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AT

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

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE  
ADVISORY COMMITTEE

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

Wednesday, August 22, 2001

9:05 a.m.

Gaithersburg Holiday Inn  
Two Montgomery Village Avenue  
Gaithersburg, Maryland

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Charles Finder, M.D., Executive Secretary

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P R O C E E D I N G S

1  
2 MS. HARVEY: Good morning and welcome to  
3 this meeting of the National Mammography Quality  
4 Assurance Advisory Committee. We welcome you.

5 Dr. Finder.

6 **Conflict of Interest Statement**

7 DR. FINDER: I would like to begin this  
8 part of the meeting by reading the conflict of  
9 interest statement.

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

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

25 Therefore, waivers from full participation

1 in general matters that come before the committee  
2 have been granted for certain participants because  
3 of their financial involvement with facilities that  
4 will be subject to FDA's regulations on mammography  
5 quality standards, with accrediting, certifying, or  
6 inspecting bodies, with manufacturers of  
7 mammography equipment, or with their professional  
8 affiliations since these organizations could be  
9 affected by the committee's deliberations.

10           These individuals are: Carolyn  
11 Brown-Davis, James Camburn, Nancy Ellingson,  
12 Maryanne Harvey, Amy Rigsby, and Drs. Kambiz  
13 Dowlath, Jessica Henderson, Debra Ikeda, Andrew  
14 Karellas, Amy Lee, Robert Nishikawa, Etta Pisano,  
15 Catalina Ramos-Hernandez, and Donald Young.

16           Copies of the waivers may be obtained from  
17 the Agency's Freedom of Information Office, Room  
18 12A-15 of the Parklawn Building.

19           Several of our members also reported that  
20 they receive compensation for lectures they have  
21 given or will give on mammography related topics,  
22 however, they have affirmed that these lectures  
23 were offered because of their expertise in the  
24 subject matter, and not because of their membership  
25 on the committee.

1 In the event that the discussions involve  
2 any other matters not already on the agenda in  
3 which an FDA participant has a financial interest,  
4 the participant should excuse him or herself from  
5 such involvement and the exclusion will be noted  
6 for the record.

7 With respect to all other participants, we  
8 ask in the interest of fairness that all persons  
9 making statements or presentations disclose any  
10 current or previous financial involvement with  
11 accreditation bodies, States doing mammography  
12 inspections under contract to FDA, certifying  
13 bodies, mobile units, breast implant imaging,  
14 consumer complaints, and mammography equipment.

15 MS. HARVEY: Thank you, Dr. Finder.

16 I think I would ask first that we all give  
17 our name and a little bio, so that we will know  
18 each other a little better as we begin our day.

19 Dr. Lee, would you begin, please.

20 DR. LEE: My name is Amy Lee. I  
21 originally started out as an ob-gyn, but currently  
22 my specialty is public health and general  
23 preventive medicine. I am currently the program  
24 director for the Northeastern Ohio University's  
25 Master of Public Health Program and also an

1 administrator for a local breast and cervical  
2 cancer project.

3 DR. DOWLAT: I am Kambiz Dowlat. It says  
4 Dowlatshahi, but everyone knows me by Dowlat. I am  
5 a surgeon in Rush University in Chicago. My  
6 expertise is in stereotactic, and I was just  
7 telling Dr. Finder there is hardly anything on the  
8 agenda on the stereotactic, but nevertheless, that  
9 is an area that I have been involved for the past  
10 15 years. I spend most of my practice in the  
11 diagnosis and treatment of breast cancer.

12 DR. IKEDA: I am Debra Ikeda from Stanford  
13 University in Stanford, California. I am an  
14 Associate Professor, and I am Director of Breast  
15 Imaging at Stanford University. I am a  
16 radiologist.

17 MS. ELLINGSON: I am Nancy Ellingson. I  
18 am a radiologic technologist. I have been involved  
19 with mammography 40 years in one form or another.  
20 I am currently a program reviewer for continuing  
21 education at the American Society of Radiologic  
22 Technology. I have served on both Oregon and New  
23 Mexico licensure boards, so I kind of come at this  
24 from several different perspectives. My contact is  
25 with the mammographers and helping them with

1 understanding our compliance with our regulations.

2 MS. BROWN-DAVIS: Good morning. I am  
3 Carolyn Brown-Davis. I am a consumer  
4 representative on this board. I am an eight-year  
5 survivor twice of breast cancer, and I am also the  
6 Executive Director of an organization called Breast  
7 Cancer Resource Committee. We are an advocacy  
8 group for African-American women diagnosed with  
9 breast cancer. Thank you.

10 MS. RIGSBY: I am Amy Rigsby. I have been  
11 a radiological technologist for 23 years and a  
12 dedicated mammographer for 16 years. Presently, I  
13 am a technical director at the Rose Breast Imaging  
14 Center in Houston, Texas.

15 DR. HENDERSON: My name is Jessica  
16 Henderson. I am a consumer representative. I was  
17 diagnosed with breast cancer seven years ago. In  
18 the meantime, I have just finished a Ph.D. in  
19 Public Health. I am a facilitator for the Corvales  
20 Breast Cancer Support Group.

21 DR. KARELLAS: I am Andrew Karellas. I am  
22 a medical physicist specializing in x-ray imaging  
23 and in mammography. I am also Professor of  
24 Radiology at the Department of Radiology at the  
25 University of Massachusetts Medical School.

1 DR. PISANO: I am Etta Pisano. I am  
2 Professor of Radiology at the University of North  
3 Carolina, and I am Chief of Breast Imaging.

4 MR. CAMBURN: I am Jim Camburn. I am  
5 Chief of the Radiation Control Program in the State  
6 of Michigan. We oversee approximately 10,000  
7 different x-ray facilities, 350 of them are  
8 mammography facilities, and our staff is  
9 responsible for inspecting them all, both under  
10 MQSA standards and under independent State  
11 standards, as well.

12 DR. RAMOS-HERNANDEZ: I am Catalina Ramos,  
13 a consumer representative. I work for the National  
14 Breast Cancer Organization. Previously, I was  
15 trained as a medical doctor and I have worked in  
16 the area of patient advocacy for the last 15 years.

17 DR. YOUNG: I am Don Young. I am from  
18 Iowa City, Iowa, former Professor of Radiology and  
19 Director of the Breast Imaging and Diagnostic  
20 Center at the University of Iowa Hospital. I have  
21 had a quarter century interest in mammography and  
22 in-depth involvement, actually was project director  
23 of one of the early VCDDPs.

24 DR. FINDER: I am Charles Finder. I am  
25 the Executive Secretary of this committee. I am

1 also a radiologist and the Associate Director for  
2 the Division of Mammography Quality and Radiation  
3 Programs at the FDA.

4 MS. HARVEY: I am Maryanne Harvey. I am  
5 the Chief of the Radiation Equipment Section and  
6 Secretary to the Board of Radiologic Technology of  
7 the New York State Department of Health.

8 My mother has had breast cancer, as has  
9 one of my aunts, and so I have interest from both a  
10 personal and a regulatory in mammography for over  
11 15 years.

12 I am pleased to welcome everyone and to  
13 get to know you better.

14 Now, I think we will move into Committee  
15 Business.

#### 16 Committee Business

17 DR. FINDER: This is Dr. Finder again. I  
18 am going to pass around these sheets of paper,  
19 asking all the members on the committee to give me  
20 their latest mailing address, phone numbers, fax,  
21 and especially e-mail because we have been having  
22 problems getting some of the materials out to you  
23 by fax, and I would like to try and do it by  
24 e-mail.

25 In addition to the committee members, I

1 would ask any of the federal liaisons out in the  
2 audience and also the AV reps if they could give me  
3 the same information because again, I am going to  
4 try and send out all the preliminary information  
5 now by e-mail instead of by fax or even by mail.

6 MS. HARVEY: I would ask each of us to say  
7 our name, state our name before we begin to speak  
8 to help with the transcription of the meeting  
9 today.

10 The next item on our agenda is the  
11 Alternative Standards Requests. Dr. Finder, do we  
12 have any?

13 **Alternative Standards Requests**

14 DR. FINDER: The short answer is no, but  
15 let me go through a little bit of background on  
16 this. FDA may approve an alternative to a quality  
17 standard under the regulation Section 900.12 when  
18 the Agency determines that the proposed alternative  
19 standard will be as least as effective in assuring  
20 quality mammography as the standard it proposed to  
21 replace and the proposed alternative is too limited  
22 in its applicability to justify an amendment to the  
23 standard, or it offers an expected benefit to human  
24 health that is so great that the time required for  
25 amending the standard would present an



1 Inspection Support Branch with the Division of  
2 Mammography Quality and Radiation Programs with the  
3 FDA.

4 [Slide.]

5 This morning I would like to give you a  
6 little overview of the MQSA program from day one  
7 and conclude with where we are today and where we  
8 hope to go.

9 [Slide.]

10 First, I will give a little, brief  
11 background about the history of MQSA and then I  
12 want to discuss the finding levels from a  
13 historical point of view, that is, from the first  
14 time we started conducting inspections.

15 Then, I want to concentrate on the Level 1  
16 and Level 2 findings, the highest findings, and I  
17 want to concentrate on the last couple of years  
18 under the final regulations. Then, I will conclude  
19 briefly with a couple of programs that are  
20 underway.

21 [Slide.]

22 As you all know, MQSA was enacted into law  
23 in October 1992 by the U.S. Congress, and authority  
24 to execute the program was delegated to the FDA  
25 sometime in 1993. The Interim Regulations then

1 were published in December of 1993 and they became  
2 effective in February of 1994, and MQSA was then  
3 ready to go for mammography starting October 1,  
4 1994. So, that is the background.

5 Later on, of course, the Final Regulations  
6 were published in 1997, October, and they became  
7 effective for the most part, most of the  
8 requirements were effective on April 28, 1999.

9 In the meantime, also, before they became  
10 effective, MQSA was reauthorized by Congress and  
11 signed into law in October 1998. A couple of  
12 things came into being as a result of the  
13 reauthorization, and that is, the lay summary must  
14 be sent to all women, not just the ones that are  
15 self-referred as under the interim regs.

16 It also dictated the release of the  
17 original mammograms whether temporary or permanent  
18 upon request by the patient, and the third item  
19 that came in there was the demonstration program,  
20 or it stated that the Secretary of Health and Human  
21 Services may institute a program to inspect  
22 facilities at a frequency of less than annual.  
23 There will be talks about this later.

24 [Slide.]

25 Before we talk about inspection findings,

1 I need to tell you what the inspection actually  
2 entails, so this slide shows you the inspection  
3 scope. I have divided it into several sections  
4 here to just give you a little perspective.

5 The first is the equipment performance  
6 section whereby the inspector goes in and performs  
7 some tests on the unit and the processor in the  
8 facility and the darkroom. So, these include dose,  
9 phantom image, quality, processing, and darkroom  
10 fog.

11 Typically speaking, this takes under an  
12 hour for a facility with one unit. The rest of the  
13 inspection is basically a records review, and it  
14 starts with quality assurance records and quality  
15 control test records, and these include the  
16 non-annual tests that are done by the facility, as  
17 well as the annual survey report and the annual  
18 reports of the equipment evaluations that are done  
19 by the medical physicists.

20 It also includes the review of the  
21 consumer complaint mechanism records or policy at  
22 the facility, and then followed by personnel  
23 qualifications, medical reports, and lay summaries,  
24 medical outcomes audit. All these are record  
25 reviews to make sure the facilities are doing their

1 job.

2 [Slide.]

3 Again, before we talk about finding  
4 levels, I need to tell you what the levels are, and  
5 we start with Level 1. That is the most serious  
6 finding at any facility. Typically speaking, when  
7 a facility gets a Level 1, it is followed by a  
8 warning letter within 15 days from the FDA District  
9 Office, and it also requires a subsequent facility  
10 response also within 15 days.

11 The next level is also serious, but we  
12 call it moderately serious, if you will, and if a  
13 facility gets Level 2 as the highest finding, then,  
14 it is incumbent upon them to respond to the FDA  
15 within 30 days to tell us how they are going to fix  
16 the problems.

17 Level 3 findings are classified as minor  
18 findings, which are nice to have, and we normally  
19 ask facilities to check on them, to fix them as  
20 soon as possible, of course, but we, in practice,  
21 we don't really follow up until the next  
22 inspection.

23 [Slide.]

24 With that in mind now, we can talk about  
25 some actual inspection results. This slide shows

1 you a history of facilities cited with the highest  
2 level of findings as listed in the slide. There  
3 are several columns for L1, meaning Level 1, L2,  
4 L3, and then No Findings meaning clean record.

5           The slide goes by fiscal year starting in  
6 '95, and I need to tell you that the first  
7 inspection was conducted actually January 15 of  
8 1995, so '95 was not the full year, it was more  
9 like three quarters, a little under three quarters  
10 of a year.

11           After that, of course, we go on all the  
12 way to Fiscal Year 01, which is now, and this  
13 slide, of course, is truncated here because we have  
14 not finished with 01 yet, so this goes only to  
15 7-31, so about 10 months under the Final  
16 Regulations here in 01.

17           If you look at the slide, if you look at  
18 the column where it says No Finding, you will see  
19 that the first year we started with 30 percent of  
20 the facilities having a clean record and then from  
21 there on, in general, it went up, which is a good  
22 sign, and if you look under all the other columns,  
23 you will that, in general, okay, I am going to say  
24 in general, they go down which is what we want.

25           Now, let's look at the next slide because

1 then I can talk to each of these probably better on  
2 the graph.

3 [Slide.]

4 This graph depicts exactly what that other  
5 slide was. On top, you see the No Finding in the  
6 white line. The No Findings here means the number  
7 of facilities that have been found with nothing at  
8 all has been going up, and right here, in 1999, it  
9 basically leveled off, and then we took a little  
10 dip in 2000, and then we are back up here.

11 I will explain what happened here in 1999  
12 and 2000. Level 3, which is the sort of green line  
13 here, started at about 40-some percent, and then  
14 went down, continued to go down, which is about 10  
15 percent right now.

16 Level 2, it started at about 20 percent,  
17 went down, and in 1997, it sort of leveled off a  
18 little bit, and then in 1998, went up, in 1999 it  
19 went up. First of all, I want to tell you what  
20 happened. In 1997, you know, we had some  
21 requirements for the technologists at the time,  
22 that the continuing experience was no longer  
23 acceptable. In '96, by the time you got inspected,  
24 many technologists did not meet the training  
25 requirements, so that provided a little hesitation

1 in the curve, if you will.

2 In 1998, the biggest contributor to the  
3 rise there was the fact that the continuing  
4 education requirements for all personnel kicked in,  
5 kicked in three years after MQSA went into effect,  
6 which was 1997, October, so the subsequent year was  
7 Fiscal Year '98, and that is where you see the jump  
8 in Level 2 findings here.

9 1999 is a different story altogether.  
10 1999 is a composite year, if you will. About three  
11 quarters of 1999 was under the Interim Regs, and  
12 then the last quarter was under the Final Regs.

13 [Slide.]

14 This is a summation of Level 1 findings  
15 over the span of six years or so. Again, you can  
16 see the coming down and in '99, we picked up a  
17 little bit as a total result, and then 2000, and  
18 now we are backing down here, so the trend is  
19 starting to come down.

20 [Slide.]

21 This is a similar slide for only Level 2  
22 findings. Again, we are coming down here, and this  
23 is the slight increase in 1997, 1998, and then  
24 1999, and then, of course, after 1999, we are  
25 talking about Final Regs here, the last two years.

1           Again, this is a percentage of facilities  
2 where the highest finding is Level 2.

3           [Slide.]

4           This is the details of what happened in  
5 Fiscal Year '99. Again, the first line is the year  
6 in total meaning mixture of Interim and Final Regs,  
7 and this is the percentage of facilities cites at  
8 these levels.

9           If you look at the first three quarters,  
10 you will see that the levels again continued to go  
11 down here from the previous time, however, the  
12 Final Regs, when they went into effect, the last  
13 quarter was a jump both here and here, and a  
14 decrease in Level 2 and in Level 3. Of course, at  
15 the same time, the total number of facilities with  
16 no findings has come down a little bit, as well.

17           [Slide.]

18           This is 1999. It is a quarter by quarter,  
19 and you can see under the Interim Regs, we  
20 continued to go down. This is Level 1 findings, by  
21 the way. We continued nicely to go down until the  
22 Final Regs kicked up.

23           [Slide.]

24           Now, I want to talk about what happened  
25 when the Final Regs went in. I want to talk about

1 the level changes and the subsequent findings, and  
2 where we go from here.

3 [Slide.]

4 In anticipation of application of the  
5 Final Regs, the Working Committee of the Conference  
6 of Radiation Control Program Directors, the CRCPD,  
7 and with input from the inspectors, with input from  
8 the States basically, and the National Mammography  
9 Quality Assurance Advisory Committee, your  
10 predecessors basically, as a result, we added, of  
11 course, some new requirements. These were dictated  
12 by the fact that the Final Regs were there, we had  
13 to do that.

14 That means we had new findings at all  
15 levels. That increased the number of findings in  
16 the first place, potential findings. We also  
17 elevated several Level 3 and Level 2 findings. By  
18 "elevated," I mean we raised the bar, so we made  
19 some of those Level 3 under the Interim Regs, we  
20 made them to Level 2's, set Level 2's also up to  
21 Level 1. At the same time, we deleted a few Level  
22 3 findings.

23 So, as a result, the total potential  
24 findings at Level 3 decreased, and those at Level 2  
25 and Level 1 did increase. So, that is a natural

1 consequence, you can't do anything about it.

2 [Slide.]

3 To put this quantitatively, this slide  
4 shows you the number of potential findings both the  
5 Interim Regs, in the first three bars, and then  
6 under the Final Regs, you can see with the color  
7 coding that both Level 1 and Level 2 went up, and  
8 Level 3 went down.

9 [Slide.]

10 The next few slides I am going to show you  
11 some details of Level 1's and Level 2's for each of  
12 the Fiscal Years 00, 00, and 01.

13 This is of 2000. You can see overall, the  
14 dashed line is about 3.9, is the total for the  
15 year, but on a quarter-by-quarter basis, you can  
16 see how these findings did change. So, you can see  
17 quarter-by-quarter, we are going down here.

18 [Slide.]

19 This is a similar slide for Level 2  
20 findings, Level 2 has continued to go down until  
21 about the end of the year, I think we were about 30  
22 there.

23 [Slide.]

24 This is 01, the current fiscal year, going  
25 down here again with minor perturbations, if you

1 will. The total for the year so far is 3.5.  
2 Again, this is to the end of July only, so the last  
3 bar is not a full quarter, it is only one month  
4 actually.

5 [Slide.]

6 The same thing for Level 2.

7 Notice here in Q3 and particularly in Q4,  
8 the Level 2 findings here just jumped up. Now,  
9 there is a reason for that, too. Every time a new  
10 requirement kicks into effect, the facilities don't  
11 react right away and behave themselves, so we find  
12 things go up.

13 So, what happened here, in the fourth  
14 quarter, this is the first month the continuing  
15 requirements for the physicists and the  
16 technologists went into effect, so we have some  
17 citations.

18 [Slide.]

19 To give you an idea of what is  
20 contributing the most to these Level 1's and Level  
21 2 findings, I summarized this for you. The first  
22 line is the total of Level 1 findings, that is, the  
23 number of facilities cited, 245, the total is 3.5  
24 percent. By the way, this data is taken to July  
25 2nd, so effectively, it is three quarters of the

1 fiscal year of 01.

2           The majority of citations at this level  
3 are the processor or the phantom QC. The reason  
4 for that again is because we raised the bar here,  
5 intentionally raised the bar based on input from  
6 the States, the inspectors, and NMQAAC.

7           The second item was results communication  
8 to the patients. Again, here, although this was a  
9 requirement before, what went in differently was  
10 the fact that the summary has to be sent to all  
11 patients, facilities didn't know exactly how to  
12 conform to that, if you will, and a lot of them  
13 were not used to the idea that a summary has to be  
14 sent to all patients, so as a result, this is a  
15 major contributor at this point.

16           The third item is the initial  
17 qualifications for any personnel. That has now  
18 become a third citation, third component.

19           I need to tell you here that what we are  
20 talking about is the lack of documentation on the  
21 part of personnel. We have never actually found,  
22 perhaps with the exception of one or two, any  
23 personnel not really qualified to do their job. It  
24 is just they never provided the documents to prove  
25 that, and that is what this is all about here.

1           The rest of Level 1's are minor. As you  
2 can see, there are under 9 altogether, some of them  
3 vary from the lack of a valid certificate,  
4 certificate would have expired and the facility  
5 would continue practice, you know, using an  
6 unaccredited unit in over a year, et cetera. They  
7 are listed down there, but they are really minor  
8 total numbers.

9           [Slide.]

10           This slide shows again a similar  
11 presentation, but for Level 2 findings. Here, of  
12 course, the total percentage is 27.6 of all  
13 facilities, and the actual number is about 1,900  
14 facilities.

15           Again, the biggest contributor is  
16 processor or phantom QC. The next one is personnel  
17 qualification requirements at Level 2. What that  
18 means is we have things like continuing education,  
19 continuing experience requirements for all  
20 personnel is Level 2. Some of the initial  
21 requirements are also at Level 2, like initial  
22 experience, the training for the technologists, and  
23 experience and training for the physicists are all  
24 initial qualifications, but they are still Level 2.

25           The third item is medical reports without

1 results or ID, identification of the interpreting  
2 physician, and this is mostly here the results are  
3 there, but they are not put in the prescription as  
4 dictated by the Final Regs, that is, they did not  
5 put down one of the six categories, so facilities  
6 are still having a hard time living up to that.

7           The rest of them are listed - medical  
8 outcomes, audit system is next, and then there is a  
9 listing on the survey report and mammography  
10 equipment evaluations, about 300 there, and this  
11 could mean any number of things, like time span  
12 between two surveys exceeded 14 months, that is a  
13 Level 2. If some of the tests that are supposed to  
14 be done by the physicists were not done or  
15 incomplete, again, it could be Level 2, et cetera.

16           The next two items are the fact that the  
17 facility did not have a consumer complaint policy  
18 or no center operating procedures for infection  
19 control. The rest are minor really.

20           [Slide.]

21           Now, when you take all that combined with  
22 our experience, and knowing that eventually, if you  
23 take the analogy to the Interim Regs, when MQSA  
24 came out first, we had 2.6 Level 1 citations the  
25 first year, but then within a year, it dropped to

1 1.6, and then continued to drop after that.

2           So, our experience plus extrapolation of  
3 the data over the last two years indicates to us  
4 with some confidence that in the foreseeable future  
5 maybe we expect the percentage of facilities with  
6 Level 1 citations to drop to below 2.5 percent, and  
7 those with Level 2 citations to drop below 25  
8 percent. Level 3 citations, right now it is  
9 hovering around 10. It may or may not drop much  
10 below that.

11           If you add all this up, of course, that  
12 leaves you with about 62 or so percent of  
13 facilities with no finding whatsoever. Now, this  
14 is our projection perhaps for the next year. Where  
15 we go from there, I mean we are hoping obviously  
16 that things will continue to improve, but it's  
17 anybody's guess.

18           [Slide.]

19           What we have underway is the Demonstration  
20 Program, and there will be a special talk on that  
21 later this afternoon, so I am going to briefly just  
22 tell you that it is scheduled to start next May,  
23 and there will be about 300 eligible facilities  
24 involved in the program from 14 States all  
25 together, and half of these, of course, will

1 undergo the biannual inspection once every two  
2 years, and then the other will be used as a control  
3 group. It will be interesting to see how that  
4 turns out.

5           The other program that went into effect is  
6 the new modality, that is, the Full-Field Digital  
7 Mammography. It is only GE right now with their  
8 Senographe 2000D that has been approved since  
9 January of 2000. By the way, your hardcopy may say  
10 6, so please correct that typo there.

11           Now, we expect some other companies to get  
12 approval in the near future, but again I can't put  
13 a date on that. So far, it is relatively still a  
14 small number of facilities and units around the  
15 country using the Senographe 2000D. We have not  
16 cited anyone yet. What we have done is asked the  
17 inspectors to check to make sure that the  
18 facilities are following the QC procedures as  
19 recommended by the manufacturer in this case GE.

20           The only thing that we have implemented  
21 that will trigger a citation regarding a new  
22 modality is the training, 8 hours training in the  
23 new modality, and we have gotten a very small  
24 number of those.

25           I believe that is it. Thank you very

1 much. Sorry for all the coughing interruptions  
2 here, but I can still handle some questions, if you  
3 like.

4 MS. HARVEY: Any questions?

5 [No response.]

6 MS. HARVEY: Thank you, Dr. Mourad.

7 DR. MOURAD: Thank you.

8 MS. HARVEY: I see that we are scheduled  
9 for a break, however, we are ahead of schedule.  
10 Perhaps, if that is all right with you, Dr. Finder,  
11 we will move ahead with the agenda and have a break  
12 a little later.

13 The next item is the Appropriateness of  
14 Current Inspection Follow-up Actions with our  
15 Committee Discussion.

16 **Appropriateness of Current Inspection**

17 **Follow-up Actions**

18 **Charles Finder, M.D.**

19 DR. FINDER: As a lead into this  
20 discussion, I wanted to focus the committee's  
21 attention on the following and get their opinions  
22 on this.

23 Under our current system of inspection  
24 finding follow-up, Level 1 inspection findings  
25 result in the generation of a warning letter from

1 FDA and a response from the facility within 15 days  
2 of receipt of that warning letter.

3 To streamline the process for responding  
4 to Level 1 inspection findings, FDA is proposing to  
5 modify the current system. We are proposing that  
6 instead of issuing a warning letter for all Level 1  
7 findings, facilities would be told that they have  
8 15 days to respond in writing to the FDA. This  
9 would be similar to the way that Level 2 findings  
10 are currently handled in which facilities have a  
11 30-day response time.

12 Warning letters could then be reserved for  
13 those cases where the facility's correction action  
14 was deemed not to be effective or timely, and FDA  
15 is asking the committee's comments on this  
16 proposal.

17 Does anybody have any comments, questions?

18 DR. PISANO: Could you just summarize  
19 again? It is basically getting rid of the warning  
20 letter, is that the main change?

21 DR. FINDER: Let me again briefly go over  
22 how the system works right now. If a facility is  
23 found to have a Level 1 citation, a warning letter  
24 is pretty much automatically generated. When the  
25 facility gets that warning letter, they have 15

1 days to respond.

2           If they generate a Level 2 currently, at  
3 the time of the inspection, that report is left  
4 with the facility. They have 30 days from that  
5 time to send a written request. What we are  
6 proposing is to change the Level 1 so it is closer  
7 to what the Level 2 is, so that at the time of the  
8 inspection, when the inspector leaves the report,  
9 the facility has 15 days to respond.

10           At that point, if the response is deemed  
11 inadequate, then, a warning letter would be  
12 generated. What we are trying to do is make this  
13 system more efficient and more responsive to the  
14 conditions that are found in the facility.

15           I will say that it is not uncommon for  
16 certain citations to find out that when the  
17 facility responds, that there is really no  
18 violation in terms of quality.

19           To give you an example, we do have a  
20 number of Level 1 citations for personnel for  
21 initial qualifications, and generally, when the  
22 facility responds, they respond with the  
23 documentation that shows that the person is  
24 qualified, it turns out it is merely a  
25 documentation issue. So, what we are trying to do

1 is eliminate those type of warning letters because  
2 they go out first under the current system.

3 So, that is what we are talking about, and  
4 we would like opinions and comments - should this  
5 be a general thing, should it be restricted to  
6 certain citations, things like that.

7 DR. YOUNG: The effect then would be to  
8 shorten the time to cure.

9 DR. FINDER: Right. Actually, that is one  
10 of the byproducts of this. We expect that we would  
11 actually get quicker responses and quicker  
12 corrections to these things than we have under the  
13 current system.

14 DR. KARELLAS: It sounds like a very  
15 reasonable approach, and it will avoid people  
16 having a warning letter, as you say, that later is  
17 found out that they may not have been in essential  
18 violation, although technically, they might be, so  
19 it sounds very reasonable.

20 MS. HARVEY: Are there any of the Level 1  
21 violations that might be of such a serious nature  
22 that we could have a two-tiered approach to some of  
23 the violations?

24 DR. FINDER: That is certainly reasonable,  
25 and we have considered that. One area that I think

1 we would want to issue a warning letter immediately  
2 is the case of a Level 1 phantom failure.

3           The reason for that is before we issue  
4 those, we generally have a verification process  
5 that checks those phantom images, so that those  
6 tend to be real, and we would want to proceed with  
7 further actions on that, so I think that is  
8 certainly one.

9           If there are others that people are aware  
10 of, I can quickly go through a list of some of them  
11 if the committee wants me to and if they feel that  
12 they should have an automatic warning letter on  
13 these types of things, we certainly can consider  
14 that if anybody wants.

15           DR. PISANO: The main question I have is  
16 how well informed the sites are about their  
17 violations when they leave, when the inspector  
18 leaves. I don't know if that is variable from  
19 State to State or pretty uniform across all States,  
20 because clearly then if you don't send a warning  
21 letter immediately, you open yourselves to concerns  
22 or complaints of not knowing that they had a Level  
23 1 violation.

24           DR. FINDER: That is a very good point. I  
25 think some of that will be addressed in a later

1 presentation where we have the facility survey that  
2 we did where we actually query the facilities on  
3 what they are told, what they think about the  
4 inspection, and those type of issues.

5 But obviously, the fact that those reports  
6 are left with the facility is notification of the  
7 citations that did occur during the inspection.

8 DR. PISANO: So, that is happening in all  
9 States is what you are saying. They are given a  
10 written document that tells them they are Level 1.

11 DR. FINDER: Generally speaking, most  
12 inspectors leave the report, because they have  
13 laptop computers that they take there with them,  
14 with printers, so they can actually generate a  
15 report in most cases.

16 Now, occasionally, they won't do that,  
17 they will send it in later, but even in those cases  
18 where they send the official report at a later  
19 date, they inform the facility. They have an exit  
20 interview where they tell the facility exactly what  
21 was found at the inspection, so they are aware of  
22 what is going on.

23 DR. PISANO: Who is generally at the exit  
24 interview?

25 DR. FINDER: Good question. Basically, it

1 is the inspector going over the results with the  
2 people that are available. They try and get the  
3 most responsible person at the facility. It is a  
4 question of who is available at the time, though,  
5 so it is variable.

6 DR. PISANO: I am just concerned about any  
7 oral communication instead of written communication  
8 because clearly, even if they are told they very  
9 explicitly, they can always say later that they  
10 didn't hear what the report said. So, if you do  
11 have to delay a written communication, it seems to  
12 me you need to create some mechanism where if there  
13 is a delay in that written communication, there has  
14 to be some confirmation that they heard.

15 DR. MOURAD: The inspectors do hand out  
16 certain documents, if you will, in writing, that  
17 are left with the facility. If it is a Level 1,  
18 they tell them you have got a Level 1, and this is  
19 what you are supposed to do, and if they get a  
20 Level 2, the same thing, so everything is there.

21 DR. PISANO: I don't mean to keep  
22 hammering on this point, but my concern is that if  
23 you don't have a letter that comes from the FDA, if  
24 there is nothing in writing, then, there could be a  
25 claim that they didn't hear the reports.

1           So, what I am suggesting is similar to  
2 what we are doing for patients, which is to provide  
3 maybe a sheet that is preprinted by FDA for the  
4 sites that can't print something up, that just  
5 allows them to check something off and sign, so  
6 that you know that they were handed a piece of  
7 paper, and they know about their Level 1 violation.

8           I am just concerned about something kind  
9 of falling through the cracks.

10           DR. FINDER: Let me just add again in the  
11 vast majority of cases, the full, complete  
12 inspection report plus how to respond to the  
13 inspection results are handed out to the facility.  
14 It is rare when they are not given the written  
15 results of the inspection. Usually, if there is a  
16 question, there is incomplete data, and the  
17 facility wants some extra time to bring this in,  
18 but usually, they get that written report then  
19 anyhow in a few days.

20           I hear your comments about it is a verbal  
21 communication and how that can be documented, and  
22 things like that. We can certainly look into that  
23 and deal with that.

24           DR. BARR: I am Helen Barr and the Deputy  
25 Director of the Division of Mammography Quality and

1 Radiation Programs.

2           One thing I wanted to mention is that in  
3 our very recent, this spring, facility satisfaction  
4 survey, we asked a question if facilities received  
5 citations, and if they did, did they understand the  
6 citations and how to respond, and I don't have my  
7 glasses on, but it looks like 96.7 percent  
8 understood their citations and how to respond to  
9 them.

10           Also, under general FDA workings, in all  
11 inspections, not just mammography inspections, but  
12 all other inspections that the Food and Drug  
13 Administration does, that the post-inspection  
14 report, which goes by other names in other  
15 inspections, but can legally serve as a written  
16 warning document, and does indicate the level on  
17 there.

18           DR. PISANO: I don't mean to keep  
19 hammering on this, but the concern I have, 96.7  
20 percent sounds great and it is wonderful, but the  
21 3.2 percent or however many are left are the ones  
22 that are going to give you problems, because those  
23 people, in a month or two, and they haven't  
24 responded, you end up moving to shut them down or  
25 whatever you are going to do with them, they will

1 file a lawsuit if you don't prove that you told  
2 them about the Level 1 violation, and that is what  
3 concerns me is the downstream consequences for the  
4 few dissatisfied people.

5 DR. BARR: As I just said, the inspection  
6 report serves as legal written documentation.

7 DR. PISANO: Okay, but it sounds like not  
8 every facility gets one at the exit interview, and  
9 that is all I am saying is for those facilities,  
10 they need a way to document that the communication  
11 took place.

12 I am thinking legally here because I do  
13 mammography every day, and I can tell you that we  
14 all think legally. You know, 100 percent is the  
15 only acceptable criteria.

16 DR. KARELLAS: Dr. Finder, you mentioned  
17 about notification. When you mention notification,  
18 I understand it to be written, so I agree with Dr.  
19 Pisano that verbal communication is not adequate,  
20 but the way I understood it is that it will be  
21 written. It will not come from the FDA, but it  
22 will be written by appropriate authorities.

23 DR. FINDER: Let me just clarify one  
24 thing. When we are talking about the inspectors  
25 leaving the inspection report, that is

1 documentation from FDA. They may be State  
2 inspectors, they may be Fda inspectors, but is part  
3 of the MQSA program, so that is our notification.

4           What I am trying to get at is that even in  
5 the cases where the reports are not left that day,  
6 they get it within a few days after that anyhow, so  
7 you are talking about a few days difference here,  
8 and I agree with you that verbal notification in  
9 and of itself is not sufficient.

10           I don't believe that in those few cases  
11 where it is not left that day, that there will be a  
12 problem in the sense that they are going to get  
13 that written report in a few days anyhow. Most of  
14 those times it is because the facilities and the  
15 inspectors have agreed to work out some issue, for  
16 example, that documentation wasn't present, but  
17 they could get it the next day, so they don't want  
18 to leave or generate a report like that. They will  
19 give them a day or two to do that.

20           MS. HARVEY: We have a comment from the  
21 audience. Please state your name.

22           MR. DEVINE: My name is Mike Devine. I  
23 work with the Division of Mammography Quality and  
24 Radiation Programs.

25           I wanted to address an issue which was

1 brought up about how we notify people, and FDA has  
2 a policy which applies across the board in terms of  
3 how we notify and how they get the documentation  
4 like the warning letter.

5 Our policy is that we try to send the  
6 warning letter to the most responsible person at  
7 the facility, and also the issue of taking  
8 regulatory action, that notification in advance is  
9 very critical, so I don't think there is ever going  
10 to be any kind of serious action taken against a  
11 facility unless they have had some warning in  
12 advance.

13 MS. HARVEY: Any other questions?

14 MR. CAMBURN: Maybe this has already been  
15 addressed. I just have a question on behalf of the  
16 MQSA inspectors out there. When they complete the  
17 inspection, are they going to be in a little more  
18 of a quandary about what the level is ultimately  
19 going to be, or will they still have the  
20 information to tell the facility you are at a Level  
21 1, and FDA, for this Level 1, is not going to give  
22 you a letter, or maybe you are a different type of  
23 Level 1, that is more serious, that you will get a  
24 letter, or are they just going to kind of throw up  
25 their hands and say, well, I am not sure exactly

1 what is going to happen?

2 DR. FINDER: If we go ahead with this,  
3 right now what happens is in addition to the  
4 inspection report, there is also a letter that goes  
5 with it that explains how to respond, how the  
6 facility should respond to the level of citation.

7 A similar type letter would be generated  
8 for this, so instead of the current letter that  
9 says that you will get a warning letter from FDA  
10 for your Level 1, and then you have to respond, it  
11 could say you have 15 days to respond in writing to  
12 FDA.

13 Now, if we decide that some Level 1's will  
14 get a warning letter and others won't, they will  
15 have the 15-day response, we will put that in that  
16 letter and clearly explain to the facility what  
17 their responsibilities are and how they are  
18 supposed to act, so the facility would know and the  
19 inspector would know.

20 DR. BARR: I would just like to say that  
21 this isn't a unique or novel idea for us. The  
22 Center for Devices and Radiologic Health is doing a  
23 warning letter pilot with the device manufacturers  
24 to give them 15 days to come up with a satisfactory  
25 corrective action plan, and then decide whether to

1 issue the warning letter.

2           The whole time frame, as Dr. Young  
3 mentioned, would actually we think be quicker than  
4 the current time frame where we are often getting  
5 Level 2 responses before we get Level 1 responses,  
6 and that is the whole idea behind it is to increase  
7 the correction response time and to decrease  
8 erroneous warning letters which don't need to be  
9 issued to the facility.

10           MS. HARVEY: Any other comments or  
11 concerns?

12           [No response.]

13           MS. HARVEY: I think not.

14           DR. FINDER: The next item on the agenda  
15 is lunch, but I think it is a little early for  
16 that.

17           MS. HARVEY: Perhaps we will move to Good  
18 Guidance.

19           DR. FINDER: Why don't we take a little  
20 break now?

21           MS. HARVEY: Okay. We will reconvene at  
22 10:15.

23           [Recess.]

24           MS. HARVEY: Now, we are going to be  
25 guided with Good Guidance Practices and Directions

1 for Discussion of MQSA Guidance under the Final  
2 Regulations.

3 Dr. Finder.

4 Good Guidance Practices and Directions for  
5 Discussion of the MQSA Guidance under the  
6 Final Regulations

7 Charles Finder, M.D.

8 DR. FINDER: Before we begin our  
9 discussion of the proposed Final Regulation  
10 guidance, I would like to briefly explain the  
11 procedures that FDA is following as it develops new  
12 guidance.

13 In response to public comment regarding  
14 the use of guidance documents, FDA held an open  
15 public meeting on April 16, 1996, and again on  
16 February 27, 1997, they published a Federal Notice  
17 outlining the steps the Agency needed to take prior  
18 to issuing guidance.

19 In brief, it stated the following:

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

25 2. While the statutes and their

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

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

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

19           The committee will be reviewing some  
20 documents, some of which have already been released  
21 to the public, and others that will soon be  
22 released for public comment.

23           Does anybody have any questions?

24           [No response.]

25           DR. FINDER: I would ask again the people

1 in the audience who are federal liaisons or AV  
2 representatives if they could give me their most  
3 current mailing and e-mail address information.

4 With that said, any of the committee  
5 members missing their questions? I have a couple  
6 extra copies.

7 I will turn this back again to Ms. Harvey.  
8 You can go this question by question, or page by  
9 page, however you feel is most appropriate.

10 MS. HARVEY: Well, I think we will begin  
11 question by question and see how that works.

12 The first question has to do with  
13 measurement of focal spots at all possible  
14 magnification values. The answer that was given  
15 allows the test to be done at magnifications if  
16 clinically used and then at a magnification factor  
17 as close to 1.5 as can be achieved by the system.

18 DR. FINDER: Let me also explain a little  
19 bit about what you are looking at here. This  
20 question actually appears in our current guidance.  
21 The underlined portion is our proposed change. The  
22 reason that we are proposing it, as in many of the  
23 other areas where we have similar type changes, is  
24 because we got comments from the public that this  
25 was still unclear, that the guidance was still

1 unclear, and we are hoping to further clarify it by  
2 making this modification. The modification we are  
3 talking about is adding the words "if magnification  
4 is clinically used and then at the magnification  
5 factor as close to 1.5."

6 So, just for people in the audience to  
7 understand what we are looking at here.

8 MS. HARVEY: Any comments? Dr. Karellas.

9 DR. KARELLAS: This appears reasonable in  
10 general. The only question I have is if there is a  
11 facility that they do routinely magnification of  
12 1.7 or 1.8, where in my own experience, at least  
13 where I am, we don't do that, because we don't get  
14 good results, but should these people switch and do  
15 it at 1.5 versus what they do routinely at 1.8?

16 DR. FINDER: Basically, yes, because if  
17 you go to much higher magnifications, we found that  
18 the criteria that we have established may not  
19 apply, and that is why we are telling facilities,  
20 if you are going to do the testing, do it at close  
21 at 1.5.

22 DR. KARELLAS: The recommendation appears  
23 reasonable, and a qualified physicist can use  
24 appropriate judgment to evaluate the performance.  
25 I believe that 1.5 is a very good reference

1 magnification for that assessment.

2 MS. HARVEY: Any other comments?

3 [No response.]

4 MS. HARVEY: Our next question has to do  
5 with the weekly phantom test. When performing the  
6 weekly phantom image test must we monitor kVp  
7 and/or mAs?

8 The major change that we see here has to  
9 do with the addition of a second alternative, which  
10 is the use of the Full-Auto mode to establish  
11 baseline mAs values corresponding to the specific  
12 kVp values usually encountered during phantom  
13 testing.

14 If the mAs value is within 10 percent of  
15 the baseline value for the post-exposure kVp value,  
16 the unit has passed that portion of  
17 post-move-pre-examination test.

18 DR. FINDER: Is that clear to everybody?

19 MS. HARVEY: That is to do essentially  
20 with mobile facilities?

21 DR. FINDER: Right.

22 MS. HARVEY: Who are required to do  
23 testing prior to initiation of examinations after  
24 they move the equipment.

25 DR. FINDER: If anybody wants some

1 background on this, I will be happy to supply it.  
2 If everybody is clear on this and happy with this,  
3 I don't have to necessarily go into it. Of course,  
4 we are ahead of schedule, so I will be more than  
5 happy to offer background. No questions?

6 MS. HARVEY: Okay. Thank you.

7 Next question, page 2. What is considered  
8 adequate weekly phantom QC monitoring for a  
9 facility that has multiple processors and multiple  
10 units?

11 This is a new question and this is a new  
12 response. It has to do with interchangeability  
13 between units and the processors. If we have more  
14 than one unit and more than one processor, we have  
15 many alternatives for which processor will be used  
16 for each unit, and there is a desire, I believe,  
17 that the test is performed for all combinations  
18 that are available.

19 Any comments?

20 DR. FINDER: Before we leave this  
21 question, I would actually like to ask a couple of  
22 specifics because I want to be sure in my mind and  
23 FDA wants to be sure that these things have been  
24 considered.

25 In order to do this, we have established

1 or created a definition here of what it means to be  
2 matched, for the processors to be matched, and we  
3 have set that as an optical density of 0.05.

4 Is that a reasonable definition for a  
5 matched processor? Do we feel that that is  
6 something that facilities can actually meet out  
7 there without too much trouble? We obviously don't  
8 want to create an option here and then find out  
9 that nobody can use it.

10 The other side to that is we don't want to  
11 create a situation where it is too easy to meet and  
12 we lose the benefits or we can negatively impact on  
13 the quality. So, the question really is do we  
14 believe that that is a reasonable definition for  
15 matching.

16 I see some heads nodding up and down  
17 rather than side to side.

18 DR. PISANO: Are you saying it's a new  
19 requirement?

20 DR. FINDER: It is not a new requirement.  
21 Actually, this is an additional option. Right now  
22 the way the regulations are written, facilities  
23 would have to do all permutations, and what we are  
24 trying to do is decrease the number of phantom  
25 images that have to be run, but we do want to do it

1 under conditions that we feel would be adequate.

2           Obviously, if the processors are very far  
3 apart, you are going to get different values, and  
4 we are worried that you are not going to ensure the  
5 same quality. So, if we are going to allow this  
6 decrease in the number of phantoms that have to be  
7 run each week, we do want to make sure that the  
8 criteria that have been established are adequate to  
9 ensure quality.

10           Now, if people want to think about this a  
11 little bit and respond later, that is fine, too,  
12 but again I seem to be seeing heads going up and  
13 down rather than side to side, so I will take that  
14 as a yes.

15           Now, if we assume that this matching  
16 criteria is adequate, does anybody have any problem  
17 with the concept that we are coming across with  
18 about allowing the decrease in the number of films?  
19 Again, I see heads going side to side, not up and  
20 down, so I will take that as a no in terms of  
21 nobody has any problems with that. Is that true?  
22 Okay.

23           My third question about this, if we have  
24 now agreed on the previous two issues, can we apply  
25 a similar type process to system resolution

1 testing? I know this wasn't included in this, but  
2 I am asking. Again, you don't have to answer or  
3 even nod your head at this moment. Think about it  
4 a little bit, and we can even talk about it later  
5 on in the meeting.

6 DR. PISANO: Could you explain what you  
7 mean exactly, what are you thinking?

8 DR. FINDER: There is also a system  
9 resolution test. In 2002, we are talking about  
10 basically evaluating the focal spot. Right now you  
11 can do it two ways. You can do it either through a  
12 system resolution test or you can do it by  
13 measuring the size of the focal test.

14 After October 2002, the only option is a  
15 system resolution test, and what we are saying is  
16 because you have to run films in order to check the  
17 resolution, can you decrease the number of films  
18 that you have to run through that system if you  
19 have got matched processors.

20 DR. KARELLAS: System resolution does not  
21 depend very much on the processor unless the  
22 exposure is way under or way over exposed. It is a  
23 function of the cassette itself, film-screen  
24 combination, and the focal spot, so it does make  
25 sense.

1 DR. FINDER: And that also brings up the  
2 other point of obviously, with these system  
3 resolution tests, we would be talking about people  
4 testing with their various film-screen  
5 combinations.

6 MS. HARVEY: Mr. Bailey.

7 MR. BAILEY: Ed Bailey from California.

8 Going back to that previous question, does  
9 this mean that a mobile facility that may be doing  
10 on-site film processing at a number of locations,  
11 all of them would have to fall within this  
12 percentage or within the 0.05 optical density?

13 DR. FINDER: Oh, you are going back to the  
14 previous question that we talked about.

15 MR. BAILEY: I am sorry, yes. For  
16 instance, if you had a mobile service that maybe  
17 had three vans that go around to five or six  
18 places, each x-ray unit and each processor at those  
19 facilities would then have to be matched.

20 DR. PISANO: You are allowing another  
21 option of them not being matched, right?

22 DR. FINDER: Basically, what these  
23 questions do is give more options than what they  
24 have got right now, but I am still unclear. You  
25 may be mixing--well, we have got two similar type

1 questions here, the previous one which talked about  
2 the mobile and giving them the use of the Full-Auto  
3 mode and that 10 percent--you are not talking about  
4 that?

5 MR. BAILEY: No, I am talking about  
6 Question 3, the one at the top of the second page.

7 DR. FINDER: Okay. We are still on that  
8 question. If the processors are not matched, all  
9 they have to do is run the phantoms through those  
10 like they would anyhow. If they are matched, they  
11 could decrease the numbers, but if they are only  
12 using one mobile unit anyhow, this doesn't really  
13 come into play, I don't believe. It is when you  
14 have multiple units and multiple processors that  
15 you can reduce the number of phantoms that you run  
16 each week.

17 MR. BAILEY: Okay.

18 MS. HARVEY: One more speaker. Yes, sir.

19 MR. USINOFF: I am Bob Usinoff, Fuji Film  
20 Medical Systems.

21 On the language in this question, I think  
22 the committee should be sure. My question is about  
23 operating levels, and I think the intention is that  
24 that is a process aim [?] level rather than a point  
25 on a given day, and that might be clear if that is

1 the language that is used in the regulations, that  
2 operating level means an aim point for a QC chart,  
3 I don't have a concern about that.

4 A second small point. Within 0.05 optical  
5 density, if the difference is 0.05, that wording  
6 might be ambiguous. I might suggest 0.05 or less,  
7 or something like that.

8 DR. PISANO: That is a good point. No  
9 greater than 0.05.

10 MS. HARVEY: Thank you.

11 Any other comment on this question?

12 [No response.]

13 MS. HARVEY: Our next question has to do  
14 with a private radiology practice that has applied  
15 for and became accredited and certified. They do  
16 not own the mammography x-ray equipment or employ a  
17 radiological technologist qualified to perform  
18 mammography. They have applied for accreditation  
19 using the x-ray unit and technologist from a  
20 certified mobile facility that visits the practice  
21 periodically.

22 Do we have to be inspected separately from  
23 the mobile facility and who is responsible for  
24 correcting any problems found? The answer, of  
25 course, is yes, and that both facilities are

1 responsible. This is new language added to the  
2 guidance to explain to facilities their  
3 responsibility.

4 Any comments? I think it is pretty  
5 straightforward. Okay.

6 Next question, the bottom of page 2. We  
7 use FDA's guidance for mobile facilities where we  
8 produce a phantom image after a move of the mobile  
9 unit and we monitor the mAs. We then process the  
10 phantom image later prior to processing the  
11 mammograms.

12 If we move the mobile unit more than once  
13 per week, do we also have to produce a weekly  
14 phantom image in addition to the phantom produced  
15 after each move? The answer to that would be no,  
16 you have the phantom images that you have produced  
17 before each one of your moves. Am I reading that  
18 correctly?

19 DR. FINDER: Well, actually, it is a  
20 little bit more detailed. You have an option  
21 there. If the mode that you are using is the one  
22 that you use clinically, then, you don't have to  
23 produce another image, but if you are not using  
24 that mode, then, you would have to produce a  
25 phantom image, because the regulations require that

1 the image that you use for the weekly phantom test  
2 be done in the mode clinically used for the  
3 standard breast.

4 DR. PISANO: What other mode would you  
5 use?

6 DR. FINDER: Well, especially with  
7 mobiles, when they were following our previous  
8 guidance, they didn't do onboard processing, and  
9 they would have to go to, let's say, an AEC mode  
10 and monitor the mAs, whereas, when they were doing  
11 patients, they would do them in a Full-Auto mode.

12 In that type of a situation, that is what  
13 we are trying to clarify here.

14 DR. PISANO: I have a question about this.  
15 What if a facility runs the mobile unit for two  
16 weeks at the same place, so they are not moving,  
17 they are staying in the same parking lot at the  
18 same factory, so they are not going to do a phantom  
19 except every two weeks in that case, is that  
20 correct?

21 DR. FINDER: No.

22 DR. PISANO: They would still have to do  
23 it weekly then?

24 DR. FINDER: Do a weekly phantom, right,  
25 they just don't have to do a post-move

1 pre-examination test.

2 DR. PISANO: So, this question refers to  
3 the extra, they don't have to do the extra ones,  
4 but they still have to do one once a week.

5 DR. FINDER: Sure, exactly.

6 DR. PISANO: Okay, only if they move it  
7 more than once a week is the way the question is  
8 worded.

9 DR. FINDER: Right.

10 MS. HARVEY: Any comments? No. I think  
11 everyone is comfortable with that.

12 Next, page 3. We have an FFDM unit and do  
13 not keep hardcopies of our exams because they  
14 retain their images electronically. When patient  
15 request the release of their exam, we create a  
16 hardcopy for them. May we charge the patient for  
17 the cost of creating the hardcopy?

18 The answer has to do with the fact that  
19 the facility may not charge for creating the first  
20 hardcopy version of the mammogram, but may charge  
21 for second copies. They may pass that cost on to  
22 the patient.

23 Any questions? Dr. Karellas.

24 DR. KARELLAS: I have a comment on this  
25 that we ought to be aware that that means that the

1 facility must have a hardcopy printer, and although  
2 I believe most will have for other reasons,  
3 educational, certification, or rather accreditation  
4 issues, but in the long term, people would  
5 anticipate having digital mammography with no  
6 printing, so that is a concern of mine from the  
7 financial point of view because filmless means  
8 filmless, and having to have a printer above and  
9 beyond that may be something that some facilities  
10 may not like, but the reality today is that most,  
11 if not all, facilities will have to have some  
12 capability for printing.

13 DR. PISANO: I have another comment on  
14 that issue, too. It is also not the case that you  
15 can just, as with the processor for mammography,  
16 when you print for mammography, you cannot  
17 necessarily print appropriately for diagnostic  
18 accuracy purposes without setting the printer up  
19 just perfectly.

20 So, if you have a printer that you use  
21 only intermittently for mammography, it is not  
22 likely to produce a diagnostic quality image. So,  
23 this is as little more complicated an issue than  
24 this question implies, because if they print up  
25 images that a patient is going to take to another

1 facility to have an interpretation read, it is not  
2 likely--unless they are using it all the time for  
3 that purpose--it is not likely it will be able to  
4 be used for that purpose.

5 MS. BROWN-DAVIS: Then, that is a problem,  
6 that is a major problem.

7 DR. PISANO: Yes, it is.

8 MS. BROWN-DAVIS: Because every woman has  
9 a right to actually have in her hand her mammogram,  
10 because we have already, you know, gone through the  
11 issue of storing--and I realize later in this  
12 document we know that those facilities that are out  
13 of business have some responsibilities, and I have  
14 some comments about that--but that is a real  
15 problem. I am glad that you brought that up.

16 DR. PISANO: Actually, I have an answer, I  
17 think, but maybe not a good one, I don't know. I  
18 agree with you completely that every woman has the  
19 right to her mammograms and should be able to get  
20 second opinions with them.

21 The issue that comes in my mind--I am sure  
22 Andrew has the same experience--is that you can  
23 provide an electronic copy of the mammogram to a  
24 woman on a CD or some other media. The issue there  
25 then becomes if you have an electronic copy is the

1 ability of the person who receives it to be able to  
2 display and read it, because there are issues of  
3 the way that the images are displayed.

4           So, any facility can provide an electronic  
5 copy with or without a printer, the question is can  
6 the user at the other end read the images if it is  
7 an electronic format, because obviously, there are  
8 requirements for that.

9           DR. KARELLAS: We may be a little bit  
10 ahead of the time, but I believe ultimately the  
11 patient could be given a CD. I think it is a  
12 little easier on a facility, and if she needs a  
13 second opinion, we are moving very fast forward in  
14 that direction in ability to read.

15           I believe that a CD with the information  
16 makes more sense than a printed film from a printer  
17 that may or may not be QA'd on a daily basis, and  
18 it would probably take more time to optimize that  
19 for each case.

20           DR. RAMOS-HERNANDEZ: I thoroughly agree  
21 because I think from the consumer perspective will  
22 be who is supposed to pay for that copy, the  
23 extract copy, is the patient, is the medical  
24 insurance, and we have several women that might not  
25 have access to those resources, so it will be

1 barrier for women to get second opinions or even to  
2 carry their own files.

3 DR. PISANO: I just want to emphasize also  
4 that just because you provide a woman a CD with the  
5 image on it, doesn't mean that the person who is  
6 being asked to give a second opinion can read the  
7 images or display the images in an appropriate way  
8 at high enough quality for diagnostic accuracy.

9 There are lots of issues about the way the  
10 images are headed. Not all the manufacturers at  
11 this point, only ones that are FDA-approved, but  
12 the ones that are out there have the appropriate  
13 Dicom header for reading mammograms on it, the  
14 latest Dicom header I should say.

15 In addition, the display systems, if you  
16 try to read a mammogram on a Windows box in your  
17 office, just a regular IBM-PC or something, there  
18 is no way you are going to have high enough  
19 quality. You really need a very fancy workstation  
20 to read mammograms with adequate quality.

21 So, this is a very complicated issue. It  
22 is going to be a hard one. We are not there yet.  
23 We will be, I agree with Andrew, we will be soon,  
24 but we are not there yet.

25 DR. KARELLAS: I agree with Dr. Pisano.

1 Giving a CD, it really automatically means that  
2 this patient will have go to some facility where  
3 they have virtually the identical equipment set up.

4 DR. PISANO: The other method is also  
5 through electronic file transfers. I mean that may  
6 actually be more useful and easier in the long run  
7 than actually providing a hardcopy. The patient  
8 could request please send to this FTP site or this  
9 location my images, and then it would be very quick  
10 and easy and cheap.

11 DR. FINDER: I would like to give a little  
12 background and hopefully clarify some of these  
13 things. The question that we are dealing with now  
14 basically deals with cost in terms of who pays for  
15 what, and what we basically said is in a similar  
16 manner to what is now required of facilities in  
17 terms of film-screen, the facility can't charge for  
18 the first copy of the digital image.

19 At the present time, we are talking about  
20 hardcopy for the patients, because the number of  
21 places that can actually use electronic versions is  
22 small at this point, and this has been discussed at  
23 other committee meetings earlier.

24 However, I believe we have addressed some  
25 of the issues that have come up already in a later

1 question on page 5, beginning line 34, where we  
2 talk about what constitutes a mammogram and what  
3 you can do with it, and we do have a modification  
4 here to address actually the issue that was just  
5 discussed, about transfer electronically of these  
6 images.

7           At the present time, what we are saying  
8 is, we are talking about hardcopy for right now  
9 except in the case where both parties are agreeable  
10 to getting electronic, and that would basically  
11 relate to situations, as we gave an example,  
12 between two digital facilities that have the same  
13 equipment, that can actually use those things, but  
14 in other cases, we are talking about facilities  
15 having the ability to create a hardcopy, and we  
16 have stated in here that it has got to be of  
17 primary interpretation quality, so that these  
18 images are useful. It obviously does no good if  
19 you do it on a printer that makes it look like it  
20 comes out of the old fax machines.

21           These copies have to be of primary  
22 diagnostic quality, and that guidance has already  
23 been out. This isn't new.

24           DR. KARELLAS: I understand that this  
25 presents a problem, but that will require the

1 radiologist to go back and review the case and  
2 print it, and the printers are slow, and it takes  
3 considerable amount of time. I am very sympathetic  
4 to the patient cost issue and the availability, and  
5 I am split between that and some allegiance that I  
6 have to the health care organization that becomes  
7 problematic in terms of the finances, so I think it  
8 is a real tough issue financially.

9 DR. BARR: Everything you are raising is  
10 certainly important. Let me just put in a reminder  
11 that at this point, though, anyone who wants  
12 to--which Penny Butler will be explaining  
13 later--anyone who wants to get accredited, which  
14 they are going to have to do shortly for the  
15 digital unit, is going to have to submit hardcopy  
16 for accreditation, so virtually, at this point in  
17 time, where we are now, is that all facilities have  
18 to have the ability to create hardcopy.

19 We aren't there yet, they are all good  
20 issues, but the accreditation procedure is going to  
21 be hardcopy, so that is pretty much where we stand  
22 right now. Thank you.

23 DR. KARELLAS: Again, to take much of your  
24 valuable time, but it is a very critical issue.  
25 For the accreditation providing a hardcopy does not

1 necessarily mean that the processor and the printer  
2 is always on a day-to-day QA mode if you never use  
3 it for patient interpretation.

4           Theoretically, I do not know whether that  
5 is proper, but you may have the processor running  
6 properly only for the time that you need the  
7 accreditation phantom. You could turn it off and  
8 say the processor will not be used for any patients  
9 until we clean it and we recalibrate it, because it  
10 doesn't make much sense if nobody uses it for  
11 interpretation to QA the printer every day.

12           DR. FINDER: Let me just add nobody is  
13 saying that you have to keep these processors  
14 operating every day. It is they have to be in  
15 limits when you need to make the films.

16           I would imagine that, for example, the  
17 number of patients for times when a patient would  
18 actually need the hardcopy might be relatively  
19 small out of the total, but the end result or the  
20 end process that we have to get is that the patient  
21 has to be able to get her films, so that she can  
22 use them, she can take them for consults.

23           Many surgeons will want to look at these  
24 images before they do surgery. They need to look  
25 at these things, so there has got to be an ability

1 to get them the information.

2           At the present time, electronic transfer  
3 just isn't there. Hopefully, it will be soon or in  
4 the not too distant future, but until that happens,  
5 all we are saying is right now you do have the  
6 option of doing electronically, but both sides have  
7 to be agreeable. If not, there has to be hardcopy  
8 available, and I think that is for the foreseeable  
9 future.

10           We have been telling digital facilities  
11 that they have to have this capability, so it is  
12 not anything new that they are getting.

13           MS. HARVEY: Clearly, this will be an  
14 issue we will be talking about in the future.

15           On to the next question, which is also  
16 about FFDM. We do not have an FFDM unit at our  
17 facility, however, some of our personnel use one at  
18 another facility. Are we responsible for  
19 maintaining documentation showing that these people  
20 have received their initial training in the new  
21 mammographic modality?

22           The answer is no, only the facility which  
23 the personnel are actively using the unit are  
24 required to maintain the document.

25           Question: How long must we maintain the

1 records of our medical outcomes audits?

2           The answer to that is that it must be  
3 maintained for at least two years. If the facility  
4 has obtained actual pathology reports, these should  
5 be maintained until the next annual inspection.

6           Any comments?

7           [No response.]

8           MS. HARVEY: The next question. When we  
9 assign a negative assessment to the mammography  
10 report, our reporting system automatically  
11 generates a normal lay summary. In rare cases, we  
12 have patients that have negative mammograms, but  
13 for other reasons we want that person to have  
14 further workup or even biopsy.

15           In such cases, can we assign a different  
16 assessment category to the mammography report, so  
17 the correct lay summary automatically goes out?  
18 Can the medical report and lay summary have  
19 recommendations that are not the ones normally  
20 associated with a specific assessment category?

21           The answer: While circumstances as  
22 described above should be relatively rare, the  
23 decision of which assessment category to assign to  
24 a specific mammography report is left up to the  
25 interpreting physician. With respect to

1 recommendations, the interpreting physician can  
2 make any recommendation he or she believes  
3 appropriate.

4 The doctors are pondering the question.

5 DR. IKEDA: As a radiologist, we will  
6 sometimes run into this situation, and I am glad  
7 that it has this clarification because on the rare  
8 occasion in which a mammogram is normal, and the  
9 woman deserves a biopsy, I think it is helpful to  
10 clarify that to both the referring physician and  
11 especially to the patient that she needs to have  
12 further workup, so I am glad that this is in here.

13 DR. PISANO: Actually, the way we have  
14 solved this problem is we actually don't give the  
15 patient--the regulation covers the way our report  
16 is supposed to read, and our lay language summary,  
17 if she needs a workup, says that she needs a  
18 workup. We don't give her a normal mammogram  
19 report. We tell her she needs a workup only. We  
20 also tell her she has a normal mammogram, but she  
21 needs a workup, so that is the bottom line that is  
22 communicated to the patient.

23 I am just surprised about this issue. I  
24 am surprised no one is doing it the way that we are  
25 doing it.

1 DR. IKEDA: I think a lot of facilities  
2 are doing that, but for those facilities who are  
3 unclear, I think that this regulation clarifies  
4 that issue.

5 DR. PISANO: That is good, I agree.

6 MS. HARVEY: Is that assessment  
7 incomplete?

8 DR. IKEDA: No, it needs a workup.

9 DR. FINDER: One thing that I do want to  
10 make mention of, these are actual questions we get  
11 in. We don't actually go hunting around and making  
12 up our own questions. So, this was a question that  
13 we got, and we assume that there are other  
14 facilities that have similar type issues, and we  
15 want to try and clarify it as much as we could.

16 DR. DOWLAT: As a surgeon, if I receive a  
17 report from Radiology saying that this is negative,  
18 yet, there is additional workup to be done, I find  
19 that very contradictory. You either are pregnant  
20 or not pregnant. Either the patient needs  
21 additional workup or doesn't need it. If they  
22 don't need it, you say so.

23 I don't know, what is the example that you  
24 have been given?

25 DR. FINDER: Let me give you the example

1 that we have been given. A patient comes in with a  
2 palpable finding. A mammogram is done, nothing  
3 seen. There are a couple of ways that that can be  
4 handled, but one of the ways, and this is where we  
5 get the question from, is what do I do now.  
6 Obviously, the mammogram is negative, however, this  
7 patient needs further workup, needs a biopsy of the  
8 palpable mass or some other evaluation of it.

9           If the decision is made to go to a biopsy  
10 rather than some other type of imaging, the person  
11 is kind of left with a quandary as to which  
12 assessment category to put this in, because the  
13 mammogram is negative, it is not suspicious really  
14 although we do allow people to pick which category  
15 they want, but truly, the mammogram is negative,  
16 but that isn't enough, that is not enough because  
17 if the only report that goes out is negative, that  
18 patient won't be adequately served, so therefore,  
19 the recommendation has to be something else, biopsy  
20 or whatever.

21           DR. PISANO: I think I can clarify where  
22 this issue comes from. It has to do with the fact  
23 that the terms in the conclusion have to be those  
24 six terms, incomplete to suspicious, you know, the  
25 whole range of terms.

1           Those are similar to, but not identical  
2 to, the BIRADs terms, because the BIRADs terms are  
3 linked to action, as well. They say, you know,  
4 benign finding, one-year follow-up, probably benign  
5 finding, six-month follow-up, et cetera. That is  
6 what BIRADs does, and the FDA do not require the  
7 BIRADs action term recommendation to be linked to  
8 the impression, what do they call it, the final  
9 assessment category, the negative, benign, probably  
10 benign, et cetera.

11           So, I think there is confusion among  
12 radiologists, that Debbie is right, she is pointing  
13 out that it is good we have clarified that, because  
14 if you try to link those in your report, you come  
15 up with the contradictory negative, follow up in  
16 one year, when you really need to biopsy, but the  
17 patient, she needs to be seen by a surgeon, or  
18 perhaps have a stereo biopsy or something, but the  
19 point is she needs a further workup despite--or  
20 probably not a stereo biopsy--but an  
21 ultrasound-guided biopsy or maybe a palpable guided  
22 biopsy.

23           It is somewhat confusing to people, I  
24 guess.

25           DR. DOWLAT: I don't think this is a rare

1 situation. We are talking about something like 10  
2 percent negative finding by mammography for a  
3 palpable mass, and I see that relatively commonly,  
4 1 in 10 or 1 in 15, with that kind of thing,  
5 totally negative mammogram and there is a palpable  
6 mass. So, it is not rare.

7 DR. FINDER: When somebody asks me that  
8 question, what I suggest to them is the following:  
9 Usually, if you have got a negative mammogram and a  
10 palpable mass, the next procedure to do would be an  
11 ultrasound. So, the assessment category on those  
12 mammograms basically would be incomplete, needs  
13 additional imaging evaluation.

14 However, there are some cases, and again,  
15 these are not questions we make up, these are ones  
16 that come in to us, what do I do when I don't want  
17 to go ahead and do any other type of imaging  
18 evaluation. It is still a negative mammogram, but  
19 there is a palpable finding, how do I handle that  
20 type case?

21 I would think that the number of cases  
22 where you have got a negative mammogram/palpable  
23 finding, and for whatever reason they don't want to  
24 go ahead and do some other imaging evaluation is  
25 small. Does anybody disagree with that from the

1 radiologists?

2 DR. IKEDA: I think that the other  
3 category that this may come from, because I have  
4 been asked this question many times at national  
5 conferences, and the question is the patient comes  
6 in, she has a palpable mass that feels awful, that  
7 is really hard, and the radiologist does a physical  
8 examination, and it feels horrible. The mammogram  
9 is normal, the ultrasound is normal, spot  
10 compression, extra mammographic views are normal or  
11 within the range of normal, multiple masses,  
12 microcalcifications, nothing really to hang your  
13 hat on and say this is going to be cancer, but the  
14 radiologist still feels that for the patient's  
15 benefit, she should be seen by a surgeon and biopsy  
16 should be considered.

17 Ordinarily, radiologists are taught, in  
18 BIRADs are taught the assessment code 1 or 2 benign  
19 are linked to follow up in one year. On the other  
20 hand, these patients deserve a surgical opinion and  
21 the possibility of biopsy.

22 So, in those cases, the radiologist now  
23 has the option of going to say the mammogram is  
24 normal, however, because of the palpable finding,  
25 consideration for biopsy might be considered.

1 DR. PISANO: Actually, I agree with Dr.  
2 Dowlat, that this is not a rare event. What you  
3 are describing, Dr. Finder, is a rare event. In  
4 our practice, for example, we do the whole workup  
5 including extra views, ultrasound, et cetera, but  
6 there are still quite a few patients that fall into  
7 this category where you feel the hard lump or  
8 something that concerns you, and you don't find  
9 anything, you still feel they need to see the  
10 surgeon. So, I don't think it is that rare also.

11 DR. BARR: I agree with all the  
12 radiologists. It happens all the time. What this  
13 is doing is what Dr. Ikeda alluded to. This  
14 guidance is now giving the radiologist the freedom  
15 to assign whatever assessment category will get the  
16 patient taken care of within the limitations of how  
17 their computer system, lay summary system,  
18 whatever, operates.

19 In this case, the purpose of the  
20 assessment system is to get the patient the correct  
21 letter and the correct follow-up they need, and not  
22 to worry about technically where it fits. This  
23 gives you now the freedom to do that.

24 DR. DOWLAT: Why didn't you give it  
25 another number?

1 DR. IKEDA: It is hard enough with five  
2 numbers.

3 [Laughter.]

4 DR. PISANO: I think if you just eliminate  
5 the fact that it is rare, I think that that is the  
6 only part of the thing that you are hearing that we  
7 don't agree with. The rest of it is good. If you  
8 eliminate that whole first clause, then, you just  
9 have a perfectly reasonable answer.

10 MS. HARVEY: Next question is just a  
11 modification of previously issued guidance. Are  
12 all regulated mammography units in the facility  
13 required to be accredited and, if so, what  
14 documentation is necessary to establish that this  
15 has been done?

16 We have removed the comment "or medical  
17 physicist's survey."

18 DR. KARELLAS: I think the rationale for  
19 that is because you do not want to create a  
20 confusion because it says "or," because the  
21 equipment evaluation, that includes part of the  
22 medical physicist, is not one or the other, right?

23 DR. FINDER: The statement as originally  
24 written created a lot of confusion because what the  
25 unit actually has to undergo is an equipment

1 evaluation, and an equipment evaluation covers  
2 certain areas that are not covered routinely in an  
3 annual survey.

4 So, we wanted to make it clear it has to  
5 undergo an equipment evaluation at this stage.  
6 That is why we took out those words.

7 MS. HARVEY: Any comments? All set.

8 The next question. This is a new question  
9 and answer. I qualified as an MQSA radiologic  
10 technologist in the past year and have been  
11 performing mammography for several years. I  
12 recently passed the test for the ARRT mammography  
13 certificate. Can I claim 24 CEUs for earning this  
14 certificate?

15 The answer is yes, you can claim the 24  
16 credits.

17 All set? The next discussion that comes  
18 up has to do with a six-month provisional  
19 certificate. A facility operating under a  
20 six-month provisional certificate (including a  
21 provisional reinstatement certificate) may be  
22 eligible for a single 90-day extension to its  
23 provisional certificate. (A facility operating  
24 under a three-year certificate is not eligible for  
25 a 90-day extension.)

1 This is all new language.

2 DR. FINDER: Let me correct. It is my  
3 handling of Word, and I couldn't control what it  
4 was doing. Actually, this is current guidance.  
5 The changes here basically refer to the areas that  
6 have been crossed out, but Word made me do it.

7 [Laughter.]

8 DR. FINDER: Again, we are trying to be  
9 more consistent with how the process is actually  
10 working and trying to clarify and simplify some of  
11 this guidance here.

12 MS. HARVEY: So, it eliminates the base  
13 effort.

14 DR. FINDER: We don't go into the details  
15 of what they have to do. They have to go through  
16 the accreditation body.

17 The next question, I think I will handle.  
18 The addition was we left out the "a" for the word  
19 "at." I don't think there will be any comment on  
20 that one.

21 MS. HARVEY: Fine. Moving right along to  
22 the next question on page 5, line 21. Do units  
23 with multiple AEC detectors have to have each  
24 detector tested individually for AEC  
25 reproducibility?

1           Essentially, the answer is each one of the  
2 AEC detectors which functions independently must be  
3 tested.

4           Dr. Karellas, are you comfortable with  
5 this?

6           DR. KARELLAS: Yes, I am comfortable with  
7 this part, yes.

8           MS. HARVEY: Any other comments?

9           [No response.]

10          MS. HARVEY: Did we actually complete this  
11 next question when we referred to it or revisited  
12 it?

13          Question: With the introduction of  
14 Full-Field Digital Mammography, what constitutes a  
15 mammogram, the digital data or the hardcopy film?

16          Is there added language here? Facilities  
17 may transfer digital images electronically as long  
18 as that is acceptable to the recipient.

19          DR. KARELLAS: Today, when a patient takes  
20 their films, they have to sign. When this is done,  
21 is there any required documentation or simply just  
22 a casual transmit upon request? I don't know  
23 whether there are any other issues. The good thing  
24 is that the digital data always remains, so you can  
25 send the mammograms many times, which provides a

1 margin of safety. Today, if somebody took their  
2 films and lost them, then, there is no record.

3 I don't think it is a huge issue at this  
4 point. I think it is more of a logistics, who will  
5 receive them.

6 DR. PISANO: I am sure there are people in  
7 this audience who are more expert on this than I,  
8 but from what I understand, HIPAA regulations apply  
9 here very strongly, and before you can transfer  
10 electronic information to anybody, you have to have  
11 the permission of the person whose information it  
12 is. So, in other words, one of the main reasons we  
13 keep records now is to just have a document that  
14 says we released it to someone who the patient is  
15 giving approval for, so that still applies to this,  
16 so you still have to keep records, I believe.

17 DR. KARELLAS: This actually raises an  
18 interesting point. We haven't addressed this, but  
19 by your comment I see we have another question and  
20 answer that has to come out, and I do believe that  
21 the answer to that question will be greatly  
22 influenced, not by MQSA, but by the HIPAA  
23 regulations, which are still under discussion.

24 We have a little different concept here.  
25 A great part of the current sign-out is to show

1 where the records actually are. In this new  
2 process, obviously, the original will still always  
3 be at the facility, but there, the need will  
4 probably be to document who they have been given  
5 out to, because you don't this to be sent out all  
6 over the place. These are patient records, and  
7 have to be handled with appropriate  
8 confidentiality.

9 The question actually is a good one for  
10 another document that will come up, but I think it  
11 is going to have to wait until the HIPAA  
12 requirements are better established and formalized.

13 MS. HARVEY: Dr. Karellas.

14 DR. KARELLAS: Of course, we have to  
15 consider the issue of confidentiality on the  
16 transmission through the web or other means, so  
17 that is a huge issue. Today, if we were able to do  
18 that today, I don't think we would do it, because  
19 we would be very concerned about the transmission  
20 part and the security.

21 MS. HARVEY: I was thinking that. Does  
22 everyone know what HIPAA stands for? Can we kind  
23 of guess what it might mean?

24 DR. FINDER: Portability and Privacy Act?  
25 We have an answer.

1 MR. LARSON: Health Insurance Portability  
2 and Accountability Act.

3 MS. HARVEY: Thank you.

4 DR. FINDER: So, we have to wait for that  
5 to be formalized. In effect, I would imagine that  
6 there won't be anything different or unique about  
7 how it is handled under MQSA versus how it is going  
8 to be handled for everybody else in terms of  
9 electronic transfer of medical records, so we  
10 should wait and see what happens, but I am sure we  
11 are going to get more questions just about that  
12 issue.

13 MS. HARVEY: We were hoping that digital  
14 would make things easier, but it doesn't sound that  
15 way, does it.

16 We have a question. With machines such as  
17 the GE 500T and 600T, which do not have a separate  
18 mechanism for compression fine adjustment, can  
19 tapping the foot pedal for fine adjustment of  
20 compression force meet the year 2002 requirement?

21 We have just one change in the language  
22 here. Facilities wishing to modify their units may  
23 try contacting third-party vendors offering such  
24 modifications for more information, since clearly,  
25 more than GE provides this service to people.

1 DR. FINDER: Actually, GE does not provide  
2 the service, so that is why we crossed that out.

3 MS. HARVEY: Now, we have a change to  
4 table involving medical physicist involvement in  
5 equipment adjustments, changes, or repairs.

6 We have a list of a few adjustments in  
7 which, at one point in time, it appeared that we  
8 needed to have medical physicists to conduct the  
9 evaluation, and we modified that.

10 Dr. Karellas, how does that look to you?

11 DR. KARELLAS: I believe this was what was  
12 already worked up previously with the physicist,  
13 Mr. Pizzutiello, who was part of the committee  
14 prior to that. I agree with the modifications.  
15 They are quite reasonable.

16 MS. HARVEY: Excellent.

17 MR. CAMBURN: Maybe I just need some more  
18 clarification on this, but it sounds like some of  
19 these adjustments are adjustments that might have  
20 an impact on image quality or patient radiation  
21 dose. If the medical physicist doesn't do the  
22 evaluation, should an evaluation be done by  
23 somebody, or is this an area that is not going to  
24 have an impact on image quality or dose?

25 DR. FINDER: Let me go over a little bit

1 of the background on this. This was an issue that  
2 we thought long and hard about and had gotten a lot  
3 of input after we actually published this, I  
4 believe it was in document number 3 or 4.  
5 Everything that you do can affect dose and image  
6 quality, virtually any change that you make in the  
7 system.

8 We got a lot of advice that the types of  
9 changes that we are talking about here should not  
10 impact adversely or significantly on dose or image  
11 quality. The other thing that you have to keep in  
12 mind here is that we are not saying that you can  
13 make these changes and not do anything.

14 What we have changed here is the fact that  
15 the medical physicist has to come in. We are  
16 saying if you are going to make these type of  
17 changes, the medical physicist should be consulted  
18 and have oversight, and if under the specific  
19 conditions they believe that it is required that  
20 they come in, then, they have that option. But we  
21 got a lot of comments that these types of changes  
22 are done fairly frequently, in some places as many  
23 as four times a year, and all you are doing is  
24 making minor adjustments to get these machines into  
25 better calibration with what they are supposed to

1 be.

2           The concept of them having to wait for the  
3 medical physicist to come in to do relatively minor  
4 things just was out of proportion to the "risk"  
5 that might be there, that you might actually change  
6 dose a small amount.

7           The other thing that we were looking at  
8 was the fact that since these adjustments are  
9 usually done as part of preventative maintenance  
10 situations, you could have the situation where  
11 somebody comes in and makes a minor adjustment, the  
12 medical physicist can't come for a couple of days,  
13 and that unit is shut down for several days at a  
14 time. We didn't want to have that happen.

15           So, from all the consensus that we got  
16 from comments that we received from the physicist  
17 community, this was a situation where we could  
18 allow oversight and not place anybody really at  
19 risk, and, in fact, prevent a lot of down side,  
20 because units would be put out of operation for  
21 extended periods of time really for no good reason.  
22 So, that is why we made the change.

23           MS. HARVEY: A burden on rural community  
24 facilities, particularly, and an expense, a high  
25 expense.

1 Dr. Karellas.

2 DR. KARELLAS: This does not mean, of  
3 course, that the physicist should not be informed  
4 or consulted. It just relates to going  
5 specifically and generate a whole new report, a  
6 fresh report on the evaluation.

7 As Dr. Finder made reference to that these  
8 minor changes have relatively small effect, we all  
9 agree that there is always some exception to some  
10 rule, but the appropriate person or technologist  
11 should always notify the physicist if something  
12 unusual happens.

13 The other item that I would like to add is  
14 that if it is not the medical physicist or the  
15 person who performs the modification or adjustment  
16 from the company, there is really no other person  
17 other than the technologist, of course, who is the  
18 person who safeguards the entire operation because  
19 they are always there.

20 MS. HARVEY: All right. We move on to a  
21 discussion regarding accreditation and  
22 certification are two separate processes and both  
23 are required of mammography facilities under MQSA.

24 Dr. Finder?

25 DR. FINDER: Again, this is current

1 guidance. We do have just a few minor  
2 modifications here. It is a lot of wordage to make  
3 these few changes, but again, it is basically just  
4 to be consistent with the way things are being  
5 handled at the accreditation bodies.

6           Again, I wouldn't call them really  
7 substantial type changes. So, I would suggest,  
8 unless anybody has any qualms about things, that we  
9 move to page 8.

10           MS. HARVEY: Are you moving past page 7,  
11 Question 1? Under what circumstances may FDA issue  
12 Interim Notices? You are including that, too.

13           DR. FINDER: Yes, this is all part of the  
14 same accreditation body guidance.

15           DR. YOUNG: Don Young with a question on  
16 page 6, beginning with line 36. It says, "To begin  
17 the process, it must first contact its selected  
18 accreditation body (the ACR or the States of  
19 Arkansas, California, Iowa, or Texas if the  
20 facility is located in one of those States)."

21           It is my understanding the States can go  
22 outside their respective boundaries for  
23 certification and accreditation. The wording of  
24 that sort of implies, it is not as clear as I think  
25 it could be.

1 DR. FINDER: We can look into modifying  
2 that language.

3 DR. YOUNG: It's line 36, 37, and 38 on  
4 page 6.

5 DR. FINDER: We can look into making the  
6 appropriate modification on that.

7 MS. HARVEY: Mr. Bailey.

8 MR. BAILEY: This may be my ignorance, but  
9 if a facility, a mobile facility, is accredited by  
10 one of the States, and it goes across to the other  
11 States, does that accreditation still apply? And  
12 the answer is yes, that they don't have to get  
13 reaccredited?

14 A specific example. Someone from  
15 California going to Nevada or Arizona or whatever.

16 MS. HARVEY: Correct, as i understand it.

17 DR. FINDER: I don't know if we have ever  
18 been asked that specifically. Do we have a  
19 definitive answer on that for him?

20 DR. BARR: No, I don't know if we have  
21 ever been asked that, but my quick blush thought is  
22 that the accreditation follows the unit wherever it  
23 happens to go would be my quick answer to that  
24 question.

25 That is a good point that Dr. Young

1 brought up, and some of you may not realize that  
2 accreditation is not bound by State boundaries if  
3 accreditation bodies wish to accredit facilities in  
4 other States, that is a possibility. We don't have  
5 that situation right now. We may in the future.

6 MS. HARVEY: Page 8, Question 2. What  
7 should a facility do if its certificate expires  
8 before it is accredited or reaccredited?

9 We have changed the language to allow for  
10 a discussion of its options for continuing to  
11 perform mammography with its accrediting body. All  
12 right.

13 Next question. Before a facility--this is  
14 an important one--before a facility ceases  
15 operations and closes its doors, what actions  
16 should it take to avoid future MQSA problems and  
17 how should it deal with retention of mammographic  
18 medical records? "Before" because "when" is too  
19 late.

20 DR. FINDER: Basically, the addition here  
21 other than the fact that we are changing from  
22 "when" to "before," obviously, you want the  
23 facilities to take these steps in an appropriate  
24 time frame, is the statement that starts on page 9,  
25 line 18. That is new.

1 DR. IKEDA: I have a question. Changing  
2 the terminology from "when" to "before" indicates  
3 on page 8, line 42 and 43, so before the facility  
4 stops doing mammography, if you change "when" to  
5 "before," it will say before the facility stops  
6 doing mammography, they are not to display their  
7 MQSA certificate, and the facility may file or  
8 destroy its MQSA certificate. Before it stops  
9 operations?

10 DR. FINDER: Yes, that will have to be  
11 fixed. We don't want them doing that. See, you  
12 change one little word.

13 MS. HARVEY: It has ramifications.

14 DR. IKEDA: And you have got some  
15 nitpicker like me.

16 DR. FINDER: No, I am glad you picked that  
17 up, because otherwise, we would have this in the  
18 next modification document instead of the current  
19 one.

20 MS. HARVEY: Can you give us an idea of  
21 how many facilities close precipitously in a year's  
22 period, leaving their patients without--

23 DR. FINDER: I would say from our  
24 experience, the ones that we get and have to deal  
25 with, it is not a large number of facilities,

1 however, the impact from any one facility can be  
2 very significant, and we take it very seriously and  
3 pursue and try and get these facilities to do what  
4 is right. It sometimes isn't easy, because  
5 sometimes by the time you find out that the  
6 facility has closed, there is nobody there, they  
7 are gone.

8 DR. BARR: Maryanne, we just published an  
9 article up on our web site about facilities'  
10 responsibilities in closure in this area of the  
11 process that we have in place, and you might want  
12 to take a look at that, and I agree with Dr.  
13 Finder.

14 We will be talking actually later in the  
15 meeting about mammography access a bit, and we may  
16 address some specific issues, but I agree with Dr.  
17 Finder that the impact on, you know, one patient  
18 who can't get her films is difficult, but we did  
19 outline our entire procedure in this article, which  
20 is the first of a series of three articles about  
21 closure and facilities' responsibilities.

22 DR. PISANO: I just have a question about  
23 enforcement of this or how you would possibly be  
24 able to make sure people did this, because the  
25 facility is gone, the people have moved away, the

1 entity no longer exists, you know, you have a  
2 radiologist who practices somewhere else now. I  
3 just don't know how you will enforce this or what  
4 you are planning to do about it if people don't do  
5 it.

6 DR. FINDER: That is a very good question.  
7 We take a two-pronged approach to this. One is, as  
8 Dr. Barr was saying, we try and put out the word  
9 what facilities are supposed to do, and the vast  
10 majority of the facilities out there, if they are  
11 aware of what they are responsible for, they will  
12 take the appropriate actions, and even without  
13 that, the vast majority are.

14 The next question is what do we do with  
15 facilities that don't care, and we are looking at  
16 all our options, the fact that somebody goes out of  
17 business necessarily doesn't mean that we are dead  
18 in the water. There are legal steps that we are  
19 considering and talking with our general counsel  
20 about going after these people.

21 They do have responsibilities. You know,  
22 it is a problem. For example, if they go into  
23 bankruptcy court, there are laws that apply there.  
24 We are trying to find out who has precedence in  
25 those type of situations. We are dealing with

1 situations where facilities have gone into  
2 bankruptcy, and we are talking with the bankruptcy  
3 courts to make sure that efforts are required, such  
4 that the films remain available to the patients.

5 So, there are steps we can take even if  
6 people walk away from things, but obviously, the  
7 more they walk away, the tougher it is to try and  
8 enforce things.

9 DR. PISANO: I just have a follow-up  
10 question. Why not require the facilities to send  
11 the images to the patient instead of to the  
12 facility of their choice, because it just would be  
13 much less problematic than having the patient tell  
14 the facility. Each patient is going to want them  
15 to send them to a different address, and you may  
16 not get all--you know, it is just hard to envision  
17 how you are really going to do this.

18 Hopefully, I will never face it myself,  
19 but I just don't know how a facility is really  
20 going to do it in practice, whereas, then, if you  
21 send them to the patient, you have the patient's  
22 address, you will know if the patient is not there,  
23 because they will be returned to you, you know,  
24 those kinds of things as opposed to just getting  
25 ahold of all the patients and finding out a place

1 where they want them sent.

2 I am just asking, I don't know what the  
3 right answer is.

4 DR. FINDER: We have looked at this. What  
5 we are trying to do here is give options. The more  
6 options we can give that still satisfy the basic  
7 need for the patient to have access to the films is  
8 what we are trying to get.

9 There are limits to what we can require.  
10 Obviously, as you pointed out, if they are gone, we  
11 can require a lot of things, and it is not going to  
12 get done until we may have to take further legal  
13 actions about it.

14 Again, what we are trying to do is give  
15 more options here. Hopefully, the more options  
16 that are available, the more likely facilities will  
17 be to at least pick one of these options. Again,  
18 all we care about is the fact that the patients  
19 have access to their records, so we are going to  
20 try and do whatever we can to do that.

21 MR. CAMBURN: In the State of Michigan, we  
22 have had a number of problems with mammography  
23 facilities going bankrupt and just walking away  
24 from their films. About two years ago, we had five  
25 facilities under one ownership close down and go

1 bankrupt. They were petitioning the bankruptcy  
2 court to allow them to put the films in a dumpster  
3 and walk way from them.

4 It took intervention from the Department  
5 of Attorney General, it took intervention from the  
6 American Cancer Society, from the Michigan National  
7 Guard to help box up films and transport them, and  
8 it took volunteer medical facilities to say they  
9 would accept the films and get them to the  
10 patients.

11 Just last fall, we had two more facilities  
12 file for bankruptcy, the same type of thing. They  
13 weren't going to throw the records out, but the  
14 responsible persons just disappeared, no money  
15 available to do anything.

16 Michigan currently is considering trying  
17 to do two things. I don't know if any of these  
18 will be satisfactory or not, but one is to require  
19 mammography facilities to post a surety bond when  
20 they become accredited and to make sure it is  
21 renewed every three years with that bond sufficient  
22 to cover the cost of closing their facilities down  
23 and storing the records, giving them to patients.

24 Another possibility is requiring them to  
25 have a contract with an independent mammography

1 company or facility, such that if either one of  
2 them goes bankrupt, the other one has a contract to  
3 accept the other facility's films and maintain  
4 them, and give them to patients.

5 This is all early and some of the  
6 negotiations in Michigan maybe won't go very far,  
7 but I suspect this is a growing problem from what  
8 we see.

9 DR. LEE: We had a condition where a  
10 provider closed their doors, and after numerous  
11 phone calls, we were able to locate where they  
12 were, and they actually did have the films stored  
13 somewhere, but for the consumer who is trying to  
14 make an appointment with the provider that closed  
15 down, they had no idea where their films were.

16 It would be nice to, of course, have the  
17 films stored somewhere, but how is that consumer  
18 supposed to find out where to get ahold of her  
19 films?

20 DR. FINDER: This addition here to the  
21 guidance actually addresses that in some manner.  
22 We are asking facilities to let us know, because we  
23 get patient complaints when the patients can't get  
24 their films, and if we had the information of who  
25 they could contact, that would be a great help, and

1 that is what we are asking for facilities to do, to  
2 send us that type of information, so we can then  
3 pass it along to patients. We do have an 800  
4 number that patients can call if they have got a  
5 problem.

6 DR. LEE: So, you would advocate that the  
7 patient actually call you to find out?

8 DR. FINDER: Well, I wouldn't advocate it,  
9 but as a last resort, that they call us.  
10 Obviously, the best situation would be where the  
11 facility has notified its patients in some manner  
12 where to get the films or that their facility has  
13 been taken over by another facility, so it's  
14 seamless, but in those cases where it isn't, there  
15 are various degrees of acceptability, and down  
16 toward the bottom is that the patient actually has  
17 to call us to try and find out where her films are.

18 It is obviously not the optimum situation,  
19 but it certainly is better that she call us and  
20 find out how to get her films than have no way to  
21 find out where things are going.

22 There is no question. This is not a good  
23 situation when a facility goes out of business and  
24 goes bankrupt or, you know, locks up their films.  
25 We are trying to come up with ways to maintain

1 access for the patients, and it is not easy. There  
2 is no simple solution.

3           As Michigan is looking at it, you know,  
4 they have got some ideas, we obviously couldn't  
5 require anything like that without having to go  
6 through a new regulation process, that would be a  
7 new regulation. Again, we are talking here about  
8 guidance. The best we can do at this point in  
9 terms of guidance is this.

10           The number of facilities that are in this  
11 type of situation are relatively small. Some of  
12 the corrections or solutions that are being  
13 proposed, I could see some of the radiologists kind  
14 of squinting about having to put up a bond to  
15 guarantee this when we have already got problems  
16 with facilities who have trouble staying in  
17 business.

18           These are things that we would probably  
19 discuss if it comes down to it, at a new regulation  
20 type, but not as a meeting where we are just  
21 discussing guidance. It is certainly something we  
22 can discuss in the future.

23           Hopefully, the processes that we have got  
24 going right now will prove fruitful and will help  
25 these patients who are in these situations get

1 their films. In fact, we use the Michigan example  
2 of where they got various groups involved and went  
3 to the bankruptcy court. We are doing the same  
4 thing in these other cases where we are aware of  
5 the facility going into bankruptcy, and we are  
6 using Michigan as an example of how to deal with  
7 some of these situations.

8 MS. ELLINGSON: I just had a thought about  
9 Dr. Pisano's idea of them sending the films back to  
10 the patients. With a mobile population, I am  
11 afraid you would have a lot of films in a dead  
12 letter file someplace. I would favor in the  
13 guidance keeping that practice together and  
14 notifying the public by some means, newspaper or  
15 whatever, that this practice has closed, the films  
16 will be maintained, and sort of keep them together  
17 and let people draw them out one at a time rather  
18 than break up the practice and you don't know where  
19 they would go.

20 DR. RAMOS-HERNANDEZ: Would it be  
21 appropriate to add some language about digital  
22 mammography since there might not be several  
23 facilities right now using it, but which will be  
24 the form that the will keep the records, because  
25 let's say that one of them closed and they keep

1 their records in hardcopy in the facility or  
2 anybody will not be able to use them?

3 DR. FINDER: I think we have kind of  
4 addressed that generally, but not in a specific  
5 question. The record retention requirement is  
6 irrespective of what type of modality, mammographic  
7 modality they are using, so the requirements are  
8 still the same. The patients still have to be able  
9 to get a usable copy whether it's digital, whether  
10 it's film-screen, whether it's xeroxed, whatever,  
11 not that there are any xerox out there anymore.

12 I think it's generally covered in that.  
13 We don't have a specific question. Maybe in the  
14 future we will get more questions specific to that,  
15 and we can address those as they come in.

16 DR. LEE: You already have in the guidance  
17 about arranging for the transfer of the medical  
18 records. I was wondering if it would be good to  
19 suggest that the facility also, as Nancy suggested,  
20 have something in the newspaper about their closing  
21 or even if you discontinue a phone number, you at  
22 least have the option of 30 days, this is the  
23 number that you can call to find out where we have  
24 your films or something like that, just so that the  
25 consumer knows where she can find her films.

1 DR. FINDER: I think that is a reasonable  
2 addition. We can come up with some wording to  
3 address that they should try and notify the  
4 patients.

5 MS. HARVEY: Mr. Bailey.

6 MR. BAILEY: Ed Bailey from California.  
7 We have had a little experience with bankruptcy.  
8 In one case, there were 4,000 patient films that we  
9 physically took possession of. They had sort of  
10 been thrown in a warehouse.

11 We went through the process of sending a  
12 letter to every single one of those people, and out  
13 of that 4,000 women for that facility, we got about  
14 1,000 people requesting their films.

15 The question of bankruptcy, and so forth,  
16 I think is very important. We recently had one  
17 company go bankrupt, had 12 facilities. That  
18 represents 1.5 percent of all the facilities in  
19 California. To me, that is a fairly significant  
20 number. I mean 1 percent, you don't think of as  
21 too much, but what happened is the bankruptcy  
22 trustee has all those records, but they are not  
23 stored in any way where they can be readily  
24 retrieved. They are in a warehouse.

25 The problem of existing records, I think