaluation by the physicist?

20 MS. BUTLER: Yes. We will have guidance in the
21 manual on that. In fact, we have provided our opinions on
22 this issue to FDA in the past and I think we are in general
23 agreement with what has been said here on the panel.

24 DR. MONSEES: As much as possible, it would be
25 helpful if the two were recommending the same thing.

1 Any other issues pertaining to the physics survey?
2 Anything else here? Pages 54 to 56 of the A document; B
3 document, 33-34.

4 We polished that one off quickly. Let's talk
5 about the time a second here. We were slotted to go until
6 6:00 p.m. today. I think we will continue here and plow
7 through some more of this. Undoubtedly, we will have to
8 carry some of this over until tomorrow, late morning, early
9 afternoon. But we are going to continue here. We are
10 planning to end by 6:00.

11 Additional mammography review and patient
12 notification are up next.

13 **Additional Mammography Review and Patient Notification**

14 Here we have got pages 65 and 66 of the A document
15 and then we have got a whole other little document, and page
16 37 of the Small Entity Compliance Guide, additional
17 mammography review and patient notification.

18 MS. BROWN-DAVIS: I am in document B on page 37.

19 DR. MONSEES: The little tiny one? Let's call it
20 C or the add-on or something. It doesn't have a page 37.
21 That can't be right.

22 Ms. Hawkins, did you have any comments on that?
23 65 to 66 in the big document, additional mammography review
24 and patient notification. I had a question pertaining to an
25 issue, actually, that occurred in our state. On page 65,

1 "If the FDA determines that any activity related to the
2 provisional mammography facility may present a serious risk
3 to human health such that patient notification is necessary,
4 facilities shall notify patients or their designees or
5 physicians," blah, blah, blah.

6 My question is how do you separate the state from
7 the FDA here and can the state do this without accrediting
8 body review? Where do the state and the FDA separate on
9 this issue?

10 DR. FINDER: In MQSA, in general, the state has
11 authority to take more stringent measures if it wants to.
12 So we cannot stop a state from doing certain things. We can
13 recommend. We can lead by example, but if the state has
14 certain laws that are more stringent than MQSA, that is
15 allowed under the law.

16 MS. BROWN-DAVIS: Is it possible to give some
17 guidance as to when the notification occurs? It says, "Some
18 notification shall occur within a time frame and in a manner
19 specified by FDA." It doesn't really--as best I can tell,
20 we don't really know what that means. It just seems to be a
21 relative kind of thing.

22 DR. FINDER: Right. The reason that it is not
23 very specific is that this is a low-number event in the
24 sense that each one is taken individually that we have to
25 deal with and each one is dependent on the individual

1 circumstances. So, depending on what kind of situation we
2 might run into will depend on how the response manifests.

3 So we didn't set down specific times, per se,
4 because we just don't know what kind of situations we are
5 going to run into. The advantage to this is that we have
6 pretty much got a fair degree of flexibility and control
7 over what we can have the facility do.

8 Again, the basis for this is to take the actions
9 that would be most beneficial to the patient in these
10 situations. That is going to be determined on an individual
11 basis. For example, there may situations where there may be
12 a problem but notifying the patient doesn't help anybody.
13 There may be other situations where we go into the facility
14 and find out the problem cases and only notify those people
15 where there is an issue.

16 It would depend on the individual situation. This
17 is more of a guideline for us and for the facilities to
18 understand what might happen but it is going to be dependent
19 on the individual circumstances.

20 MS. BROWN-DAVIS: It just seems to me that it
21 rather leaves the patient, the consumer, unprotected. And
22 that person, having no recourse--for instance, if they
23 question, they can be told, according to this, "Well, we are
24 within the time frame. We are working on it."

25 DR. FINDER: Who is working on it?

1 DR. MONSEES: But it is not going to be the
2 facility, not the FDA, that is going to say what the time
3 frame is.

4 DR. FINDER: It is not up to the facility for them
5 to decide what the time frame is. It is up to us to tell
6 them what the time frame is.

7 MS. BROWN-DAVIS: But, even so, even with FDA
8 saying--that could be whenever, whenever we get to a
9 determination. So if somebody is waiting for an answer, or
10 waiting for something to move forward, there is really
11 nothing for them to hold on to.

12 DR. FINDER: I am not exactly sure what you mean
13 by somebody is waiting to move forward.

14 DR. MONSEES: They won't know there is a question.
15 They will have gotten their report.

16 MS. BROWN-DAVIS: They will not have gotten a
17 report.

18 DR. MONSEES: They will have gotten the report.

19 MS. BROWN-DAVIS: I see.

20 DR. MONSEES: They don't know that anything is
21 wrong if something was discovered to be wrong with the
22 quality of that facility. It is uncovered during inspection
23 or reported and, therefore, an inspection is triggered and
24 there is a question about whether or not there has been a
25 problem with the quality.

1 Then it is investigated and if something is found,
2 then the FDA will say, "You initiate patient notification."
3 It may require, and it stipulates here, "additional review
4 of the films," perhaps by the accrediting body or some other
5 entity to determine whether or not it may affect what
6 happened to the patient or to the interpretation of that
7 mammography based on how poor the quality is.

8 If it is found, yes, there may have been a breach
9 of compliance but the image quality is fine and patients
10 don't really need to be notified, then they may never be
11 notified of that. Only if it is important will they be
12 contacted.

13 Is that clear?

14 MS. BROWN-DAVIS: Yes; it is clear, but it is
15 really confusing to me. Perhaps my experience is just based
16 on women who are no longer around because of poor
17 mammography. They are not here. They are dead. They are
18 women that were in our organization.

19 So I am thinking, at what point--who would FDA
20 notify in that case? It just seems as if the consumer
21 should have a little bit more involvement in this if
22 something is found to be awry at the facility.

23 DR. FINDER: Right. The situation has to be
24 tempered in the sense that some type of investigation has to
25 be done to find out how serious this is because patient

1 notification is a serious response. The intention always
2 has been when the situations arises, patients are notified
3 as soon as possible.

4 The problem that you may be talking about is the
5 fact that somebody could have had a mammography six months
6 ago and we only became aware of a problem now. The fact
7 that they haven't been notified in six months, there is
8 nothing we can do about that. We can only notify them as
9 soon as possible, as soon as we determine that there is a
10 problem.

11 But if you put in a time frame, that they must be
12 notified within 30 days of their mammogram, that is
13 impossible because we may not know that the situation arises
14 and we don't want to lock ourselves into a situation where
15 we then don't notify them because it is more than the 30
16 days since their mammogram.

17 I understand your concern that the process move
18 along as quickly as possible once an issue has come up and
19 that it be resolved as quickly as possible. That is what we
20 intend to do. Putting in certain time frames at this level,
21 we thought about that, but the issue really comes down to we
22 have to look at the individual cases.

23 So far, there haven't been enough to--

24 MS. BROWN-DAVIS: I suppose my concern--and when I
25 think about the cases that I know of, they have been

1 consumer driven. It has been around a law suit because the
2 person's cancer was diagnosed at a much later stage than if
3 the mammogram had been read correctly or done correctly or
4 whatever. So, perhaps, that is where I am coming from.

5 DR. SICKLES: The FDA is unlikely to get notified
6 or act in a situation where a law suit might be involved.
7 That is, usually, really, an interpretation issue rather
8 than anything else and the FDA would never be involved in
9 that type of situation. It is unlikely they would be.

10 DR. FINDER: I wouldn't say that. In this
11 regulation, we have the authority to get involved where the
12 accuracy of interpretation has been compromised.

13 DR. SICKLES: How would you know?

14 DR. FINDER: There are multiple methods that we
15 may be notified about these types of things. Complaints
16 from patients is one of them, or from accreditation bodies
17 more so on the quality of the film rather than
18 interpretation. But there are various mechanisms. That is
19 one of the things we don't want to box ourselves into a
20 corner to say that if we become aware of certain things, we
21 won't do anything because--

22 DR. SICKLES: As I understand this issue, the time
23 frame that you are talking about, the clock really begins
24 when the FDA becomes aware of a problem. The clock can't
25 begin any sooner than that because there is just not any way

1 of knowing there is a problem. So the only point of
2 assessing a time frame is to require the FDA to act
3 promptly.

4 As I understand it, it is an infrequent situation
5 which, I assume, the FDA would take as a high-priority
6 event. They are not going to put that one on the back
7 burner. They are going to do it quickly so I doubt that it
8 will be a significant clinical problem.

9 I don't think the FDA will be dragging its heels
10 on this type of situation where, if they really were
11 overwhelmed with work, they might let something else slide.
12 They wouldn't let this slide.

13 DR. MONSEES: On the other hand, if something is
14 found where somebody is out of compliance and it is
15 investigated, if it is not clinically important, you don't
16 want to be calling up 500 women and scaring them when, in
17 fact, they have nothing to worry about.

18 So things need to be investigated in the
19 appropriate fashion with the cooperation of the accrediting
20 bodies and whoever else can give guidance as to whether
21 there is clinical importance to the problem that was
22 detected.

23 MR. DEMPSEY: Carolyn, I would also answer that,
24 rather than the patient getting the short end of the deal,
25 what I perceive is quite the opposite that, at least now,

1 there is an official way in place combined with, as in the
2 final regs, you have to have a patient-complaint mechanism
3 spelled out that, in point of fact, perceived
4 irregularities, be it by the patient, by referring
5 physicians, by technologists, by anybody, there is a
6 mechanism in place where this gets immediate attention and
7 is investigated by the people that can investigate it and an
8 answer be gotten in a timely fashion.

9 So, in point of fact, there is something now on
10 the books, so to speak, that protects the patient and
11 whatever irregularities are determined, however, they come
12 about, can be investigated in a prompt way by the people
13 that can investigate it. So I think it is actually a very
14 great protection for the patient.

15 MS. HAWKINS: I can sort of understand, especially
16 the patient notification when you look in terms of problems
17 and that you don't want to create a public-health panic
18 which, possibly, can happen especially with the way the
19 media gets involved in situations. I know, not relating to
20 mammography, we have had, in a number of our medical
21 facilities where there have come to our attention that there
22 were uncertified or unlicensed physicians and so forth that
23 were practicing, and those types of situations.

24 But I wanted to ask--I noticed maybe a couple of
25 months ago where FDA closed a mammography facility. I

1 believe it had to do with poor imaging as far as the--this
2 was a news article so I am just--it was not a scientific
3 article or in any of the scientific journals, but I am just
4 wondering, what sort of notification followed that type of
5 action by FDA.

6 DR. FINDER: Do you remember where this occurred,
7 because we have had a couple of these types of cases where
8 we have notified patients.

9 MS. HAWKINS: I want to say maybe Chicago.

10 DR. FINDER: Basically, that was a fairly
11 complicated cases involving a facility that was operating
12 uncertified and doing some other things and having problems
13 with the quality of their mammograms. What happened is the
14 physicians of those patients and the patients were notified,
15 all by mail.

16 In fact, that was taken care of so they all got
17 notified of the conditions, those patients that were put at
18 risk because of that facility.

19 MR. MOBLEY: I hear everything that everybody is
20 saying. I think that the situation is much better than it
21 was years ago, both in terms of imaging and lower doses and
22 better diagnosis and everything. But I also have a long-
23 term history working in government and know that, at times--
24 number one, I know that we don't like to put a regulation on
25 ourselves.

1 But, at times, even though it is not something
2 that happens very frequently--and maybe those are the ones
3 that create problems sometimes, but it does seem like it is
4 awfully open-ended here and when you look at it, it is just
5 that something will happen.

6 I know it takes time to make the determination and
7 everything, but it would seem that there should be some
8 drivers there other than whenever FDA gets around to it. I
9 am saying that in that sense, and I understand. But there
10 are no drivers here that I see.

11 DR. MONSEES: Could we suggest, perhaps, that the
12 FDA has given a period of time to decide whether patient
13 notification needs to occur by a certain date, given 30 days
14 from the time of discovery, or 60 days, to determine what
15 the next step is or what needs to be the outcome?

16 DR. FINDER: Again, I think that we are talking
17 about guidance at this point. Even if we put it into the
18 regulation, we can only do what we can do. The track record
19 for this, unfortunately, has not been that great. Each case
20 is individual and each one has its own quirks and problems.

21 The other thing I would like to just mention is
22 the fact that this is a regulation for the final regs. We
23 have actually done "voluntary" patient notifications under
24 the interim regs because we didn't have the regulation to
25 back it. So we went ahead, even without the regulations in

1 those cases where we felt that the situations warranted.

2 So I would think that now we have this backing
3 and, as you will find out tomorrow, changes were put into
4 the Mammography Quality Standards Act that enhance our
5 ability to deal with these situations specifically.

6 So, as I say, things have not been perfect. We
7 are getting more and more practice with this unfortunately,
8 but the numbers are still small and each case, it turns out,
9 is very different, generally, from the one before it. So,
10 all I can say is when we get these cases, we try and deal
11 with them in an expeditious manner because we realize what
12 is going on.

13 DR. MONSEES: So let it be said that the consumer
14 advocates and people who deal with this suggest that the FDA
15 see if they can make sure that this is always kept in a high
16 priority and that this never be put on the back burner.

17 DR. FINDER: Right.

18 MS. EDGERTON: Trisha Edgerton, State of
19 California. I can tell you that in the State of California,
20 when we have done our required patient notifications, that
21 we can't set a time frame on from when we discover a problem
22 to when we decide to do patient notification.

23 But once we decide patient notification is
24 indicated, we give the facility 30 days to have notified
25 everybody. So once we feel confident that there is a need

1 for that, we do everything we can to find out as quickly as
2 possible. But then once we know, they don't have any slack.
3 They have got to notify patients.

4 DR. MONSEES: What has been the range? How long
5 did it take from the time you investigated until the time
6 you know whether patient notification was necessary? What
7 kind of range are we talking about here, in your experience?

8 MS. EDGERTON: From the next day, according to
9 California regs for some things that we have that you
10 didn't, to two months waiting for targeted clinical image
11 reviews to come back from ACR. That has been about it. But
12 we always offer then, also, the opportunity. When we decide
13 that there appears to be a global problem that we want to
14 notify, we will say, "Okay; you can either notify all your
15 patients by mail that they all possibly may need another
16 mammogram to get a diagnostic exam," or you can choose to
17 have every film read from this day to this day by another
18 radiologist that we approve of and only notify those that
19 are turned back and nondiagnostics.

20 So we offer them that opportunity and, since that
21 is at their cost, generally they notify--

22 DR. MONSEES: Every patient; okay. Any other
23 comments on this issue?

24 MR. MOBLEY: Trisha, tell me how this plays out.
25 They can have all their films read and only notify those

1 that need to be notified or they can notify all their
2 patients and have all their patients come back and have
3 another film made, additional exposure?

4 MS. EDGERTON: The letters indicate--we have them
5 review the letter. We have them send us the letter to
6 review before they send it out. All it can say in there is--
7 --we can't order them to send the women back and have
8 mammograms but the letter does state that, "There is a good
9 possibility that your exam was nondiagnostic and that we
10 recommend highly that it be repeated."

11 We did have a case recently of a facility--in
12 fact, the docs went to jail--and notified all the women, had
13 it translated into Korean and, in the court judgment, the
14 offending radiologists had to pay for all the repeat films
15 for all the women to come back.

16 Even then, we had trouble getting the women to
17 actually come back. I got in touch with the Asian-
18 something-something health organization and asked them to
19 intervene for us because a lot of the patients--obviously,
20 there is a language barrier and, also, a thought barrier.
21 They had had their one mammogram in five years and that was
22 good enough for them even though they got a letter stating
23 that the district attorney had done all these things and
24 that the guy had gone to jail.

25 So we can't force them, even in the most extreme

1 case like that.

2 DR. MONSEES: The letter was in Korean?

3 MS. EDGERTON: Yes; we had it translated. It went
4 out in English and in Korean.

5 MR. MOBLEY: My question, really, was in the sense
6 that if we can require something to be done that does not
7 require all the women to come in and have mammograms made
8 again, then we have reduced the exposure to those women for
9 which exposure is not necessary.

10 That would mean, to me, that if I have a facility
11 where films can be reread and only those that have to come
12 back in, or have to be notified that they should come back
13 in, I think that should be the driver. We are just asking
14 to expose women again unnecessarily. I know our exposures
15 are a lot less than they used to be but I still don't
16 believe in unnecessary exposure.

17 MS. EDGERTON: Neither do we. In every case, the
18 three cases I can think of off the top of my head that we
19 have required notification, there has been a global
20 catastrophe and almost all films have been absolutely
21 terrible. It is still a patient notification, not a patient
22 demand. We can only suggest.

23 We also told them that they can also pick up their
24 films--maybe this answers your question--and have them
25 reread if the physician is not wanting to. We kind of try

1 to offer them--even though sometimes when you offer them too
2 many ways to go about it, then they get so confused, they
3 don't do anything. So we try to leave it plain and simple.

4 And we always give phone numbers for them to
5 contact, give them alternatives, if they have any questions.

6 DR. MONSEES: It would seem to me that if you
7 closed a facility and you were sending out patient
8 notification, that you should notify all of the patients
9 even if somebody has reviewed those films and said they look
10 okay, because they might hear about it in the media and they
11 might wonder, knowing that they had their mammogram at that
12 facility and wonder why they hadn't been contacted.

13 Even though somebody, maybe Ed Sickles, has looked
14 at their mammograms and said, "They are really fine," they
15 may still be wondering if they haven't been contacted. You
16 are the outside expert, Ed.

17 MS. EDGERTON: In the case of the Korean clinic,
18 there were only 145 films had been done because, in fact,
19 they had been accredited by ACR but they didn't have state
20 accreditation--or certification, because we have our own
21 state certification. They had an unlicensed tech and a
22 variety of other things.

23 We finally got them shut. When 145 exams were
24 read, where all had been read as normal, 80 percent, when
25 they were reread by John Pierce at USC, were nondiagnostic

1 and eight were BI-RADS 5, highly suggestive of malignancy.
2 And they had all been read as normal.

3 So we feel pretty strongly about we really want to
4 notify everybody. It is usually that bad.

5 DR. MONSEES: Thank you.

6 MS. WILCOX-BUCHALLA: Pam Wilcox-Buchalla at ACR.
7 This is relative to the additional mammography review not
8 the patient notification. On page 65 of document A, the
9 third question from the bottom, when it is addressing who is
10 responsible for performing AMR, it says, "Either an FDA-
11 approved AB or a facility-identified entity approved by the
12 FDA."

13 In the smaller document on page 5, at the top,
14 there is a note that says, "Whoever does this should not
15 have a relationship with the facility or conduct the review
16 when it would otherwise be a conflict of interest or when
17 they have a bias in favor of or against the facility."

18 I would hope that FDA would give a little more
19 guidance than that about who the facility might select as
20 someone to do additional mammography review. It is not a
21 simple process, obviously. All of the ABs have stringent
22 requirements from FDA about who can do this.

23 I am also concerned that even if the facility
24 hires someone to do it, they are going to have to pay them.
25 And that, in itself, to me, is a conflict of interest in

1 terms of paying an AB to provide a reviewer. Obviously,
2 there are some other options but there is a conduit so that
3 the conflict of interest would be removed by contracting
4 through the AB with a reviewer.

5 So I just would ask, perhaps, if the radiologists
6 on the panel would give FDA some advice about how they might
7 expand on that guidance.

8 DR. MONSEES: Now that you point this out, it says
9 here, "Either an FDA-approved accreditation body or a
10 facility-identified entity approve by the FDA." So, in
11 other words, they are doing the leg work. I do have a
12 problem with that.

13 DR. SICKLES: I do, too. I didn't notice this but
14 why would the FDA want to allow the facility to choose
15 somebody to review them. It doesn't make sense.

16 DR. FINDER: Again, what this actually means is
17 that we would be working with them. It is not just a
18 question of them coming up with their neighbor next door and
19 picking anybody and we would say, "Oh, yes; that's fine."
20 We would be working with the facility and, generally
21 speaking, we would be looking--depending on the situation,
22 we would basically be looking for someone who is of high
23 quality in terms of, while it may not be directly from an
24 AB, it would be somebody who maybe has worked for an AB in
25 terms of a clinical review or something like that.

1 It is to give us more flexibility in terms of what
2 happens if an AB doesn't have somebody who is licensed in
3 that state and they can't send somebody down there to
4 actually reread films. You have to keep in mind, this is
5 not only clinical image quality. It is also interpretation.
6 There is the issue here about actually issuing new reports,
7 so we might need somebody, depending on the situation, who
8 could actually issue a new report.

9 So we didn't want to tie ourselves into somebody
10 who might not meet that qualification, might not be able to
11 do that. So that is where that kind of comes in from.

12 DR. MONSEES: Can we remove "facility-identified,"
13 then, because that seems to me that the facility is going to
14 get to choose and then ask for your approval.

15 DR. FINDER: We could put in other words in terms
16 of--

17 DR. SICKLES: Why don't you just take out
18 "facility-identified?" Just an, "entity approved by the
19 FDA."

20 DR. FINDER: Okay.

21 DR. SICKLES: Facility-identified smacks of some
22 favoritism there. I think what we are hearing is that the
23 FDA has no intention to let the facility identify an entity
24 anyway.

25 DR. FINDER: It is a joint process. We would be

1 working with them. Again, the issue would be not that they
2 could just pick anybody and we would then say, "Oh, sure;
3 that's fine." It is going to have to be a joint process in
4 the sense that--again, for example, let's take the situation
5 where it is a hospital in which they have got credentialing.

6 In order to get those films reread, and official
7 reports to go out, we might have to get somebody who we
8 could get credentialed at that facility in some manner.
9 Those are the kinds of situations--I don't know if that
10 would occur, but we don't want to close ourselves off to the
11 possibility of certain individuals being allowed to do this
12 type of procedure.

13 That is the only reason behind it. It is not to
14 make it easy on the facility. This is not an easy process
15 on the facility. I can assure you of that.

16 MS. BROWN-DAVIS: So taking the wording out
17 doesn't, in fact, change FDA's position in working with the
18 facility; right? So you are saying that it has to be done
19 jointly, in FDA's opinion.

20 DR. FINDER: It doesn't have to be done jointly.
21 I am saying that, in the situation, especially in the
22 situation we were dealing with under the interim regulations
23 in which it was all voluntary, we had to deal with the
24 facilities. And, in that process, we found out that it
25 seems to work.

1 Now, again, this does not mean that if the
2 facility comes up with an entity that we don't like or we
3 feel that they are trying to abuse the system, we would
4 necessarily consider that, their nomination for somebody.
5 We would just reject it.

6 MR. PIZZUTIELLO: I have a question about process.
7 The way I understand it, the accrediting bodies is where the
8 peer-review occurs, and that is where the peer-review
9 expertise rests. I don't understand how this process can
10 proceed without the accrediting body being involved in
11 selecting who does the peer review.

12 I don't doubt that FDA would want to choose
13 appropriate people but I don't quite see the logic in
14 allowing the process to proceed without the accrediting
15 body's input because I think it puts FDA in a situation of
16 deciding who is qualified to do peer review and, the way I
17 understand the process, that is the accreditation body's
18 purview.

19 DR. MONSEES: That is an important point.

20 MR. PIZZUTIELLO: If that is the case, could we
21 modify the guidance document to address that?

22 DR. MONSEES: Basically, it would say accrediting
23 body, then.

24 MR. PIZZUTIELLO: Right.

25 DR. MONSEES: No other entity.

1 MR. PIZZUTIELLO: In consultation with the
2 accrediting body.

3 DR. MONSEES: His point was that they may not have
4 somebody in that particular state who is licensed.

5 MR. PIZZUTIELLO: Right. But it wouldn't happen
6 without consultation with the accrediting body.

7 DR. MONSEES: Does the ACR have a reviewer for
8 every state? Ms. Wilcox, is there any state that there
9 wouldn't be somebody licensed to interpret the mammograms
10 and dictate the report?

11 MS. WILCOX-BUCHALLA: In terms of people who are
12 qualified reviewers, off the top of my head, there probably
13 are a couple of states. Hawaii and Alaska immediately come
14 to mind as places where we don't currently have reviewers.

15 On the other hand, I think we would be happy to
16 work with the FDA on finding someone who meets the criteria
17 and would be eligible to have credentials or whatever.
18 Every situation is different. I just felt a lot of concern
19 about facility-identified.

20 DR. MONSEES: Okay.

21 DR. SICKLES: I just had a question for Dr.
22 Finder. I am not clear on why this is an issue. If films
23 need to be reinterpreted, why does the person who is
24 reinterpreted have to be accredited at that hospital. I would
25 assume they would be licensed in the state but why would

1 they have to be accredited at the same hospital.

2 If the hospital is under review, it would seem to
3 me that requiring the outside reviewer to be accredited by
4 that hospital is inherently a conflict of interest.

5 DR. FINDER: Again, we are trying to leave
6 ourselves open to all possibilities. You may be right in
7 terms of that. The other issue is if the facility is part
8 of a hospital, we run into jurisdictional issues. But,
9 again, I am not sure about the logistics of it.

10 We were trying to leave ourselves open to deal
11 with as many options as possible to deal with this situation
12 that occurs very infrequently.

13 DR. MONSEES: I would have to agree that I would
14 feel very uncomfortable if it were some colleague of the
15 person who was called upon to do the review.

16 MR. MOBLEY: I am a little concerned about putting
17 too many requirements or suggested requirements on FDA
18 because if you were to require consultation with ACR, then
19 that is an added time factor that goes in there. This kind
20 of approach is not something that is not done elsewhere in
21 terms of requiring facilities to bring in a consultant or a
22 consultant group or something to oversee their operation.

23 They have to have that consulting group approved
24 by the regulatory agency. They pay for the consulting group
25 but the regulatory agency is the entity to which the

1 consulting group most directly reports and is also the one
2 that has the most involvement in the selection of the
3 consultant group.

4 So that is not an unheard-of regulatory approach
5 to putting somebody back on the right track. The less
6 people or entities that are involved, the earlier it is to
7 go ahead and make the decision. Obviously, that leaves that
8 decision a little bit more open because everybody is not
9 involved, but if it is the regulator, hopefully, they are
10 doing their part.

11 DR. MENDELSON: In the regulations, that sentence
12 is worded--I just saw it here--"for review by the
13 accreditation body if there is a serious risk to human
14 health, it goes, specified by FDA, for review by the
15 accreditation body or other entity designated by FDA."

16 In the guidance, I think if we reworded, further
17 down on that page, which is 65, "Who is responsible for
18 performing an AMR, either an FDA-approved accreditation body
19 or a reviewer designated by the accreditation body which FDA
20 approved, may be responsible for performing and AMR."

21 So it could be either an FDA-approved
22 accreditation body or designate of the accreditation body.
23 That might help. It takes it out of any of the contexts
24 that we were describing that may suggest conflict of
25 interest.

1 DR. MONSEES: Right. So designate in consultation
2 with the FDA, maybe.

3 DR. FINDER: Let me just give a little history
4 about in the regulation why it says, "or other entity
5 designated by FDA." That was to take into account the
6 event, which we hope will never occur, that we lose one of
7 the accreditation bodies. If that were to occur, and we
8 didn't have that sentence in there and we had this business
9 that we could only go through the accreditation body, then
10 we would be stopped dead in our tracks. We couldn't do
11 anything.

12 That is one of the things that we were thinking
13 about when that wording went in. Every time you make a
14 little change here and there, you bring up new issues that
15 sometimes have untoward effects. Now, again, I don't assume
16 that we are going to lose any accreditation bodies. We
17 certainly don't want to.

18 But if that were to occur, that would be an issue.
19 And that is the way out, with that wording. We could put it
20 in guidance because we are not bound by it, but it is
21 guidance to yourself, in some sense, what you are going to
22 do. Again, we have dealt with a few of these situations
23 already.

24 DR. MENDELSON: I just wonder what would be the
25 greater likelihood, the loss of the accreditation body or a

1 situation which I think we all recognize as getting to this
2 point which would also be quite rare.

3 DR. FINDER: That's true.

4 DR. MENDELSON: And the relative frequency of
5 each.

6 DR. FINDER: Let's put it this way. It is much
7 more rare that we lose an accreditation body than we perform
8 one of these.

9 DR. MENDELSON: I would think so.

10 MS. HAWKINS: I just wanted to ask; is this going
11 to be a process that is subject to appeal by facilities?

12 DR. FINDER: Yes.

13 MS. HAWKINS: Oh, boy.

14 DR. FINDER: They have their right. That doesn't
15 mean that the process stops. But they have the right to
16 appeal. But we also have the right to maintain the public
17 safety.

18 MS. HAWKINS: I think, too, this is a very
19 important issue and, even though we have this section that
20 is going to look to consumer complaints, in real life, few
21 consumer complaints are going to result in a facility being
22 closed down because what we are talking about here is
23 significant, level-1, findings which will result through
24 that inspection process and so forth.

25 It may be that consumers will complain once this

1 information gets to the level of consumers, once the
2 consumer reports are available, as to how facilities are
3 faring and so forth, like that.

4 DR. FINDER: Just to make a mention about that.
5 While the document talks a lot about level 1 findings, there
6 also is wording in there that describes that other things
7 can start this process. I don't want to leave the
8 impression that what we specified here in the guidance is
9 the only cause for this.

10 There are other things that we just can't
11 enumerate because they are low-volume numbers. But they may
12 be very serious so we don't want to box ourselves in.

13 DR. MONSEES: Are there any other comments on
14 additional mammography review and patient notification? If
15 not, we are going to try and tackle on other topic today.
16 Do we have any other comments here?

17 **Medical Records**

18 DR. MONSEES: We are going to try and tackle this.
19 We are going back to page 36 to 39 of the original A
20 document, 20 to 24 in the B document. It is page 25 in the
21 Small Entity Compliance Guide. If we don't have ample time
22 to finish this discussion today, we will carry it over to
23 tomorrow and the rest of the topics pertaining to the draft
24 document will be probably handled tomorrow anyway.

25 DR. SICKLES: I have a whole bunch of these. I

1 don't know if we are going to get through all of them today.

2 DR. MONSEES: Do you want to start? Might as
3 well.

4 DR. SICKLES: Sure. Let's start with A, page 37.
5 In the paragraph answer to the first question, sort of
6 middle of the page--

7 DR. FINDER: Page 37, communication of results to
8 patient?

9 DR. SICKLES: Yes.

10 DR. FINDER: Let me just say this. We can forget
11 about all that guidance in that regulation. What happened,
12 about two weeks ago--

13 DR. SICKLES: No; I don't mean the one underneath
14 it. The first question, not the second. I know what you
15 are getting at. The first question, not the second
16 question.

17 DR. MONSEES: Yes; what constitutes an acceptable
18 system for notifying patients and referring healthcare
19 providers--

20 DR. SICKLES: It does not have to do with the
21 issue of the reauthorization legislation. I know what you
22 are getting at.

23 DR. FINDER: Oh; okay.

24 DR. MONSEES: You are going to do the incompletes;
25 right?

1 DR. SICKLES: Yes; that's right. That is exactly
2 right.

3 DR. MONSEES: I have the same objection.

4 DR. SICKLES: There is a sentence, "In most cases,
5 where routine results," and then they are enumerated, "are
6 being sent;" incompletes are not routine results.

7 DR. MONSEES: I agree.

8 DR. SICKLES: Period.

9 DR. MONSEES: Right. In fact, most cancers are
10 going to fall into that category, incomplete. Those
11 patients are going to be called back for additional review.
12 Very few cancers are going to be called outright on the
13 original screen.

14 DR. SICKLES: Incomplete has to be deleted from
15 that parenthesis. Absolutely.

16 DR. MONSEES: I agree.

17 DR. SICKLES: And put in the other parenthesis.

18 DR. MONSEES: See where it says, "In most cases
19 where routine results," and they say negative/benign,
20 probably benign, incomplete--

21 DR. SICKLES: You have got a second sentence,
22 "Furthermore, when the assessment is;" incompletes should be
23 in that sentence and should not be in the sentence, "In most
24 cases," because incomplete assessments are the vast majority
25 of screening--

1 DR. FINDER: The only problem with that is the
2 regulation which specifically delineates what suspicious and
3 highly suggestive are.

4 DR. SICKLES: It delineates what suspicious and
5 highly suggestive are but does the regulation delineate that
6 incompletes may not be communicated as soon as possible?

7 DR. FINDER: No; it doesn't say it may not be.

8 DR. SICKLES: Then why can't you put in the
9 guideline that they belong there?

10 DR. FINDER: The difference is, when it talks
11 about when the assessment is suspicious or highly
12 suggestive, the results must be communicated. Again, that
13 is a regulation.

14 DR. SICKLES: So "must" makes it regulation.

15 DR. FINDER: Right. Now, if we wanted to say,
16 "And, in the case of incomplete, you should--" or something
17 like that, we certainly can move that around. But it won't
18 go into the "must" category.

19 DR. MONSEES: That's fine.

20 DR. SICKLES: Okay; that's fine. But, absolutely,
21 don't have it in the "routine." If the regulation prohibits
22 you from having it with "must," then have it be "should," a
23 separate sentence.

24 MR. DEMPSEY: A separate sentence to highlight its
25 importance.

1 DR. MONSEES: Any other comments on that page?

2 DR. SICKLES: The next paragraph is moot. Dr.
3 Finder could explain why, I guess, if you want.

4 DR. FINDER: Basically, the guidance, and even the
5 regulation has to change because Congress passed, and the
6 President signed, the reauthorization of MQSA which we will
7 discuss tomorrow. But one of the issues that was brought up
8 in the changed language is that all patients will now get
9 written communication of their results in lay terms. So we
10 have to change all this, all patients.

11 MS. HAWKINS: Concerning communication in lay
12 terms, does this--for instance, does a facility still need
13 to use terminology of the assessment categories?

14 DR. FINDER: No. The assessment category
15 terminology is for the medical report. The report that goes
16 out to all the patients is going to be the lay summary which
17 is going to be described in terms that can be understood by
18 the patient and should be kind of designed for the patient
19 population that the facility is dealing with. The only
20 exception to that is the self-referred patient who is going
21 to get both the lay summary and the medical report. That
22 will stay.

23 DR. MONSEES: The only important thing, really, is
24 that the patient know. It may be as simple as, "There is
25 something that you need to see your doctor about," as simple

1 as that. And the lay report might suffice as long as they
2 are notified as to whether it is positive or negative or
3 whether there is another next step that they need to take.

4 Dr. Sickles, any more pertaining to the medical
5 records? You said you had others.

6 DR. SICKLES: I had one other.

7 DR. MONSEES: 36 to 39 and 20 to 24.

8 DR. SICKLES: On page 20 of B. I just don't know
9 whether we are boxed in by regulations, or maybe we should
10 be boxed in by regulations, but I have heard from many
11 radiologists, having tried to begin to educate them on the
12 requirements--right up at the top of the page--to use the
13 assessment codes.

14 I have been telling people, "You must not only use
15 the assessment codes but you must use the exact wording.
16 The reason that I have been telling them that is because, in
17 the regulation, they are in quotes so I assume that they
18 mean the exact words.

19 I have gotten questions like, "Well, can you say
20 'normal' instead of 'negative.' They mean the same thing."
21 I have been saying no, you have to say negative. Or, for
22 example--it is not in this one but it is lower down for
23 category 0 where it says, "needs additional imaging
24 assessment," can I think of another way to say that other
25 than the specific wording in the regulation.

1 My answer has been no, you have to use the
2 specific wording. Is that true. And, if it is true,
3 perhaps we should state it explicitly because there is a lot
4 of questioning and concern. If the answer is no, the
5 regulations require it, then I think the guidance should
6 state explicitly that, "You must use these words. You have
7 no leeway."

8 DR. MONSEES: It says, "Shall contain." I believe
9 that means--

10 DR. SICKLES: I believe it, too. And that is why
11 I have been instructing people that way. But, since I keep
12 getting questions about it and since the response here isn't
13 as explicit as it could be, I think we ought to state that.
14 I think that we ought to state that there is no margin for
15 changing the wording. I am just getting a lot of questions
16 on it.

17 DR. MONSEES: Right. Now, you can put other
18 things in addition to this. It must contain at least this.

19 DR. SICKLES: Right.

20 DR. MONSEES: I suggest, and I tell you from my
21 own practice, that it is probably not good enough to only
22 say these words. You really need to say more than that.

23 DR. SICKLES: Absolutely.

24 DR. MONSEES: Did you have any other comments?

25 DR. SICKLES: Yes; but I have got to read through

1 them. I have got to understand--have somebody else do one
2 before I understand what I have written.

3 DR. MONSEES: Dr. Mendelson, do you have any
4 comments on these?

5 DR. SICKLES: Ah; I understand my next one,
6 because I have written myself all sorts of notes.

7 DR. FINDER: I hope you wrote "guidance" for that.

8 DR. SICKLES: I did. This is page 21. Line 758
9 through 762. This has to do with addended reports and the
10 need to send an addended report to the patient in addition
11 to sending the addended report to the clinician. Some
12 addended reports, which are substantive, clearly require
13 communication both to the clinician and to the patient.

14 In our practice, many addended reports simply add
15 on that, "The results of this report have now been
16 communicated to Dr. So-and-So at so-and-so time on so-and-so
17 date." That should not need to go to the patient. So there
18 are two types of addended reports. There are the
19 substantive ones and then there are the ones that are just
20 made for medical-legal reasons. "I called Dr. So-and-So and
21 I want it in the report."

22 I don't know how you can adjust for this but a
23 patient getting two letters basically saying the same thing
24 will confuse the patient when the only purpose of the
25 addended report is the legal notification of the clinician.

1 I am looking for a way out.

2 DR. FINDER: Now it is not the legal requirement.
3 Now it is the legal requirement that the patient get the
4 report and the lay summary, again, too. Well, not again,
5 but before it was somewhat more problematic. Now is it
6 clear as to what they are supposed to get but it still
7 leaves the issue that you brought up and how do you define
8 what is important or not.

9 We are open to suggestions because I agree,
10 sending out a lay summary only makes it more confusing.

11 DR. SICKLES: I have been thinking about this and
12 I have an idea, but I want other people to think about it.
13 One approach would be if the addended report has a
14 substantive change--for example, the assessment category
15 changes--then, clearly, the patient needs a different
16 notification.

17 If the addended report results in the same
18 assessment category--namely, there is no change in
19 management--then you could argue that sending a second
20 notification to the patient would be more confusing than
21 helpful. That is one side of the issue.

22 On the other hand, probably the most common
23 addended report is simply that we now got old films from so-
24 and-so hospital and findings are unchanged and the patient
25 might want to know that. So I am not sure that that is a

1 good endpoint.

2 DR. MONSEES: Let's hear from the consumer
3 advocates. Do you think it would be more confusing to get a
4 second report if there was no substantive change or do you
5 think that people would want to get the information even if
6 there wasn't anything important in that. Do you understand
7 the issue, what he is describing?

8 It may be an addendum that is just for bookkeeping
9 purposes or just to document that somebody else has been
10 sent a copy of the report, something like that. Would it be
11 too confusing to get a second letter?

12 MS. HAWKINS: I don't think so. In fact, I think
13 that full disclosure to the consumer is very important in
14 this process.

15 DR. MONSEES: Maybe the same exact letter that is
16 going out.

17 DR. SICKLES: The chances are that facilities will
18 send canned letters to patients rather than dictating
19 specific letters to each woman. It is not cost-effective to
20 do it with specific letters. They are going to have
21 standard form letters. A normal letter will go to patients
22 with normal interpretations and an abnormal letter will go
23 to patients with abnormal interpretations.

24 So, for example, if I were to read a case as
25 abnormal, the woman would get a letter saying, "An

1 abnormality was found on your mammogram. You need to have
2 additional testing. You should consult your doctor," et
3 cetera, et cetera, et cetera.

4 If I, then, generated an amended report that
5 simply said, "The results of this interpretation were
6 communicated to Dr. Jones on so-and-so date," because I
7 hadn't communicated yet--he wasn't available yet when I made
8 the first dictation--and I had to send a second letter, just
9 like this, to the woman, I could conceive, especially if
10 this second letter comes two days later in the mail, that
11 might be very upsetting to her, getting two of them without
12 any explanation why they are exactly the same letter.

13 Now she is wondering why did I get the second one.

14 MR. MOBLEY: Why did they make the special point
15 of notifying my physician.

16 DR. SICKLES: Well, no. She wouldn't know that.
17 She would only be getting a second letter that is exactly
18 the same as the first letter.

19 MR. MOBLEY: It wouldn't show what the intended
20 action is.

21 DR. SICKLES: No. She is not seeing the addendum.
22 The point is she is just seeing the canned report. That
23 would be confusing, I would think, to a woman.

24 DR. MONSEES: The first letter might say, "Contact
25 your physician." Another letter was going to say, "Contact

1 your physician."

2 DR. FINDER: Actually, you brought up a situation
3 that we hadn't discussed here. We had talked about the
4 repeat view or the comparison and suggested that those
5 letters go out additionally. Actually, what you are
6 sending, though, is not a lay summary of the report, not the
7 second report, because all the second report says is that
8 you notified your doctor, you talked to somebody.

9 MR. MOBLEY: You are not even sending that.

10 DR. FINDER: No; that's right. You are not
11 sending a lay summary of that second report. You are
12 sending a lay summary, again, of the first report. The
13 question should be, maybe, should you then, if you are going
14 to send out these addendums to the physician that he was
15 notified, maybe that is what the lay summary should tell the
16 patient is that, "Your doctor was notified of these results
17 as a lay summary."

18 DR. SICKLES: Is there a benefit to the patient to
19 tell the patient that, "Your doctor was notified of these
20 findings?"

21 DR. FINDER: I don't know.

22 DR. SICKLES: the assumption would be that the
23 doctor has already been notified of the findings.

24 DR. FINDER: It is a tricky situation.

25 MS. HAWKINS: I want to know, now, for instance,

1 why are you not sending me the second letter that you are
2 sending to the physician? Why are you not giving me those
3 results if there has been a change in the assessment or--

4 DR. SICKLES: If there has been a change in the
5 assessment, clearly, you are going to get a different letter
6 than you got the first time. That will be very instructive
7 because your first letter may have said A, and now you are
8 going to get a second one that says B.

9 You will see there is a difference and if you have
10 any questions--part of the letter will say, "If you have any
11 questions, please call so-and-so." And you are probably
12 going to call so-and-so because you got these two
13 conflicting letters. It will get explained to you.

14 But I am more concerned about the situation where
15 two identical letters go out with no obvious reason why the
16 second one was sent. I suspect that that will happen as a
17 matter of usual practice rather than anything else because
18 most facilities, in sending lay letters to patients, will
19 not be constructing them as voice dictations but, rather,
20 will be sending them as canned reports where they have
21 worked out very carefully the wording in the report so as
22 not to overly alarm but so as to cause sufficient concern so
23 that the woman follows through.

24 It is very hard--to find just the right language
25 for these reports to expect a radiologist to get this

1 wording right by voice dictation on a case-by-case basis is
2 asking too much.

3 DR. MENDELSON: I think it is important that, in
4 the canned reports--and one of the things I know we have
5 talked about previously is, perhaps, having prototypical
6 reports in the guidance documents so that there can be some
7 wording selected by many facilities across the country that,
8 in a way, can send out standardized notifications.

9 I think that would be a help. One of the things
10 that Dr. Sickles, I think, was afraid might happen is that
11 the identical report would go out to a patient. But there
12 could be a separate canned report saying that, "You will be
13 receiving another letter, that we are expecting to see your
14 outside films and they may affect what our recommendation is
15 for you."

16 Perhaps something of that sort may be anticipatory
17 letter for them so that when they get the final reading, in
18 lay terms, they will understand what has gone on, that what
19 was recommended for them depended upon outside films. The
20 same goes for a recall in screening for additional views or
21 for ultrasound.

22 There, they are essentially getting a translation
23 of the incomplete into lay terms saying that, "Your results
24 will be affected by your return so that we can complete your
25 study and answer whatever questions there might be."

1 So I think those reports which could be sent out
2 as canned reports and might be standardized would be a big
3 help, I think, to women in understanding what the process of
4 interpretation entails.

5 DR. MONSEES: Does the FDA want to give sample
6 reports? There are other places that these appear in the
7 literature. The Agency for Healthcare Policy and Research
8 has a series of guides and I don't think they are too
9 obsolete at this point. I think they would still suffice.
10 If people wanted to look for guidance, they could look
11 there.

12 DR. FINDER: I think that is a good suggestion.

13 MS. HAWKINS: Let me just ask Dr. Sickles if this
14 letter meets your expectations. This is a letter to a
15 consumer, being me. "The results of your recent exam
16 indicate no suspicion of breast cancer. A technical report
17 has been sent to the doctor listed below."

18 And it goes further to say, "As you know, breast
19 imaging cannot absolutely guarantee the absence of cancer.
20 We strongly recommend that you continue monthly self exams
21 and report any unusual findings to your doctor. An annual
22 physical exam by your doctor is also recommended. We will
23 mail you a reminder to schedule another mammogram in
24 accordance with national guidelines. Your films are part of
25 your permanent medical record stored at our facility.

1 Please be sure to share the date and location of these films
2 with any new physician or mammography facility."

3 And then they say, "Please feel free to call us if
4 you have any questions about our findings."

5 DR. SICKLES: That is a typical canned letter for
6 a normal situation. Actually, the one we send out has even
7 more information in it than that, but that is neither here
8 nor there. My concern is--let's say you were the patient
9 receiving this report and you received a second one that was
10 just like it. Would that confuse you?

11 You don't know why you got that second letter, but
12 let's say you just happened to get one two days later that
13 was just like that one. Would that concern you or would you
14 just say, "Oh; they must have made a mistake."

15 MS. HAWKINS: I would just say it's a--

16 DR. SICKLES: Halleluia; I got two of them.

17 DR. MONSEES: "Boy, this place is really good.
18 They are double-doing it."

19 DR. SICKLES: If that wouldn't concern you, that
20 is half of the coin. Now, what about the other half of the
21 coin? There is a parallel letter to that that you haven't
22 read for the abnormal situation where it says that, "We did
23 find something," and that you need to see your doctor and
24 you may need addition tests and you may need a biopsy,
25 without going into huge, great detail so that we don't panic

1 the woman.

2 Let's say you got the abnormal letter on Thursday
3 and then, next Monday or Tuesday, you got another one that
4 was exactly the same, having received the first one already,
5 you called your doctor and you are now trying to figure out
6 what to do. Who knows, you may have even gone in and had
7 additional testing.

8 But then, on Tuesday, you get another one.
9 Wouldn't that confuse you?

10 MS. HAWKINS: Well, if it was the same letter--

11 DR. SICKLES: It was exactly the same letter.

12 MS. HAWKINS: Same date and so on?

13 DR. SICKLES: No; it would have the new date on it
14 but it would have the same text, identical text.

15 MS. HAWKINS: I probably would call the facility
16 and ask, "Why are you mailing me all of these letters?"

17 DR. SICKLES: That second letter might be
18 generated simply because we had to make an addended report
19 saying, "We notified your physician of the results of our
20 first letter." I am wondering whether that would cause more
21 confusion than help.

22 MS. BROWN-DAVIS: I am wondering, Dr. Sickles,
23 why, in the first letter, the doctor couldn't be cc'd. Did
24 I lose you? If the doctor is going to be contacted and has
25 not been contacted yet--but is going to be contacted--why

1 can't that decision be made when the first letter is being
2 sent, and that physician would be cc'd.

3 So the woman would receive one letter and then she
4 would read the bottom. And then there would be a copy of
5 that. She is told that a copy of that has gone to her
6 physician.

7 DR. SICKLES: What I am trying to do is to follow
8 the letter of the guidance. The guidance says whenever
9 there is an addended report, you have to send another letter
10 to the patient.

11 There are situations where you make an initial
12 report, both normal and abnormal but especially abnormal,
13 where you want to, or, for medical-legal reasons, you may
14 feel you have to, verbally communicate that with the
15 physician.

16 DR. MONSEES: Call them up on telephone.

17 DR. SICKLES: Call them up on the telephone and
18 say, "Not only are you getting this in the mail, but I am
19 speaking to you about it because I don't want there to be
20 even the slightest chance that it is lost in the mail or
21 that your file-room clerk doesn't put it in the chart and
22 you never get to see it," and the woman has a breast cancer
23 going on for a whole year.

24 We telephone these. And we document the telephone
25 call, or many radiologists do, by amending the

1 interpretation to state that the physician has been called.
2 The reason for this--you may say, "Well, why do you have to
3 do that? Isn't that kind of silly? You have already made
4 the phone call." It is a medical-legal protection for the
5 radiologist because, on occasion, despite the phone call,
6 the physician receiving the phone call may deny having
7 received it.

8 This happens in medical-legal situations,
9 unfortunately, and radiologists, as a matter of routine,
10 many of them will make this type of amended report. It is a
11 technically amended report but it really is not at all
12 substantive. I am concerned about this situation.

13 DR. FINDER: My suggestion, at this point, and you
14 can probably think on it until tomorrow, is maybe there
15 should be a canned report that just says, "Your doctor was
16 notified." In fact, that would be the lay summary of the
17 second report.

18 There is some rationale for that. Obviously, if
19 you are that concerned about making sure that the doctor is
20 notified, you may want to send the second one to make sure
21 that the patient understands the importance of it.

22 DR. MONSEES: Or you could document it some other
23 way and just document--have somebody put a computer note but
24 not necessarily have a report go out or have somebody put it
25 on paper, or whatever, that the doctor has been notified and

1 not put it as an amendment to the report. Then you don't
2 end up with that situation.

3 DR. SICKLES: In our system, with our hospital
4 information system, we cannot do that. Amended reports have
5 to be added on to the initial report and actually the report
6 that goes out as an amended report is the initial report
7 plus something at the end. You can't just send a separate
8 thing. You are not allowed to do that.

9 MR. DEMPSEY: I think, really, the easiest thing
10 is since it is a canned report, since it is done by
11 computer, you can just have canned report No. 2 with the
12 same thing but, at the bottom, say, "These results have now
13 been communicated by telephone to your physician."

14 In that way, if you will, it is an amended letter
15 to the patient which would make sense. Since we are doing
16 it with the computer, it is easy to do that, I would think.
17 At least, in our computer program, you can generate as many
18 letters as you want. Just pick out which one you want.

19 In that way, again, you would have it standardized
20 and I think the patient would understand that. If the first
21 letter says, "Your physician is going to get the report,"
22 and the second letter one says, "It has now been
23 communicated by telephone," that would make sense.

24 DR. SICKLES: I understand. I have given a lot of
25 thought to this. I just don't have the right answer,

1 unfortunately. There are circumstances where the patient
2 gets--even though we try to have this not happen, the
3 patient gets notified from us directly rather than from her
4 physician.

5 It is the preferable approach to have the
6 physician notified and the physician call the patient than
7 to have her get a letter in the mail from a radiologist whom
8 she probably has never seen.

9 But that does happen. And, if that were to
10 happen, for example, because we can't reach the physician
11 because the physician is away and hasn't left anybody to
12 cover the practice, which happens, unfortunately, as well,
13 and the woman has, then, made adjustments and actually had
14 further workup, and her workup is all now determined but
15 then, a week later, she is getting this second letter that
16 says, "Your physician has now been contacted," she is going
17 to get really confused.

18 I would like some way out of this situation, if we
19 can, so that when all that has happened is that the
20 physician has been notified, that we don't have to send
21 another letter because I really think that is going to
22 confuse more than help.

23 But the regulation may not permit it.

24 DR. MONSEES: Why don't we sleep on it because we
25 are ending here. We will be continuing tomorrow morning at

at

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1 8:00 a.m. Tomorrow morning's discussion will not center,
2 early on, on the draft documents. But then, when we are
3 finished with the rest of the agenda, we will continue to
4 discuss the draft documents. So, see you at 8:00 a.m.
5 tomorrow morning.

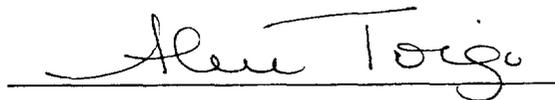
6 Thank you very much. We are adjourned for today

7 [Whereupon, at 5:50 p.m., the proceedings were
8 adjourned, to be resumed at 8 o'clock a.m., Tuesday,
9 November 3, 1998.]

10

C E R T I F I C A T E

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

A handwritten signature in cursive script, reading "Alice Toigo", is written above a horizontal line.

ALICE TOIGO