

# TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE

VOLUME I

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Pages 1 Thru 266

Gaithersburg, Maryland  
May 4, 1998

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE  
ADVISORY COMMITTEE

Volume I

1137 98 MAY 13 AIO:30

Monday, May 4, 1998

9:00 a.m.

Gaithersburg Hilton  
620 Perry Parkway  
Gaithersburg, Maryland 20877

MILLER REPORTING COMPANY, INC.  
507 C Street, N.E.  
Washington, D.C. 20002  
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P A R T I C I P A N T S

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

Carolyn Brown-Davis  
Kambiz Dowlatshahi, M.D.  
Roland G. Fletcher  
Patricia A. Hawkins, M.P.H.  
Kendra J. McCarthy, M.A.  
Ellen B. Mendelson, M.D.  
Michael H. Mobley, M.P.H.  
Laura G. Moore-Farrell, M.D.  
Sandra D. Nichols, M.D.  
Robert M. Nishikawa, Ph.D.  
Robert J. Pizzutiello, Jr., M.S.E.C.  
Edward A. Sickles, M.D.  
Patricia B. Wilson, R.T., RDMS

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P R O C E E D I N G S

CHAIRPERSON MONSEES: It's 9 o'clock. We're going to get started here. This is the National Mammography Quality Assurance Advisory Committee meeting. We're going to start out with the first item on the agenda, Dr. Finder.

DR. FINDER: I'd like to start off by reading the conflict-of-interest statement, and this is the conflict-of-interest statement for the National Mammography Quality Assurance Advisory Committee meeting, May 4 and 5, 1998.

The following announcement addresses conflict-of-interest issues associated with this meeting and is made a part of the record to preclude even the appearance of any impropriety. To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests reported by the committee participants. The conflict-of-interest statutes prohibit special government employees from participating in matters that could affect their or their employer's financial interests. However, the agency has determined that participation of certain members and consultants, the need for whose services outweighs the potential conflict of interest involved, is in the best interest of the government.

Full waivers are in effect for 14 out of 16 participants because of their financial involvement with facilities that will be subject to FDA's regulations on

1 mammography quality standards, with accrediting, certifying,  
2 or inspecting bodies, or with manufacturers of mammograph  
3 equipment, since these organizations could be affected by  
4 the committee's deliberations.

5           The participants include Dr. Barbara Monsees, Dr.  
6 Laura Moore-Farrell, Ms. Patricia Hawkins, Dr. Ellen  
7 Mendelson, Mr. Michael Mobley, Dr. Sandra Nichols, Mr.  
8 Robert Pizzutiello, Dr. Edward Sickles, Ms. Patricia Wilson,  
9 Ms. Kendra McCarthy, Dr. Kambiz Dowlath, Dr. Robert  
10 Nishikawa, Mr. Ronald Fletcher, and Dr. David Winchester.

11           Copies of these waivers may be obtained from the  
12 agency's Freedom of Information Office, Room 12A-15 of the  
13 Parklawn Building.

14           Out of abundance of caution, we have limited Dr.  
15 Sickles, Dr. Dowlath, and Dr. Nishikawa's participation in  
16 equipment standards because of their involvement with  
17 mammography devices. They are allowed to discuss mammograph  
18 technologies, including digital devices, as well as talk  
19 about their observations and experiences with these  
20 products; however, they will refrain from voting on specific  
21 equipment standards.

22           If any discussion of states as certifying bodies  
23 were to take place at this meeting, we would like to note  
24 for the record that this would be a general discussion only.  
25 No vote would be taken and no consensus would be sought.

1 The object of the discussion would be to get as many  
2 viewpoints from as many sources as possible, including  
3 opinions from the following State employees: Ms. Hawkins,  
4 Ms. McCarthy, Mr. Mobley, Dr. Moore-Farrell, and Dr.  
5 Nichols. Also, several of our members and consultants  
6 reported that they received compensation for lectures they  
7 have given or will give on mammography-related topics;  
8 however, they have affirmed that these lectures were offered  
9 because of their expertise in the subject matter and not  
10 because of their membership on the committee.

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

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

23 CHAIRPERSON MONSEES: Thank you very much.

24 We have some new panel members this morning, and,  
25 therefore, rather than just announce who they are, I'd like

1 the panel very briefly--we're talking one or two sentences  
2 so that we don't take up too much time because we do have  
3 bios in our packets--to say who you are and where you're  
4 from so that people can put a face with the packet  
5 information.

6 I'll start. I'm Barbara Monsees. I'm a  
7 radiologist from Washington University Medical Center in St.  
8 Louis, and I'm the Chair of this committee.

9 We'll start next and we'll go around the table  
10 with Mr. Pizzutiello.

11 MR. PIZZUTIELLO: My name is Bob Pizzutiello. I'm  
12 a medical physicist. I'm in private practice in upstate New  
13 York.

14 MR. FLETCHER: My name is Roland Fletcher. I'm  
15 the manager of the Maryland Radiological Health Program.

16 MS. MCCARTHY: My name is Kendra McCarthy. I'm  
17 the Director of Administrative Services for the Department  
18 of Mental Health in Virginia. I'm also a Director of  
19 Women's Cancer Advisory Network.

20 DR. NISHIKAWA: I'm Bob Nishikawa. I'm an  
21 assistant professor at the University of Chicago in  
22 radiology, and I'm a medical physicist.

23 DR. SICKLES: My name is Ed Sickles. I'm a  
24 radiologist at the University of California-San Francisco.

25 DR. DOWLATSHAHI: I'm Kambiz Dowlat. I'm a

1 surgeon at Rush University in Chicago.

2 MS. BROWN-DAVIS: Thank you. I'm Carolyn Brown-  
3 Davis. I'm the Executive Director of Breast Cancer Resource  
4 Committee, an advocacy group for African American women  
5 diagnosed with breast cancer, and we educate women about the  
6 importance of early detection and treatment.

7 DR. MENDELSON: I'm Ellen Mendelson. I'm a  
8 radiologist in practice in Pittsburgh at the Western  
9 Pennsylvania Hospital.

10 MS. HAWKINS: I'm Patrician Hawkins, a case  
11 management consultant with the Oklahoma State Department of  
12 Health in Oklahoma City.

13 DR. MOORE-FARRELL: I'm Laura Moore-Farrell. I'm  
14 in private practice in radiology in Fort Smith, Arkansas,  
15 and work with the Arkansas Department of Health on their  
16 Mammography Accrediting Committee.

17 DR. FINDER: I'm Dr. Charles Finder. I'm the  
18 Executive Secretary of this committee.

19 DR. NICHOLS: I'm Dr. Sandra Nichols. I'm the  
20 Director of the Arkansas Department of Health, and I'm a  
21 family physician by training.

22 MR. MOBLEY: I'm Mike Mobley. I'm the Director of  
23 the Division of Radiological Health in Tennessee.

24 MS. WILSON: I'm Patricia Wilson. I'm a  
25 technologist from Asheville, North Carolina.

1 CHAIRPERSON MONSEES: We're missing a few  
2 committee members this morning. The person who will not be  
3 here, the only person that will not be here during the  
4 entire meeting, as I understand, is going to be Dr. Peter  
5 Dempsey from UAB, University of Alabama-Birmingham.

6 With that, we're going to move on with the  
7 meeting. I'd like to mention to all of the committee  
8 members that we're being videotaped. This is a commercial  
9 company that is doing this for their own purposes. These  
10 are available for purchase. But I wanted you to know that  
11 you're being videotaped. Okay?

xx 12 After that, we're going to move on to Dr. Finder,  
13 who is going to talk about alternative standards requests.

14 DR. FINDER: Okay. This will be very brief since  
15 there were no alternative standards requests. I could stop  
16 at that point, but since we do have a little bit of extra  
17 time, I will go into just a little bit about what the  
18 alternative standards request is about.

19 In the regulations, there are procedures available  
20 for facilities or manufacturers or other entities to apply  
21 to the FDA if they believe that they have a different way of  
22 doing something that equals or exceeds the quality standards  
23 that are already mentioned in the regulations. So if  
24 somebody wanted to come in with an alternative request, they  
25 could and they would have to document and show to the FDA

1 that their new method either equals or exceeds the quality  
2 of the current standard.

3 As I say, at this point we don't have any.

xx

4 CHAIRPERSON MONSEES: At this time, we are going  
5 to move on to the open public hearing, but I want to make  
6 sure that our scheduled speakers are both in the audience.  
7 We need Paul Brown and John Sandrik. Are you both here?  
8 Thank you. Okay.

9 Then we will start with Paul Brown. Will you  
10 please identify yourself, if you'll come up to the podium.

11 DR. FINDER: Also, in the meantime--this is Dr.  
12 Finder--when any of the panel members speak, if they could  
13 announce who they are for the transcriptionist and the  
14 summary writer.

15 CHAIRPERSON MONSEES: Who is Mr. Brown? I'm  
16 sorry. Are you Mr. Brown? Would you like to speak over  
17 here? Do you have overheads?

18 Mr. Brown, if you will not only say who you are,  
19 but, if you will, notify us if you have a conflict of  
20 interest, please. Who you represent would be helpful.

21 MR. BROWN: My name is Paul Brown. I'm a division  
22 chief with the Illinois Department of Nuclear Safety. We're  
23 a regulatory agency in Illinois. I do not believe I have  
24 any conflicts to declare.

25 CHAIRPERSON MONSEES: Thank you.

1 MR. BROWN: I asked today to speak to you a little  
2 bit about States as Certifiers. We've been quite interested  
3 in this subject for the last four or five years. I know  
4 it's on the agenda for tomorrow. We weren't certain as to  
5 exactly what FDA would say at that time, so I want to give a  
6 brief discussion on that.

7 Again, I'm with the Department of Nuclear Safety  
8 in Illinois.

9 Next slide, please.

10 We're a very large department. Illinois is famous  
11 for having more power plants than any other state. We have  
12 seven facilities and 13 reactors, which is a driving force  
13 as far as the radiation control program.

14 Again, the Department of Nuclear Safety is a  
15 Cabinet-level agency. We have over 200 employees, a \$29  
16 million budget, about 26,000 X-ray machines, of which 400-  
17 and-some are mammography.

18 This is just a brief background. We all know  
19 about the Mammography Quality Standards Act. It was enacted  
20 in '92, and the authority to implement it was delegated to  
21 FDA, and we know about the interim rules that became  
22 effective in October of '94.

23 It requires facilities to be accredited,  
24 certified, and inspected. Again, this is basic history.

25 This is what we were interested in: The Secretary

1 may, upon application, authorize states to carry out  
2 certification program requirements.

3           And this basically entails issuing and renewing  
4 the certificate, doing the inspection and enforcement,  
5 implementing quality standards, which is, in essence,  
6 adopting the final regulations.

7           What's not included is approval to establish  
8 standards for accrediting bodies, which we have no interest  
9 in. We've had some discussions over the ability to assess  
10 and collect fees. Right now, FDA has indicated this is up  
11 in the air. We're able to do the inspections and basically  
12 run the program, but not collect the fee, which is causing  
13 us some difficulty.

14           IDNS basically stands for the Illinois Department  
15 of Nuclear Safety. Why do we want to do this? We're  
16 familiar with the people that are involved--the physicists,  
17 the technologists, the physicians. All these concepts--  
18 local control, timely response, reduced cost, familiarity--  
19 everyone who's involved in the discussions of the states  
20 doing this agree to these items.

21           This is--you know, one of our interests is in  
22 trying to reduce the cost to the facility. The last four  
23 fiscal years we've had contracts with FDA to do the  
24 inspections, and the unit cost is how much--that's what  
25 we're doing the contract per facility right now, and that's

1 regardless of how many machines are involved and the number  
2 of facilities. FY98 we only did--we're only to do 286  
3 inspections. We had a disagreement with FDA over the  
4 direction of the States as Certifiers and which ended up us  
5 not doing the contract July 1st. We had some discussions  
6 about that for three months or so before we renewed the  
7 contract.

8           Again, the concept of cost reduction, the FDA  
9 inspection fee is now \$1,549, and it's additional if there's  
10 more than one machine. Right now IDNS is doing the contract  
11 for \$718, and we've estimated that we can do the whole ball  
12 of wax for somewhere around \$750 per facility.

13           Here's the difference. If you look at the price  
14 of our contract versus what FDA is charging for the  
15 inspection, you can see the difference for the last four  
16 fiscal years. And, again, that's over \$500,000, the  
17 difference in cost, which we think is significant.

18           But, again, you know, we still believe that we're  
19 a very strong program in Illinois. We have a lot of  
20 expertise, and we believe we can run the program much more  
21 effectively and efficiently at the state level while still  
22 maintaining high quality standards.

23           This States as Certifiers, again, this was first  
24 discussed back in January of '94 when states expressed  
25 interest to the FDA regarding implementing States as

1 Certification. And we were going to try to put that on a  
2 fast track. I will not bore you with the chronological  
3 history of this, but we've had--various letters have gone  
4 from our department to FDA. We've had our director write  
5 Donna Shalala letters. We've had the governor write  
6 letters. We've had our director actually go to Washington  
7 and meet with the congressional delegation. In all this  
8 process here, we're concerned about the reauthorization and,  
9 actually, are asking that the fee issue be addressed during  
10 this reauthorization hearing.

11 In either case, we're now--well, this is another--  
12 after the reauthorization bill was introduced in the  
13 Congress, FDA established a working group to try to  
14 implements States as Certifiers on like a pilot-based  
15 program. We've had a number of meetings in that regard.

16 And it's basically now called the States as  
17 Certifiers Demonstration Project. Again, we've had a number  
18 of meetings with FDA, and we actually submitted an  
19 application in order to do this. We're working on adopting  
20 the final rule, which will be effective July 1st. We're  
21 still having some discussions regarding the fee issue.

22 These are still the problems that we're concerned  
23 with: assessment and collection of fees. Basically, the  
24 scenario that was last presented to us is that we would do  
25 the inspections under some type of a memorandum of

1 agreement. FDA would send out the bill. They would note  
2 our charge, and they're going to charge \$509 for their  
3 services, whatever they may be. And the facility will get  
4 the bill, pay the bill, and then FDA would reimburse us if  
5 the facility--if and when the facility pays them. Most of  
6 us who are under contracts right now, many states found this  
7 to be a very unsatisfactory arrangement. There was also an  
8 issue as to states--or those facilities that declared  
9 government entity status. Right now we are paid to do that  
10 under contract. FDA was insisting that we would not be able  
11 to collect the fee for those particular facilities. There's  
12 about 40 in Illinois, which really doesn't concern us,  
13 Nuclear Safety. In either case, they've changed their mind  
14 on that and now said that we would basically be reimbursed  
15 for that.

16 This demonstration project apparently right now  
17 has a one-year limitation, and then we'll have some further  
18 discussions about that.

19 That's basically what I had to say. Again, the  
20 Department of Nuclear Safety is very interested in this  
21 particular program. We believe we can do everything that  
22 needs to be done very effectively and efficiently, and at a  
23 lot less cost.

24 Thank you.

25 CHAIRPERSON MONSEES: Thank you. Will you stay

1 there in case there are any questions? Could we have the  
2 lights up, please?

3 I'd like to ask--here we go. Mr. Mobley?

4 MR. MOBLEY: Thank you.

5 CHAIRPERSON MONSEES: Identify yourself.

6 MR. MOBLEY: Mike Mobley.

7 Paul, I've got a couple of questions because  
8 Tennessee has not looked at this certifier proposal in any  
9 depth, and I need to understand a few things, if I could.

10 You made the issue or laid out the issue relative  
11 to the difference in the fees and everything. When a state  
12 would be a certifier, what level of the program effort do  
13 you believe it is that the state is carrying forward versus  
14 what the Feds would be carrying forward in that state?

15 MR. BROWN: Okay. For those of us who are doing  
16 the contracts, when we first started out with the first MQSA  
17 contract, we basically did the inspection, and that was it.

18 MR. MOBLEY: Right.

19 MR. BROWN: Over the years that has involved that  
20 we're doing more--we're not really enforcing the inspection  
21 findings, but we kind of are because we're having to follow  
22 up and make sure that the deficiencies are corrected.

23 In Illinois, we've taken a somewhat different  
24 approach in that the MQSA inspection process, as the  
25 inspector does the inspection, they print it off on their

1 little computer and they give it to the facility. In  
2 Illinois, all of our inspections, both on a state and  
3 federal level, are done by our inspectors, and they're  
4 reviewed by us in Springfield; and then when we're  
5 comfortable with the results and the content, then we  
6 actually send out the inspection findings letter. And,  
7 again, we track the enforcement.

8           But I really don't believe that under the contract  
9 right now we're basically doing the inspection. We're doing  
10 probably most of the enforcement. There's very few Level 1  
11 or even Level 2 deficiencies. Most of these are minor  
12 deficiencies that may not even require much of a response  
13 unless they're repeat violations. But we're already pretty  
14 much doing the inspection and enforcement.

15           Many of us issue certificates every day as part of  
16 our registration program or licensing program. I don't  
17 believe that's going to be a complicated process. And the  
18 fee issue, again, is something--normally, you know, we bill  
19 for an inspection or for a licensing fee. That's still up  
20 in the air.

21           Many states have very limited budgets, and they  
22 know exactly how much money they're receiving on the MQSA  
23 inspection contract. And if you get into a discussion as to  
24 whether or not you're going to receive that money based on  
25 whether or not the facility pays or when they pay under a

1 contract--right not you send them an invoice for X number of  
2 inspections, that's what you're going to get paid.

3 As the States as Certifiers was presented,  
4 although you did the inspection, you may not get paid for  
5 it. First of all, it may have been a government entity that  
6 you wouldn't be able to charge them for. Second of all, FDA  
7 indicated if the facility doesn't pay, then we're not going  
8 to get paid. So if you're on a very limited budget as a  
9 state program and you have actually employees tied to the  
10 contract, you're not going to be willing to go down that  
11 path until that's a little bit more settled.

12 MR. MOBLEY: Fine. But the question I'm asking  
13 is: How much additional work is it to move from just the  
14 pure inspection role to the certifier role? And basically  
15 what I'm hearing you say is it's a matter of being able to  
16 receive information from the facility regarding their  
17 accreditation, certify them, send them a certificate and--

18 MR. BROWN: We'll still basically be dealing  
19 directly with FDA. We'll just--right now the accrediting  
20 body indicates to FDA whether or not a facility is certified  
21 and needs a certificate. Their computer indicates to their  
22 contractor to print the certificate. Basically, we just  
23 want to be told to print the certificate, and we're going to  
24 deal directly with FDA.

25 Right now our contract is somewhere around \$720,

1 \$730 to do the inspections.

2 MR. MOBLEY: Right.

3 MR. BROWN: Again, just--and, you know, a lot of  
4 this is we don't know exactly what all is involved and to  
5 what extent, but, again, we believe we can do the whole ball  
6 of wax for somewhere around \$750.

7 MR. MOBLEY: Okay.

8 MR. BROWN: So that's not--you know, that's not  
9 much more than what we're doing right now.

10 MR. MOBLEY: Right, right. The one-year demo, is  
11 the one-year demo offered as let's do a demo and then maybe  
12 we'll roll that into a full program? Or is it a one-year  
13 demo, and then there's going to be a hiatus and nothing  
14 happens?

15 MR. BROWN: Mike, I don't think we really know.  
16 When we had the first pilot state meeting here in--with FDA,  
17 basically, you know, FDA was wanting to do rules and  
18 regulations, and they had their time frame for implementing  
19 this particular program. And FDA indicated that, you know,  
20 they had this time frame lined out, but apparently it wasn't  
21 playing very well in Peoria. And so they reassessed the  
22 need to do that now.

23 I'm not sure what the time frame will be after the  
24 one-year demonstration project.

25 DR. FINDER: It's Dr. Finder. A lot of these

1 issues, I believe, are going to be addressed tomorrow. So  
2 why don't we just wait and see what happens?

3 MR. BROWN: Okay. Thank you.

4 CHAIRPERSON MONSEES: Do we have any other  
5 questions or comments from the panel members? Dr. Sickles?

6 DR. SICKLES: Ed Sickles. Since we will be  
7 discussing this tomorrow, will you plan to be here tomorrow?

8 MR. BROWN: Yes.

9 DR. SICKLES: Good. Then because we're hearing  
10 part of it, but not all of it, it would be very helpful to  
11 hear both sides together. Thank you.

12 CHAIRPERSON MONSEES: Yes?

13 MR. FLETCHER: Roland Fletcher.

14 Paul, do you know how many other states are also  
15 wrestling with this dilemma at this time?

16 MR. BROWN: It's my understanding that Iowa and  
17 Illinois are the only two states that have applied for  
18 consideration as part of the pilot project. Again, I want  
19 to emphasize this became a very unattractive proposal  
20 because, first of all, each state had to adopt the interim  
21 rule, which is effective right now; then they had to turn  
22 around and adopt the final rule by May of '99. Those of us  
23 in regulatory programs know that when you have to do  
24 rulemaking, this is a very complicated and involved process,  
25 and few of us want--it's like having a tooth pulled. Few of

1 us want to do that twice in less than six months, or seven  
2 or eight months.

3 What we decided to do after the meetings were just  
4 go ahead and adopt the final rule effective July 1st.  
5 Again, the funding and how we were going to be paid and all  
6 that made many states back away. So right now Illinois and  
7 Iowa, to my knowledge, have submitted applications.

8 CHAIRPERSON MONSEES: Thank you very much.

9 MR. BROWN: Thank you.

10 CHAIRPERSON MONSEES: Our next scheduled speaker  
11 is John Sandrik.

12 Dr. Sandrik, will you please state who you're  
13 representing here and if you have any conflicts of interest.

14 DR. SANDRIK: Okay. I'm John Sandrik. I'm from  
15 GE Medical Systems, and I guess we do have an interest in  
16 making money on mammography equipment, but what I propose  
17 today is partly intended to save a lot of money for the  
18 facilities. So I don't think I have any particular conflict  
19 of interest in terms of what I want to talk about this  
20 morning.

21 The first slide, please? Thank you.

22 The purposes of this presentation are to identify  
23 a conflict between the quality mammography standard on X-ray  
24 field image receptor alignment and the federal performance  
25 standard on beam limitation, to present some of the

1 ramifications of this conflict, and to propose a means of  
2 resolving the conflict.

3 Next, please?

4 The quality mammography standard states that, "All  
5 systems shall have beam-limiting devices that allow the  
6 useful X-ray beam to extent to or beyond the edges of the  
7 image receptor..." The federal performance standard has  
8 prohibited and continues to prohibit manufacturers from  
9 providing equipment with this capability. Based on  
10 considerations of both image quality and cost, we believe  
11 that the facilities should be allowed to choose whether or  
12 not to use X-rays to provide film masking.

13 Next, please?

14 The detection of scattered radiation is known to  
15 reduce contrast in all forms of radiological imaging and the  
16 amount of scattered radiation reaching the detector is  
17 generally observed to increase as the size of the radiation  
18 field increases. Sources of scatter include air, the  
19 compression paddle, the breast support surface, the grid,  
20 and the screen film cassette.

21 Next, please?

22 A study reported at the RSNA in 1994 showed the  
23 density difference between the background and the image of a  
24 cylindrical contrast object increased by 0.1 to 0.2 optical  
25 density for beams collimated to the phantom compared to

1 beams opened to expose the entire image receptor.

2 As a point of reference, the quality mammograph  
3 standard sets a limit of plus or minus 0.05 optical density  
4 as a national limit for variations in such a density  
5 difference.

6 Next, please?

7 I have performed similar measurements to assess  
8 the change in subject contrast for the small change in  
9 collimation of an X-ray field that is extended from being  
10 several millimeters inside the border of the image receptor  
11 to several millimeters outside the border. Contrast objects  
12 were acrylic cylinders--the row of cylinders shown there--  
13 within a stack of breast-equivalent plastic blocks at six  
14 locations from the edge of the X-ray field. In this case,  
15 the edge of the X-ray field is along there.

16 The characteristic curve of the screen-film  
17 combination was used to convert a density difference to the  
18 subject contrast between the image of the cylinder and its  
19 background. The film, please?

20 Films obtained during this study help illustrate  
21 the nature of the problem. This is the image of a 2  
22 centimeter thick phantom. On the left and top, on this  
23 border and here, are the dreaded borders of unexposed films.  
24 The clear area to the right along this edge here is due to a  
25 sheet of lead that was placed on the breast support surface

1 adjacent to the right edge of the phantom. The important  
2 aspect to note is that all of the borders, all left, top,  
3 right, are all very well defined.

4 Next film, please? If you can slide that down?  
5 Yes, thank you.

6 This is the image of an 8 centimeter phantom  
7 exposed to provide essentially the same density in the area  
8 of the phantom as the 2 centimeter phantom. Note the  
9 density at the upper left and along the top edge of the  
10 film. Since there was no change in the collimation of the  
11 primary radiation beam, this density must be attributed to  
12 scatter. The scatter probably came from the compression  
13 paddle and the air. Those advocating the use of X-rays to  
14 provide film masking might view this as a serendipitous  
15 benefit of scattered radiation. But I would find it hard to  
16 believe that scatter had any particular affinity for  
17 unexposed film, yet did not at the same time degrade the  
18 contrast in the area of clinical interest.

19 Also note the border of the lead sheet, this edge  
20 along here. Along the edge adjacent to the unattenuated  
21 radiation, the border has become very poorly defined. This  
22 would suggest that, in addition to the scatter contributed  
23 by the air and the compression panel, which are above the  
24 breast support surface, scatter is also contributed to the  
25 image by structures under the surface, for example, the

1 buckey cover, the grid, the cassette, and the screen.

2 Next slide, please.

3 Extending the X-ray field from within the borders  
4 of the image receptor to beyond the borders caused a  
5 statistically significant loss of subject contrast of up to  
6 8 percent for a 10 mm extension at the left edge of the  
7 field and up to 14 percent for a 23 mm extension at the  
8 nipple edge of the field. The 14 percent loss of subject  
9 contrast is comparable to an 0.05 OD change in density  
10 difference at 1.6 optical density background density level.

11 The contrast loss was limited to within about 1 cm  
12 from the edge of the phantom and was mainly observed for the  
13 6 and 8 cm thick phantoms; that is, it mainly affects the  
14 larger, denser breasts already compromised by scatter  
15 generation and low contrast.

16 Some might consider that this loss of contrast is  
17 not significant because of the improvement in productivity  
18 that can be gained by using X-rays to produce film masking.  
19 My intent is to demonstrate that this method of masking is  
20 not free. There is a measurable negative effect on image  
21 quality.

22 Next, please?

23 Another conflict of regulations becomes apparent  
24 when we attempt to meet both the collimation and the  
25 resolution requirements. The quality standard on

1 collimation does not distinguish between application to  
2 large or small focal spot. Application to the small focal  
3 spot will have a significant impact on magnification  
4 imaging.

5 To provide the necessary film coverage along the  
6 anode-cathode direction, we must increase the target angle  
7 of the small focal spot. Increasing the target angle  
8 lengths the focal spot and proportionately reduces the  
9 resolution. We then find ourselves in serious conflict with  
10 the resolution regulation.

11 Next, please?

12 The resolution regulation sets lower limits on  
13 limiting spatial resolution with no bound on the  
14 magnification factor. To restore the resolution, we must  
15 shorten the focal spot. Shortening the focal spot increases  
16 the power density on the anode. Increasing the power  
17 density melts the anode. End of story--no, not quite.

18 Okay. Next slide?

19 Solutions that lead to compliance with both the  
20 collimation and resolution regulations by 28 April 1999 will  
21 require a reduction of tube current for the small focal spot  
22 by about 40 percent. This can be expected to lead to longer  
23 exposure times, loss of resolution due to patient motion,  
24 and some increase in dose due to film non-reciprocity.

25 Next, please?

1           While the focus of the MQSA is on mammography  
2 quality, with a lesser concern for cost, a hint at the  
3 magnitude of the expense the facilities might be  
4 appropriate. All systems that we have sold and currently  
5 manufacture have been designed to be compliant with 21 CFR  
6 1020.31(f)(3), the federal performance standard that  
7 prohibits the extension of the X-ray field beyond the edge  
8 of the image receptor except at the chest wall edge. In  
9 fact, it was once considered prudent to ensure that a clear  
10 border appeared on every film so that it would always be  
11 apparent to any inspector that the mammographic system was  
12 operating in compliance with the FDA performance standards.  
13 No draft of the quality mammography standards, including the  
14 proposed final regulations, ever suggested any deviation  
15 from the existing performance standard on collimation.  
16 Hence, none of the cost estimates provided by us ever  
17 included the cost of making all currently installed  
18 mammographic systems compliant with this rule.

19           Next, please?

20           In the analysis of impacts, published with their  
21 final regulations, the FDA estimated the maximum yearly cost  
22 to facilities will be \$156 million. For GE systems alone,  
23 the cost of facilities to become fully compliant with the  
24 mammography quality standard on collimation will exceed that  
25 amount, and those expenditures will need to be made prior to

1 28 April 1999 since all systems must be compliant by that  
2 date.

3 Next, please?

4 We recommend that the quality mammography standard  
5 be revised to permit the X-ray beam to extend beyond the  
6 edge of the image receptor, but not require that all  
7 facilities have systems that do so. A recommendation for  
8 the wording of the revised regulation is: "The beam-  
9 limiting devices of all systems may, but are not required  
10 to, allow the X-ray field at the plane of the image receptor  
11 to extend beyond any edge of the image receptor. Such  
12 extension shall not exceed 2 percent of the perpendicular  
13 distance from the image receptor plane to the position of  
14 the focal spot and the primary X-ray beam shall not extend  
15 beyond the edge of the image receptor support except for the  
16 chest wall side."

17 While it is not within the scope of the National  
18 Mammography Quality Assurance Advisory Committee, the FDA  
19 should also consider harmonizing the performance standard  
20 with the quality mammography standard so that it is, in  
21 fact, permissible for manufacturers to produce such systems.  
22 Masking of mammograms clearly improves the ability to  
23 observe contrast in the presence of masking devices is  
24 required by quality mammography standards. However, since  
25 extension of the X-ray field beyond the image receptor both

1 degrades image quality and increases a facility's cost, we  
2 feel that the decision to choose this method of film masking  
3 should remain with the facility and not be required by  
4 regulation.

5 I thank the committee for providing the  
6 opportunity to address you today and will be happy to try to  
7 answer any questions you might have. Thank you.

8 CHAIRPERSON MONSEES: Can we have the lights up,  
9 please?

10 Now, this item will be discussed tomorrow morning.

11 DR. SANDRIK: Right.

12 CHAIRPERSON MONSEES: Are you going to be here  
13 tomorrow morning?

14 DR. SANDRIK: I will.

15 CHAIRPERSON MONSEES: Okay. I'm going to give an  
16 opportunity--you know this is going to be discussed  
17 tomorrow. I'm going to give an opportunity to panel members  
18 at this time to make questions or comments. Do we have any?  
19 Yes?

20 DR. NISHIKAWA: Bob Nishikawa. Hi, John.

21 DR. SANDRIK: Hello.

22 DR. NISHIKAWA: I'm a little confused with your  
23 phantom image, the one that you showed, the blurring of the  
24 edge when you had the 8 cm phantom which you claim was from  
25 back scatter from the grid in the image receptor, I guess in

1 the area where the phantom wasn't. Why didn't you see it at  
2 the edge of the phantom then if it was from--

3 DR. SANDRIK: I believe it's because at the edge  
4 of the phantom--it was an 8 cm phantom, and it provided  
5 sufficient attenuation of the primary radiation that was a  
6 very small amount of radiation reaching whatever is  
7 generating the scatter under that area. But in the other  
8 area, it's totally unattenuated radiation. So, you know,  
9 it's somewhere around maybe 500 times more intense at that  
10 area and generated enough scatter to expose the film that  
11 you couldn't see generated where the phantom was.

12 DR. SICKLES: Ed Sickles. I have two questions  
13 for you. Just to follow up on that, one would then conclude  
14 that if you were to have done a breast instead of a phantom,  
15 the significant scatter would only be in the black parts of  
16 the film where the breast was not, so it would not degrade  
17 the useful image, it would only degrade the black of the  
18 air. Is that true?

19 DR. SANDRIK: No. What I'm saying is I'm sure--I  
20 don't--well, in fact, I do have the data that demonstrate  
21 the fact that, as you look at those acrylic objects within  
22 the phantom--in fact, that was the point of that one slide.  
23 You can measure the loss of contrast within the phantom.  
24 The scatter is more or less isotropic, and whereas you can  
25 see it going into the clear film, it's also going towards

1 the breast image as well.

2 DR. SICKLES: Okay. The more important question  
3 was: If the FDA were to adopt your suggestion and not  
4 require the beam to blacken the film past the edge of the  
5 film, would there be a problem limiting the amount of white  
6 that could be on the film to a reasonably small distance? I  
7 might have a problem if this were completely uncontrolled  
8 and it could be collimated down to where the breast existed.

9 DR. SANDRIK: Part of that depends on how  
10 extensive you want to do this. And I can't speak for all  
11 the manufacturers, but we are closer to reasonable  
12 solutions, for example, for a large focal spot, 18 by 24 and  
13 probably 24 by 30. For our particular equipment, if you  
14 want to try to get a 24 by 30 full blackened image with a  
15 small focal spot, it's a major problem. And since the  
16 regulation does not differentiate between field size or  
17 focal spot, it sort of becomes a problem across the board at  
18 this point.

19 DR. SICKLES: What if we were talking about just  
20 the large focal spot?

21 DR. SANDRIK: We're much closer to some sort of  
22 reasonable solution to do that. Perhaps being able to do  
23 many thousands of systems by this April will be somewhat  
24 problematic, but we're closer to a solution.

25 MR. PIZZUTIELLO: Bob Pizzutiello. Again,

1 referring to that image that you showed with the phantom and  
2 the large black fuzzy area, do you have any sense that  
3 that's caused by scatter and not by undercutting within the  
4 cassette?

5 DR. SANDRIK: Well, I mean, it doesn't show up on  
6 thinner phantoms.

7 MR. PIZZUTIELLO: Right, where there's less--

8 DR. SANDRIK: Where there's less material. I  
9 guess I could have tried expanding the experiment further,  
10 but at this particular point, the lead was sitting on the  
11 buckey surface. So it could be something else like that. I  
12 have talked to some other people on this, and one person  
13 whose work I had cited had found a paper from back maybe in  
14 the '50s and someone talking about fluorescence emission  
15 from the lead of the grid as one source of this kind of  
16 radiation, the point being that, yes, the fluorescence is a  
17 very small part of the--you know, it's a very small source  
18 of radiation, but if you have a very intense beam that's  
19 unattenuated generating some of that compared to what's in  
20 the phantom, the fluorescence radiation, say, from the lead  
21 could be comparable to what's actually transmitted through  
22 the phantom.

23 So I can't say for sure that it wasn't the  
24 undercutting. I don't see it next to the phantom. I don't  
25 see it at thinner phantom values where there's less

1 unattenuated radiation. So I kind of don't think that it's  
2 a straight--you know, like a resolution effect or something  
3 like that.

4 DR. SICKLES: Thank you.

5 DR. NISHIKAWA: Bob Nishikawa again. I'm still  
6 trying to figure out exactly what the physics is involved  
7 here. You're claiming that scatter from the grid travels  
8 from outside the breast area to a point comparable to inside  
9 the breast area, sort of like almost a 90-degree angle  
10 scatter.

11 DR. SANDRIK: Some of it, yeah. And I'm not  
12 saying it's necessarily all from the grid. That was one  
13 explanation that was found in the literature. I think some  
14 could come from the screen, the cassette cover, the buckey  
15 cover. I know we have had a situation where the buckey  
16 cover was identified as a fairly significant source of  
17 scatter and, in fact, led us to remove the cover for  
18 magnification imaging. It was found to be significantly  
19 degrading magnification contrast. So I think those are all  
20 possible sources. The thing is, I must admit I have not  
21 extended the experiments to understand exactly all the  
22 sources, but I could quantitate the level of the effect by  
23 opening up the field.

24 DR. NISHIKAWA: And for the reduction in contrast  
25 that you mentioned, what's the amount of scatter for the

1 primary beam that causes that reduction?

2 DR. SANDRIK: I haven't calculated that.

3 DR. NISHIKAWA: Okay. Could you just give me the  
4 numbers again?

5 DR. SANDRIK: Fourteen percent when the beam  
6 opened by 23 mm, and it was 8 percent for a 10 mm opening.

7 CHAIRPERSON MONSEES: Do we have any other  
8 questions or comments from the panel members?

9 [No response.]

10 CHAIRPERSON MONSEES: Thank you very much.

11 Now, tomorrow we will be spending some time on  
12 this subject, and there will be some question-and-answer  
13 from the panel after the presentations. Are there any  
14 manufacturers in the audience that will not be here tomorrow  
15 that have some comments on this that would like to make a  
16 statement?

17 [No response.]

18 CHAIRPERSON MONSEES: Okay. Thank you very much.  
19 We'll move on then.

20 We are scheduled for a break. I'm wondering  
21 whether or not we can--is that right? I'm wondering whether  
22 we can start the presentation and take the break a little  
23 bit later. I will move to John McCrohan begin his portion  
24 of the presentation. He's going to tell us about the  
25 inspection under the final regs. The format, as I

1 understand it--and correct me if I'm wrong--the format, as I  
2 understand it, is that you'll make a presentation and then  
3 call for comments and questions from the panel members.  
4 Maybe you should describe what you're planning on doing, and  
5 would you introduce yourself, please?

xx

6 MR. McCROHAN: Certainly. My name is John  
7 McCrohan. I'm currently the Acting Director of the Division  
8 of Mammography Quality and Radiation Programs. You wanted  
9 to spend some time this morning talking about the inspection  
10 program under MQSA.

11 In advance of discussions, most of which will take  
12 place this afternoon, in which we were seeking your advice  
13 on how we ought to structure the inspections under the final  
14 regulations, which has been pointed out this morning, which  
15 are going to be effective about a year from now, and we are  
16 going to be starting inspections under those regulations at  
17 that time, we have a proposal, if you will, for how we would  
18 evolve the existing inspection program from what's taking  
19 place now under the interim regulations to what we would  
20 like to take place under the final regulations. But we  
21 wanted to get your advice on that proposed inspection  
22 structure and to perhaps ask some specific questions as to  
23 how we ought to approach some of those issues.

24 In order to facilitate that discussion, which, as  
25 I say, will take place largely this afternoon, I wanted to

1 give you some background this morning, talk about how the  
2 inspection program developed, given an overview of the  
3 inspections as they have taken place under the interim  
4 regulations, and then very briefly give an overview of our  
5 plans for the inspection program under the final  
6 regulations. And then we would go on into a more detailed  
7 discussion of the specific points within the inspection  
8 program under the final regs.

9 DR. FINDER: Okay. John, before you continue, I  
10 just wanted to mention that all the committee members have  
11 copies of the overheads, so you can look at those. And,  
12 two, John, do you need both overhead projectors?

13 MR. McCROHAN: Not at the moment, no.

14 I understand the copy that you have is perhaps a  
15 slightly condensed version of this, but all of the material  
16 is there.

17 This is actually the second opportunity we've had  
18 to speak about the inspection program in front of the  
19 Advisory Committee. We spoke to the committee in October, I  
20 believe, of '96 and presented at that time the structure  
21 with respect to the inspections under the interim  
22 regulations and talked about that in considerable detail,  
23 looking for opportunities to modify the inspection program.  
24 We had a certain amount of good discussion at that time and  
25 a few suggestions for changing the program, and we wanted to

1 come back for this additional opportunity, particularly  
2 focused on the inspection under the final regs.

3 As background, I did want to say that vis-a-vis  
4 the interim regulations, we did a fairly extensive amount of  
5 work in a couple of areas, both in terms of outreach to  
6 facilities in preparation for the inspection program in  
7 training the inspectors and development of the inspection  
8 program itself. And I wanted to spend a little bit of time  
9 reminding you or reviewing for you some of those activities  
10 which will have some counterparts as we move into the  
11 inspection program under the final regs.

12 In particular, with respect to the outreach  
13 aspects in terms of how we communicated with mammography  
14 facilities about what the inspection program would entail,  
15 we had a variety of material that we presented to them in  
16 mammography matters. This, as you probably know, is the  
17 quarterly newsletter that we publish. Its 17th issue is  
18 about to go out. The first issue was in December of '94.

19 We also, at the time we were entering into the  
20 inspections under the interim regulations, had made a  
21 variety of public presentations, the RSNA, at APM and at the  
22 breast cancer conference and a variety of other things, and  
23 have continued to make presentations to those audiences as  
24 part of our attempt to outreach to mammography facilities.

25 We also had and continue to maintain and will

1 continue to maintain a facility hotline which is an 800  
2 number that facilities can call when they have questions  
3 with respect to various aspects of the MQSA program,  
4 including certainly the inspection program.

5 In advance of the inspections under the interim  
6 rules, we also published for the mammography facilities and  
7 sent to each of the facilities a document that was entitled,  
8 "What a Mammography Facility Should Do to Prepare for MQSA  
9 Inspections." We intend to revise that document and to send  
10 a version of that that's more applicable to the final  
11 regulations to all the facilities in the winter of this  
12 year.

13 We also prepared a conceptually similar document  
14 for the medical physicists, and we intend to update that as  
15 well as we move towards the implementation of the final  
16 regulations.

17 We also currently have and have had for some time  
18 a policy document on our Web site which allow facilities  
19 with that kind of access to look at the guidance that's been  
20 developed under MQSA with respect to various aspects of the  
21 regulations, including the inspections. And we intend to  
22 update the documentation on the Web site as we approach the  
23 inspections under the final rules.

24 So we've taken a variety of steps to try to keep  
25 facilities informed about what the requirements are and

1 what's expected of them, and that's certainly to make life  
2 easier for the facilities; but in terms of the inspection,  
3 it also makes life easier for us and for the inspectors  
4 because it provides the facilities the opportunity to get  
5 their records together and so on and, therefore, to reduce  
6 the impact of the inspection on them by reducing the  
7 inspection time.

8 I'd also like to point out that we spent a good  
9 deal of time in advance of the implementation of inspections  
10 under the interim rules training the MQSA inspectors. That  
11 training continued after the inspections began in January of  
12 '95. The inspectors go through three two-week-long training  
13 courses, a basic radiological health course, if you will, a  
14 quality assurance, a quality control course, and then a  
15 course on the actual MQSA inspection procedures.

16 In addition to that training, there is ongoing  
17 oversight with respect to the inspectors, and, in fact,  
18 they're audited annually. This audit is typically done as a  
19 joint audit in which an FDA auditor accompanies an inspector  
20 on a routine annual inspection. Occasionally, these are  
21 done as independent audits where the FDA auditor will follow  
22 an inspector into a facility at some time after their annual  
23 inspection and essentially repeat that inspection.

24 We keep the independent audits to the bare  
25 minimum, and that is to reduce the impact of the program on

1 facilities who in that event would be having essentially two  
2 annual inspections as opposed to the usual one. So we  
3 normally do joint audit inspections where an FDA auditor  
4 accompanies the inspector, and we do that on an annual  
5 basis. We've also established continuing experience and  
6 continuing education requirements for the inspectors, as you  
7 see indicated here.

8           Currently, we have a cadre of inspectors numbering  
9 about 196 who are state employees and an additional 37 who  
10 are FDA employees. Of those 37, 20 are also auditors. The  
11 inspectors come from virtually all of the states, the sole  
12 exception being New Mexico. We contract with states to do  
13 the vast majority of inspections under MQSA, and  
14 historically we've contracted with all of the states, with  
15 the exception of New Mexico, as well as with the District of  
16 Columbia, Puerto Rico, and New York City.

17           This coming year, I understand we probably will be  
18 doing--FDA will be doing the inspections in New Hampshire  
19 and Delaware since there have been some difficulties there  
20 in terms of maintaining inspectors on staff and so forth.

21           I would point out that the FDA inspectors do all  
22 of the audits, as I mentioned. They also do all of the  
23 inspections in federal installations, DOD facilities and so  
24 on. As you may know, the Veterans Administration is not  
25 subject to MQSA, although they have a parallel statute and

1 parallel regulations, which are intended to be equivalent to  
2 MQSA. And we are in the process of entering into an  
3 agreement with the Veterans Administration to do inspections  
4 that are essentially identical to MQSA inspections in those  
5 facilities as well.

6           The inspection itself is something I want to talk  
7 to you about in a bit of detail. I want to mention what the  
8 sort of sequence of events is in an inspection for those  
9 perhaps few of you who haven't been in a facility subject to  
10 an inspection, talk about the scope of the inspection, the  
11 range of issues that we address during the inspection, talk  
12 about what we call the findings of the various things that  
13 we can detect in the facility that are incompatible with the  
14 regulations, give you a brief update on the inspection  
15 results as they have developed over time, and then we'll  
16 talk about some of the changes that have taken place under  
17 the interim rules where we have made a number of adjustments  
18 to the inspection program as we've gone along.

19           Next, please?

20           I think one thing that's important to point out is  
21 that all of the facilities or virtually all of the  
22 facilities get advance notice of these inspections. By  
23 policy, there's a five-day minimum advance notice. There  
24 are very, very rare occurrences where we might go in  
25 unannounced, but that would be in the situation where there

1 have been some report to indicate that there was a very  
2 severe problem in a facility. And as I say, that's a highly  
3 unusual situation.

4           When the inspector calls the facility and makes  
5 the appointment for the inspection, there is a variety of  
6 things that they can do at that point to verify information  
7 that they have from our computer system about the facility  
8 and about its personnel, about its X-ray equipment and so  
9 on, that will facilitate the conduct of the inspection. And  
10 then when the inspector actually gets to the facility, they  
11 conduct an initial interview with the facility personnel to  
12 describe the process of the inspection, what's going to  
13 happen, what access to equipment and to records they need,  
14 what kind of assistance they need and so forth.

15           Typically, the inspector will need the assistance  
16 of a technologist in doing the machine measurements part of  
17 the inspection, which we'll talk about in a moment;  
18 otherwise, the facility is, at least in principle, free to  
19 operate as it normally would while the inspection is going  
20 on when the machines are not being inspected directly,  
21 because at those other times the inspector is going to be  
22 simply looking at the facility's records.

23           The inspector would then conduct the inspection,  
24 and there would be an exit interview at the end of that  
25 process during which there would be at least an oral

1 discussion of the findings, if any, that came about as a  
2 result of the inspection.

3           Typically, then, the compliance report is printed  
4 from the laptop computer that the inspector uses to gather  
5 the inspection data and is left with the facility so that in  
6 the majority of cases facilities have on hand immediately  
7 following the inspection a report which indicates what the  
8 results of the inspections were, the results of the  
9 measurements, as well as an indication of any findings.  
10 They're also given information as to what they must do in  
11 terms of dealing with any of those findings.

12           As was mentioned a little bit ago, there are some  
13 states which elect to do supervisory review of these reports  
14 before they're delivered to facilities, and in those states,  
15 those reports are mailed to the facilities within a brief  
16 time after the inspection has taken place.

17           As to the inspection itself, it covers a wide  
18 variety of areas that were addressed in the interim rules  
19 and continue to be addressed in the final rules. There are  
20 a variety of system performance tests that the inspector  
21 conducts with respect to the X-ray unit and the processor in  
22 the facility, and when we get into the detailed discussion  
23 of the proposed inspection under the final rules, we can get  
24 into the specifics of those particular tests. But suffice  
25 it to say for the moment that they involve a measurement of

1 dose, an evaluation of image quality using a phantom, an  
2 evaluation of the processing and so forth in the darkroom.

3           The remainder of the inspection really has to do  
4 with a review of records in the facilities, in particular  
5 the quality assurance and quality control records. As  
6 you'll recall, under the interim rules, the facilities were  
7 required to do a variety of things in the quality control  
8 realm. We adopted by reference in the interim rules the ACT  
9 quality control manuals, and so there was a good deal of  
10 detail and specificity in terms of what the facilities were  
11 expected to do on a daily, weekly, monthly, quarterly, semi-  
12 annual basis and so forth.

13           Under the final rules, there's somewhat less  
14 specificity. There's certainly not a reference to a  
15 document as detailed as the ACR QC manuals, but there is  
16 some level of specificity as to what tests are supposed to  
17 be done and at what frequency and some of the details of  
18 those tests, and all of that is the subject of the QA and QC  
19 record review.

20           The inspector then also looks at the medical  
21 physicist survey report. As you recall, this is an annual  
22 exercise for the facility as part of their quality control  
23 program that they bring in a physicist to do a variety of  
24 annual tests, principally on the X-ray equipment, and this  
25 report is reviewed at the time of the inspection, as well as

1 the details of the tests that were done and, to some extent,  
2 how those tests were done.

3           The inspector will also then look at the personnel  
4 records in the facility, looking at the records of the  
5 interpreting physicians, the radiologic technologists, the  
6 medical physicists, to establish that they all meet the  
7 initial and continuing requirements of MQSA; and then,  
8 finally, look at some of the medical reports to assure that  
9 those reports have been signed and so forth. And in the  
10 final rules, there will also be a step in terms of assuring  
11 that the various assessment categories were utilized in the  
12 reports. And then we'll be looking for the medical outcome  
13 audit program in the facility under the interim rules, and  
14 for that matter, under the final rules. There's relatively  
15 little specificity about the details of that program, but  
16 simply that the facility have in place a system for tracking  
17 positive mammograms, and the inspectors look to see if such  
18 a system exists in the facility.

19           There's certainly a great deal of information  
20 that's gone through in the course of the inspection, and as  
21 I say, we'll review some of that in more detail later this  
22 afternoon when we go over the proposal for the final  
23 regulation inspection. But in any of these areas, there is  
24 the potential for a variety of different findings. Level 1  
25 are the more serious findings. Those are the things which

1 we consider to be most significant and most problematic from  
2 the standpoint of quality and patient safety and so forth.

3           If a facility has such a finding, then it will  
4 receive a warning letter from FDA and will be required to  
5 respond to that warning letter in writing to the agency  
6 within 15 days. The agency then, with assistance from the  
7 states, at least in some instances, will review that  
8 response and determine whether or not the response is  
9 adequate. This is the first stage, if you will, of the  
10 compliance follow-up.

11           As we'll see in a moment, about 1 percent of  
12 inspections have a Level 1 finding and, therefore, get the  
13 warning letter and require this 15-day response and the  
14 review and so forth of that response.

15           More facilities will have a finding that it is, in  
16 our view, a moderate problem, and this is called a Level 2  
17 finding. The facility will be informed about that through  
18 their compliance report at the end of the inspection and  
19 will be required to provide to the agency a 30-day written  
20 response as to how they plan to correct that problem. And,  
21 again, the compliance follow-up involves the review of that  
22 response and the determination that that response is  
23 adequate, and in the cases where it's not, some continued  
24 correspondence with the facility until the agency's  
25 satisfied that the facility has responded appropriately to

1 the finding.

2 In the case of Level 3 or minor findings, there is  
3 no requirement for the facility to respond. These are minor  
4 findings, and we follow up on those at the next annual  
5 inspection.

6 I'd like to take just a moment now to go over a  
7 summary of the findings so far during the inspection  
8 program, and then right after that, we'll talk about the way  
9 the inspection time has evolved as the program has gone on.

10 As I mentioned earlier, we started inspections in  
11 '95. This was in January of '95, a quarter of the way  
12 through that fiscal year. And at that time, we were still  
13 building our cadre of inspectors and so on, and as you can  
14 see, the number of inspections that were done, the 4,851  
15 that were done in '95, was somewhat lower than we have done  
16 in subsequent years as we have built the cadre of  
17 inspectors. And we're now at a point where we ought to be  
18 able to get to the approximate 10,000 facilities on a  
19 roughly annual basis.

20 You'll notice that we had a fairly good result in  
21 terms of the inspection program as we started out, about 30  
22 percent of facilities with no findings on their initial  
23 inspection. That was, frankly, somewhat of a surprise to  
24 some of us, including myself, because the inspection program  
25 is fairly detailed and the rules and regulations are fairly

1 complex. And yet a third of the facilities, roughly, were  
2 able to meet all of those requirements even though they were  
3 brand new.

4 You also see that the vast majority of findings  
5 were at the minor or Level 3, in that category, with, as we  
6 started out, a little less than 3 percent having had serious  
7 findings.

8 As you look down, as the years have advanced, you  
9 can see that the number of serious findings has continued to  
10 drop. We have a little bit of an uptick this year, if  
11 that's statistically significant--and that's not entirely  
12 clear at this point--but, clearly, a very small proportion  
13 of facilities with very serious findings; a more significant  
14 number of facilities with moderate or Level 2 findings, but  
15 you can see that that dropped after the initial year as  
16 facilities became used to the requirements and got all of  
17 their paperwork together and got their programs together and  
18 so forth.

19 One of the things I would point out in looking at  
20 the Level 2 data is that in October, October 1st of '96, at  
21 the beginning of FY97, there was a new requirement that came  
22 into effect, and that was the continuing experience  
23 requirement for the interpreting physicians. That had not  
24 previously been something that we checked because that has a  
25 two-year averaging period. So the first time that any

1 interpreting physician would have, in fact, been subject to  
2 that requirement was two years after the initiation of the  
3 MQSA and, therefore, 10/1/96. And so in FY97, we had that  
4 new requirement, and so, as you see, the Level 2 findings  
5 stayed essentially the same, didn't continue to drop during  
6 that period. And I think that at least one of the reasons  
7 for that is the fact that we were first then looking at the  
8 interpreting physician continuing requirements--for  
9 continuing experience, at least.

10 At the beginning of FY98, on October 1, '97, was  
11 the first time that all of the personnel categories were  
12 subject to the continuing education requirement. This has  
13 essentially a three-year averaging period, so the first time  
14 that that would come into play was three years after the  
15 effective date of the rules and, therefore, 10/1/97. And so  
16 you can see an increase in the number of Level 2 findings,  
17 which we believe to be associated with this initiation of  
18 looking at the continuing experience requirements.

19 I think the more interesting thing is that the  
20 number of facilities or percentage of facilities with no  
21 findings has continued to go up as the program has gone on  
22 and now is approaching 60 percent.

23 At the same time, we wanted to take a quick look  
24 at the inspection times. They have stayed relatively  
25 stable, although they've been decreasing slightly since the

1 initial round of inspections. We're not showing data here  
2 from '95 where the information would suggest that the  
3 inspections were a little bit longer as facilities were just  
4 getting used to the inspection process, and as were the  
5 inspectors, for that matter. But we've seen slight  
6 decreases in the average national time in terms of what the  
7 inspector spends on-site in a facility, and this is across  
8 all facilities and, therefore, across facilities of a range  
9 of sizes, although the typical facility has about 1.25 or  
10 1.3 units and probably has a few interpreting physicians,  
11 radiologic technologists, and a single medical physicist.  
12 And so the time in the facility is down to somewhat under  
13 the initial time of six hours, and the total time  
14 incorporates time that the inspector might spend in  
15 preparation for the inspection and time spent after the  
16 inspection in terms of follow-up or sending the report to  
17 the facility and so on.

18 I just want to hint at the evolutionary process  
19 that we've been going through with respect to the  
20 inspections under the interim regulations. We started out,  
21 not surprisingly, with Version 1.0 of our inspection  
22 software at the very outset. We then, in fact, changed the  
23 contractors who were supporting us in that effort, and we  
24 have gone through a variety of versions since then, 1.1a  
25 through 1.1m, which is where we are now. A number of those

1 were to correct issues that were brought to our attention by  
2 inspectors and so forth. A number of them were to reduce,  
3 to some extent, the number of questions that we were asking  
4 during the inspections, some of the issues that we were  
5 addressing and so forth. So there has been a variety of  
6 adjustments made, and I suppose it's true to say that the  
7 only constant in the program up to this point has been  
8 change. We're hoping that we can stabilize things somewhat  
9 from here on out, but I think it's important to note that  
10 there are continuing needs for adjustment in a variety of  
11 respects, with at least the software that's assisting the  
12 inspector in gathering the inspection data, if not the  
13 underlying inspection procedures themselves.

14 We are scheduled this summer to release a new  
15 version of the inspection software, and it will be new in a  
16 variety of respects. A principal respect is that it will be  
17 a Windows 95-based system, and we're taking this action in  
18 anticipation of needing to revise the inspection program  
19 under the final rules and to be able to maintain the level  
20 of flexibility that I just mentioned.

21 The existing software that we have is very  
22 difficult to change by the nature of its design,  
23 unfortunately, and it's difficult to change in a clean sort  
24 of fashion. And it often has turned out that every time you  
25 fix a problem, you actually turn out to create one or two

1 others. So we're moving to a Windows 95-based operating  
2 system so that we can make adjustments in the inspection  
3 software with greater ease and, therefore, keep up with  
4 whatever changes we need to make to the inspection program  
5 itself.

6 We're also going to be reformatting a number of  
7 the questions when we move to Version 2.0 of the software,  
8 and the intent there is to make the software easier to use  
9 for the inspector, make it more--make it simpler for the  
10 inspector to collect the information that they need to  
11 collect in a timely fashion, and hopefully thereby to reduce  
12 to some extent the amount of time taken during the  
13 inspection.

14 It is also expected that there will be some  
15 reduction in the questions and some eliminations there to  
16 reduce the potential number of citations or findings that a  
17 facility could be subject to. So we expect that there will  
18 be some reduction in the inspection time as a consequence of  
19 going to this new version of the software, although the  
20 software itself is, again, still reflecting the inspection  
21 program under the interim rules, and there will be no really  
22 substantial changes when we make this version change. The  
23 substantial changes will take place when about a year from  
24 now we make the change to the inspection program under the  
25 final rules.

1 Under the final rules, we intend to reduce the  
2 number of findings or levels of findings and just have Level  
3 1 and Level 2 findings and remove, in effect, the minor  
4 findings which would have previously been the type that  
5 would be followed up at the next inspection. We intend in  
6 the process of doing that to, if you will, sort of tighten  
7 the requirements somewhat in some of the areas, and we can  
8 talk about those more specifically this afternoon.

9 But, in particular, we're going to be adding a  
10 Level 1 finding to the processor performance test, the so-  
11 called STEP test. It currently has a Level 2 finding.  
12 That's going to remain the same as it always has been, but  
13 we're going to add a Level 1 finding for the more extreme  
14 failures, if you will, to meet the performance requirement.

15 We're also going to be tightening to some extent  
16 the processor quality control findings. Right now in order  
17 to--the only facilities that would receive a Level 1 finding  
18 for processor quality control--and, incidentally, this is,  
19 of course, the most important, I think, of the quality  
20 control tests, is the daily test and probably the single  
21 most critical element of the imaging chain from a quality  
22 control perspective. And if you essentially never did any  
23 processor control ever, you would qualify, if you will, for  
24 a Level 1 finding and getting a warning letter from the  
25 agency.

1           We're far enough into the program now that I think  
2 we believe that it's reasonable to elevate that somewhat,  
3 and so we're proposing that the Level 1 finding now would be  
4 failure to do the processor quality control more than 30  
5 percent of the time. Still, a pretty high value, and it's  
6 one of the things that you may be interested in commenting  
7 on this afternoon.

8           We're also making some adjustments in a similar  
9 sort of fashion for the phantom quality control, and we're  
10 reducing, if you will, the number of findings for the dose  
11 value. We're simply making what had been the Level 2  
12 finding, turning that into a Level 1 finding for doses over  
13 350 millirads.

14           The issue there is that we've had very, very few  
15 cases where there have been any problems with respect to  
16 dose, and so the facilities, the very few facilities that  
17 would be significantly over the statutory limit of 300 we  
18 feel would be reasonable to send a warning letter to in this  
19 regard.

20           We're also going to be making some changes with  
21 respect--proposing to make some changes with respect to the  
22 personnel requirements, and in particular with respect to  
23 the initial requirements with respect to training and  
24 experience.

25           Next?

1           So we'll go through this afternoon, when we talk  
2 about the specifics, some of those individual changes. But  
3 suffice it to say that we're proposing to make a number of  
4 changes with respect to things that were looked at during  
5 the interim--under the interim rules; we're also, of course,  
6 going to be adding to the inspection a number of things that  
7 are new for the final rules, perhaps the most obvious  
8 example being the continuing experience requirements for  
9 radiologic technologists and medical physicists. And we'll  
10 go over those in some detail later.

11           I'd also like to mention in closing that in  
12 parallel, if you will, with our development of the  
13 inspection program and the inspection procedures and  
14 software for the final rules which will be implemented a  
15 year from now, we're also developing guidance, and there is  
16 a guidance development process in place now under  
17 government-wide and FDA-wide regulations, which is somewhat  
18 different from that which was in place when we were entering  
19 the initial inspection programs under the interim rules.

20           There are many more steps in terms of approval  
21 that are necessary now for guidance that's developed to help  
22 direct facilities as to what was intended by the words that  
23 were put down in the regulations.

24           One of the things that's important to realize is  
25 that there is a substantial amount of public input now

1 required when we develop guidance, which is, in effect,  
2 comparable to the public input for the development of  
3 regulations themselves. And, in fact, when we speak the  
4 first time about items which are new under the final rules,  
5 that falls under the category of Level 1 guidance and will  
6 ultimately be published in the Federal Register with a  
7 public comment period, and there will be a following process  
8 of reviewing those comments and potential revision of the  
9 guidance before it's published and effective.

10           If we subsequent to that modify some of those  
11 guidance statements, then that would fall into the category  
12 of Level 2 guidance. Similarly, modifications to guidance  
13 we had already provided under the interim rules would fall  
14 into this category as well. And that has a somewhat shorter  
15 approval process to go through, but still needs to be  
16 approved and needs to be reviewed.

17           The guidance that we're developing for the final  
18 regulations, at least in its initial version, is directed  
19 primarily to the inspection program and that side of the  
20 process, and we'll be seeking your comments on that guidance  
21 as we go along and will be publishing that later this winter  
22 for the facilities and providing it--and essentially  
23 providing that guidance to them through that "how to prepare  
24 for inspections" letter that we plan to be sending out after  
25 the first of the year. And it will also be on the FDA home

1 page on the Web.

2           This afternoon or later this morning, depending on  
3 how time goes, we'll begin to talk about the more detailed  
4 issues with respect to the questions under the final reg  
5 version of the inspection. And then I think we want to  
6 talk, at least very briefly, about some inspection issues  
7 for the future, if you will.

8           Someone mentioned earlier the issue of MQSA  
9 reauthorization. The statute was due to be reauthorized  
10 last fall, and, in fact, the Senate and House both  
11 introduced bills to reauthorize MQSA. The Senate passed the  
12 bill last fall. The House did not. The House is now in the  
13 process of considering that bill, and, in fact, there is due  
14 to be a hearing for a subcommittee of the House Commerce  
15 Committee this Friday to talk about reauthorization of MQSA.

16           When the Senate bill was passed, Senator Mikulski  
17 urged that we consider some changes in the inspection  
18 program and, in particular, a process that might allow us to  
19 give some benefit, if you will, to those facilities who have  
20 a history of good performance in their inspections under the  
21 interim rules. And what was proposed is that we might look  
22 at the prospect of having a shorter version of the  
23 inspection for such facilities as opposed to the full  
24 version of the inspection for facilities that had had  
25 problems or had had findings under the inspections under the

1 interim rules.

2           There are other proposals that we understand would  
3 suggest that the statute be changed to give the agency some  
4 flexibility with respect to inspection frequency, and that's  
5 another way to provide some benefit for the high-performing  
6 facilities. So as opposed to getting a shorter inspection,  
7 for example, they might not get an inspection in the  
8 subsequent year. So those are things that may lie in our  
9 future, and there are some issues associated with that that  
10 might be worth spending a little bit of time on, although  
11 it's somewhat speculative at this point since we don't know  
12 what the result of the reauthorization process is likely to  
13 be. But we would like to get some advice on those sorts of  
14 matters at some point in the future.

15           Thank you.

16           CHAIRPERSON MONSEES: Thank you very much.

17           What we will do now is go to break, and then we  
18 will take questions and comments from the panel on the  
19 presentation that we had this morning. Many of you are very  
20 conversant with the interim regs and the rules, et cetera,  
21 that we've been living under, and if you need any background  
22 information, ask during the break, or you can ask John  
23 formally during the question-and-answer session so that you  
24 can become familiar enough to go on to the next step, which  
25 is going to be the discussion of the final regs.

1           So let's break. We will have a 20-minute break.  
2 I have 10:20, so we'll start at 10:40. Synchronize our  
3 watches.

4           [Recess.]

5           CHAIRPERSON MONSEES: All right. Where we left  
6 off was the presentation, and now we're going to offer the  
7 panel a chance to ask questions or make comments on the  
8 earlier presentation. And then, as I understand it, we will  
9 be moving on to the document that you should have been  
10 mailed in advance, the proposed inspection questions and  
11 non-compliance levels under the final regs, so you may want  
12 to pull that out of your packet.

13           Does anybody have any questions or comments about  
14 what we heard before the break, primarily about the interim  
15 regs and then some plans for the final regs? Yes?

16           MR. FLETCHER: Roland Fletcher. John, in our  
17 experience with the inspector program, we have run into some  
18 problems, and the problems have indirectly involved almost  
19 the bypassing of the inspector supervisors so that the  
20 inspectors feel like they work for the FDA and the FDA feels  
21 like the inspectors work for them, and there's no one, you  
22 know, who should be in between.

23           In reality, of course, they work for the state,  
24 and I wonder if your interim--in your inspector guidance  
25 you're going to take that into account so that we can

1 preclude some of these problems in the future.

2 MR. McCROHAN: We've attempted to do some things  
3 to ease that problem, which we've been aware of for some  
4 time. Others have sort of brought it to our attention.

5 In my view, it's more of an artifact than a plan,  
6 and I think to some extent it's an artifact of the  
7 technology that we have with respect to the laptop computer,  
8 because that provided us with the ability to communicate  
9 directly with inspectors, in effect, to send e-mail messages  
10 and so on to them through the laptop. And that's a  
11 different sort of approach than I think would have been  
12 taken without that technology, where I think the instinct  
13 would have been to, you know, go through the program  
14 directors and the supervisors and go down in the more normal  
15 chain of command.

16 So I think that it's a fact that has played  
17 variously in various places. But I think a number of people  
18 have raised it to our attention, and it's something we would  
19 like to try to deal with better. It's certainly not our  
20 intent to, you know, treat the state employees as though  
21 they're FDA employees and to cut out the supervisors. In  
22 fact, I think that there is, you know, clearly, even from  
23 our point of view, much less from your point of view, a  
24 necessary role for the supervisors in terms of maintaining  
25 the uniformity and so forth across the inspectors. And with

1 a cadre of 250 inspectors, even with the training and so  
2 forth, there really is an issue in terms of, you know,  
3 uniformity.

4 I think that the problem was exacerbated in the  
5 early part of the program by the fact that we were putting  
6 out guidance to the inspectors with incredible frequency,  
7 and I think that the situation may have stabilized somewhat,  
8 and I think that, in effect, there are a number of blessings  
9 associated with the good guidance practices, procedures that  
10 I mentioned earlier. One of those is that I think it's  
11 going to necessarily make us a lot more thoughtful about how  
12 often, you know, we want to produce guidance or amend  
13 guidance and so on. So I think that the frequency with  
14 which we're going to be communicating those kinds of things  
15 will be different. So I think there will be a better  
16 opportunity, if we can find the means, to keep the  
17 supervisors in the loop and perhaps even ahead of the  
18 inspectors.

19 MR. FLETCHER: First of all, just as follow-up,  
20 may I--

21 CHAIRPERSON MONSEES: State your name when you do.

22 MR. FLETCHER: Roland Fletcher again. May I  
23 suggest you add one more computer to each of the states?

24 The second question or second point is that in  
25 some cases it appears as though facility performance, for

1 example, the levels of violation, aren't getting back to the  
2 states quickly. Realizing that enforcement is not directly  
3 under the states, there's still an obligation, particularly  
4 in keeping, you know, management informed, et cetera, as to  
5 how these facilities are performing. And I don't know if  
6 that's being addressed or not as far as more rapid  
7 publication or addressing of violations.

8 And let me just hit the third point, and then you  
9 can perhaps put both together.

10 I notice in the levels of findings, everything  
11 seems to be--even if it's a serious violation, the response  
12 time is often more than a state would allow a similar  
13 facility with a similar violation, and I wonder if that's  
14 been addressed.

15 MR. McCROHAN: Let me take them in order. I think  
16 I'd need to talk to you individually, and certainly we have  
17 the meeting upcoming in Arizona in which I'll have an  
18 opportunity to talk to you and all of your colleagues from  
19 the state about that point, and I think that we do have an  
20 obligation to let you know in a timely fashion whether a  
21 facility's response to a set of findings has been accepted,  
22 you know, and so forth, and what the status of that is. And  
23 you're quite correct, I think, to point out that if a  
24 facility has a Level 1 finding and consequently they get a  
25 warning letter, it takes us time to get the warning letter,

1 and then it takes--the facility has 15 days to respond. If  
2 it's a Level 2 and we leave the report behind, they have  
3 immediate notice of the Level 2, and they have 30 days to  
4 respond.

5 Well, if you do the math, the response to the  
6 Level 1 is likely to be behind the response to the Level 2,  
7 if you will, depending on the time frames and so on. I  
8 think that's more, you know, an artifact of those time  
9 frames. I think that the issue with respect to getting a  
10 warning letter to a facility is as a predicate to whatever  
11 subsequent actions the agency might need to take, presuming  
12 that the response to the finding was not adequate. In terms  
13 of FDA's procedures, there are a variety of things that we  
14 can do subsequent to a Level 1 finding, including the  
15 suspension and revocation of the certificate and so forth.  
16 But all of those are founded on having delivered the warning  
17 letter to the facility and their having in a legal sense  
18 notice of their situation and what they're supposed to do so  
19 and so on.

20 So in spite of the fact that the time differences  
21 between the two is small, I think from our perspectives it's  
22 necessary that we go through the mechanism of doing a  
23 warning letter for those few cases where the response turns  
24 out not to be adequate and we need to take subsequent  
25 action. And we don't want to have to backtrack and do that.

1           But I think you put your finger in both of these  
2 respects on one of the reasons--and I think perhaps the  
3 critical reason--why the States as Certifiers program would  
4 be of interest--I'm somewhat speculating here, putting  
5 myself in your place--but why the States as Certifiers  
6 program would be of interest to states. And that is, I  
7 think, that being in control of the compliance follow-up  
8 process and having your own mechanisms for dealing with  
9 that, there are ways in which states can deal perhaps more  
10 rapidly with situations, particularly very serious  
11 situations.

12           You have opportunities--in some states, at least--  
13 to issue cease-and-desist orders and so forth, and at least  
14 temporarily shut a facility down, which is not an authority  
15 that we have under MQSA, where the quickest thing we could  
16 do would be to suspend a facility's certificate, and that's  
17 going to take some period of time and a number of steps and  
18 may or may not include a hearing before we can suspend the  
19 certificate.

20           So the regulatory mechanisms in MQSA weren't  
21 designed to be lightning fast, and so it certainly is the  
22 case that in a lot of states, those compliance processes  
23 could happen more quickly under a States as Certifiers  
24 program. And I think that's from some perspectives a real  
25 appeal that's built into that program.

1           CHAIRPERSON MONSEES: Any other questions or  
2 comments before we go on? Yes, Mr. Mobley, please?

3           MR. MOBLEY: John, I've got a couple of thoughts  
4 or questions or whatever. You noted in your presentation  
5 that with the inspection software there would be a net  
6 reduction in questions and citations. I don't understand  
7 how you change software and how the net reduction in  
8 questions and citations, unless you're changing your  
9 enforcement activities or what it is you're looking for or  
10 whatever.

11           MR. McCROHAN: Okay. I think there have been some  
12 few changes, such as you just mentioned, but I think in a  
13 structural or a format sense, the reduction in the  
14 inspection time is likely to flow from the way we've  
15 arranged the questions. In the existing software, the  
16 inspector is essentially forced to answer each and every  
17 question on that--through the whole inspection.

18           We recognized and some inspectors pointed out to  
19 us that there were opportunities to sort of structure some  
20 of those questions so that you could answer a logically  
21 higher level question yes, for example, the facility meets  
22 the requirements, and then not have to individually answer  
23 all of the subordinate questions. So there's just some  
24 ways, I think, that we can structure the software that will  
25 facilitate gathering the data. We're essentially gathering

1 the same information, but in a somewhat facilitated fashion.  
2 I think at least that is the intent.

3 MR. MOBLEY: But I guess I--and I understand that,  
4 and that's one of the things we all strive for in the  
5 inspection program, is to minimize your time, as everybody  
6 does, to minimize your time in doing whatever you're doing  
7 so you can move on. But I didn't understand how that was  
8 going to minimize the citations unless it is that you've  
9 missed something.

10 MR. McCROHAN: I think that doesn't in itself  
11 minimize the number of citations, although what it does is  
12 it can create a situation in which--let's take an example of  
13 the initial requirements or initial personnel requirements  
14 for one of the categories. We can say now, Does this  
15 individual meet the initial requirements, yes or no? The  
16 higher-level question, if you will. There are some embedded  
17 details, and there can be now a single citation for fails to  
18 meet the initial requirements, instead of three or four  
19 citations, one of which would be attached to each of the  
20 subparts.

21 So it's an accounting kind of issue more than it  
22 is anything else, I think.

23 MR. MOBLEY: Okay. I want to talk for just a  
24 minute on the level--the change of the Level 1, Level 2.  
25 I'm a little concerned about doing that, and let me express

1 my concern. It's just been my experience that in any  
2 program of this nature, when you're--as you presented us the  
3 statistics up here this morning, you know, you've developed  
4 statistics over time based on certain parameters. And when  
5 you then start changing your parameters, you change your  
6 statistics, and it's very important to understand what it is  
7 you're doing when you start--and I have to use this term, I  
8 don't mean it this way, but when you start monkeying with  
9 these things, you have to understand what it is you're  
10 doing, and that you may be blowing your whole analysis at  
11 this point in time, and is now the time to do that? Is the  
12 driver such that we believe that we have to change these  
13 things from--taking away the Level 3, pushing Level 1's and  
14 2's up or down as appropriate?

15 I'm not saying that it's not appropriate,  
16 necessarily. In fact, I think it's important to look at  
17 those things and make those adjustments. But I guess I  
18 didn't feel like--and, again, I know you were just giving us  
19 a quick presentation. But I guess I just didn't feel like I  
20 heard enough to make me believe that there was this need for  
21 this change at this point in time.

22 MR. McCROHAN: I mean, I appreciate your comment,  
23 and we'd thought about the issue before about how you--in a  
24 data system sense, how you bridge the two regimes if you're  
25 going to make a change and how you have to do that in a

1 thoughtful fashion so that you can tie back to the  
2 information that was collected under the previous regime and  
3 be able to see how things are working in terms of the trends  
4 that may be developing.

5 I think that we have, with the advent of the final  
6 regs, a change of that sort of nature which we really can't  
7 avoid. I mean, there are some things which are being added.  
8 Obviously, no trend issue there because there is no  
9 predicate. But there are some things that don't exist in  
10 the final rules, some level of detail, perhaps, that we  
11 extracted from the ACR QC manuals as we adopted them by  
12 reference under the interim rules. So I think we do need to  
13 be real thoughtful about that.

14 I think that the overall impetus is to focus more  
15 clearly on the things which are most significant, and under  
16 the interim rules, there was certainly a fairly high  
17 proportion of the, if you will, potential number of findings  
18 that one might encounter in a facility that were in that  
19 minor category. And we've certainly been asked on a number  
20 of occasions questions to the effect of, If they're so  
21 minor, why are you spending time and resources and money and  
22 facilities' time and so forth looking at them?

23 So I think one of the things that we need to get  
24 from you all is some sense of whether that focus is right,  
25 and the extent to which you feel that the various things are

1 important and what level, if you will, of detail we need to  
2 get into in order to assure ourselves that we have a  
3 facility that's operating within the regulations and  
4 providing the kind of quality that we want. I don't think  
5 we want to be spending time in the inspection looking at  
6 things for the sake of looking at them, but we want to look  
7 at the things which matter.

8 So that's, you know, the broad challenge. Whether  
9 we're approaching that in the right way is another question,  
10 and we're certainly open for your advice on that.

11 MR. MOBLEY: Thank you.

12 MS. HAWKINS: Hawkins. I'd like to go back--

13 CHAIRPERSON MONSEES: Speak into the microphone  
14 more. I'm not sure it's picking up.

15 MS. HAWKINS: Patricia Hawkins, and I'd like to  
16 just go back to the compliance report. In your discussion  
17 with Mr. Fletcher, I understand that this can be a lengthy  
18 interaction between FDA and states. My concern is about  
19 public dissemination because, as a consumer, this report may  
20 have some impact upon my selection of a facility. And so  
21 what types of mechanisms will be in place to disseminate  
22 this information to the public and how quickly?

23 MR. McCROHAN: At the moment, the principal means  
24 is--I think you would probably say not very quick. There is  
25 an annual report that's required under the statute, and it

1 requires us to publish, in effect, the identity of  
2 facilities against which serious actions have been taken,  
3 suspensions or revocations, civil penalties and so forth.  
4 And also in there we report on actions that the states may  
5 have taken independent, if you will. But that's quite some  
6 time after the fact, and it focuses certainly on the most  
7 significant actions that someone has taken against a  
8 facility.

9 I think that it's important to focus to some  
10 extent on what we believe to be the intent of the statute in  
11 the first place. And it's not--I mean, it certainly is to  
12 assure quality, but also there is an access component to the  
13 statute. So there's a necessity to balance the quality and  
14 the access. And as a consequence, and as a consequence of a  
15 variety of broader trends, I think, in governing, we have  
16 tried to focus the program on encouraging facilities to  
17 correct the problems that are discovered and to focus,  
18 therefore, if you will, on voluntary compliance and to  
19 create a situation in which a woman can have a high degree  
20 of confidence that, when you go into a facility that has a  
21 certificate, that it is a facility that's performing in  
22 accordance with the regulations and delivering the quality  
23 service.

24 That's not to say that we might not find some  
25 issue, particularly some minor issue, when we go into a

1 facility. But I think that we were somewhat loath to  
2 publish too rapidly the names of facilities that had had  
3 this or that finding when the point of the program was to  
4 bring those facilities up to standard and keep them  
5 functioning.

6           There is a circumstance, historical, in one of the  
7 states in the mammography area in which the state  
8 essentially, as a result of an inspection, developed, if you  
9 will, kind of a grade for the facilities. And my  
10 recollection is that it was something like you were an A or  
11 a B or a C, depending on the nature and extent of the  
12 violations, and that was made public, your grade was made  
13 public. And, of course, who wouldn't want to go to an A  
14 facility and who wouldn't want to avoid a C facility, even  
15 though that's a passing grade, so to speak, even though the  
16 assessment was that the quality in that facility was  
17 adequate?

18           So I think we do need to be somewhat careful about  
19 how much we stratify the facilities and the extent to which  
20 we make that information public as it impacts on how the  
21 facility--or how the public is going to view that facility.  
22 So I think that we had the intent, at least, of identifying  
23 and pointing out to people and making public those  
24 facilities which were the worst in terms of performance, but  
25 one could argue about where that threshold is set, I

1 suppose.

2 In terms of the compliance report itself, anything  
3 that we have in our database, which includes the compliance  
4 report, for an individual facility inspection is subject to  
5 the Freedom of Information Act, with the sole exception of  
6 some of its content in particular to the names of the  
7 individuals who work in the facility and so forth. We're  
8 told that those identities aren't publicly disclosable, but  
9 certainly the report and the results of the inspection in  
10 its details would be.

11 So, in theory, anyone could get that information  
12 if they want it, so I think the real question is to what  
13 extent, you know, you or others would advise us to be  
14 proactive about making public and in what way and in what  
15 frequency and at what level that kind of information.

16 DR. MENDELSON: Just a question--Ellen Mendelson.  
17 Just a question about the inspectors themselves. For  
18 clarification--and I don't know whether it has changed since  
19 the inception of the inspection program or not--what is the  
20 educational background and basic qualifications for becoming  
21 an inspector? Are inspectors full-time positions? Are they  
22 part-time positions? Are the inspection responsibilities of  
23 maintaining 12 per year to keep themselves up to date and  
24 with it part of another position? How is this arranged?

25 MR. McCROHAN: Okay. I can get you the policy

1 with respect to the qualifications that are required. I  
2 think it's--let me just say on that point, though, without  
3 consulting the specific sheet of paper, at the outset of the  
4 program--I think it's fair to say that the qualifications  
5 had some breadth in terms of education of the people that we  
6 had in the program at the outset. Having established the  
7 policy, I think it's the intent to raise those standards, if  
8 you will, for inspectors coming into the program in the  
9 future.

10 But I think that we need to realize that education  
11 isn't the sole criterion on which one would judge the  
12 qualifications of the inspector, and I think one of the  
13 things that is to the credit of the various state programs  
14 that were participants with us in this process is that my  
15 sense is, at least, that we got the cream of the crop, that  
16 we got the most experienced people in the state programs.  
17 And for the vast majority, I think it's fair to say that  
18 we're talking about people with at least a bachelor's level  
19 education--a lot of them are former radiologic technologists  
20 with bachelor's educations--and a fair amount of experience  
21 in terms of doing X-ray inspections in the field and so  
22 forth. So they have some experience not only in the  
23 mechanics, if you will, of the inspection, the physics,  
24 making the measurements, but also experience in interacting  
25 with facilities. And I think that's particularly critical

1 in this area where I think we wanted to have, to the extent  
2 we could, inspectors who were sensitive to the issues that  
3 the facilities had. Hark back to the five-day advance  
4 notice. In fact, it turns out from the results of a  
5 facilities satisfaction survey that we did that the average  
6 advance notice, at least among those thousand facilities,  
7 was more like ten days. The facilities still would have  
8 preferred more time.

9           But, be that as it may, I mean, I think the point  
10 being we need people who have experience and have some level  
11 of sensitivity to the issues in the facility, the impact  
12 that their being there is having on the practice of the  
13 facility and the women who are the subjects.

14           So I think we have what we think to be reasonable  
15 qualifications, and we can get you all a copy of that in  
16 terms of the requirements. But as I say, the education is  
17 only a piece of it. The experience is important as well.  
18 And I think we did get the best of the available staff from  
19 the states in that respect.

20           It's not--as far as I know, it's not, I would say,  
21 primarily a full-time job. Certainly there are places where  
22 that is the case, where the states made the decision that  
23 the person should be full-time on MQSA. But that is  
24 essentially a state decision, and it gets into the various  
25 aspects of their contract with us and so forth and how they

1 choose to manage their staff. So it may be in a lot of  
2 cases a part-time position.

3 That actually, I think, plays to everybody's  
4 advantage in the sense that particularly in states which  
5 have some large geographic area to deal with. If you have  
6 people who are part-time on MQSA and part-time doing, say,  
7 state inspections of X-ray or dental facilities or what have  
8 you, you can send an individual to a particular part of the  
9 state, and you can do all of that work more efficiently than  
10 if you have an individual and you have to, you know, send  
11 them around without being able to get some of this other  
12 activity taken care of while they were on the road, so to  
13 speak.

14 So I think that it's principally the case, I would  
15 guess--but it is that, really--that more often than not it's  
16 a part-time kind of position.

17 That being the case, we felt it was necessary to  
18 set some sort of a floor and to set a continuing experience  
19 qualification that we thought was, on the one hand,  
20 reasonable but, on the other hand, would provide some  
21 assurance that people who had been trained had enough  
22 continuing experience with the inspection process and so on,  
23 that that training, you know, wouldn't evaporate, so to  
24 speak, with lack of use. And that's why we established the  
25 minimum of 12 inspections.

1           There are--I think probably the people who are at  
2 that minimum for the most part are likely to be supervisors  
3 of other inspectors, people that we may have trained several  
4 years ago who have moved on in their career, still want to  
5 be active inspectors or have the potential to be. And  
6 there's a value in that in that it takes us a long time to  
7 replace an inspector through that education process. So  
8 having some elasticity in the system and the cadre of  
9 inspectors by having some people who are, say, supervisors  
10 who do approximately the minimum or some fairly small number  
11 of inspections still has some value to the system as a  
12 whole. But that was why we put that in because we didn't  
13 want to train someone and have them not do an inspection for  
14 two or three years, you know, lose their edge, so to speak,  
15 and then still be considered an MQSA inspector.

16           DR. NICHOLS: Sandra Nichols, Arkansas. I hope  
17 you all are very open to allowing the states to work with  
18 you on looking at whether part-time versus full-time. The  
19 challenge that most states will have from a part-time  
20 perspective, that if we're going to do a good job of  
21 education as well as inspection, it's going to take more  
22 than a part-time position. And as far as allocating  
23 resources, I can certainly take five of my employees and  
24 make 20 percent of their time equal to a full-time person  
25 and have them do the state job as well as your job. But we

1 more often than not run into a situation where your  
2 inspection takes more than a part-time employee, which  
3 impacts my budget as a state leader. So I certainly hope we  
4 can have more discussions on that.

5           Secondly, I wanted to follow up on Ms. Hawkins'  
6 question. It certainly will be concerning to the citizens  
7 who are receiving mammograms in individual units as to  
8 whether or not that particular unit is a Level 1, a serious  
9 problem. Do we have a check and balance or follow-up system  
10 in order that we can re-evaluate whatever the issues might  
11 be within that unit? I.e., 'if there are problems with the  
12 actual mammograms, is there another system in place where  
13 they can be a secondary level of evaluation to make sure  
14 those patients are protected? And what are we doing about  
15 that?

16           Then, secondly, you talked about giving an  
17 incentive to those individuals who have good reports. What  
18 are we doing for those who have bad reports outside of the  
19 15-day FDA? Are we saying to them we will inspect them more  
20 often? It's very clear, no matter how many times we inspect  
21 them, unless we're on the site on a regular basis or a daily  
22 basis, we're not going to have every single unit get 100  
23 percent, and we need to be able to work with them very  
24 closely. I think education is going to be the key, but  
25 certainly is there something in place or recommendations

1 that the follow-up evaluation of those mammogram units be  
2 more often?

3 MR. McCROHAN: In terms of the--say a facility was  
4 a Level 1 finding, there are some subsequent steps that we  
5 and the facility can go through. There are certain things  
6 which can lead to a Level 1 finding, for example, the  
7 phantom image quality test, which are best verified--the  
8 correction of that problem is best verified by doing a  
9 follow-up inspection, and we do have that facility. We  
10 frankly don't have many of those problems and haven't done  
11 many follow-up inspections. But there is that element to  
12 the program to satisfy ourselves that the corrective action  
13 the facility took was effective.

14 Now, there are a lot of things which lead to Level  
15 1 findings and that fall in, for example, to the personnel  
16 area. And those things aren't really subject to, in our  
17 view, appropriate follow-up on an on-site basis.

18 If we were dealing with an interpreting physician,  
19 for example, who didn't meet one of the initial  
20 qualification requirements, the expectation would be the  
21 facility would tell us initially that person isn't  
22 interpreting mammograms anymore and/or, you know, we've  
23 gotten that person to complete whatever was necessary in  
24 order to meet the qualification requirements and here's the  
25 documentation that establishes that that's the case. So

1 there is that level of follow-up for those kinds of  
2 significant findings.

3           There is also the opportunity--and you might have  
4 noticed this in the final regulations. There's an  
5 opportunity in certain instances for us to identify a  
6 particular situation where there may be a significant  
7 prospect that the clinical image quality is compromised.  
8 One of the things that I think we need to be aware of when  
9 we talk about the inspections is that we're looking at a  
10 variety of things which I think are fair to call secondary  
11 indicators of clinical image quality. We're not sending  
12 inspectors in to look at clinical images--they're not  
13 qualified to do that--much less to look at the diagnosis or  
14 the accuracy of the diagnosis that follows from the quality  
15 of the clinical image.

16           So we're looking at are secondary and tertiary  
17 indicators of the quality in the facility. So it isn't  
18 reasonable, we think, to assume that a certain type or level  
19 or number of findings is necessarily indicative in a direct  
20 sense of compromise in clinical image quality.

21           A lot of the things, quality control being a good  
22 example, are actions that the facility needs to take to  
23 identify problems before they become visible in the clinical  
24 image or before they have impact on the clinical image  
25 quality. So a failure to do a certain quality control test

1 at the appropriate frequency doesn't in and of itself means  
2 that we're dealing with a facility that has poor clinical  
3 image quality.

4 So I think bearing that in mind, there are  
5 relatively few things which we've identified in our program  
6 as sufficiently likely to suggest poor clinical image  
7 quality that we want to take a follow-up step, which is  
8 called additional mammography review. And under the final  
9 regulations, that's more codified than it was under the  
10 interim regulations. And this is a situation in which the  
11 accrediting body of that facility would take another look at  
12 a set of clinical images from that facility to directly  
13 assess whether the clinical image quality in that facility  
14 is compromised. And then if it is, there can be follow-on  
15 from that in terms of what we do as far as the compliance  
16 with that facility and also what we do in terms of  
17 notification of patients whose images and whose diagnoses as  
18 an effect might have been compromised if we find that there  
19 is a significant problem with clinical image quality.

20 So there are those elements to the program, but so  
21 far, at least, those have been relatively rarely employed.

22 CHAIRPERSON MONSEES: Any other questions or  
23 comments this morning? Mr. Mobley?

24 MR. MOBLEY: I just wanted to comment that I think  
25 that the question that was asked about MQSA inspector

1 qualifications and policies, that's addressed in one of the  
2 handouts that we received in January--

3 MR. McCROHAN: Okay.

4 MR. MOBLEY: --relative to the States as Certifier  
5 meeting. It had that information laid out in there, and I  
6 will just echo John's comments that at least the initial  
7 effort brought from the states, probably some of the best  
8 trained people in the mammography arena because of the  
9 experience that they'd had with the previous program carried  
10 out by HCFA, and also the efforts made by the states and FDA  
11 to identify problems in mammography through the Nex(?)  
12 program and some other areas.

13 We found in Tennessee that these people that we  
14 initially threw into the program in the early days were in a  
15 number of cases senior staff that we have had to try to pull  
16 out as we could train new inspectors, but those new  
17 inspectors do have the benefit of the experience and  
18 training of their supervisors that were involved in this  
19 program earlier on. And, in fact, in Tennessee, we have a  
20 dedicated individual that heads up this program for us that  
21 works with all of our inspectors in the field distributed  
22 across the state to assure that we are doing the things that  
23 need to be done both for FDA as well as what we feel needs  
24 to be done in the State of Tennessee.

25 John, I would ask a couple of things. You've

1 presented us with some statistics that were not in our  
2 handout relative to the Level 1, Level 3 findings, and I  
3 would appreciate getting a copy of that.

4 MR. McCROHAN: Sure.

5 MR. MOBLEY: I would also--I know from my previous  
6 experience in dealing with FDA that you all do a lot or in  
7 the past have done a lot of analysis of information, and it  
8 would be very interesting to see--I presume that you've done  
9 this in this case--to see an analysis of the various types  
10 of findings that have been made in the field in terms of,  
11 you know, what are we looking at for those Level 1, Level 2,  
12 Level 3 findings out there. Are these paperwork problems  
13 relative to training and whatever of individuals? Are they  
14 equipment problems? Exactly what are they? And I have not  
15 seen that in any of our material for this committee, and  
16 possibly you have presented it somewhere and I just didn't  
17 see it elsewhere.

18 MR. McCROHAN: Well, we've certainly presented  
19 some of that sort of information in the past. In fact, I  
20 did at RSNA last year. We can certainly provide you with a  
21 more detailed breakdown. In fact, we have an analysis that  
22 indicates the frequency with which each of the potentially  
23 citable findings has, in fact, been cited and how that has  
24 changed from the initiation of the program in January '95  
25 through to the present. And it's a document where we sort

1 of normalized everything so that it, in effect, shows the  
2 numbers of violations we would have found had we looked at  
3 10,000 facilities, just because there's some slight  
4 variations from year to year in the number of inspections we  
5 actually did. And we can provide that to the committee.

6 MR. MOBLEY: Thank you.

7 CHAIRPERSON MONSEES: Yes, I'll recognize--please  
8 state who you are and where you're from.

9 MS. EDGERTON: Trisha Edgerton, State of  
10 California accreditation body. I have a few questions for  
11 you, John, from observations that we've had from the state  
12 level also in California, and also having the background of  
13 being an accrediting body and seeing how that works with  
14 inspections, too.

15 One thing that we've noticed and been very  
16 frustrated with is a real lack of action on the part of FDA  
17 with some very serious facilities, and just to bring up a  
18 couple of specifics, we had a facility that was not  
19 certified, and they continued doing mammography. And we  
20 took action from the state side, and when we called FDA,  
21 when we tried to get someone involved at the local level and  
22 finally went to the office here, we were told, well, since  
23 they're not certified, they're not covered under the act, so  
24 there's nothing we can do. And they were continuing to do  
25 very poor mammography.

1           There's a second example of a facility that we  
2 prosecuted at the state level, had the clinic owner and the  
3 radiologist go to jail and pay \$10,000 and \$15,000  
4 respectively to the Susan G. Komen Breast Cancer Foundation.  
5 They were accredited by another accrediting body, and they  
6 had no certified tech, they had no QC program. FDA did not  
7 go out and do anything with us. We tried to get them  
8 involved in the inspection. And they were never suspended.  
9 And when the films were re-read from the physician who they  
10 contracted to read, 80 percent were read as non-diagnostic,  
11 and of the 120, 8 were read as highly suspicious for  
12 malignancy where they'd all been read as normal.

13           And we see those as real serious problems. I  
14 mean, we're not talking little problems. We're talking big.  
15 And we can't get the FDA involved. I don't know why. Why  
16 can't we get inspectors out there? And why can't they have  
17 some teeth? I see no teeth, I guess, in the national  
18 inspection arena.

19           MR. McCROHAN: I mean, I think it's probably fair  
20 to say that the teeth are different from the teeth that you  
21 have as a state, and I think one of the things that--again,  
22 back to the point of the advantages, I think, to states and  
23 also the advantages to women of having the states in a  
24 states-as-certifiers role, may well be the ability of the  
25 state to do compliance actions or take compliance actions

1 more expeditiously than we can, given the authorities that  
2 you have under state law which we don't have in a comparable  
3 fashion under MQSA.

4           To speak to the issue of the uncertified facility,  
5 one of the difficulties that we have with the current  
6 statute and one of the things that we had suggested as what  
7 you might call a technical amendment and which was part of  
8 the Senate bill which was passed last fall to reauthorize  
9 MQSA was a minor wording change which had the effect of  
10 giving us access to uncertified facilities. The way the  
11 statute was originally worded, we have authority over  
12 facilities that we certify. We don't have authority over  
13 facilities we don't certify. It seems asinine, but there it  
14 was.

15           I don't think that was a plan, you know, when the  
16 statute was put together. I think that's an artifact, you  
17 know, of how the statute came out, if you will, and one of  
18 the reasons why we want to make a correction. So that we'll  
19 have clearer access--now, I mean, I think the states clearly  
20 have pretty unfettered access to those facilities and,  
21 therefore, can get in, can document the existence of the  
22 problem, and can take rather immediate action. We even have  
23 trouble getting in on our own, and when we do get in, what  
24 things are available to us to take an action against the  
25 facility?

1           We can in principle suspend or revoke the  
2 certificate. In the future, I think that it is fair to say  
3 that those paths will have been trodden often enough that we  
4 will have processes in place that may work faster than they  
5 do now, albeit, I think, not as fast as a cease-and-desist  
6 order from the state might work. But right now we've  
7 suspended, I think, in two or three facilities in the  
8 history of the program and have not yet revoked a  
9 certificate. And one of the reasons for that is that,  
10 number one, the situations, as egregious as they are that  
11 you mentioned, are exceedingly rare, which is--that part of  
12 it is a good thing. It's not a good thing for those  
13 individuals who were associated with that facility, but they  
14 are exceedingly rare, as a consequence of which all the  
15 processes haven't really been worked through as they have in  
16 the history of your program, for example, or in the history  
17 of other states who have had their perhaps non-MQSA-specific  
18 authorities in place for 20 and 30 and 50 years and,  
19 therefore, have worked through all of the processes to be  
20 able to take actions against a facility and, in fact,  
21 probably over the history of the program, have instituted  
22 legislative or regulatory changes which make that process  
23 easier and make that process function better.

24           I think that perhaps we haven't learned  
25 sufficiently in the--or didn't learn sufficiently in the

1 structuring of MQSA initially, and perhaps somewhat at the  
2 regulatory stage, from the experience that states have in  
3 being able to take care of those things. I appreciate the  
4 frustration, and it's certainly a frustration that we feel  
5 as well. And it's not a matter where we hear something like  
6 that and we want to be standing here saying, yeah, we didn't  
7 want to do anything, and--you know.

8           It is the fact that we're frustrated by a variety  
9 of things in taking the kind of expeditious action which I  
10 think most states are in a position to do. And, in effect,  
11 it's sort of an odd situation from a certain perspective  
12 that we're kind of behind you all in this respect, where you  
13 can under existing state laws, which may not, you know, look  
14 exactly like MQSA, still in a general sense you can go in  
15 and close down a facility much more quickly than we can.

16           We have a number of things built into the statute  
17 which provide the facility the opportunity for, for example,  
18 a hearing before a suspension, and so there are a lot more  
19 steps and a lot more time is likely to elapse. And so I  
20 think there's a tendency, in effect, for us, consciously or  
21 not, to sort of lean on you when it comes to those kinds of  
22 situations where we appreciate that the state can take quick  
23 action and certainly encourage you to do that, but it's  
24 not...

25           MS. EDGERTON: Well, I suggest, since the

1 inspection program is such a large part of MQSA and it is  
2 coming from the federal level, that you take it seriously.  
3 It appears that you have this program and the mechanism, the  
4 computers and the people and the training, and that's where  
5 it stops. They go out to the facility, and in our  
6 experience we have had very little or no support from--when  
7 there's a problem with the federal regulation versus state,  
8 we'll take care of our state part. But there are some  
9 things that can only be enforced at the federal level.

10           When we contract it, this is another problem.

11 When we were doing our negotiations for our upcoming  
12 contract, even our RHR, which is the radial--is it region?

13           MR. McCROHAN: Regional radiological health  
14 representative.

15           MS. EDGERTON: Regional radiological health  
16 representative, yeah, he supervises the FDA region, local  
17 region in our case so you have like nine states. Even he  
18 said in there that he was suggesting that we get paid,  
19 because currently we're not being paid for follow-up  
20 inspections of bad facilities. And he knows that the FDA  
21 won't go out and follow up with them, so he was suggesting  
22 that we get paid. He's even throwing up his hands and  
23 saying that the oversight of his FDA personnel that go out  
24 and do mammography inspections is done in such a way that he  
25 has no control over even getting them up and getting them

1 out there. And so there are just--there is some disconnect  
2 that I suggest you look at and come up with a much--get more  
3 teeth and be more active in this.

4 This is--I think I've used this every time when I  
5 get the opportunity--where the rubber meets the road. You  
6 can create all the paperwork, you can create all the  
7 bureaucracy, but where it matters is at the patient level.  
8 So that's just my suggestion.

9 Just in reference, someone brought up the annual  
10 report. I've noticed year a watering-down of the annual  
11 report. We're asked to submit the names of facilities and  
12 the action that occurred when we've taken escalated  
13 enforcement against them. And every year the number we  
14 submit goes up, but the number reported in the report go  
15 down. And this year I've noticed the report's due in the  
16 middle of May, that they're saying only report the most  
17 egregious. You know, they included the report from last  
18 year. I know I submitted 15, 20 facilities with all the  
19 documentation. One got reported in the annual report. So,  
20 you know, using the criteria that we were given to create  
21 the report, that just one comes out in publication.

22 So I don't know what's going on there, either. I  
23 just thought I'd let you know.

24 MR. McCROHAN: Nor do I. Let me take a look into  
25 that, although I would say that the report is intended to

1 reflect the actions which FDA is authorized to take and has  
2 taken against facilities and comparable state actions. So I  
3 think there's--at least in theory, there might be an issue  
4 about whether or not the action, the adverse action, for  
5 example, that you did take was, shall we say, similar to the  
6 suspension sanction that we have or the revocation sanction  
7 that we have. You may have sanctions that you can take  
8 against facilities that are, if you will, a lower level of  
9 action, which you might report but which might not be  
10 comparable to something that we do. So I'll have to take a  
11 look at that and see.

12 MS. EDGERTON: Well, there are two reports. One  
13 is we have to report any facilities that have been  
14 suspended, and then a separate report, we report against  
15 those that were shut down or temporarily suspended due to  
16 compliance. And a lot of those are using unregistered  
17 techs. You go there, and the only tech they have is  
18 unregistered, and they have to stop doing work. Those  
19 aren't being reported. Of course, on our suspension report,  
20 everybody suspended does. But this is a whole separate--

21 MR. McCROHAN: And when you mention an  
22 unregistered tech, what does that term mean to you?

23 MS. EDGERTON: They are not authorized to perform  
24 mammography under state rule nor MQSA rules, and they are  
25 performing mammography.

1 MR. McCROHAN: Okay.

2 MS. EDGERTON: And so, therefore, you have to--the  
3 facility has to stop until they get a certified tech-  
4 nologist.

5 MR. McCROHAN: One of the things that I would  
6 point out is that there are--it's certainly clear in the  
7 statute in subsection M that states can have more strict  
8 requirements than MQSA, and that's not a problem from the  
9 standpoint of the statute or from the standpoint of our  
10 program. But it does mean that states can take actions in  
11 situations where the agency would not be able to take  
12 action, and that's one of the things that probably needs to  
13 be teased out as well in terms of the report that goes to  
14 Congress with respect to those--

15 MS. EDGERTON: Well, this violation that I'm  
16 referring to is also an MQSA violation. It's not strictly  
17 state.

18 Thank you.

19 CHAIRPERSON MONSEES: Pertaining to states and  
20 variability, et cetera, I'd like to make a comment  
21 pertaining to the state in which I live, which is the State  
22 of Missouri, which has its own inspection and charges  
23 another \$200 per unit during that inspection, which is a  
24 little bit in excess of what's done under federal regs. And  
25 I have a question as to whether the FDA is tracking how many

1 states do this and what they charge, and this pertains to  
2 cost-effectiveness when we talk about really what we're  
3 getting for our buck. And the other thing pertaining to the  
4 states is you mentioned that the state can act where the FDA  
5 doesn't. In the State of Missouri, there were a number of  
6 patient recalls which may or may not have been appropriate,  
7 and so there's the other side of that coin, and that is,  
8 there's a lot of variability in what's going on state to  
9 state, and how are we going to get a handle on that?

10 MR. McCROHAN: I think to some extent the  
11 variability is built into the system in the sense that, as I  
12 said, subsection M of MQSA allows the states to have more  
13 stringent requirements. I think there's a--beyond that,  
14 there's sort of an interpretive issue, and in the case that  
15 you allude to in Missouri, that was certainly the case.  
16 They have a state law, regulation, which allows them to do  
17 the kinds of patient recall or patient notification that you  
18 mention.

19 The issue that we had was with respect to the  
20 circumstances under which they thought that was appropriate,  
21 and it goes back to the point that I made earlier. You can  
22 find a variety of things when you do an inspection of a  
23 facility which are worth noting to that facility and are  
24 worth having that facility fix, but which are not in and of  
25 themselves directly indicative of compromised image quality.

1 And, in fact, when we look at quality control, for example,  
2 we're dealing with a system whose design intent is to  
3 identify things before they become problems at the clinical  
4 image level. And so at least in theory, there's a prospect  
5 that you can be doing some quality control test in a less  
6 than optimal way and still not have yet resulted in a  
7 problem with the clinical images. And, in fact, my  
8 recollection of the situation is that there were some  
9 quality control kinds of findings which we would have said  
10 were Level 3, minor findings, which were being used, at  
11 least intended to be used by Missouri as the basis for those  
12 kinds of notifications to patients, which we thought was  
13 inappropriate, and we communicated that fact to them more  
14 than once.

15 And in doing all of that, I mislaid your first  
16 question.

17 CHAIRPERSON MONSEES: The cost. The cost-  
18 effectiveness and the additional charges in our state.

19 MR. McCROHAN: Right.

20 CHAIRPERSON MONSEES: Do you know how many other  
21 states are charging in addition to the FDA charge? Which  
22 just went up, by the way.

23 MR. McCROHAN: Right.

24 CHAIRPERSON MONSEES: How much and how widely  
25 that's being utilized.

1 MR. McCROHAN: I do not. And one of the things  
2 that would be a concern to me in that regard is that  
3 whatever the facts are in a given state need to be taken  
4 into account when FDA negotiates the contract with that  
5 state to do the MQSA inspections. If the Federal Government  
6 and, through the Federal Government, the facilities are  
7 paying the state to go to the facility, to spend X hours  
8 doing an inspection, and return, if the inspector at the  
9 same time is taking an additional half-hour, hour, whatever  
10 it might be, to do additional state work while they're in  
11 the facility, then whatever fee they charge ought to be  
12 reasonably congruent with that amount of extra work since,  
13 in effect, the Federal Government through the contract has  
14 already paid them to go to and from the facility and the  
15 facility, through the fee, has paid for it as well.

16 So I think we would want to be able to take those  
17 kinds of issues into account in negotiating the contracts  
18 with the states. We don't want, by the same token, to  
19 discourage the state from doing that--taking the time in  
20 concert with an MQSA inspection to do whatever other  
21 additional tests or record checks are required by the state  
22 law. It would be not in the facility's interest to have the  
23 MQSA inspection totally decoupled from whatever other kinds  
24 of things the state might want to do or might need to do  
25 under its regulations.

1           If it were, then we'd be in a situation where the  
2 facility through the fee would pay for the MQSA inspector to  
3 come out to do the MQSA inspection and then the next day, if  
4 you will, pay the state fee for the state inspector to come  
5 back and do the state inspection. It would be more  
6 intrusive. It would be more expensive. And so I think we  
7 want to encourage, you know, a level of efficiency and cost-  
8 effectiveness in that sense. But I do think we need to know  
9 what's going on, and we need to take that into account in  
10 doing the negotiations to make sure that there isn't the  
11 kind of overlap that's implied by the question.

12           CHAIRPERSON MONSEES: When the GAO evaluates for  
13 cost-effectiveness, are they collecting this data so that  
14 they can look at what the true, quote, cost is and whatever  
15 addition--and gathering data, for example, on whatever  
16 additional the state is uncovering by doing this and by  
17 charging this to see whether there's actually any  
18 effectiveness that goes along with it?

19           MR. McCROHAN: Good question. I don't know the  
20 answer. I do know that in doing the various reports--and  
21 they did study us three times and published three quite  
22 positive reports on the program--I know GAO spoke with  
23 people from various states--I don't know if Missouri was one  
24 of them--and they certainly--I would guess certainly didn't  
25 speak to people from all of the states. I'm sure that they

1 looked at some of those issues, but I don't know that they  
2 would have felt they had the authority to address the  
3 question of what it is the state rules and regulations and  
4 legislation allows or requires them to do that might go  
5 beyond MQSA. That might have been going somewhat beyond  
6 their mandate.

7 But, you know, we could take a look at those  
8 reports. I don't know specifically--actually, it might take  
9 somebody from GAO to answer the question in terms of who  
10 they asked and what they asked.

11 CHAIRPERSON MONSEES: You might pass that on to  
12 them for their next audit.

13 Unless you have any other points, I'm going to  
14 take one quick question from the audience, and then we're  
15 going to break for lunch.

16 MR. McCROHAN: Okay.

17 CHAIRPERSON MONSEES: Yes?

18 MR. HENDRICK: Can I borrow your--don't go away.  
19 Ed Hendrick, University of Colorado. My quick question is:  
20 When we implemented MQSA four years ago, we found three  
21 kinds of problems at sites identified by the inspections:  
22 real problems; documentation problems, where it turned out  
23 there wasn't a real problem but there was a problem of  
24 having the paperwork in place at the time of the MQSA  
25 inspection to show that everything was being done correctly;

1 and the third were inspection problems, that is, things were  
2 being done correctly, the documentation was in place, and  
3 there was a misinterpretation of the requirements by the  
4 inspectors.

5           And my question is: Is there to be a way to  
6 separate the real problems from the documentation problems  
7 in the final--in the inspections under the final rules?  
8 And, second, is there a way to minimize the inspection  
9 problems which are problems identified at the site by the  
10 inspector but not actual problems, a misinterpretation of  
11 the final rules by the inspectors themselves?

12           I heard how you trained existing inspectors, but I  
13 didn't hear specifically what you had in mind to train  
14 existing inspectors for education about implementing the  
15 final rules. And so I think that will help eliminate  
16 inspection problems, but I'm also concerned about  
17 differentiating between real problems and just problems of  
18 missing documentation at the time of inspection.

19           CHAIRPERSON MONSEES: Thank you.

20           Do you want to address this quickly? And then  
21 we'll break for lunch. Or do you think--

22           MR. McCROHAN: Sure. With respect to the  
23 documentation problem issue, I guess I would make two points  
24 just as an example, and we can get back into this later.

25           One is that if we are absent documentation about

1 the qualifications of an individual in the facility, that  
2 doesn't in and of itself result in a finding. We provide  
3 the facility an opportunity to provide us the documentation,  
4 although one might ask, since the requirements are clear,  
5 why the documentation, you know, wouldn't be available, say,  
6 for the medical licensure of the interpreting physician or  
7 what have you. But there is an opportunity for the  
8 inspectors to make a note in the record and for the facility  
9 to be given some time to provide that documentation.

10 The second point with respect to documentation is  
11 that in quality control, documentation, in effect, is pretty  
12 fundamental to the whole process of having the information  
13 that you need to know whether or not things have been done  
14 or whether the quality is what you would want it to be.

15 It is certainly an issue, but one of the things  
16 that frustrates us, I suppose, is the fact that we are not  
17 in the facility on an hour-to-hour basis observing  
18 performance. So all we can observe is the consequences of  
19 that performance. We can observe the consequences of that  
20 and some documentations and some records that the facility  
21 might have. We can also see the consequences in some of the  
22 physical measurements that we make with respect to the  
23 equipment in the facility. But certainly I think that in  
24 the quality control area, documentation is very fundamental  
25 to the whole process of quality control.

1           So for somebody to say I've done my processor  
2 quality control, for example, every day for the last month,  
3 I just don't have any record of that, is really not, I  
4 think, adequate quality control. You may have--you assured  
5 yourself every morning that things are in control, but  
6 you're not being able to see the trends and so forth unless  
7 you have the appropriate documentation.

8           With respect to the last issue, we are planning to  
9 do training for all of the existing 250 or so inspectors in  
10 the early part of next winter, probably February and March  
11 with respect to the new issues under the final regs, so  
12 there will be additional direct training of the inspectors  
13 with respect to those issues.

14           We do allot--and we'd certainly, you know, be open  
15 to other suggestions of other things that we can do with  
16 respect to the quality control. We certainly accept through  
17 the hotline and through other mechanisms complaints or  
18 concerns from facilities about things which have happened  
19 that they think are inappropriate during an inspection, an  
20 inappropriate citation or what have you. But it is equally  
21 possible that the misinterpretation of a particular  
22 requirement is at the facility end as opposed to the  
23 inspector end, and so there's a lot of things that need to  
24 be sorted out in that area. But we'd be open to other  
25 suggestions for the quality control vis-a-vis the inspectors

1 during the inspections.

2 CHAIRPERSON MONSEES: Since these inspections are  
3 conducted using a database that you were describing earlier,  
4 isn't it just a matter of interrogating the database to find  
5 out what falls into the different categories that Dr.  
6 Hendrick was talking about? And can't these things be--an  
7 overview of these things be published and made known perhaps  
8 in mammography matters or whatever?

9 MR. McCROHAN: I think the difficulty with the  
10 last item, what you called, I think, inspection problems, is  
11 that what would be in the record is an indication that there  
12 was a problem with the facility in a particular respect.  
13 What we don't have in the database is whatever the  
14 underlying information was that led the inspector to the  
15 conclusion that there was a problem. So if that conclusion  
16 was inappropriate, then we would have the data of that  
17 inappropriate conclusion in the database but not a way to  
18 check against the primary source, if you will, of the  
19 underlying record or what have you.

20 The only issue--the only time where we would have  
21 the information would be if the inspection error was with  
22 respect to a physical measurement where we would actually  
23 have some of the data to go on. But in that event, it's  
24 really not the inspector that's making the decision, but the  
25 algorithm in the computer that's making the decision about

1 whether this data represents a finding.

2 CHAIRPERSON MONSEES: Well, when the facility  
3 appeals or whatever, you certainly are going to track that  
4 type of information.

5 MR. McCROHAN: Yes.

6 CHAIRPERSON MONSEES: So then you will get it at a  
7 later point in time.

8 MR. McCROHAN: Right. And there may--

9 CHAIRPERSON MONSEES: It's obtainable.

10 MR. McCROHAN: Right. I mean, it's a matter of  
11 going back to whatever the primary source was in the  
12 facility and checking that against the conclusion that was  
13 drawn from it.

14 CHAIRPERSON MONSEES: Okay. All right. I think  
15 with that we're going to break for lunch. I have an  
16 announcement to make. The panel members, there is a buffet,  
17 if you'd like to join us, we're at the front of the  
18 restaurant, which is reserved for the committee.

19 We will reconvene this meeting at 1 o'clock.

20 Thank you.

21 [Luncheon recess.]

AFTERNOON SESSION

[1:08 p.m.]

CHAIRPERSON MONSEES: We finished our question-and-answer session this morning, and what we're going to be working on now is a set of overheads that goes along with the document that panel members should have that looks like this, the thing that you thought was written in a foreign language. Right. Greek or something like that. This is really what we're going to be going through.

And the way we're going to do this, I think--and we'll kind of fix it as we need to--is that John is going to show two sets of overheads. The one on the left is going to be a more general set, kind of give you the big picture, and then the one on the right is going to be more specific to the item that he's discussing in detail at that time. He's going to break in between each one--or not each individual one but each group, for the Q&A part, after he does the presentation. Okay? And then we'll do questions and comments on that.

And I'm sure there will be questions and comments from the audience. I don't want to do that necessarily at each opportunity that the panel is going to have to do questions and answers, but we will ask for questions and comments from the audience as well. So take notes and be ready when we do that.

1 Any other preparatory information, John? Okay.  
2 Why don't you get started?

3 MR. McCROHAN: Thank you. As we said, on the  
4 left-hand side we want to use a set of overheads to kind of  
5 keep ourselves oriented to the general picture as we go  
6 through the foreign-language document on the right. It is  
7 somewhat dense, but I think that it's the best way that we  
8 could figure out to go through what we had proposed and get  
9 your input on any points that you want to make at various  
10 points where we have an interest in getting your input or  
11 questions that we have to ask. So we're going to talk about  
12 the sections of the final reg inspection, just very briefly  
13 on some of the general information that we gather on the  
14 general requirements, spend a few overheads talking about  
15 the system performance tests, and then spend the bulk of the  
16 time talking about the various aspects of the records  
17 review.

18 So we'll start, as this graphic suggests, with the  
19 general facility data and machine information, which you can  
20 see on the overhead on your right.

21 As you can see, we're going to continue, as we  
22 have under the--propose to continue as we have under the  
23 interim rules to look for the certificate. We consider that  
24 to be critical in terms of informing patients that they're  
25 in a facility that's certified against the requirements.

1 We're also going to be checking the expiration date on the  
2 certificate. And given the circumstances under the final  
3 rules, we're in a position to cite facilities that are  
4 operating uncertified, which would be done on that basis.

5 In terms of the machine information, I'd point out  
6 that there's a fair amount of information that we're going  
7 to have the inspectors collect about the description of the  
8 facility and the description of equipment and so on and so  
9 forth that we haven't bothered to put in here because it  
10 doesn't pertain particularly to something that could be a  
11 finding, but there is some underlying basic information that  
12 we and the inspectors are going to be keeping track of. But  
13 for brevity's sake, if you will, we decided not to include  
14 that on the overheads.

15 But we do certainly want to have the inspector  
16 check and see if the X-ray unit is one which is prohibited  
17 from mammography as defined under the final rules, and then,  
18 secondarily, check a couple of items which the final rules  
19 require that a piece of equipment meet. And we have  
20 selected in this respect a question about whether or not the  
21 image receptors, grids, and compression paddles, two sizes  
22 of image receptors are available for the machine, and then  
23 also question with respect to the requirements for the  
24 automatic exposure control and the post-exposure display of  
25 the technique factors and so forth.

1           Those seems to us to be a couple of the six or  
2 eight or so items under the equipment requirements under the  
3 final rules that would make sense to look at. There were a  
4 number of requirements in the final rule, for example,  
5 controlling the motion of the tube head, for example, and a  
6 variety of other things that we thought were not  
7 particularly productive for the inspector to be checking on  
8 on a routine basis. So we did want to check to see if the  
9 machine in this general sense met the final rule  
10 requirements.

11           Skipping the next line to the unit evaluation  
12 question, this is one where I think you may--both of these  
13 are ones which you may have some input on. The unit  
14 evaluation, as you may recall, is something new in the final  
15 rules, and it's a requirement that when a machine is new and  
16 newly installed or when a machine is disassembled and  
17 reassembled or moved, and when a machine is repaired--this  
18 is an X-ray machine or a processor--that an equipment  
19 evaluation or unit evaluation needs to be done by the  
20 medical physicist to re-establish the fact that the system  
21 is performing as intended.

22           There are questions, at least in our mind, as to  
23 defining what ought to constitute the circumstances under  
24 which an equipment evaluation is required, and once those  
25 circumstances have been defined, to define what kind of

1 tests are necessary to be included in the equipment  
2 evaluation.

3           Examples that we have considered are from the  
4 repair perspective, when the X-ray tube is replaced, when  
5 the AEC is replaced, possibly when the collimator is  
6 replaced, and certainly there are tests that are required as  
7 part of the physicist's survey which would be appropriate in  
8 each of those instances in order to verify that the repair  
9 had been conducted properly.

10           The next issue, moving down the screen on the  
11 right-hand side, pertains to the issue of whether or not we  
12 are dealing with a mobile unit, and when we get to the  
13 quality control section, we'll be talking about issues  
14 related to the post-move pre-use test that's required in the  
15 final regs for mobile systems.

16           We can skip over, I think, the next few sections  
17 which talk about the image receptor. And the last question  
18 on this slide is the issue of whether or not the unit is  
19 accredited. That's a requirement when you put a new unit  
20 in. You'll notice that we have a possible answer there of P  
21 for pending, and that's in the situation where the facility  
22 has applied to have the unit accredited. They've sent in  
23 their application to their accrediting body but haven't yet  
24 received a decision on that application. And that's  
25 considered to be a situation which is acceptable. What

1 we're talking about is wanting to be sure that they have at  
2 least applied for the accreditation of that unit, and it  
3 would be a Level 2 non-compliance if we got an answer of no,  
4 there's no application--no accreditation or no application  
5 pending.

6 So at this point, I think it would be convenient  
7 to take any questions or comments that you have with regard  
8 to the general and machine information issues, and there  
9 were a couple there that--

10 CHAIRPERSON MONSEES: Okay. Turn the lights up  
11 again so I can see. Yes?

12 DR. SICKLES: Ed Sickles. Just the briefest  
13 comment about that last thing. To apply for accreditation,  
14 you have to already have the unit in service for a while.  
15 So what would you do for the facility that is caught in that  
16 narrow window?

17 MR. McCROHAN: That's a good question. What would  
18 you advise?

19 DR. SICKLES: I think either defer the inspection  
20 if the inspection is requested, and the facility can  
21 identify that in that particular time frame they will have a  
22 unit that's caught in limbo so they could put it off for a  
23 month, or to just give them a P. Either one.

24 MR. McCROHAN: Yes, I think that they--it's clear  
25 that they'd have to have the equipment evaluation completed

1 in order to put it in use in the first place. They  
2 certainly have to have it in use to generate the clinical  
3 images that are ultimately required. I'd have to check to  
4 see whether those are required with the initial application  
5 or if they're a piece that can follow fairly immediately.  
6 But--

7 DR. SICKLES: I believe you--to put equipment in  
8 service, you have to have the physicist's evaluation  
9 completed, which should be done before any patients are  
10 imaged. But I also believe you can apply for accreditation  
11 before the clinical images are produced. But that's just a  
12 paper application. You prove nothing other than filling out  
13 the paper form.

14 MR. McCROHAN: Right. And I think that's what we  
15 had in mind, is that at least that paper part of it was in  
16 process. I think it's unreasonable to--I mean, it's a  
17 Catch-22 if we expect people to be accredited and yet they  
18 haven't had the opportunity to create the clinical images  
19 which are a predicate to accreditation. So we need to have  
20 a reasonable way of getting a unit on board, but we'll look  
21 at the issue of what we'll do in that potentially narrow  
22 window.

23 CHAIRPERSON MONSEES: Yes?

24 MR. PIZZUTIELLO: Bob Pizzutiello. Dr. Sickles is  
25 correct, as far as I know, that a physicist's survey has to

1 be done. But when a new machine comes in, the way I  
2 understand the accreditation process is the facility has to  
3 get a new machine application into the ACR. So, in essence,  
4 that is pending, and then the first step is to get the  
5 application form in, then the physicist does their survey  
6 and then things proceed. So I'm not sure that I see--if you  
7 interpret pending meaning the paperwork has been begun and  
8 the physicist's survey has been done, then I think that  
9 would cover that situation.

10 MR. McCROHAN: Yes, that's what we intend.

11 One point of clarification. The survey per se is  
12 not required as a predicate to accreditation. In fact, it's  
13 one of the quirks of the statute that you can't--we can't  
14 require the survey at the initial application stage to get a  
15 facility, for example, a provisional certificate. That's  
16 why the equipment evaluation process, if you will, was  
17 created, because I think there's a good deal of concern on  
18 our part and on the part of others, states, for example,  
19 that before units are used on patients that there be some  
20 evaluation. But, per se, we can't require the survey, in  
21 the case of a new facility, at least, as a predicate to  
22 getting the provisional certificate. They have to be able  
23 to submit the application to get the provisional--the survey  
24 certainly has to come along before they get a final decision  
25 from the accrediting body and are finally accredited. But

1 that's, as I say, a little quirk in the law.

2 CHAIRPERSON MONSEES: Any other comments from  
3 here?

4 [No response.]

5 CHAIRPERSON MONSEES: All right. I'm going to  
6 allow some questions from accrediting bodies and people in  
7 the audience who may want to ask about this before we move  
8 on. I see one over here. ACR and states, if you have any  
9 questions about this?

10 MR. HENDRICK: Ed Hendrick, University of  
11 Colorado. I would just caution against not having the  
12 inspection done in this situation where they're not  
13 accredited yet because this is a place that might be the  
14 place that sites that are doing the poorest quality  
15 mammography would hide, either because they're freshly on  
16 board and haven't been through the process before or they've  
17 flunked accreditation and this is their way of getting  
18 reinstatement as a site. So I would very much argue that  
19 this survey by--or the inspection by the MQSA inspector  
20 should be done at this point to see--even if their  
21 accreditation is pending, to see if they are meeting  
22 standards.

23 CHAIRPERSON MONSEES: Thank you.

24 Do we have any other questions from the audience  
25 at this point?

1 [No response.]

2 CHAIRPERSON MONSEES: Okay. Do you want to move  
3 on, John?

4 MR. McCROHAN: Okay. We can move on on both  
5 sides.

6 We're now going to talk about the system  
7 performance tests which are outlined on the left, and we'll  
8 go through two or three overheads on the right to talk about  
9 each of those.

10 As you can see at the top, we're planning to  
11 continue in essentially the same way as under the interim  
12 rules the collimation assessment. In particular, we're  
13 going to be looking at the X-ray and image receptor  
14 alignment at the chest wall and the paddle alignment in that  
15 location.

16 MR. McCROHAN: The next section is just a  
17 mechanism for collecting the technique factors, and then  
18 under the heading of Dose Estimation is the section where we  
19 would collect the exposure results for images using the  
20 standard technique and the imaging phantom with three  
21 different cassettes.

22 We are proposing somewhat of a change here. This  
23 is done under the interim rules of inspection, and in fact,  
24 those three images become, as we will see in a moment, the  
25 two phantom images that are scored for the facility and the

1 image that is used in the darkroom fog test.

2 But what we are proposing to, at least in some  
3 instances, shorten the inspection somewhat is to use these  
4 three exposures to create an average exposure for the  
5 calculation of the dose, and if the exposures for each of  
6 three cassettes fall within a reasonable range of each other  
7 in terms of reproducibility, then, we would be comfortable  
8 using the average exposure to compute the dose.

9 If the three exposures with the three different  
10 cassettes didn't meet that coefficient of variation  
11 requirement, we would then do as we do today, that is to say  
12 do four exposure with a single cassette having removed the  
13 cassette now as a variable and looking at the  
14 reproducibility, then, calculating the dose on the basis of  
15 that more accurate, if you will, average exposure, and then  
16 there is also the potential if the coefficient of variation,  
17 if the requirement isn't met with the four exposures, to do  
18 an additional set of exposures because the requirement that  
19 really derives from the x-ray standard under a different law  
20 is for the reproducibility under a scheme where you do 10  
21 exposures.

22 We then will do the beam quality measurement as we  
23 do now and calculate the dose on the basis of that average  
24 exposure and the beam quality, so the principal change here  
25 in the dose estimate is with respect to doing some exposures

1 on several cassettes and then using that set of numbers to  
2 do the average exposure calculation for the dose estimate,  
3 and then back up to the top of the page, looking at the  
4 collimation more or less as we do now, checking the  
5 alignment of the field and the image receptor at the chest  
6 wall and checking the paddle alignment.

7 CHAIRPERSON MONSEES: Okay. Lights on. Q and A  
8 here.

9 Do any of our physicists have any questions about  
10 these things?

11 MR. MOBLEY: Mike Mobley.

12 On your coefficient of variation dose estimate and  
13 collapsing this all together, is all of that going to be  
14 designed into the computer program, such that the inspector  
15 gets a notification you have to do these additional tests or  
16 do they have to do that themselves as a calculation on the  
17 fly while they are there?

18 MR. McCROHAN: No, the software will do that. So,  
19 they will look at the three values, if it meets the  
20 threshold, it will go on from there. If it doesn't, then,  
21 they will be reminded to do or instructed to do the four  
22 measurements with the single cassette, and so on.

23 MR. MOBLEY: And if it doesn't meet the criteria  
24 under the four, then, it will roll out to the 10.

25 MR. McCROHAN: Right, which is how it works today,

1 yes.

2 MR. MOBLEY: Okay. Thank you.

3 CHAIRPERSON MONSEES: Yes.

4 MR. PIZZUTIELLO: Bob Pizzutiello.

5 On some of the machines, when you are in the fully  
6 automatic mode where the automatic exposure control is  
7 selecting multiple parameters, such as kV density control  
8 target, filter, and so on, sometimes when you put a phantom  
9 in, it's right on the decision point between, let's say, 25  
10 kVp and 26 kVp, and if you take multiple exposures, you  
11 might get a fairly wide disparity in exposure measurement  
12 because one exposure might be at 25 kVp with a higher MAS,  
13 and one might be at 26 kV with a lower MAS.

14 Do you have some facility to look after that and  
15 how you are going to handle it?

16 MR. McCROHAN: Well, I think what we are trying to  
17 do is sort of create the situation in which we can in some  
18 circumstances, but not obviously in all circumstances,  
19 shorten the number of measurements that need to be made in  
20 the time, and so forth.

21 That situation that you describe obtains today. I  
22 think that it has been our general desire, I suppose, to  
23 have the inspection done in somewhat other than the fully  
24 automatic mode. It is fine for it and it should be done in  
25 the AEC mode, but if you have it in a full auto mode where

1 the machine is selecting the kV, and so forth, it is not  
2 clear to me at least whether the phantom will drive the  
3 machine appropriately in all circumstances, and I think  
4 that, you know, the circumstance that you point out is a  
5 case in point.

6           Would have any suggestions, if that behavior, if  
7 you will, or response of the unit is observed, what would  
8 you recommend be done in terms of this aspect of the  
9 inspection, recognizing that it is not simply the case that  
10 we are driving the exposures here, so we get a variable  
11 exposure whose average might still be reasonable, but we are  
12 also doing the images at this point, which we are then going  
13 to evaluate for image quality?

14           MR. PIZZUTIELLO: I like the idea of doing the  
15 imaging preferably in the mode that's on the technique  
16 chart, but in this case, the fully automatic mode sometimes  
17 will produce what looks like bizarre results, but they are  
18 really not bizarre.

19           It's just that in any software there has to be a  
20 point where you have to decide sometimes you are going to do  
21 25 kV, sometimes you are going to choose 26 kV, so I think  
22 it makes sense that in those circumstances, to back off from  
23 the most fully automatic mode to the mode that only controls  
24 the exposure time and select an appropriate clinical kV.

25           As long as you do that, then, all the subsequent

1 measurements will be reasonable. I just want to make sure  
2 that the software doesn't try to average exposures, one of  
3 which is taken at 25 kV and one of which is taken at 26.  
4 So, your solution sounds good.

5 MR. McCROHAN: And that would certainly be  
6 inappropriate since we are going to make the HVL measurement  
7 at some kV and we ought to be using that in conjunction with  
8 an average exposure at the same kV in order to do dose  
9 calculations. Okay.

10 We can go one forward on the right.

11 As we mentioned, the three exposures that we just  
12 talked about, the first two of those are used to create the  
13 two phantom images that are potentially evaluated. I say  
14 "potentially" because for a variety of reasons including  
15 issues like the reproducibility that was just mentioned and  
16 some issues also related to reproducibility in terms of  
17 artifacts, we have two images to evaluate, two phantom  
18 images to evaluate, but the performance of the facility is  
19 assessed on the basis of the best of those two images.

20 So, if the first image passes the various  
21 criteria, then, it is not, strictly speaking, necessary to  
22 evaluate the various characteristics with respect to the  
23 second image.

24 The criteria that you see listed at the bottom  
25 effectively translate into the facility being fine and there

1 being no findings if they meet the 4, 5, or 3 speck group  
2 and 3 mass criteria, which is the accreditation criteria,  
3 they get a Level 2 finding if any of those elements were  
4 significantly below that level of 4, 3, 3, but they wouldn't  
5 get to A, a Level 1, until they were below that by a full 5  
6 speck group or mass.

7 That is to reflect to some extent the uncertainty  
8 in terms of how the images are scored and variability,  
9 inevitable variability between various interpreters of those  
10 images in terms of how they generate that score.

11 So, we want the score to be at a level where we  
12 are certain it is below the required level in order to sort  
13 of issue if you will, the Level 1 finding, but if it appears  
14 to be below, but might be, if you will, sort of within the  
15 0.5 uncertainty in this measurement, the facility would get  
16 the Level 2.

17 CHAIRPERSON MONSEES: Turn the lights up here, so  
18 I can see. Does anybody have any comments about this? Yes.

19 DR. NISHIKAWA: Bob Nishikawa.

20 It is unclear to me what you do with the artifact  
21 measurements like number of fibro-artifacts.

22 MR. McCROHAN: The process that we are going to be  
23 using or at least we intend to use is the same process that  
24 we use now, and it's the process essentially which the  
25 medical physicists are directed to use through the ACR QC

1 manual.

2           There is somewhat of a debate, I suppose you might  
3 say, on this point. In fact, in the ACR manual, there are  
4 two different evaluation procedures that are recommended for  
5 the medical physicist, on the one hand, and the  
6 technologists, on the other, as it relates to how you deal  
7 with artifacts.

8           What we are talking about here is if there is an  
9 artifact, and it is often a processing artifact which  
10 obscures one of the larger objects, say, a fiber, then, the  
11 score for that element would be determined by which object  
12 in the phantom was obscured by the artifact.

13           You would stop evaluation at that point and you  
14 wouldn't count, if you will, the smaller objects in that  
15 group even if they might be visible. As I say, that is a  
16 bit of a controversy to how to deal with that. It's the one  
17 way to have the artifacts that may be present in the image  
18 and may be a problem from a clinical imaging standpoint,  
19 have some impact on the phantom image score and avoid the  
20 necessity in the alternative of creating some kind of a  
21 subjective assessment or subjective rating scale for  
22 artifacts in the phantom image, which we are a little  
23 uncomfortable with in terms of being able to do that in a  
24 consistent way across our cadre of inspectors.

25           I think the one sort of out here is the fact that

1 we are dealing with two images, and in order for an artifact  
2 to have impact on the score, it would really need to appear  
3 and obscure or partly obscure the same object in the two  
4 images, and so forth, so I think there is a sense in which  
5 the artifact would need to be persistent in order to have  
6 the impact on the result of the phantom image test, but it  
7 is sort of a controversial area, and if you have any  
8 suggestions in that regard, I would be more than happy to  
9 hear them.

10 DR. NISHIKAWA: I don't know if I have any  
11 suggestions, but I still have a problem with that because  
12 you are relying on the artifact to superimpose on some  
13 object in the phantom, which I am not sure how likely that  
14 is to happen.

15 MR. McCROHAN: It is a relatively, I suppose, low  
16 likely event, and the artifact can appear right next to the  
17 object in the phantom, and then it wouldn't affect the base  
18 score per se.

19 We do count artifacts and subtract from that base  
20 score later on. Say we are looking at the fibers and you  
21 see the first four fibers, but there is also a fiberlike  
22 artifact, then, you would have a base score, if you will, or  
23 a gross score of 4, and you would subtract 1 for the  
24 fiberlike artifact and get a score of 3, and you would be  
25 judged on that basis, so it can have impact in that respect,

1 as well, but it is a difficult area I think.

2 DR. NISHIKAWA: There is also a problem, for  
3 example, speck artifacts are going to look like specks, they  
4 are not going to mask anything, so there could be some  
5 center, for example, who doesn't clean their screens and you  
6 will have a lot of artifacts.

7 I don't see the mechanism to cite the site for not  
8 cleaning their screens, for example.

9 MR. McCROHAN: I think it just shows up basically  
10 as a count of artifactual specks which has impact on the  
11 last speck group, that would otherwise have been counted in  
12 the phantom image, and that may or may not be significant in  
13 terms of the phantom image score and then resulting in a  
14 finding.

15 So, I mean it is kind of an anomaly that you can  
16 have an image which on the surface, you know, isn't one that  
17 you would like to see and yet the score per se can be  
18 passing. Again, it seemed an awkward situation to try to  
19 create some kind of independent evaluation of artifacts, the  
20 number, the extent, the type, the location, and so forth,  
21 and to do that in a way which was consistent across  
22 inspectors, so that is sort of why we avoided that, but if  
23 there is a way to address that more appropriately, as I  
24 said, we would be happy to hear about it.

25 CHAIRPERSON MONSEES: Yes.

1 MR. PIZZUTIELLO: To address the issue of  
2 artifacts in particular on the phantom scoring, the way the  
3 American College of Radiology Mammography Accreditation  
4 Program scores them is that artifacts are assessed in two  
5 different ways.

6 If an artifact were to obscure full visualization  
7 of any test object, then, you sort of stop the scoring  
8 there. In addition to that, the entire image field is  
9 scanned for any object that looks -- any artifact that looks  
10 as much like the last object that was scored, and the  
11 thinking there is that if we see an object that is  
12 artifactual, that looks just like the last one we scored,  
13 then, we really can't be sure that the last one we scored  
14 was, in fact, really visualized, so therefore, it is  
15 subtracted.

16 So, while it is admittedly not a perfect system of  
17 assessing the impact of artifacts, if there are artifacts  
18 that really might legitimately fool someone reviewing the  
19 phantom, and ultimately, a radiologist interpreting  
20 position, looking at the image, then, there is a mechanism  
21 for deducting for that.

22 I guess I would encourage that whatever system is  
23 current with the accreditation program, and in fact, we have  
24 made some recent enhancements to the scoring procedure, and  
25 so on, at the College, that that be as consistent as

1 possible given the ensemble of multiple inspectors over the  
2 universe of the United States.

3 CHAIRPERSON MONSEES: Has this been a problem, is  
4 there a disparity between what the inspectors have been  
5 finding and then, by appeals process, find that it is  
6 overturned, or has this been fairly straightforward?

7 MR. McCROHAN: I think it has been relatively  
8 straightforward in terms of this issue of the artifacts  
9 because it is a relatively rare occurrence, and while you  
10 described it a lot better than I did, what you described is  
11 essentially what we do.

12 I did understand that there was some consideration  
13 being given to perhaps modifying that, and we would be happy  
14 to be in concert.

15 CHAIRPERSON MONSEES: We have a question from the  
16 audience.

17 DR. HENDRICK: Ed Hendrick. It is more of a  
18 comment. We finally have gotten to the point, I think,  
19 where what is in the manual, ACR QC manuals, is what is  
20 being done by accreditation program reviewers who score  
21 phantom images and is identical to what is being done in the  
22 MQSA inspection program.

23 This is just an embodiment of that scoring  
24 methodology, and we have convinced the set of about 1,000  
25 medical physicists out there to use this methodology, and in

1 the revision of ACR QC manual, which will be coming out just  
2 before the final rules go into effect, and hopefully will be  
3 consistent with the final rules, we are making sure that the  
4 technologists have exactly the same instructions as the  
5 physicists and the ACR reviewers and the MQSA inspectors.

6           If you want to confuse a whole generation of sites  
7 out there, then, just change the methodology one more time.  
8 I mean now that we are all in agreement, it's a great time  
9 for the Advisory Committee to make another change. I am  
10 being facetious. Please don't change it. I mean it works.  
11 This is just understanding how the data entry occurs on the  
12 form, and if you change it, you are going to confuse a lot  
13 of people out there.

14           CHAIRPERSON MONSEES: It is important to hear that  
15 it works. That's good. Thank you.

16           One more question.

17           MR. MOBLEY: I hear what Ed is saying and I hear  
18 what everybody is saying, but I am always concerned when  
19 everybody says this is wonderful and don't change it and  
20 everything, because, you know, there is other thoughts,  
21 other -- you know is this really the perfect answer or is  
22 this the best we can do at this point in time, and we are  
23 going to continue to work on it, is everybody, is the whole  
24 universe in agreement with this, because as I see this, I  
25 sense that it is reasonable, but I also sense that there is

1 some level of arbitrariness here in how -- and I don't use  
2 that in a negative sense -- but some arbitrariness in how we  
3 make this assessment relative to the artifacts or whatever.

4 Do you want to take a cut at that?

5 MR. McCROHAN: Well, I think that we would be open  
6 to the prospect that somebody might be able to propose an  
7 easily implemented and consistent method for assessing  
8 artifacts in and of themselves, at which point I think we  
9 might be able to modify the existing procedure, but I think  
10 as Ed said, I think we would want to do that thoughtfully  
11 and do that across the board, and it is going to take some  
12 convincing, frankly, if somebody comes up with a proposal  
13 for evaluating artifacts because at least as best anybody  
14 can judge at this point, that would be a highly subjective  
15 assessment, and that level of subjectivity is something we  
16 would like to avoid as much as we can in the inspections  
17 because I think it would really be prone to what I think Ed  
18 earlier this morning called inspection problems or errors or  
19 what have you.

20 CHAIRPERSON MONSEES: Yes, Ed.

21 DR. SICKLES: Ed Sickles. To get the level of  
22 consensus that has been achieved is a demonstration that  
23 there is general acceptance of the process.

24 CHAIRPERSON MONSEES: Okay. From the audience?

25 MR. BROWN: Paul Brown, State of Illinois.

1 I just want to inject one thought here.  
2 Inspectors are not physicists and are not consultants, and  
3 they are not even x-ray technologists, and believe me, I  
4 know from experience that our inspectors' eyesights are not  
5 evaluated every year as part of the certification process.

6 In trying to keep things simple, what I would  
7 always suggest is that the phantom be scored for the masses,  
8 specks, and fibers, and if there is artifacts noted on the  
9 film, you would say artifacts noted, further investigation  
10 warranted, or numerous artifacts noted, further  
11 investigation and correction required.

12 I think that is a lot simpler process than  
13 starting to subtract scoring from the fiber, mass, or speck  
14 group.

15 CHAIRPERSON MONSEES: Thank you for that comment.  
16 Let's go on.

17 MR. McCROHAN: The next slide on the right  
18 indicates the data that is going to be collected for the  
19 process or evaluation of the darkroom fog, and when we are  
20 done with this, we will be finished with the machine  
21 performance part of the inspection.

22 The evaluation of the processor is done using a  
23 technique called STEP, sensitometric technique for the  
24 evaluation of processing. We have been using this since the  
25 outset of the program, and if you look on the slide, about

1 midway down on the righthand side, you will see that if the  
2 processing speed for standard processing is less than 80,  
3 that that has been traditionally a Level 2 finding, and for  
4 processing speeds below 100 for extended processing, it has  
5 been a Level 2 finding.

6 That is going to remain unchanged. It is our  
7 intent, however, to create a level below that, where the  
8 processing speed is below 65 and below 85 respectively, that  
9 would be a Level 1 finding, and consequently get the warning  
10 letter and provide the basis for more significant follow-up  
11 action should that be warranted later on.

12 In terms of the darkroom fog, we are essentially  
13 at the same point that we were with respect to the interim  
14 rules with the fog level of greater than 0.06 leading to the  
15 Level 2 finding.

16 The questions just above that for, in particular,  
17 the border visible question, is just sort of a shortcut. If  
18 the inspector isn't able to see a border on the phantom  
19 image which indicates that there is perceptible fog, then,  
20 you can put a "no" there and the rest of the questions don't  
21 need to be answered.

22 CHAIRPERSON MONSEES: Any questions or comments on  
23 this? Okay. Let's go on.

24 MR. McCROHAN: We can proceed to the record review  
25 section of the inspection. We are going to start with the

1 discussion of the quality assurance, proceed through the  
2 quality control and survey, talk about the personnel  
3 requirements, and then finally get to the medical records  
4 and medical outcome audit section.

5           This certainly is the bulk of the inspection. On  
6 the right we are starting with the quality assurance  
7 question. I want to take a little bit of time here because  
8 it's somewhat indicative of how other questions are handled  
9 later on in the software.

10           We have essentially four issues that we are  
11 looking for in evaluating whether the fundamental quality  
12 assurance program in the facility is adequate. We are going  
13 to go on, as we will see momentarily, to look in some detail  
14 at the quality control results, and so forth, but in terms  
15 of the quality assurance per se, we are looking to see  
16 whether responsible parties have been assigned the various  
17 functions defined in the regulations within the quality  
18 assurance and quality control program, also, look to see  
19 that there is a current technique chart with the unit, and  
20 then two new items which are new additions under the final  
21 regulations relating to infection control and handling  
22 consumer complaints.

23           In both instances, we are simply looking to see  
24 that the facility has an SOP for dealing with those issues.  
25 The regulations are not particularly specific in those areas

1 and certainly, particularly with respect to infection  
2 control, there is lots of guidance in other areas in terms  
3 of universal precautions, and so on. So, we are simply  
4 looking to see that there is an SOP.

5           Effectively, we have a single finding potential  
6 here of the quality control program being inadequate if  
7 there is "no" to that question. You can answer that  
8 question "yes" and proceed on if you have established in  
9 your own mind that the personnel are assigned appropriately  
10 and the other things are in place.

11           If you are find in your review that any of those  
12 things are not in place, then, there will be an opportunity  
13 to indicate that in the software, so, in effect, a "no" to  
14 any of those subordinate questions will sort of roll up to  
15 become a "no" to the higher level question.

16           So, this is a mechanism for allowing the inspector  
17 to essentially do fewer key strokes to capture the data in  
18 the majority of cases where there isn't going to be a  
19 problem present that needs to be documented or recorded.

20           CHAIRPERSON MONSEES: Do you want to stop there  
21 for questions or do you want to go on to the next? Yes.

22           MS. EDGERTON: Trisha Edgerton, State of  
23 California.

24           I am just wondering if this is where you would  
25 also have the standard operating procedure for the patient

1 notification requirement, or is that somewhere else, is that  
2 later, because that is the biggest thing I am hearing back  
3 from departments, that is a major change to their  
4 operations, and it does state in there that you do need  
5 policy and procedures pertaining to it, and you also need  
6 documentation of how you have met 1, 2, 3, or 4, you know,  
7 of the types.

8 MR. McCROHAN: This would be I think an  
9 appropriate location for that, and we will consider that.

10 CHAIRPERSON MONSEES: Thank you.

11 Mr. Mobley.

12 MR. MOBLEY: When the lead question comes up, the  
13 inspector is not answering the lead question, he is actually  
14 answering -- he or she is actually answering the pop-up  
15 questions, and then that leads to the answer of the lead  
16 question. It may or may not?

17 MR. McCROHAN: It sort of depends on how you look  
18 at it. That pop-up is going to be present when they look at  
19 the lead question. If they can answer the lead question  
20 "yes," then, they are done. If they answer any of those  
21 subordinate questions "no," they can also be done, and will  
22 fill the rest of those questions in with a "yes."

23 So, it is just a mechanism that we are trying to  
24 design into the format of the software to reduce, as I said,  
25 reduce the amount of data entry that is required in order to

1 capture the situation accurately.

2 MR. MOBLEY: I am just trying to understand  
3 exactly how it is going to work in terms of if I answer  
4 "yes," do I have to answer any of the rest of the questions,  
5 and have I short-circuited the system.

6 MR. McCROHAN: If you answer "yes," truthfully,  
7 then, in effect you have answered all of the subordinate  
8 questions "yes," and that's the way the database is  
9 populated.

10 One of the things I think we are going to have to  
11 look at is that this is essentially the structure that we  
12 are going to have in Version 2 of the software under the  
13 interim rules, and so we will have about six months to nine  
14 months to look at how that plays out in practice, so, in  
15 fact, we will have the opportunity to make some  
16 modifications of this essentially format issue.

17 What we were looking for are ways to minimize the  
18 overhead, if you will, in terms of recording whatever data  
19 is necessary to establish or characterize the situation the  
20 inspector found.

21 MR. MOBLEY: I guess it's the basis of my  
22 training, I question everything even the results of my own  
23 inspectors to some extent, and people just have to live with  
24 that, but if you have this here, then, it short-circuits the  
25 system, then, as the pressure comes on in terms of people

1 doing inspections and getting their numbers up, et cetera,  
2 then, I will have greater concern that you might drop out  
3 some things that might not otherwise have been picked up.  
4 Obviously, I guess they could drop down and answer yes, yes,  
5 yes, to all the four. I don't know, I am just telling you  
6 it leaves a question in my mind.

7 Thank you.

8 MS. EDGERTON: Another quick comment. Trisha  
9 Edgerton, State of California.

10 This also may be the place for facilities who  
11 accept self-referred patients to show that they have  
12 documentation that they have an agreement with an outside  
13 provider to follow up with that patient, and, in fact, those  
14 two things, I am now starting to agree with Mike, that as  
15 far as the requirement for patient notification and the  
16 requirement to refer a self-referred woman to a health care  
17 provider when she has a positive result are so important  
18 that I also wouldn't want those skipped over.

19 MR. McCROHAN: The first point that you made is  
20 mentioned in the medical records and medical audit section,  
21 which we will come to last, and if by patient notification  
22 you meant simply provide a woman with the results of the  
23 exam, those issues are dealt with there, as well, so maybe  
24 we come back to that point then.

25 CHAIRPERSON MONSEES: Did you have a question?

1 MS. WILCOX-BUCHALLA: Pam Wilcox, ACR.

2 This seems like an appropriate point to go back to  
3 a question that arose to me this morning, and that is the  
4 issue of changing from three levels of citation to two.

5 One of the reasons that I am concerned about it, I  
6 think Mr. Mobley's comments this morning about you are not  
7 comparing apples to apples when you do that, but the other  
8 issue is here, when you have new regulations coming into  
9 effect, and we will have things that, under the old scenario  
10 would have been a Level 3, for instance, the SOP for  
11 infection control and consumer complaints, which are brand-  
12 new to sites and they will have to phase them in, and there  
13 are likely to be paperwork or documentation issues missing,  
14 and if we go back to John's stats from this morning, in the  
15 first year of the implementation of the inspection process,  
16 47.6 percent of sites had a Level 3. It is now down to half  
17 that, and that is because people know how to provide the  
18 documentation.

19 I am very concerned that by putting the new regs  
20 in at a Level 2, it is going to look like the community  
21 really was in much bigger trouble under the interim regs  
22 than we thought it was, and people are not going to have an  
23 opportunity to adjust to the changes in a reasonable  
24 fashion. It's not going to be a light switch on April 28th  
25 of 1999.

1 I would strongly recommend that you consider going  
2 to one year under the final regs at Level 1, 2, 3, and then  
3 switch over to this new system when people have had a chance  
4 to take care of those documentation issues and understand  
5 the implications of the new regs.

6 CHAIRPERSON MONSEES: Do you want to reply to  
7 that?

8 MR. McCROHAN: It's an interesting suggestion and  
9 one which we will take a look at.

10 CHAIRPERSON MONSEES: Let's move on then.

11 MR. McCROHAN: If we can go forward on the right,  
12 we are now getting into the quality control tests and, in  
13 fact, starting off with the processor quality control.

14 The scheme is substantially the same as it was  
15 under the interim rules where we are looking at the  
16 processor quality control records and determining what  
17 proportion of the time the facility appropriately conducts  
18 that important quality control test.

19 We have focused our attention on what we talk  
20 about as the worst month in the quality control records for  
21 this purpose. What we intend by that is for the inspector  
22 essentially to quickly scan the records for a year, identify  
23 roughly which month looks the worst, and then focus  
24 attention there and actually do some calculations with  
25 respect to the proportion of days in which mammography is

1 actually done, that the process of quality control is  
2 actually done.

3 We have hopefully simplified this somewhat here  
4 just from a calculational standpoint where the inspector  
5 will indicate the number of days of use and the number of  
6 days without charted data, and then the calculation will be  
7 done by the computer for the percent of time that charting  
8 wasn't done.

9 As I mentioned earlier, we have established a  
10 Level 1 here for the processor control, processor quality  
11 control not done in excess of 30 percent of the time, 10 to  
12 30 percent is Level 2, and as is currently the case, failing  
13 to do the processor quality control less than 10 percent of  
14 time is not a finding.

15 We are of the mind that there is some reasonable  
16 sort of level of occasional missteps, if you will, with  
17 respect to this daily test, that would occur by happenstance  
18 even in good facilities, so we want to give facilities some  
19 freedom, if you will, from citation even if there is an  
20 occasional miss during the course of the year.

21 So, I guess one of the issues on which you might  
22 want to give us some advice is whether that level is at the  
23 right place and whether the differentiation between Level 1  
24 and Level 2 is at the right place.

25 We are also looking at the issue, which is a new

1 one, of what are the number of consecutive days missed. The  
2 question here is since we are focused on the worst month, we  
3 can have days missing at the end of one month, at the  
4 beginning of the next month, which don't necessarily create  
5 a problem as far as the calculated percentage is concerned,  
6 but we could have a significant period of time during an  
7 operational week when the condition of the processor was not  
8 known, and that is considered to be problematic to not be  
9 aware of whether or not the processor was out of control for  
10 that period of time.

11 We are also asking, as we have under the interim  
12 rules, the inspector to record the number of days during  
13 which they were doing mammography when the processor was out  
14 of control and yet they still operated. You can see the  
15 various levels that we selected there.

16 The corrective action documented is as it was  
17 under the interim rules, the requirement that if there is a  
18 problem, they simply document what they did to correct the  
19 problem. I would point out that it is not, from our  
20 perspective, a problem to have difficulties with your  
21 processor. The real problem is when you identify that you  
22 have difficulties with your processor and then you don't  
23 correct those problems before you do patients.

24 So, the issue is we don't want you to operate out  
25 of control. It is, I suppose, reasonable to expect that

1 some facilities some of the time will test their processor  
2 and find that it is out of control, and they simply need to  
3 then take the corrective action before they continue doing  
4 patients.

5           The fixer retention quality control is indicated  
6 below. That is a quarterly test and is essentially as we  
7 have done it under the interim rules with the exception that  
8 we have a Level 2 here now.

9           CHAIRPERSON MONSEES: I presume if you are doing  
10 mobile or any type of backup processor you are using, that  
11 these are not scored for those days, correct, if you are out  
12 of control, if you are using a different processor or you  
13 are batch processing.

14           MR. McCROHAN: Right. There is an issue of how we  
15 would deal with backup processors during the inspection,  
16 that certainly would be treated like the primary processor  
17 if they are in operation on the day of the inspection, I  
18 mean functioning as the primary processor on that day, but  
19 there is a question, I think, about whether or not or what  
20 the requirement ought to be for the backup, which may not be  
21 used for mammography most of the time.

22           So, that has been an issue we have sort of  
23 struggled with a bit. In the case of a mobile, if we have  
24 an onboard processor, then, we would expect that the daily  
25 processor checks, as with a fixed facility, if we have a

1 batch processing situation where that mobile is sending to a  
2 central site, then, certainly it is necessary for the  
3 processor quality control to be done on the day when the  
4 central site does that batch processing.

5 CHAIRPERSON MONSEES: Yes.

6 DR. SICKLES: I didn't hear what your outcome was,  
7 your outcome judgment was in terms of backup processing,  
8 what have you decided to do?

9 MR. McCROHAN: I think what we are trying to do is  
10 apply, in effect, the same standards to the backup that we  
11 do to the primary, but the difficulty is that the backup is  
12 likely to be in use much less.

13 In that event, we are probably going to need to  
14 look at the backup and the quality control for the backup on  
15 a yearly basis rather than a monthly basis, because there  
16 may not be enough days of use in a particular month, and it  
17 would be somewhat problematic, I think, if we looked at it  
18 on a monthly basis.

19 So, I think we are still trying to refine that,  
20 and if you have any suggestions, I would certainly be open  
21 to those.

22 DR. SICKLES: Are you collecting, are you asking  
23 facilities to collect data on the backup processor on a  
24 daily basis or only on those days in which it is used?

25 MR. McCROHAN: I think if you look at the reg --

1 staff will correct me if I am off on this -- but I think  
2 that the situation is that you have to do the sensitometry  
3 on every day of use, so that is what creates somewhat of the  
4 difficulty vis-a-vis the backup, which is infrequently used.

5           Clearly, if the backup is the regular departmental  
6 processor for other reasons unrelated to MQSA, we would  
7 certainly anticipate that it would be subject to daily  
8 processor quality control. That is not a regulatory issue  
9 from an MQSA standpoint, but as a practical matter, it is  
10 likely to be under that level of scrutiny in most cases.

11           But as I say, it is a bit of a difficult issue to  
12 deal with how we ought to address the backup processor.

13           DR. SICKLES: I could see a situation in a  
14 facility where they are using this backup processor for  
15 other non-mammographic imaging on a daily basis, but using  
16 it as a backup mammographic processor once every three  
17 months, when the other one is down, that they might choose  
18 not to do the MQSA-type QC except when they needed to.

19           MR. McCROHAN: Right.

20           DR. SICKLES: Is that what you are seeing in the  
21 field now?

22           MR. McCROHAN: I believe that is the case, and I  
23 believe that certainly meets the requirement. They need to  
24 do, from an MQSA standpoint, the sensitometry only on the  
25 days of use.

1 DR. SICKLES: I would think that would create a  
2 major problem with your software because you are not going  
3 to have a month at all. You may only have six days in the  
4 whole year.

5 MR. McCROHAN: Right. That's why I said I think  
6 we need to look at it on an annualized basis rather than on  
7 a monthly basis, and we are still struggling over that issue  
8 as we move on.

9 CHAIRPERSON MONSEES: Yes.

10 MR. PIZZUTIELLO: I would like to say that I think  
11 that your percentages for the number of days without  
12 charting for the Level 1 and Level 2, 10 and 30 percent,  
13 they seem pretty reasonable to me.

14 Even really good facilities, occasionally,  
15 somebody forgets to do it. I think what is important is  
16 that there is at least a second-level check in that. If the  
17 films are really bad, the radiologist is going to look at  
18 the films or at least the technologist will look at the  
19 films and say this is not right.

20 Let me just throw out a concern that occurred to  
21 me. When you have QC for facilities where, say, mobiles are  
22 coming in and they are batch processing 50 or 100 films at a  
23 time, if that happens to be the day when they have not done  
24 any processor quality control, then, a whole lot of films  
25 get processed before anybody can tell that they are poor.

1           So, I guess in that case, I would suggest that you  
2 consider allowing no variation, in other words, it is a  
3 significant violation anytime batch processing is done and  
4 processor QC is not (a) done, and (b) within tolerance  
5 before you process those images because there is no way to  
6 check until 50 films come out of the processor that they are  
7 all bad.

8           MR. McCROHAN: That is a good point.

9           DR. SICKLES: I would amend that by saying that  
10 would be true if batch processing was the first activity  
11 done in the processor that day. If batch processing is done  
12 at the end of the day rather than the beginning of the day,  
13 then, presumably, you would have a whole day's worth of  
14 constantly monitored cases, so you wouldn't need that  
15 circumstance.

16           MR. MOBLEY: I am trying to understand this backup  
17 processor concept, because I mean we are tracking the  
18 primary processor, and I guess my perspective is unless that  
19 primary processor is totally down, I know more about that  
20 processor than I know about the backup processor that I am  
21 going to bring in to replace it under certain circumstances.

22           So, to me, those defined circumstances for  
23 bringing in that backup processor must be pretty horrendous,  
24 I guess, or I have got to have something more here on that  
25 backup processor than I hear and believe is the case, and

1 then I hear that you are struggling with this, which I think  
2 maybe is the right thing to do, but I am not so sure that we  
3 don't need to put something in place there that says this  
4 backup processor, there has to be a certain level of effort  
5 put forward there before we just say we are out of limits on  
6 our primary processor and we will go to the backup  
7 processor, and we may be way out of limits there, but we  
8 don't know it.

9 MR. McCROHAN: Well, I think the intent clearly is  
10 to expect the facility to test the backup sensitometrically  
11 before they put it in use, so you don't know where you are  
12 relative to any previous day's performance with respect to  
13 the backup if you, in fact, haven't been doing sensitometry  
14 routinely, but at least in effect you know where you are  
15 with the backup vis-a-vis the primary processor.

16 Of course, you wouldn't use the backup if it were  
17 out of control, but there are a lot of issues attendant to  
18 this in terms of we are essentially saying you can use a  
19 backup on one day's test if you establish that it's in the  
20 same control limits as the primary, but there are some  
21 issues there in terms of whether that is too rigid a  
22 requirement or not, but I think we thought we needed to  
23 have, obviously have some assurance that when they bring a  
24 backup on line that it's in control.

25 CHAIRPERSON MONSEES: It's a very uncomfortable

1 thing here because you wonder, you know, a strip, is that  
2 adequate to really be able to process all those films.

3 Any comments? I saw two. This gentleman right  
4 here.

5 MR. SULEIMAN: Orhan Suleiman, FDA.

6 I think the batch issue, the batch film  
7 processing, the backup processor processing have been  
8 discussed extensively. It's a case of how we translate it  
9 into the inspection procedure. No facility should be  
10 processing films in any alternate processor unless they have  
11 verified that it meets the existing control limits of the  
12 existing processor.

13 Now, how you translate that into a frequency  
14 issue, how often or whatever, that is I think the confusing  
15 issue.

16 CHAIRPERSON MONSEES: Yes.

17 MS. WILSON: I don't feel that doing a strip only  
18 on the day that your primary processor is out of limits is  
19 sufficient. That basically tells you very little about your  
20 backup processor.

21 At our facility, we run QC strips through both  
22 processors on a daily basis. Of course, if our primary  
23 processor is within limits, if the backup processor was out  
24 of limits for mammography film, but we were not using it  
25 that day, we would not worry about it.

1           In addition to this, we also perform the safelight  
2 fog test in the backup processor, the high-pro retention  
3 test, and on the rare occasion in which we would go to the  
4 backup processor for mammography processing, we would do a  
5 phantom that would have to score and pass prior to using  
6 that processor.

7           MR. McCROHAN: Those are good suggestions. I  
8 think our question continues to be how far can we go within  
9 the confines of the existing regulation, you know, in terms  
10 of requiring certain things on a piece of equipment, which  
11 is not routinely used for mammography, you know, within the  
12 context of MQSA.

13           I think that what you are doing, what you  
14 described doing is certainly the ideal, and I think that if  
15 we wanted to have anything more than the strip on the day of  
16 use, in effect wanting more sense of the history of the  
17 control of that processor, then, essentially, you are saying  
18 every day that you use the primary, you need to test the  
19 backup, as well, and that is not an unreasonable thing to do  
20 certainly.

21           I guess my question is, is it a reasonable thing  
22 for us to require, and it is valuable to get your advice on  
23 that.

24           CHAIRPERSON MONSEES: Did you want to make a  
25 comment on that?

1 DR. HENDRICK: I have heard several different  
2 things here. I guess I don't want the committee to be under  
3 the delusion that you are testing the adequacy of processing  
4 even if you run the strip every hour through your processor,  
5 all you are testing is consistency.

6 The STEP test, which the inspectors do, is some  
7 loose measurement of adequacy in terms of speed, but there  
8 is no test of adequacy in terms of contrast in the image at  
9 any optical density.

10 So, at best, this processor QC that you are  
11 requiring the sites to do daily, only tests consistency of  
12 the processor and you are debating whether you have to have  
13 this consistency, and if you don't have it in your primary  
14 processor, what you do about that, and I have heard two  
15 different things.

16 One is to process films at all, you have to have  
17 some second processor which is in control with itself, which  
18 means, as Mike pointed out, that it could be much worse than  
19 your primary processor, or you force it to be in control  
20 with your primary processor, which may mean lowering its  
21 standard to that of your primary processor.

22 None of these are really great solutions. I mean  
23 this is part of the problem of debating inspection  
24 requirements that don't really get at adequacy. You are  
25 just mandating inspection requirements that see if the sites

1 are maintaining consistency.

2 So, I don't think it matters a whole lot actually  
3 given that you are not measuring adequacy.

4 CHAIRPERSON MONSEES: Any other comments here? Go  
5 on.

6 MR. McCROHAN: We can go forward on both.

7 The next quality control test is the phantom image  
8 test, and we also, in the same section of the inspection  
9 program, are going to be looking at the compression QC,  
10 which also relates to the x-ray unit, and then we get  
11 further on into the facility level quality control tests  
12 beginning with the repeat analysis.

13 In terms of the phantom QC, we are essentially  
14 looking at the same sort of issue that we did under the  
15 interim rules. I think we have changed the levels slightly  
16 to make the requirements somewhat tighter in terms of when a  
17 Level 2 or a Level 1 would be found depending on the number  
18 of months -- or I am sorry -- the number of weeks since this  
19 is now, under the final rules, a weekly test that were  
20 missed in terms of the conduct of this test.

21 There are a variety of other -- three items in  
22 particular with respect with the way the phantom QC test is  
23 done, and those are the same issues that we look at under  
24 the interim regs.

25 A little further down is the issue of mobile

1 units, and as I mentioned, there is a requirement in the  
2 final rules for a pre-use or post-move, pre-use check being  
3 done on the mobile unit, and there is an opportunity here to  
4 verify whether or not the facility has conducted that test  
5 at the appropriate frequency.

6 We have yet to deal explicitly with the issue of  
7 how many misses, if you will, of this test lead to what  
8 level of noncompliance, and I think that we might in theory  
9 have a Level 1 here if the post-move, pre-use check was very  
10 frequently missed, and the Level 2 if it was infrequently  
11 missed, and perhaps even a level below which we would be  
12 talking as we were in processing or the occasional mistake  
13 that could be made in any facility.

14 So, one of the issues I think that you might have  
15 some input on is the issue of where the levels ought to be  
16 set with respect to the mobile unit depending on whether or  
17 not the test was done pre-use on that unit.

18 Recall that there are a variety ways of doing that  
19 test, but certainly the mobile unit can be subjected to the  
20 phantom QC test. This presumes that there is on-board  
21 processing or local processing available to the mobile unit.

22 It is also possible to do other kinds of  
23 verifications like looking at the tracking of MIS for the  
24 phantom exposure to establish that the unit is still in  
25 reasonable control given the local conditions prior to use n

1 patients. The compression QC is much like what we have for  
2 the interim rules. Of course, as is always the case, the  
3 level here is Level 2.

4           On the bottom of this page we get to the first of  
5 the facility tests, which is the repeat analysis test, and  
6 this has been somewhat of a controversial issue, I think.  
7 We are looking to see whether is indication of the facility  
8 having done the repeat analysis at the required frequency,  
9 which is quarterly, whether they have actually evaluated the  
10 results of that repeat analysis, that is to say, they have  
11 done more than collect the repeated films, that they have  
12 actually looked at the categories for the reasons for the  
13 repeat being necessary, and then whether there is  
14 documentation for corrective action when the repeat rate  
15 changes substantially.

16           There is a sort of persistent issue, which we  
17 probably can't directly address as to how many films ought  
18 to be part of the sample, if you will, for the repeat  
19 analysis, and there are a range of views all the way from  
20 every case during the quarter ought to be part of the repeat  
21 analysis study, to the thought which was embedded in the ACR  
22 QC manuals and consequently was guidance under the interim  
23 rules that there be at least 250 cases involved for high  
24 workload facilities which might do a lot more cases during  
25 the calendar quarter, so that they didn't have to go through

1 the process of evaluating repeats from every case.

2 So, it might be valuable to hear the committee's  
3 view on that issue, although I think there is a question at  
4 least in my mind of how directly we can guide facilities in  
5 this regard, given the nature of the regulations at this  
6 point.

7 CHAIRPERSON MONSEES: Lights up. Questions. Yes.

8 MR. PIZZUTIELLO: On the repeat analysis, when you  
9 say that corrective action must be documented when a given  
10 repeat percent changes by more than 2 percent, is that the  
11 overall institutional repeat rate or the rate for a  
12 particular cause like too light or motion?

13 MR. McCROHAN: Overall.

14 CHAIRPERSON MONSEES: Any other comments, any  
15 guidance here? Yes, ma'am.

16 MS. WILCOX-BUCHALLA: If the change is a decrease  
17 of more than 2 percent, would that require corrective  
18 action? Isn't that a good thing?

19 MR. McCROHAN: It might seem so, it might even be  
20 so in a lot of cases. One of the things that is problematic  
21 about the repeat analysis in a particular setting, a  
22 particular standard, which we chose not to do for that  
23 repeat value, is that any standard that was set could be met  
24 by anybody simply by adjusting the level of quality that  
25 they were willing to accept.

1           One of the concerns, I guess, with a significant  
2 decrease in the repeat rate, is that it could be  
3 attributable to a variety of factors. It could actually be  
4 an improvement in the performance in the facility, and that  
5 would be great.

6           It could also be a change in the effective  
7 criteria that the facility is applying in terms of  
8 establishing whether or not something should be repeated,  
9 and so I think at least that ought to be addressed to see if  
10 this repeat rate dropped because we have, for example, new  
11 personnel on-board who have a much looser criterion, if you  
12 will, for what to accept. I think that is kind of the dark  
13 side of a reduced repeat rate that we would be concerned  
14 about.

15           CHAIRPERSON MONSEES: Any other comments? The  
16 only other comment I have about the repeat rate is that it  
17 doesn't differentiate between films that are repeated while  
18 the patient is still in the department as opposed to being  
19 found to be technically inadequate when the radiologist  
20 reviews them and then called the patient back. I am not  
21 talking about callbacks for a suspicious abnormality, but we  
22 differentiate in our department whether or not this is  
23 repeated by the tech at the time she sees it, while she is  
24 doing her QC or whether we are forced to call that patient  
25 back because we think it is inadequate, it is not tracked

1 here.

2 MR. McCROHAN: I believe that we would intend that  
3 both of those be included.

4 CHAIRPERSON MONSEES: Oh, yes, right.

5 MR. McCROHAN: And I think that is the appropriate  
6 way to go since the issue is the quality of the image and  
7 how often that is problematic as opposed to when that is  
8 detected.

9 We certainly would want to identify situations in  
10 which there were, say, for a particular tech, frequent  
11 repeats, for positioning, let's say, even if that tech  
12 recognizes that in looking at the film. You know, it  
13 clearly is an issue that needs to be dealt with in terms of  
14 training, or what have you.

15 CHAIRPERSON MONSEES: You are right. The  
16 technical quality of the image is what is important from a  
17 consumer standpoint. Patients don't like to be called back,  
18 and there is a little bit of a difference there.

19 Any other comments or questions before we move on?  
20 Okay.

21 MR. McCROHAN: Moving on to some of the other  
22 quality control, the screen-film contact quality control,  
23 which again is much as we have had under the interim rules  
24 with the same set of subordinate questions with the  
25 question, a Level 2, as it is now, the same thing with

1 darkroom fog, and these are both semiannual tests.

2 More problematic, I think, is the issue that is  
3 beginning to loom before us, of what we do vis-a-vis digital  
4 mammography, and I think that we certainly need to have some  
5 considerable development in this regard. We are not yet, at  
6 least not immediately, faced with inspections of full-field  
7 digital systems, but certainly that is undoubtedly in our  
8 future.

9 At this point, given the nature of the  
10 regulations, the facility would be required to follow the  
11 manufacturer's recommended QC procedures, and we would have  
12 to evaluate, as best we could, whether the particular  
13 facility was doing that or not.

14 We don't know enough yet to know what appropriate  
15 QC procedures should be for those kinds of systems, and so I  
16 think there will be a later evolution as more systems get  
17 into use and more systems come along, there will probably be  
18 a developing consensus on what kind of quality control  
19 procedures are appropriate to do for digital mammography  
20 systems.

21 At this point, it has to be, I think, a fairly  
22 general issue about whether or not the manufacturer's  
23 recommended QC procedures are followed, whatever they may  
24 be.

25 DR. SICKLES: Presumably, when the FDA gets to the

1 point of approving full-field digital systems for commercial  
2 use, the FDA will require certain of these QC procedures to  
3 be required by the manufacturer. It will be built into the  
4 manuals and required in the labeling. I would assume that.

5 Then, at least you would have that to go on.

6 Right now, with the experimental units that are out, there  
7 is nothing.

8 MR. McCROHAN: I think we are going to need to  
9 look at, at least initially, what the manufacturers think is  
10 appropriate. I think that in terms of -- this is somewhat  
11 out of my field, if you will -- but in terms of the  
12 preapproval process, premarket approval process, I think we  
13 would certainly be looking to see that the manufacturer had  
14 specified quality control tests and frequencies and  
15 performance criteria, and so on.

16 It is not nearly as clear that we would be  
17 specifying what any of that should be at the outset, but I  
18 think perhaps ultimately, that would be the case. I think  
19 that would sort of mirror developments in other areas where,  
20 in point of fact, I think the regulatory requirements have  
21 sort of followed the development of a community consensus  
22 about what ought be done in a particular area.

23 MR. PIZZUTIELLO: I noticed that there is no level  
24 after the digital mammography section.

25 MR. McCROHAN: I noticed that, too.

1 MR. SAMPAYO: At this point, we are just gathering  
2 data, because it is not included.

3 MR. PIZZUTIELLO: I guess my question is, is this  
4 going to be, is there any teeth in this portion of the  
5 regulation? For example, if a facility were to have a  
6 digital system and were to say, well, we are really too busy  
7 to do quality control, it's a brand-new machine, and the  
8 service engineers are in here all the time, and we are sure  
9 that it's okay, is there anything in the regulation or in  
10 the inspection where you can come up with a stick and say  
11 you really need to do this, 'we are not asking you

12 MR. McCROHAN: I think we need to establish a level  
13 here, but I think we were struggling somewhat with what the  
14 appropriate level would be. I suppose a Level 2 would be  
15 the appropriate place to start.

16 It is going to be a little complex because we may,  
17 for example, in the not too distant future see units from  
18 more than one manufacturer, and then we are going to have to  
19 be looking with respect to an inspection involving one of  
20 those units at that manufacturer's recommendations and  
21 requirements, and then for the alternative unit at another  
22 facility, looking at a different set of requirements, so it  
23 is going to be difficult for us to deal with that as we  
24 start out, but I do think that we need to put some teeth.

25 Would you suggest that Level 2 would be an

1 appropriate place to start? Then, I guess the question  
2 would become if the manufacturer's recommendations were  
3 multiple, you know, you do this at this frequency, and two  
4 or three other things at a different frequency, then, you  
5 know, should failure in any of those respects result in that  
6 finding.

7 MR. PIZZUTIELLO: I guess in terms of my  
8 experience with facilities, I would say Level 2 is the  
9 appropriate place to start, and the order would be  
10 essentially something like substantial compliance, again  
11 because it's a new system and new requirements, it might be  
12 very reasonable to expect facilities not to do 100 percent  
13 of whatever the manufacturer recommends all the time.

14 But I guess I would like to defer to my colleague,  
15 Dr. Nishikawa, who has more experience with the digital  
16 systems.

17 DR. SICKLES: This is Ed Sickles, not Bob  
18 Nishikawa. We have such a system, and we use it, and we do  
19 not operate it without doing -- on a daily basis -- without  
20 doing what we are told to do by the manufacturer, but I  
21 think at the outset, when you plan to regulate this, I would  
22 start with Level 2, and I would think of it in terms of  
23 starting any new regulation like when you first put in the  
24 auditing regulations, you have to be broad, because you  
25 really don't know, number one, whether your requirements are

1 at all effective, and number two, your inspectors are  
2 probably going to be faced with four or five different sets  
3 of manufacturers' recommendations, and they are going to  
4 have a very hard time keeping up with them.

5 So, you may start out with just a general question  
6 like are the manufacturer's recommendations substantially  
7 being followed, yes, no, Level 2.

8 CHAIRPERSON MONSEES: Ed, you are also looking at  
9 film copy, correct, as opposed to you are looking at film,  
10 they are being reproduced on an analog image?

11 DR. SICKLES: Actually, in our implementation, we  
12 never use hard-copy film, we only do soft-copy  
13 interpretation.

14 CHAIRPERSON MONSEES: I see, so you are using  
15 soft-copy display.

16 DR. SICKLES: Yes.

17 CHAIRPERSON MONSEES: Well, this is something that  
18 is going to evolve as time goes on, and this is not going to  
19 be covered here today.

20 MR. McCROHAN: Let me just comment that I think it  
21 would be -- I mean I sort of took it as understood that if  
22 we were in a situation where the digital images were read on  
23 hard-copy, that we would be needing to look at the film  
24 processing system, et cetera, that is involved there, and so  
25 forth, and similarly, I think there are probably some other

1 of the quality control tests that we have covered that would  
2 be in effect independent of whether this was a digital unit  
3 or not.

4           So, I think that we are not talking about -- you  
5 know, the film-screen unit, you have all these things to do,  
6 and the digital unit, you have nothing to do. Repeat  
7 analysis, for example, would be independent of whether it  
8 was a screen-film or a digital system presumably.

9           As I say that, I am not quite sure, particularly,  
10 if you are looking at things in the soft-copy mode, how you  
11 deal with that. So, I think you made a good point, that  
12 this is undoubtedly going to evolve and is not well defined  
13 at the moment.

14           DR. SICKLES: Repeat analysis is actually a very  
15 important thing that you should require of digital systems,  
16 especially if they are using soft-copy, because that's one  
17 of the only things that you can document clearly, you know,  
18 did the patient need to have two exposures of the C-C view  
19 in order to get something that was readable.

20           CHAIRPERSON MONSEES: Did you have a comment?

21           DR. HENDRICK: We have a digital prototype unit  
22 and the University of Massachusetts, we have done over 1,000  
23 patients, U. Mass. has done over 900 patients, and we have  
24 developed a QC program for digital. It is for a specific  
25 manufacturer GE, and John Sandrik has been in on developing

1 the QC process. Martin Yaffe has done a similar thing for  
2 the development of the QC program for the Fisher digital and  
3 other people are working with the Trek System QC program,  
4 and the hope is that within a year, that we merge these into  
5 a generic QC program for full-field digital mammography that  
6 includes all the issues of how do you monitor repeats where  
7 you don't product hard-copy, and how you do processor QC  
8 when you do print hardcopy.

9 All these issues should be worked out under the  
10 ACR, producing the QC manual for digitals. So, hopefully,  
11 by the time they are clinically approved, we will have at  
12 least a draft of such a manual available for you.

13 CHAIRPERSON MONSEES: In the back. Yes.

14 MS. HEINLEIN: Rita Heinlein, mammography  
15 consultant.

16 John, I have one question. With Level 2, that  
17 would still require a 30-day response, and is that like a  
18 written letter that facility would then have to submit to  
19 FDA>

20 MR. McCROHAN: Yes.

21 MS. HEINLEIN: Well, I think that with facilities  
22 adapting to and preparing for the final regulation, I think  
23 that again to take a year or even two of having Level 1, 2,  
24 and 3, before we move away from QC, because I look at if  
25 there is one day that someone operates out of control in the

1 processor QC, that is a Level 2, and that would be one day  
2 out of processor control in the year, is that correct?

3 MR. McCROHAN: Yes.

4 MS. HEINLEIN: And that would be a Level 2 that  
5 they would have to write a letter to you within 30 days  
6 explaining how they are responding to being out of control  
7 this one day sometime in the past year.

8 MR. McCROHAN: Right.

9 MS. HEINLEIN: Again, I just think it would be  
10 important to try to give them a little bit of time to get  
11 into that and have maybe a couple of the routine Level 1, 2,  
12 and 3 for a year or so until they can adapt to that.

13 DR. FINDER: I just wanted to add it's not only  
14 that they were operating out of control, but they were using  
15 that. They knew it, and they still did mammography. It's  
16 not just that they were out of control.

17 MR. McCROHAN: Right. I mean I tried to make that  
18 point earlier that we are not suggesting that the processor  
19 might not go out of control in any facility for a variety of  
20 reasons at some point in time. The real issue is that if  
21 you are doing as you should, the daily processor control,  
22 you know when it goes out of control and that you take  
23 appropriate action to bring it back into control before you  
24 do patients.

25 I take the general point, you know, in terms of,

1 as some of the other speakers have said, recommending that  
2 there be some period of adjustment where, you know, problems  
3 of this magnitude not result in a letter to the agency, and  
4 so forth. I think that, you know, one could certainly take  
5 that as a general point, but on this specific issue, at  
6 least we certainly were of the view that knowingly  
7 operating, knowingly processing mammograms when you know the  
8 processor to be out of control was a pretty serious matter,  
9 and I was a little less, personally, a little less  
10 comfortable giving facilities some slack in that sense.

11 One of the complications in all of this is that,  
12 you know, you did one test that you were supposed to do  
13 appropriately, you did the processor quality control test.  
14 That is how you would out you were out of control. If you  
15 make two mistakes, if you don't do the processor quality  
16 control and you happen to be out of control, there is no  
17 indication in the record of anything but the first problem,  
18 and we are saying that not doing your processor control  
19 occasionally is, in effect, an acceptable fact of life.

20 MS. HEINLEIN: It is actually if they miss one day  
21 of not doing processor control, then, they have to do a  
22 Level 2, isn't that right?

23 MR. McCROHAN: No.

24 MS. HEINLEIN: Or is that consecutive days, so  
25 that they would have to miss a day and then the second day,

1 so if it was two days in the year consecutively?

2 MR. McCROHAN: Right. We would certainly take  
3 anybody's advice on how we ought to adjust the level in  
4 terms of consecutive days of use. We do suggest in the  
5 structure that facilities can occasionally forget, as  
6 someone pointed out, to do the processor quality control,  
7 and that is sort of below our regulatory concern, if you  
8 will.

9 So, the question is at what level of occasional  
10 forgetfulness should it become a matter of regulatory  
11 concern, and then how do we translate that into -- in  
12 effect, translate that into the real world if we are, as I  
13 said, focusing on the worst month, then, missing a couple of  
14 days at the end of one month and then missing also a couple  
15 of days at the beginning of the next month, maybe if you  
16 separate those things they are below our level of regulatory  
17 concern, but if it means, in effect, that you have operated  
18 for a week without the processor being checked, then, we are  
19 concerned about that.

20 So, there is a whole lot of issues that need to be  
21 balanced out in here in order to create sort of a network of  
22 approaches that sort of capture the situation that we are  
23 interested in identifying, and that is to say a less than  
24 adequate or seriously less than adequate assessment of the  
25 processing.

1 MS. HEINLEIN: Thank you.

2 CHAIRPERSON MONSEES: I have a question because I  
3 did not understand this before. You say in here, processor  
4 QC days without charted data. I did not assume that that  
5 meant that they didn't do a strip. I thought it just meant  
6 that they did chart it, because that happens at our  
7 institution where they will do it, look at it, and know that  
8 it is in control, but they will not necessarily chart it,  
9 but it is available to look at. I didn't understand that,  
10 and it should be clarified. That is much worse, obviously,  
11 if they don't do the strip at all compared to if they don't  
12 chart it.

13 MR. McCROHAN: Right. I made this point in  
14 response to a question this morning, and it's an issue that  
15 we have certainly struggled with and it's an issue that we  
16 are sensitive to, and that is the question of whether or not  
17 certain things were, in fact, done, or whether or not the  
18 fact that they were done was documented.

19 When we go into the facility for an inspection, we  
20 cannot examine or cannot readily examine the behavior of  
21 persons in the facility for the preceding year since the  
22 last inspection. I am being facetious, but we certainly  
23 wouldn't want to be reviewing a videotape of all those hours  
24 of operation to see how they have done, so we are dependent,  
25 as a practical matter, on documentation that the facility

1 has created in relation to the various quality control  
2 tests, for example, that they do.

3 In the case of the processor quality control test  
4 and the phantom, and some others which create a film of some  
5 sort, then, there is beyond the documentation, if you will,  
6 of a chart or something like that, there is a physical item  
7 that was the result of the test, and in theory, one could go  
8 back and review those or look at those.

9 I think in terms of trying to make the inspection  
10 efficient what we would like to do is to look at the record,  
11 look at the documentation the facility has created as a  
12 routine part of its quality control program, which it  
13 creates incidently for its own purposes, not for ours, for  
14 its own purposes in monitoring the performance of its  
15 equipment and its processes, so that it can take action as  
16 appropriate.

17 I don't view the QC records as things which we at  
18 the agency for inspectional purposes require the facility to  
19 create without some underlying usefulness as far as the  
20 facility is concerned.

21 CHAIRPERSON MONSEES: John, my only point is that  
22 when we were giving you information about whether these  
23 levels of compliance were appropriate, I misunderstood. I  
24 don't know whether or not anybody else misunderstood that,  
25 because charting is different from not doing it. So, maybe

1 we want to change our mind about that.

2 Does anybody change their mind based on that? Ed.

3 DR. SICKLES: No, I understood it the way it was  
4 intended, but I have a more basic question. To what extent  
5 are these recommendations different than what you are doing  
6 now? Perhaps I just don't know the nitty-gritty of how the  
7 inspector actually looks at it, but aren't they now looking  
8 at these same things, and don't you have a track record of  
9 what is being done already?

10 MR. McCROHAN: To some extent. We certainly have  
11 been routinely looking at the issue of how many days of use  
12 or the percentage of days of use did the records not  
13 indicate that the processor quality control was done, and as  
14 I said earlier, our intent was to in effect sort of tighten  
15 the requirements there on the basis of what we had found,  
16 and we think that even with the tightened requirements, we  
17 are not going to be going overboard in terms of citing  
18 findings.

19 There are two other things, though, that we are  
20 attempting to solidify a little bit. Right now, as I said,  
21 under the interim rules and its inspection procedure, there  
22 is no explicit attempt to look at the issue of number of  
23 consecutive days missed because it may cross a month  
24 boundary, and then secondarily, the operating out of control  
25 is a fairly subjective kind of thing where the inspector is

1 asked to decide whether this was, quote, unquote, "frequent"  
2 or not. So, we have tried to quantitate that a little bit,  
3 because we have gotten lots of questions from inspectors  
4 about what we meant.

5 DR. SICKLES: As a response to that, from my  
6 vantage point, anytime a facility knows it is out of control  
7 and chooses to continue to operate, that is a serious  
8 problem, period. That is a zero tolerance issue as far as I  
9 am concerned.

10 CHAIRPERSON MONSEES: Right. But the other point  
11 -- I am sorry to interrupt -- that he made that is very  
12 important is that if they don't do the QC --

13 DR. SICKLES: I understand that. I was getting to  
14 that. If you do it and you know you are out of control, and  
15 you still operate, I don't think you should have any  
16 tolerance for that, but I what I would suggest that you do  
17 in terms of the other set of scenarios where it is just not  
18 charted, so therefore you just don't know whether it was  
19 done is look to your existing experience, and when you  
20 implement the new regulations, set thresholds, so that you  
21 don't achieve all of a sudden, just by the new threshold, 20  
22 percent of facilities are going to get Level 2 the first  
23 time, because then it is going to look like some terrible  
24 thing happened around the country, and it is just because  
25 you set the threshold at a point where maybe it is not

1 realistic.

2 MR. McCROHAN: Thank you.

3 CHAIRPERSON MONSEES: I think we are going to take  
4 a break now because we have been at this -- it seems longer  
5 -- but it is only an hour and 40 minutes that we have been  
6 at this. We will take a 15-minute break, and we will be  
7 back, then, at 10 minutes to 3:00

8 [Recess.]

9 CHAIRPERSON MONSEES: We are going to begin again.  
10 Before you get started, John, Mr. Mobley did a survey in his  
11 state that he would like to share briefly with us. It will  
12 just take a couple of minutes. This is an Information Only,  
13 not a discussion item, that he wants to share with us and  
14 get into the record. He is going to have to leave later, so  
15 I am going to let him do it right now.

16 MR. MOBLEY: Thank you. This survey was done in  
17 Tennessee a couple of months ago as a result of us sending  
18 out a bulletin to all of our mammography facilities  
19 regarding some changes we were making in Tennessee relative  
20 to the program.

21 I asked our people to survey all the facilities,  
22 one, about the inspection frequency, and two, about  
23 facilities that they referred their patients to for needle  
24 localization procedures, and I will just read the memo I  
25 have here. This is from the person in our program that

1 deals with MQSA for the State.

2           The results of our survey indicate that of 211  
3 responses -- and I believe that is all the facilities that  
4 we have in Tennessee, we did it by mail initially, we had  
5 some 50 or so facilities that didn't respond, and we called  
6 them on the phone to get their responses -- of 211  
7 responses, 59 percent preferred annual inspections, 40  
8 percent preferred less frequent inspections, and 0.4 percent  
9 requested more frequent inspections. Of those, of the 40  
10 percent that preferred less frequent inspections, 65 percent  
11 preferred every two years and 35 percent, every three years.

12           They also commented on if we went to the less  
13 frequent inspection, less than annual, to try to coordinate  
14 it with the ACR cycle, et cetera, to make it fit into that  
15 cycle.

16           Talking about needle localization procedures, of  
17 the 211 facilities surveyed, 107 of those do needle  
18 localizations. All of those obviously, since they are  
19 facilities that we are doing mammography inspections at, all  
20 of those are fully certified, but we do not know, we cannot  
21 with certainty claim that the needle localizations are all  
22 performed on fully accredited equipment. We did not capture  
23 that data. But of all the facilities that are doing needle  
24 localization in Tennessee, all of them, the facility is  
25 accredited to do mammography. It just may be that they are

1 doing their needle loc. work on a non-accredited machine or  
2 it could be that they are doing that.

3 I would be happy, if anybody would like a copy of  
4 this, I would be happy to share it, and I would be happy if  
5 you look at it and think, well, hey, maybe we can pull some  
6 other tidbit out of there. We have this information, and  
7 possibly we can pull that out if anybody would like to ask  
8 us a question about it.

9 Thank you.

10 CHAIRPERSON MONSEES: Thank you.

11 Let's go on, John.' Page 5.

12 MR. McCROHAN: The next subject we are going to  
13 address is the medical physicist survey, which is part of  
14 the facilities quality control program, and comprises the  
15 annual tests, and under the final regs, will include a  
16 repeat, if you will, of the weekly phantom tests which,  
17 under the regulations, is listed in that area.

18 I would like to make a couple of sort of  
19 introductory comments. When the program started, there  
20 were, I think it is fair to say, some significant  
21 deficiencies in this area of the medical physicist survey in  
22 terms of surveys that were incomplete, in terms of tests not  
23 being included, or tests being conducted without some of the  
24 critical test conditions being met.

25 But as time has gone on, our analysis indicates

1 that the number of findings with respect to the medical  
2 physicist survey have decreased quite dramatically, so I  
3 think there has been a considerable degree of improvement in  
4 this area that I was particularly noting given my  
5 background.

6 I think the other thing to bear in mind with  
7 respect to the medical physicist survey is that we are  
8 dealing with a relatively small population of individuals as  
9 compared to the universe of interpreting physicians or  
10 radiologic technologists. There are many fewer medical  
11 physicists performing surveys in facilities than there are  
12 facilities.

13 Certainly there are some medical physicists who do  
14 the survey only in their facility, but it is much more the  
15 case that they do surveys in multiple facilities, so  
16 progress, if you will, that is made, if you will, in an  
17 educational sense, has sort of a multiplying effect.

18 I would remind you that we regulate and we certify  
19 facilities. We don't regulate or certify individuals, and  
20 this is pertinent both to the survey and for the personnel  
21 requirements that we are going to talk about later, so we  
22 are dealing with findings that are addressed to the facility  
23 for their use of an unqualified individual, for example, or  
24 in this instance, the use of a medical physicist who might  
25 not do the medical physicist survey completely.

1           Just another point for orientation is that a  
2 fairly large fraction of the individual elements of the  
3 inspection under the interim regulations relate to the  
4 medical physicist survey in terms of just the number of  
5 potential findings.

6           We have tried to do a bit to collapse that with  
7 respect to our proposal here with respect to the final  
8 regulations. If you look at the slide on the right, you can  
9 see that we are looking to see if there is a survey,  
10 available survey report available, and the report incidently  
11 under the final regulations need to be provided to the  
12 facility by the medical physicist within 30 days of the  
13 actual survey.

14           We collect the date of the current survey. We  
15 will be able to download from our database the underlying  
16 date there, the date of the previous survey, and in order to  
17 meet the annual requirement, there certainly needs to be a  
18 survey and the most current survey needs to be less than 14  
19 months old, and we are also going to be checking to see if  
20 the time difference between the current and the previous  
21 survey is less than 14 months.

22           So, we are giving the facility a little bit of  
23 slack in terms of the annual characteristic of the  
24 requirement, but we are looking to see that there is  
25 actually a survey done on an annual basis, not simply that

1 there is a current survey in place. It is the current  
2 survey that we would be looking at with respect to the  
3 details that are dealt with below.

4 As in the interim rules, we are looking to see  
5 whether the facility has taken action as appropriate when  
6 recommendations are made by the physicist in the survey  
7 report, and then we get to the meat of the survey, and that  
8 is the question of whether the survey is complete.

9 There are, as I mentioned, a large number of  
10 individual items, tests under the survey, and there are also  
11 critical test conditions that apply to some of these tests  
12 which are laid out in the final regs. So, when we are  
13 evaluating whether or not the survey is complete, we are  
14 asking the question of whether all the tests that are  
15 required, and so forth, were done, and done appropriately.

16 As is a couple of instances I have talked about  
17 before, if one looks at the survey and establishes that all  
18 of that is correct and complete, then, you can simply answer  
19 the survey complete question yes and be done as opposed to  
20 having, as under the current software, the non-windows-based  
21 software, having to answer a whole lot of individual  
22 questions yes in order to get the same result, if you will,  
23 in terms of the data that is used to populate the database.

24 So, in terms of the survey itself, we are looking  
25 to see that the physicist provided a pass/fail list or

1 recommendations for failed items to the facility, so they  
2 have some basis for their action.

3           We are looking to see that the physicist evaluated  
4 the technologist QC tests and a variety of tests that are  
5 indicated on these slides, and the critical test conditions  
6 that fall under them. These are essentially the same as  
7 those under the interim rules and of the items that are  
8 specified under the final regs.

9           I would like to point out a couple of things which  
10 are new on this medical physicist survey. All of the tests  
11 that you see here and the ones we skipped over for the sake  
12 of time are ones which were part of the survey since the  
13 program was initiated and were specified in the ACR QC  
14 manuals, which we adopted by reference.

15           The new tests that have been added under the final  
16 rules are the radiation output, the decompression, and the  
17 quality control tests for new modalities, which are listed  
18 at the bottom of both of these overheads.

19           I think that the principal question at least that  
20 is on my mind is, as a general matter, how we should assure  
21 ourselves that the medical physicist survey, number one, has  
22 been done, and number two, is complete in the various  
23 respects that are required by the regulations.

24           As I said, there are relatively fewer physicists  
25 than there are facilities, so it seems that there might be

1 some opportunity for efficiency in addressing these issues,  
2 and one of the reasons that we put the question, so to  
3 speak, at the top of the screen of is the survey complete  
4 was to recognize the fact that the inspectors would likely  
5 see individual medical physicists and their reports with a  
6 fair degree of frequency in their geographic area.

7           Once you have seen -- in my view at least -- once  
8 you have seen a number of reports from a particular medical  
9 physicist, you develop a sense of assurance about whether or  
10 not that medical physicist is doing the survey in a complete  
11 and comprehensive manner, and at that point, I think it is  
12 less necessary, at least in terms of every inspection, to  
13 look in great detail at what is in those reports, because I  
14 think that the individual medical physicists develop a habit  
15 or sort of behavior in terms of how complete and how the  
16 reports are organized, and so forth, so we wanted to provide  
17 the inspectors with the opportunity to be able to answer the  
18 question when the answer was obvious in terms of whether the  
19 survey was complete without having to go through an  
20 inordinate number of key strokes in order to be able to  
21 document what they already knew to be the case.

22           So, I would like a little bit of feedback from you  
23 all on that issue in terms of how we deal with the survey  
24 under the final rules. The only difference is basically  
25 between the survey, as I pointed out, under the final rules

1 and under the interim rules are the last three items listed  
2 on both sides of both of the overheads, and those are  
3 reflections of some changes in the final regs and some  
4 additional annual tests that were added.

5 CHAIRPERSON MONSEES: Lights on.

6 DR. SICKLES: Two comments. First, in terms of  
7 having the overall -- yes, now, I don't have problems with  
8 that as long as the inspectors aren't going to be skipping  
9 whole areas, as long as they don't look at this as, oh, I  
10 don't have to look at the other things, all I have to do is  
11 say yes/no.

12 The second question is just informational, what is  
13 decompression?

14 MR. McCROHAN: I am tempted to say it is what I am  
15 going to be in after the meeting is over today.

16 What we are actually talking about is the  
17 functioning of the automatic decompression system on the x-  
18 ray unit, and there is a requirement in the regulation. It  
19 is in the QA section, I believe, where it talks about  
20 testing to make sure that if there is a system for  
21 automatically releasing the compression at the end of the  
22 exposure, that that functions, that there is an override  
23 provided, that that functions, and so on.

24 DR. SICKLES: It might be better to term it  
25 compression release.

1 MR. McCROHAN: Okay.

2 MR. PIZZUTIELLO: I have two questions. One is on  
3 the levels for the medical physicist survey, the date of the  
4 previous survey, and so on. How far back will the  
5 inspectors be going? The only question that comes to mind  
6 is things sort of change next year. If you then start to  
7 say, well, how many months was it from, let's say, the  
8 January '99 survey to the survey before that, you have moved  
9 what formerly was a lower level citation, up to a Level 1  
10 citation, kind of after the fact.

11 So, I might suggest that there be a starting date  
12 like effective when these new requirements come through,  
13 that you not go back further than that because if a  
14 physicist is a little late in the past, they knew that it  
15 wasn't the end of the world, they shouldn't do it, but it  
16 was a Level 2 or 3 or something, and that Level 1 is quite a  
17 different story.

18 MR. McCROHAN: That is a good point. I would just  
19 again remind you that the inspection is of the facility, and  
20 the findings are against the facility, and so the issue  
21 really is has the facility been conscientious about getting  
22 a survey on what we would consider an actual annual basis.

23 We certainly don't want to require that on the  
24 literal anniversary of the survey, that the next one be  
25 done. I think that facilities need to have some level of

1 flexibility there. We thought a couple months was  
2 reasonable. We are not unaware of the opportunity for some  
3 creep here if the surveys are done 14 months apart,  
4 eventually, you are going to get to the point where, on the  
5 average, you didn't have it on an annual basis, but we  
6 trying to make sort of a reasonable compromise here.

7 I think that your point is well taken. What we  
8 want to do at some point in time, starting at some point in  
9 time, is assure ourselves that an inordinate amount of time  
10 didn't pass between surveys, and if we simply look at the  
11 most recent survey when we go in, we really don't know  
12 whether that is the case or not.

13 We don't intend to go back beyond the most recent  
14 survey preceding the current one, but I take your point  
15 about when we initiate that.

16 MR. PIZZUTIELLO: The second comment. You raised  
17 the question about medical physicist select name from the  
18 list and the fact that there are many fewer medical  
19 physicists than the other personnel involved in this whole  
20 process.

21 There has been talk from time to time in this  
22 committee over the years about it could save potentially a  
23 lot of time in the on-site inspections if personnel could be  
24 sort of qualified in advance periodically directly through  
25 the home office. For example, I had a case recently where

1 three of my clients in the same radiology group were  
2 inspected on three consecutive days. In those three  
3 consecutive days, the inspectors spent probably three hours  
4 at each place looking at my credentials and the  
5 radiologist's and the technologist's who were the same.

6 In the perfect world, it would be great if  
7 everybody could be centralized, but perhaps as a starting  
8 point, since the number of medical physicists is more  
9 constrained, it might be worth thinking about having  
10 physicists submit credentials to DMQRP and then they sort of  
11 get approved with a start date and an end date or something  
12 like that, or at a lesser stage, if an inspector verifies  
13 that a physicist's qualifications are current through a  
14 certain period of time, then, they wouldn't need to review  
15 those qualifications again at every single facility.

16 That probably would begin to save some significant  
17 time in the inspection process and leading to dollar savings  
18 down the road.

19 MR. McCROHAN: We have been giving that issue some  
20 thought, and, in fact, there was some consideration given to  
21 it from the outset. What somewhat dissuaded us was that we  
22 would be creating a database which would need to meet a  
23 whole new set of requirements in terms of those kinds of  
24 databases that contain information about people, and we  
25 would have to have unique identifiers for the individual

1 medical physicists and RTs. We have that, if you will, for  
2 the interpreting physician, or at least such things exist,  
3 but there are a variety of federal laws that would be  
4 imposed on us and on the structure of the database and  
5 confidentiality of the database, and so forth, if we were to  
6 do that.

7           It is still something, I think, that we would be  
8 interested in considering. I think my point with respect to  
9 the medical physicists and the fact that they are fewer in  
10 number is simply that they are likely to be more familiar to  
11 -- more of them are likely to be more familiar to more  
12 inspectors, and what they do in terms of the survey, I think  
13 is relatively consistent across an individual medical  
14 physicist since they perform in time.

15           So, I think that we are looking for some way to  
16 gain some efficiency from that fact, and it is not clear  
17 exactly how to do that.

18           The situation that you mentioned, which certainly  
19 occasionally happens, where a set of people, all of whom are  
20 from a common organization, are evaluated on three  
21 successive days and three different facilities by three  
22 different inspectors, to deal with that again would require  
23 the database that had the characteristics that I described  
24 earlier and also the ability to communicate on a very  
25 frequent basis with the inspectors, so that the information

1 they download out of the data system could be current in  
2 terms of what evaluation had been done and how recently it  
3 had been done, and what the results of that evaluation were  
4 by an inspector in another state in all probability.

5           There is some complications when we get into the  
6 States and Certifiers program if we move in that direction  
7 because I think that states might be somewhat reluctant to  
8 just accept at face value the evaluation by an employee of a  
9 different state, so there is lots of complications, but I  
10 think we are open to looking at ways to increase the  
11 efficiency in this respect.

12           CHAIRPERSON MONSEES: Yes.

13           MS. HAWKINS: Is this an area of the survey where  
14 there may be high chances of abuse as far as, for instance,  
15 you know, with there being fewer physicists than there are  
16 facilities, is that perhaps, you know, within regulations  
17 and certifications, these things happen, and facilities, you  
18 know, know who to call, and so forth, I just wonder if this  
19 is an area that need special focus, because this is an area  
20 where there could be, you know, abuse.

21           You know, I noticed that the survey here that we  
22 are looking at, the level of seriousness, there is Level 1,  
23 as to whether or not the survey is in place, whether or not  
24 it has been completed, and so forth, like that.

25           MR. McCROHAN: As you pointed out, whether it is

1 there or not, meeting the annual requirement is Level 1,  
2 whether it is complete is Level 2.

3           If I understand your point, I think perhaps there  
4 is some potential there for -- pardon my use of the term --  
5 a rogue physicist having impact in a variety of facilities.  
6 What is unclear is how that would manifest itself in the  
7 survey and to what extent that would be identifiable.

8           Of course, it certainly is the case that that  
9 potential for abuse exists across the board, and, in fact,  
10 there is one case so far where there have been criminal  
11 indictments lodged against a facility for the falsification  
12 of quality control records, and so on.

13           So, I mean certainly, given that, it is by no  
14 means impossible that there could be some abuses of the type  
15 I think you are alluding to, but I am not sure that it is  
16 more significant here than elsewhere.

17           CHAIRPERSON MONSEES: Yes, Mr. Fletcher.

18           MR. FLETCHER: This morning you gave us some data  
19 indicating the amount of time inspectors spend on average  
20 over the last few years, both on site and total, but in  
21 going through this analysis, you pointed out several places  
22 where shortcuts could be taken without necessarily being  
23 reporting.

24           I guess I am just trying to tie together what your  
25 level of reliability on your total time numbers might be and

1 how, from a State perspective, we might have some assurances  
2 that the amount of time inspectors are taking is accurate.

3 MR. McCROHAN: It is self-reported, so that is I  
4 mean I suppose potentially an issue. One of the things the  
5 inspector does at the end of the inspection is log in the  
6 amount of hours that they spent in the facility, so our  
7 analyses are dependent on the fundamental accuracy of that  
8 self-reported number.

9 I am not sure what else to add to that.

10 CHAIRPERSON MONSEES: Two questions from the  
11 audience. Dr. Hendrick first.

12 DR. HENDRICK: I would just like to respond to  
13 your question about potential abuse because there are so few  
14 medical physicists.

15 I think it is probably one of the areas of least  
16 likely abuse, and the reasons are that everything the  
17 medical physicist tests goes down in black and white in the  
18 medical physicist's report, and about half of those things  
19 that are in the medical physicist's report with numerical  
20 values are repeated by the MQSA inspector.

21 The measurement of average glandular dose, the  
22 half-value layer measurements, image quality is assessed by  
23 a phantom. All of these things are in black and white in  
24 the report, they are in black and white in the MQSA  
25 inspector's survey or inspection report, as well, and if

1 there are discrepancies between those, major discrepancies  
2 between those, they are going to emerge in the comparison of  
3 results.

4           So, I would say if the MQSA inspector is doing his  
5 or her job, this should be one of the least likely areas for  
6 abuse simply because of the numbers of inspectors, and it is  
7 least likely because everything is in black and white. So,  
8 I think it really helps to prevent that, that the full  
9 report is always available at the facility for the MQSA  
10 inspector to review.

11           CHAIRPERSON MONSEES: Yes.

12           MR. BROWN: Paul Brown, State of Illinois.

13           I just wanted to make a couple of points regarding  
14 the time of the inspection which results in the expense of  
15 the inspection. Most state programs are under cost  
16 reimbursement contracts. There is no incentive for us to  
17 really take less time to do the inspection, so if it takes  
18 six or seven hours to do the inspection, instead of two or  
19 three, most of us are not going to complain.

20           Right now, in Illinois, it is taking three to four  
21 hours to do an inspection of which 50 percent of that time  
22 is spent looking at the personnel qualifications. As Dr.  
23 Pizzutiello indicated, if he had two or three facilities, we  
24 would still have to see all that documentation about him in  
25 each one of those facilities, but there is a much simpler

1 way.

2           The accrediting bodies have already reviewed the  
3 qualifications, experience, training, education, all that of  
4 the physician, the tech, the physicist. That was necessary  
5 for them to approve them before certification took place.

6           If we go in to do the inspection. the laptop  
7 computer can print out the name of the facility, the  
8 address, the city, state, zip, all that, and I don't know  
9 why it can't spit out who the interpreting physicians are,  
10 who the techs are, and who the physicists are that was  
11 provided to the accrediting body.

12           If during the inspection process, all those people  
13 are still there, why are we reviewing all this information  
14 again? One of the reasons might be, well, we don't trust  
15 the accrediting body to do their job or whatever. Well, we  
16 do, but if perhaps FDA doesn't, they can go over to the  
17 accrediting body and spend time going through all those  
18 records and reviewing all that data and auditing them to  
19 determine that everything is okay.

20           We are doing 100 percent auditing right now. Now,  
21 I am not saying if you go in a facility and all of a sudden,  
22 a physician's name turns up who is not on the list, well,  
23 yes, we have to check that, and we also have to determine if  
24 they have updated that information with the accrediting  
25 body, but we are spending an inordinate amount of time

1 reviewing all these personnel qualifications that I don't  
2 believe is necessary.

3 CHAIRPERSON MONSEES: Dr. Sickles.

4 DR. SICKLES: Again, I think that is a very good  
5 point. What I am not sure of is whether the continuing  
6 education and experience requirements are maintained by the  
7 accrediting body or whether it is just an initial evaluation  
8 or assessment. If it doesn't involve the continuing  
9 education and experience, then, that does have to be  
10 monitored.

11 CHAIRPERSON MONSEES: Certainly they don't look at  
12 the CME certificates as is stipulated. Would you like to  
13 comment, ACR, on this issue as to whether you think that you  
14 could come forth with a list of "accredited" physicians and  
15 technologists?

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

17 In fact, once the inspection process began, we  
18 stopped collecting all of that backup paperwork, and it is  
19 only kept on site, so we asked the facilities whether the  
20 staff needs it. There are attestations which, of course,  
21 have the legal implications of fraud if they are signed  
22 unethically, but we don't collect all that paperwork  
23 anymore.

24 CHAIRPERSON MONSEES: Now, if that were passed  
25 back to you, could you give an estimate as to how much more

1 work that might be and what that might cost?

2 MS. WILCOX-BUCHALLA: Well, first, for the Clairol  
3 it would cost me, it would be a significant cost to take it  
4 back. On the other hand, I think that we would be very  
5 willing to consider taking back some of that cost if it were  
6 seen as a reduction in cost to sites, so we would have to  
7 take that into consideration.

8 I can't tell you what the estimate would be. I  
9 would guesstimate it would increase our workload probably  
10 about 30 percent over what we are currently doing, but if we  
11 can see a commensurate reduction in the fee to facilities  
12 because of reduced time, then, I think the College would  
13 certainly be willing to take it into consideration.

14 CHAIRPERSON MONSEES: Thank you.

15 Any other comments on this? Why don't you move  
16 on.

17 MR. McCROHAN: We will now continue to talk about  
18 the personnel issues which have been alluded to in the last  
19 few moments. In particular, we will be looking at obviously  
20 the interpreting physician, the radiologic technologist, and  
21 the medical physicist requirements. If we can go forward on  
22 the left, we will first be talking about the interpreting  
23 physician requirements.

24 The structure of the current software and of the  
25 software under the final rules will, in fact, provide the

1 inspector with the identity of the interpreting physicians,  
2 the RTs, and the medical physicists who are associated with  
3 the facility at the time of the last inspection.

4 That provides the opportunity to use, if you will,  
5 the assessment of the initial qualifications that do not  
6 change from one inspection to the next, and reduce the  
7 necessity to continue to look at the initial qualifications  
8 of people who have been evaluated in that facility  
9 previously.

10 As I said earlier, since we don't have a database  
11 related to the individuals, but only a database related to  
12 the facilities, we don't have the facility to track  
13 individual people and look at their evaluations as they have  
14 been reported in the various facilities in which they may  
15 operate, and keep that whole process up to date, but we do  
16 provide the inspectors with the information from the  
17 previous inspection of a facility that they are currently  
18 inspecting, and that includes the assessment of the initial  
19 qualifications of all the personnel who were there at the  
20 time.

21 So, it is simply necessary for them to do an  
22 assessment of the initial qualifications of the individuals  
23 who are new in that facility since the time of the last  
24 inspection, and then review any qualifications, mostly  
25 continuing qualifications that change as a function of time.

1           The other example is, for example, the licensure  
2 of the interpreting physicians, which is an ongoing  
3 requirement. So, you can see that in the case of the  
4 interpreting physicians, we have a structure as with the  
5 other categories of looking at initial qualifications and  
6 then looking at continuing qualifications.

7           The situation under the final rules is much more  
8 parallel than it is under the interim rules where there is a  
9 basic licensure or certification required and also initial  
10 training and initial experience for all of the personnel  
11 categories that we will talk about.

12           The changes from the interim to the final rules  
13 with respect to the interpreting physicians are reflected in  
14 the change from two months of training as the alternative to  
15 board certification, to three months of training under the  
16 final rules, and the change from 40 hours of initial  
17 training to 60 hours of initial training under the final  
18 rules. Those obviously apply to interpreting physicians who  
19 initially qualify after the effective date of 4-28-99.

20           A new element under the final rules has to do with  
21 the training in new modalities. If a particular  
22 interpreting physician or, for that matter, someone in  
23 another personnel category begins to operate in a new  
24 modality, such as digital, where they previously operated in  
25 screen-film, then, there is a requirement for eight hours in

1 the case of the interpreting physician, eight hours of  
2 initial training prior to independently operating in that  
3 new modality.

4 In terms of the continuing experience and  
5 continuing education, these items are under the final rules  
6 as they are under the interim rules, with the one exception  
7 being that there is a new modality requirement for  
8 continuing education for those people who are operating  
9 under multiple modalities.

10 CHAIRPERSON MONSEES: Panel comments, questions?

11 This is a first. There is not any question or  
12 comment.

13 MR. McCROHAN: That is not the one I would have  
14 guessed.

15 CHAIRPERSON MONSEES: Let's go on.

16 MR. McCROHAN: In a parallel fashion with respect  
17 to the radiologic technologist, we look at the initial and  
18 continuing qualifications, and the differences under the  
19 final rules are that instead of technologist, as under the  
20 interim rules being licensed and certified and having  
21 specific training in mammography, now, there is a little bit  
22 more in terms of the requirement and therefore a little bit  
23 more that we are going to have to look at in the records for  
24 radiologic technologists who qualify after 4-28-99.

25 In particular, we are going to be looking for 40

1 hours of training instead of a nonspecific training in  
2 mammography. In addition, that 40 hours needs to include an  
3 initial experience of 25 exams, and there is also for the  
4 radiologic technologist, a new modality requirement that we  
5 mentioned earlier for the interpreting physicians.

6 Also new under the final rules is the continuing  
7 experience requirement for radiologic technologists that  
8 needs to be checked during the inspection, and as with the  
9 interpreting physician, failure to meet that requirement is  
10 a Level 2.

11 CHAIRPERSON MONSEES: Questions and comments on  
12 this part of the technologist? Yes.

13 MR. MOBLEY: I would just note that on the  
14 previous slide for the physicians, the eight-hour training,  
15 new modality training was a separate entity, whereas, here  
16 it is a subset. It would seem to be the same.

17 MR. McCROHAN: That is essentially an artifact of  
18 how the regulations were written, and they are a slightly  
19 different structure for the three personnel groups, and I  
20 think we can modify the inspection procedures, and so forth,  
21 to make it more parallel, just to make it more efficient as  
22 far as the inspector is concerned. Thank you.

23 CHAIRPERSON MONSEES: Anybody else? Yes.

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

25 I have a question about the continuing experience

1 for technologists. In prior committee meetings, there has  
2 been a very strong position on the part of the committee  
3 that 200 every 24 months is a critical element.

4 I am wondering what advice FDA is going to be  
5 offering of other ways to meet this compliance, instead of  
6 just 200 hands-on, is that going to be the only way to meet  
7 this? I know there has been a lot of discussion about rural  
8 sites with small volume, and while I strongly support this,  
9 I would like to hear what is going on internally in FDA  
10 about advice to sites that have small numbers and more than  
11 one technologist.

12 MR. McCROHAN: I think that we are intending to  
13 take an approach or it would certainly be reasonable to  
14 anticipate an approach which was like the approach taken for  
15 interpreting physicians under the interim rules vis-a-vis  
16 the same requirement.

17 In that instance, we are talking about  
18 interpreting physicians meeting the continuing experience  
19 requirement by obviously doing new examinations, but in  
20 addition, there is the opportunity to multi-read and to read  
21 past cases, and if you are doing an exam or interpreting an  
22 exam, and you are comparing it to a past exam which you  
23 didn't interpret, then, that could count as two, and so  
24 forth.

25 So, I think there are sort of somewhat parallel

1 opportunities for the radiologic technologist in terms of  
2 ways in which we can accommodate to the difficulties that  
3 some of them may have in low workload environments.

4 I think that certainly one of the opportunities  
5 that is open to them is to spend a brief period of time  
6 through some sort of an agreement with a high workload  
7 facility and to help meet the requirement in that way, but I  
8 think there are probably other opportunities that would  
9 present themselves, and we would certainly be open to the  
10 committee's advice on what kinds of things we ought to look  
11 for.

12 I believe that there may have been some of this  
13 issue addressed in the guidance document which you all were  
14 given to review, and which we will get your comments on in  
15 due course.

16 CHAIRPERSON MONSEES: Ms. McCarthy.

17 MS. MCCARTHY: Kendra McCarthy.

18 On the continuing education, is there any reason  
19 why we can't require a certain amount of those hours to be  
20 specific to mammography?

21 MR. McCROHAN: In fact, they are. The continuing  
22 education requirement under MQSA is with respect to  
23 mammography, although I think it is fair to say -- and Dr.  
24 Finder can correct me if I am wrong -- that we have tried to  
25 be reasonably broad in our interpretation of what subject

1 matter constitutes mammography.

2           We want not to exclude things or subjects for  
3 continuing education which would have a positive impact on  
4 an individual's performance of mammography. So, we want to  
5 try to not be too narrow, let alone narrow-minded, in that  
6 respect. It is, as a lot of these things are, it sort of a  
7 balancing act to try to be relatively open to those kinds of  
8 continuing education which would have a positive impact even  
9 though per se they are not, in a narrow sense, mammography  
10 without being unreasonable in terms of how broad we define  
11 that. But the basic requirement is for 15 hours or three  
12 years in mammography, if you will, or in subject that are  
13 pertinent to mammography I guess would be a better way to  
14 put it.

15           CHAIRPERSON MONSEES: Yes.

16           MS. HEINLEIN: As far as the other methods that a  
17 technologist might be able to reach the 200 exams in 24  
18 months, I would hope that the final decision by the FDA as  
19 to how they could go about that would be limited, that it  
20 must include hands-on of a live person, and must have an  
21 image that is produced from that hands-on.

22           I have worked with a lot of technologists in a  
23 workshop setting where they say, well, yes, I have pulled  
24 this muscle around, and yet when you work with them in a  
25 clinical setting, and they say, yes, that they did that, and

1 then the resulting mammographic image tells otherwise, so I  
2 would hope that it would be with live people and have to  
3 produce a resulting image, not meaning that if there were  
4 two technologists, and you had one patient, one could do the  
5 left breast and one could do the right breast. Maybe that  
6 would be a way to count that, but I hope it would not  
7 include just doing it in a workshop setting without a  
8 resulting mammographic image.

9           Also, a question. With the 200 exams every 24  
10 months, when will that actually be inspected on? I notice  
11 like above you have prior to 4-28-99. Since this does not  
12 really go into effect until 4-28-99, does the count for the  
13 24 months start on that day, so that then they would really  
14 not be inspected on this until 4-28-2001?

15           MR. McCROHAN: That is correct. That is  
16 essentially the same approach that was taken with continuing  
17 experience for interpreting physicians under the interim  
18 rules where the earliest date that physicians could be  
19 initially qualified was 10-1-94, and the earliest date that  
20 interpreting physicians were subject to the continuing  
21 experience check, if you will, was 10-1-96.

22           So, the period of action that is subject to that  
23 review all postdated the effective date of the rule.

24           MS. HEINLEIN: Thank you.

25           MR. McCROHAN: Just an observation with respect to

1 one of those points.

2           Clearly, I think we would want to count, as we do  
3 in the continuing education arena, there, we look at credits  
4 that you received from being trained, but we also count, if  
5 you will, the effective credits that you taught, so that  
6 instructors in continuing education programs get credit, if  
7 you will, against this requirement for teaching, and the  
8 same thing is probably true for the supervisors of people in  
9 training when that issue is practical training in terms of  
10 the actual interpretation of the actual conduct of the exam.

11           CHAIRPERSON MONSEES: I have a couple of questions  
12 that I need to go back to the personnel. For the physician  
13 in a residency program, this pertains to people who do  
14 fellowship.

15           The way the regs are stated, it says that if you  
16 pass the boards at the first available time, you know that  
17 part I am talking to, some people do two years of  
18 fellowship, for example, neuroradiology. So, let's say they  
19 read 240 mammograms in the last two years and passed the  
20 boards at the first available time, which is indicated in  
21 the regs, but then they do two years of neuroradiology  
22 fellowship.

23           Do those 240 mammograms that they did possibly  
24 three or four years ago count?

25           DR. FINDER: Let me answer that because we have

1 been dealing with situations like that.

2           Basically, what happens in that case is that  
3 person becomes qualified, they meeting their starting date  
4 the day that they leave their residency, and in the event  
5 that they don't read another mammogram for the next two  
6 years, what happens basically is that they fail to meet the  
7 continuing experience requirement, and at that point they  
8 then have to requalify, and in order to requalify, they will  
9 have to read 240 mammograms within a six-month period under  
10 direct supervision before they are allowed to read  
11 independently.

12           CHAIRPERSON MONSEES: And then for the point of  
13 CME, does it start also the day they finish, so that they  
14 are two years under it, therefore, they owe, in one year, 15  
15 credits?

16           DR. FINDER: That is correct. The starting date  
17 is the starting date they leave their residency. Actually  
18 it is the date that they first meet all the initial  
19 qualifications, and that doesn't change. So, once that date  
20 is set, they have to meet the continuing requirements.

21           CHAIRPERSON MONSEES: I did not find this  
22 information in the draft of the guidance document, and I  
23 would request that that be made more explicit in there. We  
24 are getting a lot of questions from people who are finishing  
25 their training.

1 DR. FINDER: So am I.

2 CHAIRPERSON MONSEES: That is because it is  
3 unclear at this point, and it's their livelihood.

4 Should we move on?

5 MR. McCROHAN: When we go on to the medical  
6 physicist, we see a parallel situation to a considerable  
7 extent, where we are looking, as before, the initial  
8 qualifications and the continuing qualifications.

9 With respect to the medical physicist, however,  
10 there are some differences. If you were qualified under the  
11 interim regulations, there will now be some additional  
12 checks. One is with respect to your having at least a  
13 Bachelor's Degree and some requirements with respect to the  
14 number of hours of physics associated with that degree in  
15 physical science, the requirement to document 40 hours of  
16 initial training, and some initial experience.

17 This again is in parallel with the various other  
18 personnel categories. If you qualify under the final  
19 regulations, your date of initial qualification is after 4-  
20 28-99, then, of course, you will have to be board certified  
21 or state license approved, and that is the same as the sort  
22 of fundamental requirement under the interim rules, but then  
23 in addition to that, you will have to have the Master's  
24 Degree and 20 hours of training and initial experience, and  
25 those things will need to be checked for people who qualify

1 after the effective date of the final rules.

2 We also have here, as with the other two  
3 categories, the new modality requirement for eight hours of  
4 initial training, and that again is part of the continuing  
5 education requirement.

6 As with the radiologic technologist, there is now  
7 a new continuing experience requirement which doesn't exist  
8 under the interim rules, but will under the final rules,  
9 again, to bring all of the three groups into parallel, if  
10 you will.

11 CHAIRPERSON MONSEES: Lights on. Questions?  
12 First, we will take them from the panel.

13 MR. PIZZUTIELLO: You say generally, the physical  
14 science. I assume that that is a fairly broad description  
15 with a list of about eight or 10 different degrees?

16 MR. McCROHAN: Yes.

17 MR. PIZZUTIELLO: The reason why I raise that  
18 question is because when we discussed this several years  
19 ago, the development of this guidance, we talked about the  
20 fact that when you apply to one of the boards to be  
21 certified as a medical physicist, they say medical physics  
22 degree or other degree that is considered appropriate, and  
23 there, there are medical physicists who sit on those panels  
24 who can decide in the borderline cases.

25 For example, in 1998, most medical physicists that

1 come into the profession come in through a medical physics  
2 program, but people, who are as old as I am, or even some  
3 older, who came in from other disciplines, their degrees are  
4 not necessarily in physics. I want to make sure that your  
5 requirement, your instructions to the inspectors clarify  
6 that there are lists, and what are you going to do about  
7 cases that may be borderline?

8 MR. McCROHAN: That issue has already come up. In  
9 effect, it is an example, from my perspective of the  
10 application of alternative standards, and the individual  
11 certainly has an opportunity to apply to the agency for  
12 consideration, and provide us with information about their  
13 background, their training, their experience, and so forth,  
14 and get a determination about their qualifications.

15 One of the things that I think is critical to  
16 understand is that the requirements in the regulations --  
17 and certainly this is the case with guidance, as well -- are  
18 not necessarily the only way to do particular things.

19 When we put out guidance, we are saying this is a  
20 way of doing something to meet the requirements of the  
21 regulations, but there may be alternative ways, and even  
22 with respect to the regulation itself, where we have made a  
23 specification, the individuals have or facilities have an  
24 opportunity to apply for an alternative standard.

25 It simply requires that they demonstrate that

1 whatever it is that they are proposing as the alternative  
2 standard meets the same intent and achieves the same level  
3 of quality.

4 I think that we will have some of that with  
5 respect to particularly the medical physicist and  
6 particularly in the circumstance that you indicate, where I  
7 think the tradeoff, if you will, is between a good deal of  
8 experience in all likelihood as against meeting the letter  
9 of the law with respect to a particular degree and that sort  
10 of thing, and so we can deal with those, and are dealing  
11 with those, on a case-by-case basis.

12 CHAIRPERSON MONSEES: Yes.

13 DR. MENDELSON: I just have questions about new  
14 modalities, and they are in all sections with respect to  
15 personnel. How are they to be defined, when will they be  
16 specified? The example given is xeromammography. That is  
17 not really new. It may be a rediscovery, but it is not  
18 really new.

19 Digital mammography is the example in point. What  
20 about other imaging techniques as they evolve and as they  
21 are included. Radionuclide imaging of the breast, I think  
22 we will probably see more of, or at least we will be looking  
23 at data in support of or against its use.

24 Will those be accepted, if so, will they be  
25 specified, and will there be a further set of requirements

1 and criteria to fulfill --

2 MR. McCROHAN: I take your point. I think perhaps  
3 new was not perhaps the best word, and perhaps alternative  
4 would have been better. I think that the presumption  
5 underlying a lot of this, the example you mentioned  
6 notwithstanding, even though it's our example, was that we  
7 are essentially a screen-film world at this point, and I  
8 don't really anticipate the resurrection of xeromammography,  
9 but I think we were looking forward to digital and realizing  
10 that in order for people to operate independently in their  
11 particular sphere with respect to a new modality or digital,  
12 if you will, screen-film individual in the past, it was  
13 reasonable to expect some initial training in that modality  
14 as we had established initial training with respect to  
15 whatever your original modality is.

16 I expect that as soon as full-field digital is  
17 approved and is no longer in an experimental stage or an IDE  
18 stage, we will need to explicitly indicate that we consider  
19 that to be a new modality and subject to these requirements.

20 I think one of the things that we have to bear in  
21 mind is there are some very fundamental limitations imposed  
22 by MQSA itself in terms of what potential imaging modalities  
23 would or would not come under MQSA. In particular, the one  
24 that you mentioned, radionuclide imaging, I think would not,  
25 and there are a variety of other thing, ultrasound being

1 another example which don't come under the purview of MQSA  
2 and therefore wouldn't be subject to these kinds of  
3 requirements.

4 CHAIRPERSON MONSEES: You had a question.

5 MS. WILCOX-BUCHALLA: I don't have the guidance  
6 document in front of me, and so I may be asking a question  
7 that the panel knows the answer to.

8 What documentation will be required for physicists  
9 who are older than Bob Pizzutiello, who qualified many years  
10 go, so what documentation is going to be required? For  
11 instance, my concern is the issue where residents have to  
12 have a statement from their residency director, and, of  
13 course, that is not going to be a reasonable option for some  
14 of these people. Will board certification itself meet those  
15 requirements or in what other documentation for those who  
16 are not board certified would the inspectors be looking for?

17 MR. McCROHAN: That is a good question. With  
18 respect to whether board certification itself should  
19 suffice, we would certainly be open to the committee's  
20 advice on that point, but let me just reflect back to the  
21 reason that we got here in the first place in terms of the  
22 medical physicist.

23 Under the interim rules, one could qualify by  
24 being state licensed or state approved, and yet there was  
25 not, for a variety of legal reasons, a way to, if you will,

1 constrain states in terms of what constituted an approval.  
2 process of licensing process, so there was some concern that  
3 this too widely opened the door to various people qualifying  
4 as "medical physicists," and providing a service to  
5 mammography facilities.

6           The intent under the final rules was, in effect,  
7 to build a floor under the requirements, but I think in  
8 terms of equity, it is important that the floor be in effect  
9 under everybody, and so to the extent that board  
10 certification per se could guarantee that the various  
11 qualifications had been met; then, I think we would be  
12 comfortable with that, but as Bob points out, there are some  
13 few individuals from the early days of certification who  
14 wouldn't meet the specific requirements with respect to,  
15 say, the Master's Degree.

16           So, I think that we do need, under the final  
17 rules, to be looking for documentation of those particular  
18 items, which gets me back to your question, and I think that  
19 I would point to the historical precedent with respect to  
20 the initial qualifications of interpreting physicians under  
21 the interim rules, because there are certainly some  
22 parallelism here.

23           We felt strongly that in establishing an initial  
24 qualification, we needed to see, if you will, physical  
25 documentation, a piece of paper that assured us that the

1 individual interpreting physician was a licensed physician  
2 and that that person was board certified or had the two  
3 months of basic training, which goes back to the issue of  
4 getting a letter from whoever was the provider of that  
5 training and alternative to board certification.

6           When we look at the initial training and the  
7 initial experience, which are the third and fourth elements  
8 of the initial qualifications for interpreting physicians  
9 under the interim rules, I would just remind the committee  
10 that when the interim rules went into effect, there was a  
11 period of time during which we accepted at a station with  
12 respect to that training requirement and that experience  
13 requirement in recognition of the fact that those activities  
14 could have predated the effective date of the interim rules  
15 by some considerable number of years, and that those  
16 activities were less likely than a medical license or a  
17 board certificate to have naturally created a document which  
18 would have persisted in time and would therefore be  
19 available for review at the time of inspection.

20           So, I think that we need to be, for the medical  
21 physicist, cognizant of those same issues and recognize the  
22 fact that some people who qualified under the interim rules,  
23 even if they were board certified, might, for example, have  
24 had a degree that went back some considerable period of time  
25 and as with their training.

1 I think it is not unreasonable to expect someone  
2 could be able to provide a physical document of a Bachelor's  
3 or graduate degree. On the other hand, it may not be  
4 reasonable to expect them to be able to document the number  
5 of hours of training that they may have had 10 or 20 years  
6 ago.

7 So, I think the same kinds of issues obtain, and I  
8 think it would be reasonable to expect a similar kind of  
9 resolution to what we did with respect to the interpreting  
10 physicians under the interim rules.

11 MR. PIZZUTIELLO: I would like to follow up on  
12 that. The issue is really, if you are a medical physicist  
13 and you are board certified, then, at least in the last  
14 decade or so, the boards require that you submit  
15 documentation. I know that I had to go back to my  
16 university and get -- I can't even remember what you call it  
17 -- but it lists all the courses that you took --

18 MR. McCROHAN: Transcript?

19 MR. PIZZUTIELLO: Transcript, thank you -- and it  
20 had to be stamped and official. I think I had to pay 25  
21 bucks or whatever. So, I think it is clear, and I hope it  
22 is clear, that we are not expecting medical physicists to  
23 provide official, stamped transcripts to each of their  
24 facilities because I that would be I think way excessive.

25 I think it would be appropriate for FDA to contact

1 the two boards or the three boards that certify medical  
2 physicists, the American Board of Radiology, American Board  
3 of Medical Physics, and the Canadian Board, and find out if  
4 there is anything in their recent history that says, well,  
5 beginning in 1980, we had requirements that said that the  
6 following number of hours were required and the following  
7 type of degree was acceptable.

8           If that were the case, then, you could streamline  
9 the process for everybody, inspectors and physicists, and  
10 say if you have been board certified by these boards,  
11 effective this and such date, then, your board certificate  
12 is sufficient. If it is older than that, then, you can  
13 decide if an attestation or some other method, and that  
14 would probably help a lot in terms of maybe 70 or 80 percent  
15 of the physicists who are out there, it would streamline the  
16 paperwork, and it would also make it simpler for facilities  
17 who won't have to keep track of all this paperwork on their  
18 physicists.

19           MR. McCROHAN: Thank you.

20           CHAIRPERSON MONSEES: Any other -- someone from  
21 the audience?

22           MR. BROWN: Paul Brown, State of Illinois.

23           We have had a great deal of unhappiness over this  
24 particular item of the physicists' qualifications. I want  
25 to point out that, as I indicated at my initial

1 presentation, that we are in the process of trying to do the  
2 certification, and in order to do that, we have to adopt  
3 comparable rules, so we are much more familiar with what the  
4 final rule says than a lot of people.

5           The difficulty that those of us have that are  
6 regulators is we write a rule to tell everybody how we are  
7 going to do something, okay, and then when there is a  
8 problem with the rule, we start saying, well, that's okay,  
9 trust us, by policy, that we will do this differently.

10           The final rule narrowly defines physical science  
11 as physics, chemistry, radiation science, and engineering.  
12 Now, that is in our final proposed rule, so when that goes  
13 out for the public, and people look at that, how are they  
14 going to know that, oh, there is really like 10 other  
15 degrees that we are going to consider?

16           Secondly, the process is state approval -- well,  
17 if you go back to the statute, it was state approval, board  
18 certification, or some other criteria FDA specified. The  
19 final proposed rule came out basically state approval with  
20 these other criterias for board certification.

21           We argued that that shouldn't have happened. We  
22 have apparently lost that argument. We recognize there are  
23 people out there who are not board certified and who don't  
24 have degrees in this particular physical science, that are  
25 doing a good job, that have done it for the last five or six

1 years, so what are we going to do with them?

2 We asked FDA that question, and they alluded to  
3 this alternate standard. Our concept of an alternate  
4 standard is you have the rule and someone comes in and says  
5 there is a better way to do that, and we will propose a  
6 different rule or a modification to the rule.

7 It really wasn't intended to be an exemption  
8 process that various physicists would send their resumes and  
9 transcripts to FDA and have them review them and say, okay,  
10 you are okay.

11 So, I just want to try to give you a flavor as to,  
12 you know, all of a sudden we are going to become like a  
13 regulatory agency and enforce this particular standard, and  
14 I guess we have a lot more apprehension about how it is  
15 going to work than FDA does.

16 I think there is a number of problems with this,  
17 and I have already had physicists in our state that have  
18 contacted FDA and received letters from FDA that they are  
19 basically okay, and I don't know how to incorporate that  
20 process into the rule.

21 CHAIRPERSON MONSEES: Any more discussion on that  
22 or would you like to answer that?

23 MR. McCROHAN: Let me just make one point in  
24 response, and that is that we were careful, and I think  
25 successful, in making it clear that the additional

1 requirement of degree, training, and experience applied to  
2 everyone, not just to people who come through the state  
3 approval/licensure route, that it applies to board-certified  
4 medical physicists, as well.

5           It is a separate point as to whether or not, as  
6 previously discussed, the board certification in itself is a  
7 demonstration of having met all of those requirements. As  
8 we have discussed previously, there are clearly instances in  
9 which the board certification itself does not, and certainly  
10 in those instances, we are going to need to look to be sure  
11 that those additional requirements are also met.

12           So, it is not entirely accurate to say that this  
13 was an additional requirement imposed on physicists who came  
14 through the state approval process as opposed to the board  
15 certification process.

16           CHAIRPERSON MONSEES: I have one other question  
17 pertaining to the personnel requirements for physicians, and  
18 this may have been covered when the interim regs were  
19 developed and now it is extended to three months, but  
20 pertaining to the initial requirement of two and now three  
21 months.

22           That is, in some residency programs, mammography  
23 or breast imaging is not a stand-alone rotation, whereas,  
24 they may be doing a whole variety of different things and  
25 doing some mammography.

1           Did the FDA have any discussion in the original  
2 panel as to whether that satisfies the requirement? It  
3 seems to me there is a vast difference between that type of  
4 experience and dedicated month or two experience. For  
5 residency programs that have to make decisions about whether  
6 to have stand-alone months of mammography, I would like that  
7 to be addressed if it hasn't been already.

8           MR. McCROHAN: Let me ask Dr. Finder to comment on  
9 that. Let me just add as introduction a point. I think in  
10 an overall sense, our intent with respect to the personnel  
11 requirements and particularly as we transition from the  
12 interim rules to the final rules, was to, as best we could,  
13 avoid this enfranchising of individuals who were patently  
14 qualified, and so we are looking for ways to, if you will,  
15 repair whatever -- I hesitate to use the word -- damage  
16 might be done in individual cases by our choice with respect  
17 to the requirements under the final rule.

18           Those choices were made in an attempt to provide  
19 the best possible assurance or to increase the probability,  
20 let me say, that the individuals who are so qualified are  
21 competent to do what they are intended to do.

22           That is not to say that people who don't meet the  
23 letter of some particular requirement are necessarily  
24 incompetent. So, I think particularly for people who have  
25 been operating under MQSA, under the interim rules, we

1 sought ways to reasonably evaluate those people's  
2 qualifications and allow them to continue if those  
3 qualifications seemed to be reasonable in terms of assuring  
4 their competence.

5           One of the things that I would point out is that  
6 for the interpreting physicians and for radiologic  
7 technologists, we essentially grandparented all the people  
8 who were qualified under the interim rules. We treated the  
9 medical physicists somewhat differently and are being  
10 somewhat stricter with them, and the reasons have to do with  
11 the concerns I mentioned earlier that were brought up  
12 earlier in the process in the development of the final rule.

13           So, I think it was appropriate to have that sort  
14 of difference. But with that general comment out of the  
15 way, if Dr. Finder would respond to your specific question  
16 about interpreting physicians and the residency issue.

17           DR. FINDER: Basically, I think I will address  
18 that by mentioning that we have been in contact with all the  
19 residency programs. We actually have sent them out letters  
20 describing the standards that are necessary, and elaborating  
21 on them to those programs.

22           Basically, what we have said is there are certain  
23 requirements in the regulations that have to be met, and  
24 most of these refer specifically to mammography. There are  
25 some other areas that also have to be met including areas in

1 radiation physics, radiation biology, radiation protection,  
2 so those are also included in that period of time.

3 Now, we have decided, in fact, we have discussed  
4 it with this committee earlier whether there should be set  
5 standard as to how much time in each individual area, and  
6 after a lot of discussion, we did not set any specific  
7 amount of time for each of those components. So, we leave  
8 it up to the programs themselves to serve as the documenting  
9 source for that, but it should be in mammography.

10 CHAIRPERSON MONSEES: So, when you, say, they are  
11 not board certified and they go by the alternative pathway,  
12 does that mean they have had three months of training in  
13 mammography, solely dedicated to mammography, or can they be  
14 seeing five mammograms a day and reading barium enemas and  
15 other things, or you just don't want to get into addressing  
16 this issue? I am just curious.

17 DR. FINDER: Well, what we have done, as you said,  
18 it has to be three months, and how the residency program  
19 works that out, whether it is half a day in one thing and  
20 half a day on another rotation, that is up to the program.  
21 We didn't want to get that prescriptive.

22 CHAIRPERSON MONSEES: Okay.

23 DR. SICKLES: Just to clarify, as you know, many  
24 training programs will have an ambulatory care rotation, and  
25 mammography might be anywhere from 20 to 80 percent of that

1 rotation. Would you expect -- are you just going to allow  
2 the residency program to certify somebody who went through  
3 that rotation as having a full month of mammography even  
4 though they did that rotation?

5 DR. FINDER: We would expect them to take 20  
6 percent.

7 DR. SICKLES: As long as the guidance document  
8 makes that clear, I think it will be very straightforward.  
9 As long as it doesn't make it clear, there is going to be  
10 some abuse of that.

11 CHAIRPERSON MONSEES: That is what I am after is  
12 that type of information, because there is a difference  
13 between intensive training and part of another rotation.

14 Yes.

15 DR. MENDELSON: I think it should be noted that  
16 about six or seven years ago, I can't remember exactly when,  
17 the American Board of Radiology -- in 1990, Ed said  
18 something about how fast the years are going -- the breast  
19 imaging section was instituted, and at that time I think  
20 program directors for radiology residencies recognized the  
21 need, and it was concomitant I guess with the institution of  
22 the oral exam, to beef up their breast imaging rotations,  
23 and whether you splice breast imaging into rotations that  
24 involve other examinations or whether they are dedicated  
25 months, I think the realization is there and it is in the

1 Green Book as a recommendation for the RRC that at least two  
2 months, and essentially dedicated months, of breast imaging  
3 be part of the residency program and training of every  
4 radiology resident, so it is there and I think that there  
5 will be an increase really in emphasis in this area, and it  
6 should be recognized here.

7 CHAIRPERSON MONSEES: Thank you.

8 Why don't we move on.

9 MR. McCROHAN: We are down on the left and if we  
10 can move forward one on the right. We are going to be on,  
11 believe it or not, the last overhead.

12 This related to the medical record and medical  
13 outcome analysis sections of the inspection, and speaks to  
14 some issues that were raised earlier today.

15 As you can see, we are continuing to ask  
16 facilities whether they provide service to self-referred  
17 patients, and if so, then, looking to see if they have  
18 available a standard, if you will, lay summary or examples  
19 of lay summaries to verify that they have a mechanism in  
20 place to communicate to the individual patients.

21 Then, of course, we have a new requirement that  
22 reflects the final regulations about their communication  
23 system with self-referred patients and with particular  
24 emphasis on the situation where the interpretation or the  
25 assessment was suspicious or highly suggestive of

1 malignancy.

2           In a like manner, we have question with respect to  
3 the communication to referring physicians. As you recall,  
4 under the final rules, we have given the facility a certain  
5 degree of flexibility in terms of how the communication with  
6 their patients takes place, whether that is direct or  
7 through the interpreting physicians.

8           That was an area of some considerable controversy  
9 during the proposal stage, and there were very numerous  
10 comments on this point, and the result was the final regs  
11 provide the facility some flexibility in how they do that,  
12 and we are looking to see that the facility has a system in  
13 place in particular to communicate with both of these  
14 groups, self-referred women and referred women.

15           As under the interim rules, the inspector will  
16 then look at five randomly selected reports, and under the  
17 final rules, we will be looking to see, not only whether the  
18 interpreting physician is identified in the report, but also  
19 to see whether the assessment category is one of the five  
20 assessment categories that is used.

21           With respect to the medical audit and outcome  
22 analysis section, we are looking to see, much as we did  
23 under the interim rules, that they have a system in place.  
24 That system is judged to be adequate if there is evidence  
25 that they have tracked all positive patients as opposed to

1 only tracking patients representing some particular subset  
2 of their population, that they have gotten or attempted to  
3 get biopsy results to correlate with positive mammograms,  
4 and if they have designated a reviewing interpreting  
5 physician whose responsibility it is to look at the results  
6 of the medical outcome analysis and communicate those  
7 results to the other interpreting physicians.

8 We are also initially looking to see that this  
9 review takes place on an annual basis. So, there are a few  
10 more specifics with respect to the medical audit and outcome  
11 analysis than under the interim rule, but the questions in  
12 respect to the medical records and audit are largely like  
13 they were under the interim regs.

14 CHAIRPERSON MONSEES: A quick question while  
15 people are thinking. Do you have to have a number of the  
16 assessment category or can you have the terminology that is  
17 used for those, so, for example, can it say normal or benign  
18 finding or highly suspicious, or whatever, or does it have  
19 to have a number, zero, 1 through 5?

20 MR. McCROHAN: I don't know that we specifically  
21 addressed that point in guidance. I assume either way would  
22 be appropriate. It seems reasonable.

23 CHAIRPERSON MONSEES: Dr. Sickles.

24 DR. SICKLES: My understanding was, in terms of  
25 the number, that they wanted the text rather than the

1 number.

2 CHAIRPERSON MONSEES: That is why I am asking. I  
3 didn't know whether or not we could have both or whether we  
4 could have one. It seems the text is obviously more  
5 important because people understand that.

6 DR. SICKLES: One would think the text would be  
7 more important than the number although with time, people  
8 may come to learn the intent of the number, and I certainly  
9 wouldn't discourage people from using the number because it  
10 might be simpler in the long run.

11 Is this the appropriate time or will we be  
12 discussing later the issue of reports directly to patients?  
13 Is that an issue for tomorrow?

14 CHAIRPERSON MONSEES: I think this is the time to  
15 do that.

16 DR. SICKLES: This is the time to do that?

17 CHAIRPERSON MONSEES: This is the time.

18 We are questioning whether we should take a break.  
19 I think we are close enough that we can -- do you need a  
20 break?

21 MR. McCROHAN: If you don't mind.

22 CHAIRPERSON MONSEES: We are going to take a 10-  
23 minute break here, and we will be back in 10 minutes.

24 [Recess.]

25 CHAIRPERSON MONSEES: We are down to medical

1 records and medical audit and outcome analysis.

2 We asked you to hold that thought, Dr Sickles, and  
3 now go with it, run with it.

4 DR. SICKLES: There is potential confusion in  
5 implementing the direct patient reporting requirement. I am  
6 not talking about the requirement for women who do not have  
7 a referring provider, but for women who do have a referring  
8 provider. There is some potential confusion here.

9 At the outset, I personally welcome this concept.  
10 I think it is very important, but the alternate pathways to  
11 simply having the radiology facility inform the woman, which  
12 is very straightforward, can cause confusion, and I think we  
13 need to have some clarification in the guidance  
14 documentation as to what will and won't be acceptable.

15 For example, in the guidance documentation, for  
16 the radiology facility directly informing the patient, it  
17 indicates that this can be done either in the form of a  
18 written lay report or in the form of a personal  
19 communication. If it's a personal communication, it can be  
20 documented simply in the report that is stored, that this  
21 information was discussed with the patient on so and so day.  
22 That is very straightforward.

23 In terms of sending a lay summary of the findings  
24 to the woman, this could be documented according to the  
25 printed guidance information in one of two ways. You could

1 either keep a copy of the exact letter that was sent to the  
2 woman in the patient's chart, radiology chart, or more  
3 simply, and obviously more cost effective, place appropriate  
4 description of methods in your procedures manual, so you  
5 would indicate how in every case the woman would be notified  
6 in writing of her findings.

7           You would just have to make it clear in the  
8 procedures manual how this would involve all women rather  
9 than just a select number of women.

10           The problem exists with the alternate pathway  
11 where the woman's primary care provider or referring  
12 provider -- I notice you say physician, but it really could  
13 be provider -- would do this instead of the radiology  
14 facility, and the problem here relates to the ultimate  
15 responsibility -- and this is in the regulations, so you  
16 can't change it -- the ultimate responsibility falling back  
17 to the radiologist or the radiology practice rather than the  
18 designated other provider, and specifically to the wording  
19 that says that if the radiology facility is relying on the  
20 other facility to do this, number one, you have to have some  
21 kind of attestation that it will be done, and number two,  
22 the inspector reserves the right to ask for documentation  
23 that it really was done.

24           The problem isn't with the attestation. That is  
25 very clear. The problem is with what the inspector might

1 request, and this can be interpreted in all sorts of strange  
2 ways and already has been interpreted by people who don't  
3 know the right answer in various different ways.

4           What I would suggest that you do, because it seems  
5 to be workable from the radiologist's point of view, what I  
6 would suggest that you do from the ultimate provider is to  
7 allow for a procedure manual of the alternate provider to be  
8 created along the same guidelines as the procedure manual  
9 would be documented within the radiology facility, and then  
10 have the radiology facility maintain a copy of this in their  
11 own procedure manual, so they can refer the inspector, when  
12 he asks for documentation that letters really went out to  
13 patients, say, here is our attestation and here is the  
14 standard operating procedure manual of the group that has  
15 signed this attestation, and therefore, this ought to  
16 satisfy the requirement.

17           If that is done in a straightforward way, I don't  
18 think there will be confusion.

19           CHAIRPERSON MONSEES: I have a question about the  
20 wording in the final regs says that each facility shall  
21 maintain -- to ensure that the results of each mammographic  
22 examination are communicated. Now, what does that exactly  
23 mean "ensure," and you can send reports, but how do you know  
24 that they are received? Likewise, how do you ensure that if  
25 you sent a physician, your referring physician a report, how

1 do you ensure as to what they did? I think we need some  
2 guidance on that, as well, and the guidance document needs  
3 to be much more specific.

4 Do you want to address that?

5 MR. McCROHAN: Mainly to say we would appreciate  
6 your advice on how to make that clearer, although I think  
7 what Dr. Sickles suggested was, in effect, what we had in  
8 mind. It does seem to me, thinking about the questions you  
9 have asked, not to be reasonable, you know, to expect a  
10 radiology facility to have in the literal sense a copy of  
11 every letter that their collection of referring physicians  
12 had sent to any patients, I think that what we had in mind  
13 was something more like an indication that there was an  
14 agreement between the radiology facility and the referring  
15 physician, and that there was evidence of the standard  
16 procedure that the referring physician or referring  
17 physician group was attesting to use as opposed to going the  
18 step further looking for the specific copies of letters that  
19 that referring physician might have sent.

20 So, I think that we need to be open to your  
21 suggestions and try to be more clear in the guidance as to  
22 what we think is a reasonable way of meeting the  
23 requirement.

24 DR. SICKLES: Just to follow up on that, one thing  
25 that you might consider putting in the guidance

1 documentation is slightly different wording than -- the way  
2 the wording is right now, you have got in there ensure and  
3 guarantee, and things like that, and although those words  
4 are good and they are the optimal situation, it really isn't  
5 possible for any facility to guarantee anything.

6           So, I think it would be better to have in the  
7 wording something like make reasonable attempt to guarantee,  
8 and a reasonable attempt would be, for example, to send a  
9 letter to the woman at the address the woman gave the  
10 facility when she had her exam, but if you don't put in  
11 "reasonable attempt," then "guarantee" could be  
12 misinterpreted as having to send out a detective agency to  
13 try and find her.

14           If you sent the letter to the address she gave  
15 you, and it came back undelivered, and you telephoned the  
16 number that she gave you, and there was nobody at that  
17 address, and that happens unfortunately, and there is  
18 nothing the facility can do in that situation other than  
19 make those standard approaches.

20           CHAIRPERSON MONSEES: Or even worse than that,  
21 that it doesn't come back to you, and you don't know that  
22 she or the facility did not get it, and we have got "ensure"  
23 written in the document here as words in the final reg.

24           Although we are not making regs for this purpose,  
25 it does have implications for the medical-legal community,

1 because if it is stipulated "ensure," that means that every  
2 last case of failure to communicate is going to come back to  
3 the facility because it has been stipulated in these federal  
4 regs, so I think this is something of great importance.

5 I think that as long as there is a policy in some  
6 way that is reasonable, it is different from saying  
7 absolutely ensure and guarantee.

8 DR. FINDER: I agree with everything that has been  
9 said. I just want to bring up one other point that I feel  
10 we have to keep in mind. Whether there is a regulation or  
11 not, if the patient doesn't receive the report, and there is  
12 a problem, you will hear about it anyhow, whether it was  
13 because of that regulation or not.

14 I agree with you the terms "ensure," you cannot  
15 guarantee anything 100 percent, and I think that the wording  
16 here is supposed to be reasonable attempt to do that, and I  
17 think that is what we are going to be looking for.

18 DR. SICKLES: Yes, it's just not in there yet, but  
19 should be.

20 CHAIRPERSON MONSEES: Yes.

21 MS. HAWKINS: I have two concerns here, but as it  
22 relates to communication to women, I think it is a very  
23 legitimate concern because in cases where mammography is  
24 negative, women are not getting reports, and oftentimes it  
25 does not even come from the physician that is treating them,

1 that has referred them over for mammograms, because in just  
2 basically asking women about concerns, and so forth, I am  
3 talking to a number of them who are not getting any sort of  
4 results back, and they are just assuming that those results  
5 are negative.

6 I also wanted to ask or make a comment related to  
7 the medical audit and outcome analysis, and I noticed that  
8 the emphasis is on the tracking of positives, you know,  
9 those positive reports, and so forth, and I am just  
10 basically thinking in terms of the Boston report that very  
11 recently appeared in the paper, and so forth, about the  
12 number of false positives.

13 It raises my concern about the number of false  
14 negatives that may also be out there, and just basically how  
15 and what sort of a tracking system is going to be put in  
16 place to ensure that there are not false negatives that are  
17 floating around out there.

18 It all comes back to the point that when you  
19 outlined this procedure, and so forth, is that you talked  
20 about outreach to facilities and your training and your  
21 inspection program, but I think a very vital component to  
22 this whole issue of standards is going to be outreach to  
23 consumers.

24 Whether we are looking at home health care or  
25 Medicare or Medicaid, we just cannot overlook the issue of

1 fraud and abuse, and I think that there is a potential that  
2 it will happen, you know, in the implication of these  
3 standards, and so forth, and basically around mammography,  
4 and so I think that important to just basically being able  
5 to avoid that is going to take, you know, very intense and  
6 involved commitments from consumers, and there has to be a  
7 special outreach component to consumers.

8 MR. McCROHAN: Let me just respond briefly to that  
9 last point. I think it certainly is the case that our  
10 outreach staff probably sees as its prime focus the  
11 facilities that we certify, and those are the people who  
12 get, for example, mammography matters and whatnot.

13 That is not to suggest that we haven't made  
14 efforts to communicate with groups that could multiply the  
15 effect in an attempt to communicate with women directly. I  
16 think that just as a practical matter, given the populations  
17 involved, we can more appropriately communicate about issues  
18 related to MQSA to patient advocacy groups, and so on, and I  
19 think we attempt to do that.

20 We may need to do more in that respect. We may  
21 need to focus our attention a little bit better, and we  
22 would certainly be open to specific advice that you might  
23 have now or in the future with respect to that, but I think  
24 that is sort of the most cost effective way that we can deal  
25 with the issue that you raise without getting into the issue

1 of trying to communicate directly with women. The  
2 population of women is very large and would be difficult for  
3 us to reach them and difficult or inappropriate, I think,  
4 for us to sort of reinvent the wheel that has already been  
5 invented by the various patient advocacy groups who have  
6 channels of communication to women more generally.

7 So, I think we want to use what is in place. I do  
8 think that we have probably have certainly focused more  
9 attention on communication with facilities and communication  
10 with various personnel groups who are involved in  
11 mammography, and so forth, and probably equal weight hasn't  
12 been given to attempts through other third parties to  
13 communicate with patients, and that is a good point.

14 CHAIRPERSON MONSEES: Yes.

15 DR. SICKLES: I would like to respond to the first  
16 part of your comment, which related to false negatives.  
17 Although that is a very, very useful piece of information  
18 for any radiology facility to have, and, in fact, when we  
19 teach radiology facilities about auditing, we emphasize the  
20 importance of it, as a practical matter, it is very  
21 difficult to collect that data.

22 Ninety or 95 percent of what is interpreted is  
23 negative, and only a small percent is positive, so tracking  
24 the negatives imposes a large burden right at the outset,  
25 because you have got to track 20 times more cases.

1           Secondly, in the situation of tracking a positive,  
2 you expect something to be done, and, in fact, you know,  
3 part of the regulations are that it should be done, and  
4 getting the answer is relatively simple, because something  
5 is supposed to be done, it is going to be done within the  
6 next month or two or three, you know, in a reasonably short  
7 period of time.

8           When you assess false negatives, you don't expect  
9 anything to be done, and the only way you know that it is  
10 negative is if the woman does not get breast cancer within  
11 the next screening interval; which is usually a year.

12           What that would impose a facility or any agency  
13 that had to track false negatives, whether is the facility  
14 or the FDA or anyplace, would be having to contact every  
15 single woman who had mammography read as negative, which is  
16 90 or 95 percent of the women, and then contact each of  
17 those women a year later to try to find out whether she was  
18 known to have breast cancer at that time. That is just not  
19 practical. Although it would be nice, it is just not  
20 practical.

21           The only practical way to have that done is beyond  
22 the scope of the FDA, and that is for the Congress to  
23 establish a national tumor registry, which has not happened  
24 yet, but should, and then have that tumor registry be  
25 accessible to facilities, so the facilities could provide

1 the names of the examined women in a confidential way, so  
2 patient confidentiality is protected, and they could get  
3 back with these ones of your exams that were negative,  
4 ultimately were found to be breast cancer.

5           It's the only way to do it reasonably, and  
6 unfortunately, it hasn't been legislated or funded yet. I  
7 think this is a very important thing that should be done.  
8 It is just I think beyond the purview of the FDA.

9           MS. HAWKINS: Well, let me just ask you this, but  
10 when we think in terms of groups of women, especially black  
11 women, who are diagnosed at later stages with cancer, do you  
12 think any of these can be linked perhaps to false negatives?

13           DR. SICKLES: I think in any circumstance, some  
14 false negatives will account for later diagnoses of breast  
15 cancer. I don't know that it relates to specific groups of  
16 individuals, although probably it relates more to  
17 underserved individuals than better served individuals. I  
18 don't know if you can take it further than that, but again  
19 it is impossible to track, it's just not practical to track.

20           In my practice, we are very fortunate in having --  
21 and this is not available to virtually any other practice in  
22 the country -- we can link our own individual results with a  
23 regional tumor registry. It is a federally-funded regional  
24 tumor registry, and the only reason we can do it is that we  
25 have a research grant. Nobody else in the country can do

1 that.

2 It is just not practical to make regulations that  
3 require people to do it when they can't physically achieved  
4 the result. What I would urge the consumer groups to do is  
5 to petition the Congress to fund a national tumor registry,  
6 which is a very important thing to be done, but it is way  
7 beyond the purview of this committee.

8 CHAIRPERSON MONSEES: Ed, don't you believe that  
9 the false negative rate among the underserved pertains more  
10 to their lack of access and their lack of compliance with  
11 getting mammography, and its inaffordability, rather than a  
12 higher false negative rate among that population of women  
13 who are actually screened?

14 So, in other words, it is not that their  
15 mammograms aren't as good or read as accurately, but that,  
16 in fact, they are not accessing mammography, and would you  
17 say that that is a correct statement?

18 DR. SICKLES: I think that the evidence that we  
19 have to date suggests that is true, because when we screen  
20 underserved women, as we do in our practice and as you do in  
21 yours, we wind up having the same false negative rates as we  
22 do in all other screened populations, so I don't think it is  
23 a problem with the mammography per se, it's a problem with  
24 access.

25 CHAIRPERSON MONSEES: Right. I agree with that.

1           We have another question.

2           MS. BROWN-DAVIS: Carolyn Brown-Davis. I actually  
3 had a comment on communication outreach, but I want to  
4 address something that you just said.

5           How do you explain the fact that -- well, first of  
6 all, we have a lot of contact with African-American women  
7 because of a support group. We graduate three groups of  
8 women a year just to show you how many are being diagnosed.

9           So many of these women find their lumps months  
10 after a mammogram. So, that is a real concern to me. These  
11 are not -- they may be underserved, but they are not poor  
12 women, and mammography is not picking up the way it should.  
13 I was fortunate, it did for me, but -- so how do you explain  
14 that?

15           CHAIRPERSON MONSEES: I am not sure we have any  
16 data that shows that we have a higher false negative rate  
17 among this population.

18           MS. BROWN-DAVIS: Are there any studies that have  
19 been done?

20           CHAIRPERSON MONSEES: Go ahead, Ed, and the other  
21 thing is looking at anecdotal data is something that we have  
22 to be careful and not to necessarily do we need to look at  
23 important scientific data.

24           Do you want to comment on that, Ed?

25           DR. SICKLES: There are a few -- not enough -- but

1 there are a few articles published looking specifically at  
2 underserved populations with breakdowns as to ethnic  
3 background, and these studies, as limited as they are, don't  
4 show any differences.

5 My own practice, we actually have that -- we have  
6 the ability to look at that -- and in my own practice we  
7 have the same results, but the data that you would like to  
8 have are not forthcoming on a large-scale basis because it  
9 is very hard to acquire them, because underserved women just  
10 are underserved, and there is not that much data to come  
11 from those groups.

12 CHAIRPERSON MONSEES: I am going to limit the  
13 discussion on this because it is really outside of our  
14 mission right now. I think it is an important issue, but it  
15 is outside of our mission. So, let's go back to  
16 communication issues and medical audit outcome analysis  
17 issues.

18 Yes.

19 MS. EDGERTON: Cut me off right when I -- I work  
20 with underserved women in the breast cancer early detection  
21 program and breast and cervical cancer control program, but  
22 I won't go there.

23 My comment is now I am back where I was at the  
24 beginning. I don't notice anything here on something that I  
25 think is important, that I know stresses a lot of radiology

1 departments as I go around and speak on these new regs, but  
2 I think is very important, and that is, if women don't have  
3 a provider, their own health care provider, it is now  
4 incumbent upon the radiology facility to have an agreement  
5 with some other provider that she can be referred to, and I  
6 don't see a question here to check out and see that that has  
7 actually been done.

8 I think it should be added since you added it to  
9 the regs, and have made it -- I mean this is where we can  
10 save women's lives, where they actually get sent to a health  
11 care provider.

12 CHAIRPERSON MONSEES: Maybe that should be added  
13 upfront where the other ones were rather than in here.

14 MS. EDGERTON: This is where it is with the regs,  
15 it's in this part of the regs.

16 CHAIRPERSON MONSEES: Okay.

17 MR. McCROHAN: Thank you.

18 CHAIRPERSON MONSEES: Did you want to make a  
19 comment?

20 MS. BROWN-DAVIS: For this issue, I would like to  
21 see something done for the education of women as to what is  
22 expected of the facility. I think that is very important,  
23 and so that some decision would have to be made as to what  
24 is feasible, what is reasonable.

25 I know that for the women without a referring

1 physician, it was suggested in the regs, if I am not  
2 mistaken, 48 to 72 hours, is that realistic, and because I  
3 think that the communication, the outreach that is actually  
4 done, can include what a woman can expect.

5 I think it is very important to educate consumers.

6 CHAIRPERSON MONSEES: Thank you very much. I  
7 think that is an important issue that maybe FDA should  
8 address. We have mammography matters that goes to  
9 interested parties, facilities, et cetera. What does FDA do  
10 to make it known, is there a brochure for lay individuals,  
11 for women that are going for mammography to know what to be  
12 expected from their facility? Has any thought been given to  
13 this, has anything been proposed, et cetera? An important  
14 point.

15 MR. McCROHAN: To the best of my knowledge,  
16 nothing specific to that point exists, although I think it  
17 is a good point and something worthwhile for us to consider.

18 As I said earlier, I think that we are perhaps  
19 more immediately inclined to depend on the various patient  
20 advocacy groups who certainly have access to mammography  
21 matters, and who I would hope would be on the mailing list  
22 for that.

23 Certainly, we would welcome any communication from  
24 them and we would be happy to look at materials that others  
25 might develop, but we will have to think about the issue of

1 whether or not we want to develop direct contact materials  
2 for women.

3 I think that it is not so much of a problem of  
4 developing such materials although that takes some effort  
5 certainly. I think the bigger issue is once you have it,  
6 then, what responsibilities have you assumed in terms of  
7 distributing that, and so forth, and what is the resource  
8 commitment and whatnot.

9 Again, I think working through multiplier  
10 organizations is a more cost effective way for us to go, but  
11 it is clear that the regulations carry with them  
12 implications for what women ought to expect when they visit  
13 a facility and what kinds of things they ought to be  
14 cognizant of and ought to be looking for.

15 So, I think it is a reasonable suggestion that we  
16 do what we can to see that women have that information, so  
17 that they are aware when things don't go as they would have  
18 expected, and they have some indication that they ought to  
19 be thinking about what they should do in that event.

20 CHAIRPERSON MONSEES: A patient bill of rights or  
21 something like that, you know, a one-page document that  
22 could be available in each facility, something like that  
23 might address those needs.

24 We will take first from Ms. McCarthy, and then  
25 from the audience.

1 MS. McCARTHY: I also want to talk about patient  
2 education related to what their expectations can be of the  
3 facility.

4 It seems to me that just adding a question is  
5 there a patient education program in place would be a very  
6 valuable one for the inspectors to ask, you know, to look to  
7 the quality. Also, I am concerned about what happens after  
8 the mammogram and alerting women that there may be a recall  
9 or that there would be a negative finding, and it seems to  
10 me that that is the mammography center's responsibility to  
11 do.

12 MR. McCROHAN: I certainly don't disagree at all  
13 with the variety of suggestions that have been made in terms  
14 of what mammography facilities might reasonably do to  
15 communicate more fully and better with facilities.

16 I think the one thing that we are going to have to  
17 take into account is what the regulations say and require,  
18 and, in particular, instances whether the regulations  
19 provide a basis for a particular kind of requirement in that  
20 respect. So, we will take a look at that.

21 CHAIRPERSON MONSEES: Dr. Hendrick.

22 DR. HENDRICK: I just wanted to mention four years  
23 ago when the quality determinants of mammography guidelines  
24 were published, there was accompanying that the publication  
25 of a very small pamphlet for women getting mammography, and

1 that might serve as a model for what you are talking about.

2 It needs to be updated obviously. It was  
3 translated into Spanish and it would be very useful to  
4 update that to include sort of current facts about  
5 mammography and MQSA.

6 MS. BROWN-DAVIS: That is exactly what I would  
7 like to see. I don't see it as a difficult thing to do, and  
8 I really don't see something that isn't, you know, easily  
9 understood by most people. As a matter of fact, there might  
10 even be an explanation of false negatives and just general  
11 things that might come up with a mammogram.

12 CHAIRPERSON MONSEES: I think a one-page document  
13 could be derived really of issues that are important to the  
14 woman. Obviously, she is not going to want to know nor need  
15 to be conversant with all of the quality assurance issues,  
16 but there are certain patient issues that I think would be  
17 perfect for that. I don't see any reason why that couldn't  
18 be developed.

19 Dr. Sickles.

20 DR. SICKLES: To get into slightly more detail in  
21 terms of communication issues directly with women, and I am  
22 talking now principally about the written letter that might  
23 go to the woman, we can expect -- I don't know that the FDA  
24 really has to get into this, they probably think they  
25 shouldn't get into this -- but we can expect that there will

1 be forthcoming a series of standard letters that will be  
2 constructed by radiologists and widely distributed among  
3 radiologists with a template of a typical normal letter  
4 which would be sent to a woman, and a typical abnormal  
5 letter which would be sent to a woman in the two  
6 circumstances which would happen, the mammogram is positive  
7 or it's negative.

8           The normal letter would basically say that you  
9 have had your mammography and it's normal, and you should  
10 also get a clinical exam if you haven't had one, and the  
11 letter that we have constructed gives her a lot more  
12 information than that, all on one page -- you can get a lot  
13 of information on one page -- advising her that if she gets  
14 a lump at some point in the next year, she should go and see  
15 her doctor right away, and not just wait until a year is up.  
16 Some women apparently are not aware of that.

17           The letter can inform her, can tell her where her  
18 mammograms are being stored in case she needs them, to be  
19 used at the next exam. There is a whole bunch of  
20 information you can get in there, and radiologists, I think,  
21 will very effectively disseminate these types of template  
22 letters among ourselves, so that when this April 28th  
23 deadline comes around, the vast majority of practices will  
24 have very nicely constructed letters to go to women.

25           I don't think really it is the FDA's job to be the

1 police and read the individual letters that are coming out  
2 from facilities to make sure that they fit the exact wording  
3 of a given form, because I don't think any one form is that  
4 much better than another, but basic information can be  
5 contributed.

6           The question that I have, and this is for you to  
7 consider, relates to the abnormal situation, not the  
8 negative where, you know, it's come back in a year with a  
9 few educational things, but the abnormal situation.

10           My view would be that the intent of this letter  
11 would be to inform the woman that findings are not  
12 completely normal, that additional work needs to be done,  
13 and that she needs to consult with her primary care provider  
14 or if the radiology facility wants, with the radiology  
15 facility, it could be their choice, in order to get  
16 additional testing done.

17           What I don't think would be a particularly useful  
18 approach would be to get very specific about exactly what  
19 was seen on the mammogram, you know, this part of this  
20 breast with this finding, because that imposes on the  
21 radiology facility the need to make actually two separate  
22 dictations.

23           You can construct a very nice, comprehensive,  
24 abnormal letter that has all of the necessary information in  
25 it without being specific as to what the abnormality is,

1 which would be very directive and which will encourage any  
2 woman who reads that and who understands it to know what to  
3 do next.

4 That is really the sense of it, and I would hope  
5 the FDA does not require a more directive letter that has to  
6 be individually done, but you may want to comment on it.

7 CHAIRPERSON MONSEES: I would like to say that I  
8 also agree with that. I think that is important here in  
9 communication that a woman knows is it positive or not, and  
10 what is her next step, not that we have to explain every  
11 last detail to her, that she may or may not understand,  
12 which might frighten her more, but just I think -- and I am  
13 speaking for the consumer groups to some extent, but I have  
14 done a lot of work with this in my local community -- I  
15 think what concerns people most is that somebody might fall  
16 through the cracks or that they don't know what to do next.  
17 Am I right about that?

18 I think just yes or no, is it normal or not, and  
19 what should they expect, to get a letter in the mail, if  
20 they don't get it, what do they do next, or if they do get  
21 it, and it's abnormal, and I should think that would  
22 suffice.

23 Mr. Fletcher.

24 MR. FLETCHER: I am not sure where we are as far  
25 as the requirements are, but I have heard a lot of ideas. I

1 know that one of the things that we already have in place  
2 are the inspectors and their checklists. I think it would  
3 be beneficial that some question be added regarding what  
4 kind of outreach there is or at least to ensure there is  
5 outreach.

6 I think that can be done without a lot of fanfare,  
7 not being specific saying you have to have this, you have to  
8 have that, but is there an outreach program. That draws  
9 attention of the facility to the fact that we are concerned  
10 about the level of outreach.

11 I don't know what we, as a committee, can do to  
12 bring about the actual publication of some kind of a -- a  
13 republication perhaps of the kind of document Dr. Hendrick  
14 talked about, but I would like to ensure that we don't just  
15 talk about it and then the next meeting talk about it again.

16 CHAIRPERSON MONSEES: Well, let me just say we  
17 will ask our speaker here, but this is not regulated by the  
18 Federal Government, it is not in the regs. It is not  
19 stipulated there has to be an outreach, so the inspector  
20 really shouldn't be asking that question as best I can tell.  
21 I will defer to you.

22 I think that it may be in the best interests of  
23 the FDA and the community at large for the FDA to develop  
24 some communication documents with lay individuals on a  
25 national basis. I think that is a good idea, but I am not

1 sure that collecting that data when it is not in the federal  
2 regs is the answer to that.

3 Do you want to comment on that?

4 MR. McCROHAN: Yes, I would agree. I think that  
5 we do have to be -- we have a responsibility to be careful  
6 that we don't impose requirements on facilities that aren't  
7 responding to something that is in the regulations.

8 It is not to say that we don't support more  
9 patient education, and it doesn't say that we can't do some  
10 things to facilitate clearer patient communication, patient  
11 education. In fact, staff reminded me that we, in the  
12 process of publicizing the final regulations, if you will,  
13 sent a letter and a copy of the regulations to a large  
14 number of consumer organizations, and I think that we would  
15 like to look for some mechanism for working with groups like  
16 that to address the issues that have been raised that would  
17 benefit from clearer communication with patients, but I do  
18 think we need to be mindful of what the regulations require  
19 and limit the requirements that we impose on facilities to  
20 things that are in the regulations.

21 DR. FINDER: I just wanted to mention about what  
22 Dr. Sickles was saying in terms of the letters. What he  
23 envisions is what I believe that we would be talking about  
24 in guidance, not getting any more specific in terms of --  
25 just saying positive or negative or abnormal or that you

1 need some further workup and then what to do about it.

2 CHAIRPERSON MONSEES: In the interests of time,  
3 let's readdress what we have up here. Are you finished  
4 discussing this?

5 DR. MENDELSON: I wanted to comment I think it is  
6 very important, and communication works both ways. Women  
7 who seek mammogram and breast evaluation are interested in  
8 finding out their results, and for many years, a number of  
9 practices, particularly in dealing with diagnostic studies,  
10 have had verbal communications with women where women can  
11 ask questions and be shown films, and discuss the meaning of  
12 what the findings are and what they should do next, and can  
13 seek help from the diagnosticians with respect to the steps  
14 that they need to follow to make certain that what needs to  
15 be done is done.

16 I think that there is provision currently in the  
17 regulations for that type of communication, and that that  
18 should persist. I think the importance of that is  
19 educational fulfillment, as well. That type of personal  
20 communication, I think can mean a lot, and where it is  
21 feasible, it should be encouraged, and how -- I agree with  
22 Dr. Sickles' comments about removing strong verbiage,  
23 ensure, guarantee, sign on the dotted line type of thing, it  
24 should be qualified, and in the report, mention can be made  
25 that these findings and recommendations were discussed with

1 the patient, and whatever was said would also be within that  
2 report, as well. I think that is important.

3 The standard letters I think are something that  
4 would be very valuable to develop, and there will be a lot  
5 of input from a lot of people with respect to making them  
6 clear, and not frightening people.

7 I think it is important to encourage that.

8 CHAIRPERSON MONSEES: Yes.

9 MS. McCARTHY: I am not real sure whether this  
10 belongs here or in the next medical audit piece, but I don't  
11 see anything about the consumer complaint system that is  
12 supposed to be in there. Pardon, it is at the front?

13 CHAIRPERSON MONSEES: Yes, we have already covered  
14 that.

15 MS. McCARTHY: Sorry.

16 MR. McCROHAN: Within the quality assurance  
17 program. That was one of the SOPs we were looking for.

18 CHAIRPERSON MONSEES: One other comment here.

19 DR. NICHOLS: I hope that we are very careful as  
20 we begin to get into an arena that has been very challenging  
21 to me as a formal practicing physician in rural Arkansas as  
22 the director of the health department where we educate every  
23 single day, and as working with advocacy groups.

24 Oftentimes when a patient receives patient  
25 education information from a mammogram entity, it is

1 foreign, and we have to be reminded that our literacy rate  
2 is not extremely high within the state.

3 I really like the terminology used from a facility  
4 perspective. I think HHS, NIH, the health department, the  
5 advocacy groups, all those people are out there in the  
6 business of education, and they are holding sessions quite  
7 often in order to work with those women one on one and  
8 answer their questions, and that is the big key, will be to  
9 answer their questions and being able to communicate, so I  
10 hope we will be very careful as we get into an area or arena  
11 where we may leave more questions than answers, and allow  
12 for someone to be there to answer those questions, and the  
13 advocacy group and all the entities who do that very well  
14 may be where we can best serve the public.

15 MR. McCROHAN: Thank you.

16 CHAIRPERSON MONSEES: I think that is a very  
17 important comment especially because if we are starting to  
18 talk about sending reports to women who may or may not be  
19 literate, we may not be able to know whether or not they are  
20 able to interpret what is coming in the mail to them. So,  
21 we should be very sensitive to that issue, I think.

22 I can just offer that in our institution -- I am  
23 not saying that this is necessarily what everybody should do  
24 -- we belong to the paranoid school, and so we duplicate  
25 things over and over. We tell people and hand them a card

1 when they are in the department that you should be getting  
2 something in the mail and to look for that, and if they  
3 don't get it, at the bottom of that card, here is the  
4 telephone number, you know, it doesn't mean no news is good  
5 news, et cetera, and our technologists are trained and have  
6 had special training to look for literacy, and now it is  
7 very difficult, but we have an information sheet that a  
8 patient needs to fill out, and if she is not filling that  
9 out, they are supposed to broach that subject with that  
10 particular patient to see if she is literate or not, so that  
11 when she gets the report, she will be able to read it.

12           So, those are the kinds of things that we should  
13 pay attention to. We can't mandate it, but just something  
14 that we do at our institution that I thought I would comment  
15 on.

16           Yes.

17           MS. EDGERTON: Just a quick comment that is  
18 important, not just for illiteracy, but for foreign  
19 languages. This institution that we had to go through and  
20 have all the films re-read, and call back all the women, as  
21 a Korean clinic, and we went through some organizations to  
22 ensure that all of the letters were not only sent in  
23 English, but translated to Korean.

24           That particularly frightens us just because we  
25 know that it was an underserved population and also with

1 some of the ethnic groups, it is very hard to get them in,  
2 in the first place, and once you get them in, you are not  
3 going to get them in again for a long time.

4 We actually enlisted a national Asian women's  
5 organization to contact these women individually, because  
6 many of them said, well, I am just going to go back to where  
7 I had it done even though our letter stated that the  
8 physician and the clinic owner had been prosecuted and spent  
9 time in jail, so here they were, literate, but the language  
10 or the culture was a problem, too, so that is a whole other  
11 issue that is not regulated; but is so important.

12 CHAIRPERSON MONSEES: Thank you.

13 Do we have any other, John, that you want to talk  
14 about on medical records or medical audit?

15 MR. McCROHAN: No.

16 CHAIRPERSON MONSEES: We have a question.

17 MR. PIZZUTIELLO: I just wanted to coalesce some  
18 of these things. There was concern about limited resources  
19 of the division in FDA to do the communication, and maybe if  
20 I can just summarize.

21 If FDA puts together an information packet on  
22 these are the kinds of things that will change next year  
23 when the regulations change, and that these are the kinds of  
24 things that women should expect to be different as they  
25 experience mammography in their lives, and then let FDA find

1 all the advocacy groups and provide that information to the  
2 advocacy groups, and then let the communication occur at the  
3 level closest to the grass-roots, that wouldn't put a  
4 tremendous strain on resources, it gets the information to  
5 the people, and it relates specifically to the way things  
6 will change next year when the final regs go into effect.

7 MR. McCROHAN: Very good point.

8 CHAIRPERSON MONSEES: Yes, Ms. Hawkins.

9 MS. HAWKINS: Just as a final comment, is that  
10 even when we think, not only in terms of literacy, but also  
11 in terms of culturally competent care, and I think that even  
12 from the FDA perspective, is that emphasis should be put on  
13 the fact that this is a client-oriented procedure that we  
14 are doing. This is a person. This is not one that we are  
15 looking at in terms of just procedures and facilities, and  
16 so forth, but it is a procedure that should be client  
17 oriented and to always keep that even in mind as we do these  
18 inspections, that this is a client-oriented process that we  
19 are focusing on.

20 You know, this is women's issues, and so I think  
21 that even though, you know, your regulations may not have to  
22 speak to that, but it can be, you know, a whole new movement  
23 toward this fact that women's health issues should not have  
24 become social problems because of, you know, issues of  
25 neglect.

1 CHAIRPERSON MONSEES: Thank you.

2 MR. McCROHAN: Just one quick comment. I think  
3 that sort or takes me at least in a very small way back to a  
4 comment I made earlier with respect to the prior  
5 notification of the facility for the inspection.

6 So, one of the things that I think we feel  
7 responsible for doing is implementing the inspection program  
8 in such a way that it doesn't unduly put burden on patients  
9 who have scheduled examinations in advance of when the  
10 facility knew there was going to be an inspection, and so  
11 forth, so at least to that small extent, as an example, we  
12 are trying to be sensitive to the issues that you mentioned,  
13 recognize the character of the examination we are talking  
14 about.

15 CHAIRPERSON MONSEES: Thank you. In fact, that is  
16 an important point because if you don't do it far enough in  
17 advance, the schedule may be filled for those days. At  
18 least at our facility, when somebody comes to inspect, we  
19 have to plan down time for the rooms in order to be able to  
20 accommodate our patients, so we need to work with our local  
21 inspectors, and we have done successfully in the past.

22 At this point, I want to give our speaker the  
23 opportunity to ask the panel for other guidance, anything  
24 else that has not been discussed, and there was -- do you  
25 have an overhead on this page?

1 MR. McCROHAN: No, I don't.

2 CHAIRPERSON MONSEES: In the inspection procedure,  
3 the last page, guidance issues where NMQAAC input is  
4 solicited. We are not necessarily going to go through each  
5 of these, but I am going to give you the opportunity to say  
6 which of these things or maybe other things you need help  
7 on.

8 MR. McCROHAN: If I might begin with a question in  
9 terms of when you were hoping to terminate the proceedings  
10 today.

11 CHAIRPERSON MONSEES: We are talking 5:30, 20  
12 minutes.

13 MR. McCROHAN: Thank you.

14 There are a number of things listed on that last  
15 page of your handout, and we would certainly be appreciative  
16 of any written advice or comments that you would care to  
17 give us, particularly on any of the issues that we don't get  
18 to talk about directly here.

19 Similarly, we would be appreciative of your  
20 comments with respect to the guidance document you were sent  
21 in advance of the meeting that addresses a variety of  
22 inspection issues.

23 At the risk of harking back to my background and  
24 refocusing on equipment issues, which are about as far  
25 removed from the issues we were just recently discussing at

1 you can get, I would like to get some advice from the  
2 committee with respect to a couple of equipment-related  
3 points.

4           One is No. 8, I believe on the list that you have,  
5 and it relates to the issue of what the agency ought to do  
6 at the time of inspection if there is a machine in the  
7 facility that is being inspected, which is there on a  
8 temporary basis, and the extent to which we ought to focus  
9 attention on that unit and its performance, if any.

10           By policy, under the interim rules, we gave  
11 facilities the opportunity to bring a unit in to replace one  
12 that was out to the manufacturer for repair or to bring a  
13 unit in for evaluation purposes, and so forth, and there  
14 were I think some time frames of a month or something on  
15 that order, that the facility could have that unit and be  
16 using that unit without incurring the requirement to get  
17 that unit specifically accredited.

18           But if we do an inspection where such a unit is in  
19 place and operating, is there any sense that we either ought  
20 to subject that unit to the same physical tests that we  
21 talked about for the normal situation or that we should not,  
22 and I appreciate anybody's input on that.

23           CHAIRPERSON MONSEES: So this is loaner units.  
24 For those of you in the audience who don't have a copy of  
25 this, should MQSA inspectors inspect loaner units or those

1 being evaluated prior to purchase if they are being used on  
2 patients. I would like to hear from the audience.

3 First, we will hear from the panel.

4 MR. FLETCHER: First of all, from my perspective,  
5 the answer is yes, and for more than one reason. I am not  
6 sure as time passes that loaner units may not become more  
7 and more in use just so that a facility doesn't have to  
8 purchase a unit, and then find that two or three years  
9 later, the state of the art changes, and their unit starts  
10 to become obsolete.

11 We may be seeing a trend, maybe not a big trend,  
12 but we may start to see a trend in lease units of this  
13 nature that we may want to get in front of.

14 The second part of that is the fact that patients  
15 are being screened by these units, so that to me, that puts  
16 them in the same category as those being screened on the  
17 purchased units.

18 MR. McCROHAN: Just a point of clarification, if I  
19 may. It doesn't make any difference or we don't  
20 differentiate in terms of whether the unit was purchased or  
21 leased or rented or what have you, if it is a permanent  
22 fixture in the facility, so to speak, then, we are going to  
23 treat that in a normal fashion.

24 The question really referred to when you are  
25 bringing in a unit for a brief period of time for evaluation

1 or you have a replacement unit in for a week or a month, and  
2 you happen to be inspected during that time.

3 That was the situation we are talking about, and I  
4 take your point to be that at least from your perspective,  
5 it ought to be subjected to the same evaluation.

6 DR. SICKLES: From my perspective as a  
7 radiologist, number one, any kind of loaner unit shouldn't  
8 be put into operation unless the physicist has done the  
9 initial acceptance testing of the loaner unit, and you  
10 should expect to see that kind of a report when the  
11 inspector comes by and there is such a loaner unit.

12 I wouldn't expect the facility to be providing a  
13 year's worth of data on it, because it won't be there that  
14 long, but I do think it is quite reasonable for the  
15 inspectors to be performing the same on-site tests that they  
16 do on the other units on this loaner unit, because it is  
17 there and it is being used, and I don't see why it can't  
18 have a phantom image and everything else that they do.

19 I would hope that if this is a requirement --  
20 which I think it should be -- that the facilities would be  
21 very careful in looking at physicist acceptance report to  
22 make sure that if they happen to get inspected when they  
23 have one of these things, it is going to pass.

24 MR. PIZZUTIELLO: I think clearly the patient  
25 safety issue and quality of care issue has to apply to every

1 patient that walks through the door, whether they are going  
2 into a loaner unit or not.

3           The other thing is, as Dr. Sickles mentioned, it  
4 is really important to send a message to facilities that  
5 this is, in fact, important and necessary because there is a  
6 cost associated with it, and generally speaking, that cost  
7 ends up being borne by the manufacturer who is providing  
8 this equipment in order to entice someone to purchase it.

9           So, I think if it is in the inspection protocol,  
10 then, the manufacturers will be set on notice that if  
11 someone, an inspector were to come in and find a loaner  
12 unit, and there hasn't been an appropriate physics survey or  
13 equipment test, whatever you want to call it, and that the  
14 equipment is not performing properly, then, the facility  
15 will be responsible, and that will ensure that there is no  
16 skirting of these rules for these machines that might only  
17 be in for a few days, and it's probably okay, it is probably  
18 not okay.

19           CHAIRPERSON MONSEES: Yes.

20           DR. NISHIKAWA: I agree with all the statements  
21 made in regard to this topic except if this unit is going to  
22 be there for, let's say, a month, my understanding of what  
23 you presented today, the worse that can happen, they get an  
24 L1, which they have 15 days to reply to why this is not in  
25 regulation, at which time probably the loaner will be

1 returned.

2 MR. McCROHAN: I think the point to be made is  
3 that if the facility were using a unit in the circumstances  
4 you described, hadn't had an application for accreditation  
5 or if it is in for a very temporary period of time, hadn't  
6 had the equipment evaluation, and so on, and they get a  
7 warning letter, the real issue is, number one, putting the  
8 facility on notice, number two, what we expect in response  
9 to the warning letter, this issue is moot because the unit  
10 is gone, what we expect from the warning letter, from the  
11 facility is this is what we have done to assure that this  
12 situation never happens again in our facility, this is how  
13 we have changed our policy or practices or SOP, or what have  
14 you.

15 That is what constitutes correction, if you will,  
16 of the problem, rather than mooting it out by getting rid of  
17 the unit.

18 CHAIRPERSON MONSEES: One more quick comment and  
19 then I am going to give him the opportunity to ask us some  
20 other questions.

21 Go ahead.

22 MS. HAWKINS: Well, as a consumer, if I go into a  
23 facility, and it is a loaner unit and not inspected, I would  
24 like to have a sign posted that this is an uninspected piece  
25 of equipment, and so use it at your own risk.

1 CHAIRPERSON MONSEES: Proceed at your own risk,  
2 okay. That's clear, I think, in red letters.

3 MR. McCROHAN: Whatever its color, I think the  
4 committee has made its point.

5 CHAIRPERSON MONSEES: Yes.

6 DR. SICKLES: I would like to answer your Question  
7 No. 1, and maybe Barbara wants to attack that, too.

8 CHAIRPERSON MONSEES: He didn't ask that one yet.

9 DR. SICKLES: He did.

10 CHAIRPERSON MONSEES: Okay. He said he is going  
11 to do 1 next?

12 DR. SICKLES: Oh, do you want to do another one?

13 MR. McCROHAN: I would be happy to do 1 next.

14 DR. SICKLES: Barbara and I can help you with this  
15 one. I think the easiest test for --

16 MR. McCROHAN: Perhaps one of us ought to read it  
17 for the benefit of the audience.

18 CHAIRPERSON MONSEES: I think you should read it,  
19 Ed.

20 DR. SICKLES: I am sorry. What is an acceptable  
21 test or procedure for performance verification after a move  
22 mobile meaning the regulation that when a mobile unit  
23 physically changes its location, that the equipment needs to  
24 have some testing done to make sure that it hasn't been  
25 rendered inoperable because of the physical move.

1 I would break this down into two categories. For  
2 equipment where there is on-board processing, the easiest  
3 thing to do is just to have the regular testing done, have a  
4 phantom image done. For the mobile unit that does batch  
5 processing off-site, the easiest thing to do is what we do,  
6 and that is to have a phantom image taken and to assess --  
7 this is done with phototiming, with AC, and to have the AC  
8 record the MAS value, and as long as the MAS value is plus  
9 or minus whatever you want to say, that imaging continues  
10 for that day, but then the image itself is processed before,  
11 not after, but before any of the clinical images are  
12 processed at the end of the day, and scored before the 50  
13 cases are processed at the end of the day.

14 We have found that to be highly reliable and also  
15 very workable because it is just a matter of taking that  
16 image, making sure your MAS value is okay, and then looking  
17 at the image before you commit your 50 cases to the  
18 processing.

19 CHAIRPERSON MONSEES: Were you looking for any  
20 other types other than the phantom test, were you looking  
21 for any other guidance here as acceptable?

22 MR. McCROHAN: Yes, I think what we and staff had  
23 in mind was exactly what Dr. Sickles was saying. I didn't  
24 know if there were any other thoughts on that point and  
25 whether there were any alternatives. It is certainly not

1 necessary for there to be those alternatives now, if they  
2 come up in the future, we can evaluate them.

3 DR. SICKLES: I am sure there are others that  
4 would work as effectively, but I am not sure there are  
5 others that would work as easily. That happens to be a very  
6 easy, simple thing to do.

7 MR. PIZZUTIELLO: We have several clients, and we  
8 have recommended exactly that, and they have found it to be  
9 very efficient and has occasionally picked up a problem and  
10 not intrusive into their practice, so I support that.

11 CHAIRPERSON MONSEES: Thank you. Does that answer  
12 No. 1?

13 MR. McCROHAN: Yes.

14 DR. FINDER: I just had a question, a  
15 clarification actually. Let's say the phantom image doesn't  
16 pass. Does that mean you don't run the films, you don't  
17 process the films?

18 DR. SICKLES: It depends on what the problem is  
19 with the phantom image. If the problem with the phantom  
20 image seems to relate to processing, then, I would be leery  
21 of running all 50 patient images. What I would probably do  
22 is run one film of one patient, and look at it and make an  
23 assessment.

24 We have yet to have that situation happen in many  
25 years of operation, so I don't think it is going to happen

1 frequently, but if you ensure that that image is looked at  
2 before the cases are processed, the patient films are  
3 processed, I think that is the best you can do.

4           If, for example, you saw that all of a sudden you  
5 didn't see the specks, that probably is not a processor  
6 problem, it is probably an equipment problem and it may  
7 relate to the quality of all the images that have already  
8 been taken, but you can't do anything about it.

9           MR. PIZZUTIELLO: Charles, that has happened at  
10 one of my client's. When they called us and said what do we  
11 do, we said don't process any of the films, and we will get  
12 right on it, it turned out that the processor was fine in  
13 the morning when they did processor QC, but the thermostat  
14 didn't hold up during the day, so by the end of the day, the  
15 temperature was out of whack, so we are able to find that  
16 systemic problem, they did not process those films, we got  
17 it straightened out, and then they processed it.

18           So, if there is a problem with the processing at  
19 the time of batching 50 films, you get a good warning  
20 beforehand.

21           MR. McCROHAN: Are we ready to go on to the next?

22           CHAIRPERSON MONSEES: We are ready for the next.

23           MR. McCROHAN: Question No. 2 related to the  
24 equipment evaluation tests or, more broadly, the equipment  
25 evaluation, and the question really has to do with what

1 tests ought to be performed and under what circumstances.

2 As the reg says, if we get a new unit, you need to  
3 perform an equipment evaluation to establish its performance  
4 prior to use on patients, if we disassemble and reassemble,  
5 if we repair, and so forth, are opportunities for doing  
6 equipment evaluation.

7 It would be my view that if we are talking about a  
8 new unit or if we are talking about disassembly or  
9 reassembly, the equipment evaluation ought to include  
10 essentially all of the elements of a normal survey, all of  
11 those various equipment-related tests ought to be done since  
12 this is sort of the first time this unit has been out of the  
13 box or has been disassembled and reassembled, it is  
14 essentially a new unit.

15 The difference in that respect between the  
16 evaluation and the survey would be that you wouldn't do any  
17 of the tests that were more facility-based, such as uniform  
18 your screen speed, for example, and you wouldn't do the  
19 evaluation of how well the technologists are doing, the  
20 quality control, and so forth.

21 In the case of a repair -- I guess the question I  
22 would ask, after you tell me whether you agree with me or  
23 not on the first point -- in the case of repair, I guess the  
24 question I would ask is which repairs would you consider to  
25 be sufficiently major that they should require equipment

1 evaluation, and, if so, would you agree that the tests that  
2 comprise the evaluation in that circumstance should  
3 reasonably be targeted to the nature of the repair that was  
4 made.

5 CHAIRPERSON MONSEES: I am going to look to a  
6 physicist for that. Yes.

7 MR. PIZZUTIELLO: I certainly agree with the first  
8 statements, that you do all the tests on the equipment that  
9 are equipment based in the major situation.

10 I haven't exactly decided if I think that the  
11 regulation, that the inspection should get that detailed as  
12 to what exactly is done. In our practice, for example, we  
13 sat down and we listed about five or six different major  
14 repairs that might occur on a machine.

15 So, we said if the x-ray tube gets replaced, we  
16 have a grid, we test this, this, that isn't necessary, well,  
17 we will take a little picture of that, if that is okay, we  
18 won't -- we make sort of a decision tree, and it is based on  
19 our professional expertise as medical physicists.

20 So, I guess what I might suggest is that you might  
21 say that the medical physicist must do appropriate tests and  
22 that they ought to explain in some simple way why they do  
23 some tests and why they don't do others.

24 I think that allows for a professional to make a  
25 judgment to say, well, I took a phantom, and they really

1 weren't playing with the AEC, so there is no reason to  
2 suspect that it would be different, or I took a phantom and  
3 it wasn't the same as it was last time, so I decided to  
4 follow that up a little bit further.

5           It is not simply a question of going through the  
6 cookbook. So, I think that a physicist should do the  
7 appropriate tests on the aspects of the equipment that may  
8 have changed. It should be up to their professional  
9 judgment to decide what to do, but that they should make a  
10 reasonable stab at explaining why they have done some  
11 things, and why they have not done others.

12           CHAIRPERSON MONSEES: Does that give you the  
13 guidance that you need?

14           MR. McCROHAN: Yes.

15           DR. SICKLES: I agree with that completely. The  
16 only thing that I didn't hear is can you provide the FDA  
17 some guidance as to which types of repairs would be subject  
18 to this. Obviously, replacement of the tube is a major  
19 repair, but what happens if they have to change a rheostat,  
20 that kind of thing.

21           MR. PIZZUTIELLO: Certainly the most important  
22 repair besides x-ray tube are automatic exposure control,  
23 but a very frequent repair to the automatic exposure control  
24 is a very minor one, where they recalibrate, what we call  
25 recalibrating the phototimer. What used to be minus 1 is

1 now zero.

2 I think that that doesn't require a medical  
3 physicist to come out if the facility does a phantom and  
4 they talk with their physicist, that should be just  
5 perfectly fine, and, in fact, usually, that recalibration  
6 happens in consultation with a physicist.

7 But if there is a more significant AEC rework, if  
8 a new board is put in or if there is a major recalibration,  
9 then, that should be tested, anything where the filter may  
10 be impacted, and that can even include changing the light  
11 bulb on some machines is the opportunity for the filter to  
12 be damaged or to produce an artifact in subsequent images.

13 So, that is an area where we have occasionally  
14 found problems creep in, so certainly changing the filter,  
15 AEC, x-ray tube, if the AEC sensor is changed, on a rare  
16 occasion that has happened. Other than that, if I come up  
17 with any other ideas, I will write you a letter.

18 MR. McCROHAN: Thank you.

19 CHAIRPERSON MONSEES: We may have another idea  
20 here.

21 DR. HENDRICK: We addressed this some time ago  
22 through the ACR Quality Assurance Committee, and I think the  
23 plan is to put a list of some of these things in the QC  
24 manual for medical physicists, so equipment changes and  
25 appropriate tests to do after them, and that all gets run by

1 the FDA before it gets published, so hopefully, we will be  
2 on the same track here.

3 CHAIRPERSON MONSEES: Very good. We will be on  
4 the same wavelength.

5 MR. McCROHAN: Very good.

6 CHAIRPERSON MONSEES: Some of these things  
7 certainly you don't need answers to because they have been  
8 covered, but I am going to give you a crack. How about  
9 another seven minutes or something like that tops?

10 MR. McCROHAN: Okay.

11 CHAIRPERSON MONSEES: And we are done. You don't  
12 have to go in order. What is your next wish?

13 MR. McCROHAN: I would like to address sort of 6  
14 and 7 in concert, and those relate to the evaluation of  
15 continuing experience and continuing education. As someone  
16 pointed out earlier, there is a fair amount of time spent in  
17 looking at records in those two areas, and will be an  
18 increasing amount of time given that it won't just be  
19 interpreting physicians anymore, that it will have to meet  
20 both of those kinds of requirements, but also radiologic  
21 technologists and medical physicists, and I would be  
22 interested in the committee's views of which of those two  
23 things is of greater importance in sort of the cosmic scheme  
24 of things, what your advice would be about the level of  
25 importance we attach to those requirements, say, as opposed

1 to the initial requirements or things outside the personnel  
2 area.

3 CHAIRPERSON MONSEES: The questions are, for those  
4 in the audience who don't have a copy, should MQSA  
5 inspectors check the continuing experience requirements and  
6 the continuing education requirements every year. Who wants  
7 to answer this? Dr. Sickles, should they do this every  
8 year?

9 DR. SICKLES: This is a matter of opinion. If you  
10 are going to cut back on this, I would suggest, number one,  
11 that the things to target your cutting back on are, number  
12 one, people who already were assessed previously, and  
13 especially people who were assessed -- not new people -- but  
14 people who were already assessed previously, that were found  
15 to be in compliance for, say, two years in a row.

16 That would make the most sense. Now, assuming  
17 that you would have those records, because you are doing  
18 these ongoing surveys, your software might even be able to  
19 tell the inspector these are the people that you have to  
20 look at because these other ones were okay last year, and  
21 they were okay the year before, so you can skip them for one  
22 year. That is what I would recommend.

23 CHAIRPERSON MONSEES: Any other? Yes, Mr.  
24 Fletcher.

25 MR. FLETCHER: You had mentioned the time that is

1 being consumed during an inspection, is it so significant  
2 that we really need to look at this? I am always reluctant,  
3 especially in a relatively new program, to start changing  
4 some of the parameters before it really has a good  
5 grounding, and we are still early in the whole inspection  
6 scheme. I am a regulator at heart. If it's not broke, I  
7 don't think you should fix it.

8 MR. McCROHAN: I agree that we are fairly early  
9 and certainly we are a year early even from the effective  
10 date of the final regulations. I don't think we would be  
11 envisioning doing anything for some period of time after  
12 that, but as I mentioned earlier today, there is some  
13 consideration that we need to give to this issue given the  
14 advice we received from Senator Mikulski in the passage of  
15 the Senate reauthorization bill last fall, and there is  
16 certainly going to be some discussion on these kinds of  
17 points I think at the House reauthorization hearing later  
18 this week, where the focus may, in fact, be more on how  
19 often we inspect as opposed to how comprehensively we  
20 inspect.

21 I think those are in some sense two sides of the  
22 same coin, and I take Dr. Sickles' point that if we are  
23 talking about basing this on prior performance of  
24 facilities, whether we choose to select certain things to  
25 look at every other year or we actually give facilities

1 inspections every other year, it ought to be based on  
2 performance.

3 I think the point that I was interested in is  
4 since the continuing experience requirement is averaged over  
5 two years, and continuing education is averaged over three  
6 years, certainly, in the past we have looked at those kinds  
7 of issues every year, so that there is kind of a moving  
8 window, if you will, if we were to look at those things on a  
9 biennial or triennial basis, then, there is certainly the  
10 possibility that there would be some brief periods of time  
11 because the inspections aren't absolutely split up, that we  
12 would not be assessing whether or not a person was sort of  
13 in compliance, but I am not sure that that is a major  
14 problem given the resource commitment.

15 We don't know precisely how much of the time is  
16 devoted for this. We don't have the ability to subdivide  
17 how much of the six hours is devoted to various parts of the  
18 inspection at least at the moment.

19 CHAIRPERSON MONSEES: I was going to end it here.  
20 Tomorrow, we begin at 8:00 a.m. We will be starting with  
21 mammographic collimation updates, States as Certifiers  
22 update, and then we will move to voluntary stereotactic  
23 accreditation programs, presentation and update,  
24 interventional mammography, and then we can complete  
25 discussion of any agenda items or issues that we would like

1 to do at that time.

2 See you at 8:00 a.m. Is there any other important  
3 information I need to tell people?

4 DR. FINDER: The only other thing I would say is  
5 that if you have any written comments or any other thoughts  
6 about guidance that we don't get to discuss either today or  
7 tomorrow, just leave them with us and we will look at them.

8 CHAIRPERSON MONSEES: Thank you for your  
9 attention. We are adjourned. See you at 8:00 a.m.

10 [Whereupon, at 5:37 p.m., the meeting was  
11 adjourned, to reconvene at 8:00 a.m., Tuesday, May 5, 1998.]

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**C E R T I F I C A T E**

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

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

**THOMAS C. BITSKO**