

FOOD AND DRUG ADMINISTRATION

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY  
COMMITTEE

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MEETING

+ + + + +

MONDAY,

SEPTEMBER 26, 2005

+ + + + +

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

ORIGINAL

The meeting was held in the Whetstone Room of the Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, at 9:04 a.m., Carolyn B. Hendricks, M.D., Chairperson, presiding.

COMMITTEE MEMBERS PRESENT:

CAROLYN B. HENDRICKS, M.D., Chairperson

CHARLES FINDER, M.D., Executive Secretary

SCOTT FERGUSON, M.D., Member

ALISA GILBERT, Member

JACQUELIN S. HOLLAND, R.N., C.R., Member

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COMMITTEE MEMBERS PRESENT (Continued):

MILES G. HARRISON, JR., M.D., Member

CAROL J. MOUNT, R.T. (R) (M), Member

DEBRA L. MONTICCIOLO, M.D., Member

MELISSA C. MARTIN, M.S., Member

LINDA S. PURA, R.N., M.P.A., Member

WILLIAM A. PASSETTI, B.S., A.A., Member

DIANE I. RINELLA, RT (R) (M), Member

JANE B. SEGELKEN, B.S., M.A., Member

MARK B. WILLIAMS, Ph.D., Member

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P R O C E E D I N G S

(9:04 a.m.)

1  
2  
3 CHAIRPERSON HENDRICKS: Good morning. I'd  
4 like to call this meeting of the National Mammography  
5 Quality Assurance Advisory Committee to order.

6 I also request that everyone in attendance  
7 at this meeting sign in on the attendance sheet that  
8 is available at the door.

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

14 To determine if any conflict existed, the  
15 agency reviewed the submitted agenda and all financial  
16 interests reported by the committee participants. The  
17 conflict of interest statutes prohibits special  
18 government employees from participating in matters  
19 that could affect their or their employer's financial  
20 interests.

21 However, the agency has determined that  
22 participation of certain members, the need for whose

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1 services outweighs the potential conflict of interest  
2 involved is in the best interest of the government.

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

13 These individuals are Ms. Diane Rinella,  
14 Ms. Jacquelin Holland, Ms. Debra Monticciolo, Mr.  
15 William Passeti, Dr. Mark Williams, and Ms. Jane  
16 Segelken.

17 Waivers are currently on file for Dr.  
18 Carolyn Hendricks, Dr. Scott Ferguson, Ms. Carol  
19 Mount, Ms. Alisa Gilbert, Dr. Miles Harrison, Ms.  
20 Linda Pura, and Ms. Melissa Martin.

21 Copies of the waivers may be obtained from  
22 the agency's Freedom of Information Office, Room 12A-

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1 15 of the Parklawn Building.

2 We would like to note for the record that  
3 if any discussion of states or certifying bodies was  
4 to take place in any meetings of the committee, it  
5 would be a general discussion only. No vote would be  
6 taken and no consensus sought.

7 In the interest of getting as many  
8 viewpoints as possible all SGEs, including state  
9 employees, would be allowed to participate in the  
10 general discussion so that all viewpoints could be  
11 heard.

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

18 With respect to all other participants, we  
19 ask in the interest of fairness that all persons  
20 making statements or presentations disclose any  
21 current or previous financial involvement with  
22 accreditation bodies, states doing mammography

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1 inspections under contract to FDA, certifying bodies,  
2 mobile units, breast implant imaging, consumer  
3 complaints, and mammography equipment.

4 CHAIRPERSON HENDRICKS: I note for the  
5 record that the voting members present constitute a  
6 quorum as required by 21 CFR Part 14.

7 At this time we'd like to move to the  
8 introduction of the panel members. Beginning from the  
9 right side, I'd like to have each member make a brief  
10 introduction.

11 MS. PURA: Good morning. I'm Linda Pura.  
12 I am Clinical Coordinator from the Los Angeles County  
13 Regional Partnership for Cancer Detection; also am a  
14 Susan G. Coleman Breast Cancer Foundation volunteer.

15 MS. HOLLAND: Good morning. My name is  
16 Jacquelin Holland, and I'm Program Director of the  
17 Diversity Enhancement Program at the James Cancer  
18 Hospital and Soloff (phonetic) Research Institute in  
19 Columbus Ohio.

20 MS. GILBERT: Good morning. I'm Alisa  
21 Gilbert from the Office of Native Cancer Survivorship  
22 in Alaska, Anchorage, Alaska.

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1 DR. WILLIAMS: And I'm Mark Williams from  
2 the University of Virginia, and I'm an Associate  
3 Professor of Radiology, Biomedical Engineering and  
4 Physics there.

5 MS. SEGELKEN: I'm Jane Segelken. I'm a  
6 breast cancer survivor, and I'm a volunteer with the  
7 Ithaca Breast Cancer Alliance.

8 DR. MONTICCIOLO: Good morning. I'm  
9 Debbie Monticciolo. I'm a Professor of Radiology and  
10 Section Chief of Breast Imaging at Texas A&M in  
11 Temple, Texas.

12 DR. FERGUSON: I'm Scott Ferguson. I'm a  
13 diagnostic radiologist from the State of Arkansas.

14 MS. RINELLA: Good morning. I'm Diane  
15 Rinella, mammography technologist and consultant.

16 DR. FINDER: Charles Finder. I'm a  
17 radiologist. I work for the Food and Drug  
18 Administration. I'm the Executive Secretary of this  
19 Committee.

20 CHAIRPERSON HENDRICKS: I'm Carolyn  
21 Hendricks. I'm a medical oncologist in private  
22 practice, and I focus on breast disease, and I'm

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1 chairing this committee.

2 MR. PASSETTI: Bill Passetti. I'm  
3 Director of Florida's Radiation Control Agency from  
4 Tallahassee, Florida.

5 MS. MOUNT: I'm Carol Mount, a manager of  
6 the Breast Imaging and Intervention Center, Mayo  
7 Clinic, Rochester, Minnesota.

8 DR. MARTIN: Melissa Martin. I'm a  
9 consulting medical physicist in Southern California  
10 area.

11 DR. FINDER: Dr. Harrison is coming in by  
12 telephone teleconference. Dr. Harrison?

13 DR. HARRISON: Yes. Good morning. I'm  
14 Miles Harrison of Baltimore, Maryland, a breast  
15 surgeon.

16 DR. FINDER: Thank you.

17 CHAIRPERSON HENDRICKS: At this time I'd  
18 like to make a brief statement specifically addressed  
19 to the individuals who will be speaking in the open  
20 public hearing sections of this meeting.

21 Both the FDA and the public believe in a  
22 transparent process for information gathering and

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1 decision making. To insure such transparency at the  
2 open public hearing session of this Advisory  
3 Committee, FDA believes it is important to understand  
4 the context of an individual's presentation. For this  
5 reason, FDA encourages you, the open public hearing  
6 speaking at the beginning of your written or oral  
7 statement to advise this committee of any financial  
8 relationship that you may have with the sponsor, its  
9 product, and if know, its direct competitors.

10 For example, this financial information  
11 may include the sponsor's payment of your travel,  
12 lodging or other expenses in connection with your  
13 attendance at this meeting.

14 Likewise, FDA encourages you at the  
15 beginning of your statement to advise this committee  
16 if you do not have any such financial relationships.

17 If you choose not to address this issue of financial  
18 relationships at the beginning of your statement,  
19 however, it will not preclude you from speaking.

20 DR. FINDER: Okay. Before we get to the  
21 public speakers, I want to mention about alternative  
22 standards that we have approved since the last

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1 meeting.

2 For those not familiar with this section  
3 of the regulations, FDA may approve an alternative to  
4 a quality standard that exists under Section 900.12,  
5 when the agency determines that, one, the proposed  
6 alternative standard will be at least as effective in  
7 assuring quality mammography as the standard it  
8 proposes to replace; and, two, the proposed  
9 alternative is too limited in its applicability to  
10 justify an amendment to the standard or offers an  
11 expected benefit to human health that is so great that  
12 the time required for amending this standard would  
13 present an unjustifiable risk to human health, and the  
14 granting of the alternative is in keeping with the  
15 purpose of Statute 42, USB 263(b).

16 Since last April's meeting the division  
17 has approved two alternative standards. The first  
18 deals with the system artifact testing at remote  
19 mobile mammography sites where film processing takes  
20 place using processors permanently located at that  
21 site.

22 This alternative permits a special trained

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1 quality controlled technologist to make system  
2 artifact films and phantom images at remote processing  
3 sites used by mobile mammography facilities and then  
4 submit them to the facility medical physicist for  
5 evaluation.

6 This relieves the facility from the need  
7 to have the medical physicist visit each remote  
8 processing site as part of the annual survey.

9 The second deals with system artifact  
10 testing of target filter combinations. The approved  
11 alternative permits the system artifact tests to be  
12 performed without testing all target filter  
13 combinations during the annual physics survey. These  
14 alternative standards in their entirety are available  
15 on our Web site in the policy guidance help system.

16 If anybody has any questions about these  
17 alternatives, I do have copies of the full wording for  
18 any of those.

19 I believe not.

20 CHAIRPERSON HENDRICKS: At this time we'll  
21 move it into the first public session. We will  
22 introduce the scheduled public speakers one by one.

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1           Our first speaker under the topic of  
2 approved alternative standards is Dr. Carol Lee, and  
3 she'll be speaking from ACR.

4           Dr. Lee.

5           DR. LEE: I want to thank this committee  
6 for allowing me the opportunity to address it. I am  
7 representing here the American College of Radiology,  
8 which is a 30,000 member professional organization  
9 representing diagnostic radiologist, radiation  
10 oncologists, and medical physicists.

11           And I also want to say that my travel  
12 expenses have been paid by the American College of  
13 Radiology to attend this meeting.

14           Is there any way that I can advance these?

15           Oh, okay. Could I have the next?

16           I hope you can read these slides. They're  
17 a little busy.

18           The American College of Radiology has a  
19 longstanding record of a commitment to quality in  
20 breast imaging. This began in part with a voluntary  
21 mammography accreditation program that was begun in  
22 1987 that laid the foundation for subsequent

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1 Mammography Quality Standards Act.

2 In 1993, the breast imaging reporting and  
3 database system was developed by the ACR, and provided  
4 a lexicon for description of breast findings and a  
5 reporting system that helped standardize and clarify  
6 mammographic reporting in this country.

7 In 1996, an accreditation program for  
8 stereotactic biopsy was developed. BI-RADS was  
9 expanded to include breast ultrasound and breast MRI  
10 in the most recent edition published in 2003, and this  
11 past year the American College of Radiology  
12 established a permanent breast imaging commission as  
13 part of its Board of Chancellors, replacing an ad hoc  
14 task force to deal with matters relating to breast  
15 imaging in this country.

16 The ACR also has a record of providing  
17 educational and self-assessment tools to breast  
18 imagers, including a biennial national conference on  
19 breast cancer. The ACR has developed a self-  
20 assessment tool that's available to the public and  
21 also sponsors a regular mammography education program  
22 at the Armed Forces Institute of Pathology for

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1 radiology residents across the country.

2 Next slide, please.

3 Now, in addressing problems with  
4 mammography interpretation, the IOM report  
5 unfortunately did not really specify what particular  
6 problems need to be addressed. It was sort of an  
7 overall assumption that there is a problem. Whether  
8 or not this is manifest as too many false negatives in  
9 mammographic interpretation, a recall rate that's too  
10 high or too low, a positive predictive value of  
11 biopsies that's too low, too much variability or all  
12 of the above was not specifically stated, and it's  
13 difficult to know how to develop programs or mandates  
14 or regulations to address problems when the problem  
15 itself it not specifically stated.

16 In terms of mammography interpretation,  
17 certainly there is room for improvement. Certainly  
18 mammographic interpretation is not perfect, but --  
19 next slide, please -- I do want to point out that  
20 mammographic interpretation in the United States has  
21 been compared unfavorably to that in the United  
22 Kingdom. It has been published that the recall rate

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1 from screening in this country is double that of the  
2 United Kingdom.

3           However, it should be kept in mind that  
4 practice climate, the malpractice situation differs  
5 dramatically between the two countries, and in  
6 looking at the report comparing U.S. to U.K.  
7 mammographic interpretation, there actually are more  
8 cancers that were picked up in the United States over  
9 the study period. There were 55 cancers per thousand  
10 women screened over 20 years compared to 43 in the  
11 United Kingdom. And most of the additional cases that  
12 were detected in the U.S. were due to small, invasive  
13 cancers, and DCIS, which is just the type of tumor  
14 that we hope to be able to detect through screening.

15           Next slide, please.

16           In addition, there are studies that have  
17 shown that the size of tumors within stages has  
18 decreased since the advent of modern mammography, and  
19 whereas in the period from 1975 to 1979, fewer than  
20 ten percent of breast cancers were under one  
21 centimeter. One quarter of all localized breast  
22 cancers were under a centimeter in the period from

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1 1995 to 1999.

2 Next slide.

3 And it's important also to keep in mind  
4 that breast cancer mortality in this country has  
5 decreased by 25 percent in the past ten years. The  
6 decrease in tumor size within stage over the past 30  
7 years accounts for most of the observed improvement in  
8 survival in localized breast cancer.

9 Next slide.

10 Now, that's a quick summary of the good  
11 news. The bad news is that there is an impending  
12 manpower crisis in breast imaging in this country.  
13 For this past July, only 33 percent of breast imaging  
14 fellowship positions within the fellowship match were  
15 filled. The proportion of radiology residents who  
16 state that they want to spend a significant percentage  
17 of their future practices in breast imaging has  
18 declined from 29 percent in a study done by Dr.  
19 Bassett, who will be addressing this committee later  
20 this morning, and in a more recent study of  
21 Massachusetts residents, only three percent said that  
22 they would like to spend a significant portion of

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1 their time doing mammography.

2 Next slide.

3 When looking at this study a little bit  
4 more in depth, these were 63 senior radiology  
5 residents that were surveyed in Massachusetts, and  
6 they were asked about their future career plans and  
7 about attitudes towards mammography.

8 Next.

9 Only eight percent said they wanted to do  
10 any mammography in their future jobs, and only three  
11 percent stated that they wanted to spend at least 25  
12 percent of their clinical time reading mammograms, and  
13 only one of the 63 intended to pursue a breast imaging  
14 fellowship.

15 So it's a bit disheartening, and there's  
16 no reason to think that Massachusetts is any different  
17 from any other state in this country.

18 Next.

19 When asked why they did not want to spend  
20 time doing mammography, the majority said that they  
21 were afraid of lawsuits and the medical legal climate.

22 Next.

1           Now, in talking about, in addressing the  
2 IOM regulatory recommendation in the recent report  
3 improving mammography quality standards, I want to  
4 address some of the requirements specifically.

5           Could I have the next slide?

6           One of these recommendations suggested  
7 requiring separate tracking of results of screening  
8 and diagnostic mammographs in order to be able to  
9 compare to established benchmarks.

10           The problem with this recommendation is  
11 that the definition of screening varies among  
12 practices and makes comparison among facilities quite  
13 difficult. I've recently found -- I've spent the past  
14 20 years doing breast imaging at Yale University in an  
15 academic practice, and just this past year I have been  
16 working as a breast imager in a private practice in  
17 Honolulu, Hawaii, and I can tell you that the practice  
18 varies considerably in terms of what is considered a  
19 screening mammograph, what is considered a diagnostic  
20 mammogram.

21           Both facilities produced very high quality  
22 images, and I think the personnel at both facilities

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1 are comparable in terms of their degree of expertise,  
2 but I can tell you that the practice patterns vary  
3 quite a bit.

4 Some facilities don't differentiate  
5 between screening and diagnostic examinations, and  
6 some facilities in the way they handle the  
7 examinations handle them differently to make this  
8 differentiation difficult.

9 And I also question the applicability of  
10 benchmarks to individual practices. As I was saying,  
11 my performance has not changed since I moved to  
12 Honolulu, but because the patient population differs  
13 so much as a high Asian population, women with very  
14 dense breasts are the norm rather than the exception.

15 There is a lower prior probability because the risk  
16 of breast cancer in this population is inherently  
17 lower, and my performance hasn't changed, but my  
18 benchmarks have. My recall rate is higher. My  
19 positive predictive value is lower. So I really  
20 question the applicability.

21 Next slide, please.

22 In terms of required tracking of outcome

1 of all cases with BI-RADS 0 assessment, this is not  
2 easily achieved. It's quite difficult to achieve this  
3 even with commercially available software tracking  
4 programs, and again, I have experience with two  
5 different, very widespread, widely utilized tracking  
6 programs, and this is a difficult audit to achieve  
7 with both of them. This requires a substantial  
8 increase in time and effort and expense, and we  
9 already track the BI-RADS, four and five cases that  
10 come out of the BI-RADS 0.

11 As stated in the IOM report itself, there  
12 has been no provide benefit to this additional  
13 tracking.

14 Next slide.

15 The inclusion of interventional  
16 mammographic procedures, specifically stereotactic  
17 biopsy, in the MQSA, we believe, would be justified  
18 because we do think that this would lead to quality in  
19 these procedures, and there is a stereotactic program  
20 again sponsored by the ACR that is in place.

21 Next slide, please.

22 Regulation of breast ultrasound and breast

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1 MRI are also mandates that are likely to result in  
2 improved technical quality. Unfortunately this is not  
3 yet feasible for breast MRI because the accreditation  
4 program has not been established, and also, the  
5 hardware and software is still in development in terms  
6 of technique for breast MRI.

7 Next please.

8 So increased regulation, particularly if  
9 it's unfunded, runs the risk of decreasing access  
10 through worsening manpower shortages and increased  
11 facility closure. I was recently at an ACR meeting  
12 where several of the attendees stated that their  
13 practices were considering dropping mammography  
14 services.

15 the goals of improvement inequality should  
16 be clearly understood, and new regulations should have  
17 a high likelihood of improving these targeted quality  
18 parameters.

19 Next please. Can you switch? In the  
20 interest of time, next slide.

21 So in conclusion, the ACR has a proven  
22 commitment to quality improvement that has been

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1 demonstrated over the years, and certainly these  
2 efforts should continue. The increased mandatory  
3 auditing requirements have not been shown to  
4 translate into improved quality that would justify the  
5 quite substantial commitment of time, effort and  
6 expense involved, and this that I'm referring to  
7 specifically is separating the screening and  
8 diagnostic auditing and the tracking of the BI-RAD 0  
9 cases.

10 We do feel that stereotactic breast biopsy  
11 and accreditation of breast ultrasound is likely to  
12 result in improvement in quality. It's premature to  
13 require regulation of breast MRI at this time.

14 Thank you very much.

15 CHAIRPERSON HENDRICKS: Thank you, Dr.  
16 Lee.

17 Are there any questions?

18 (No response.)

19 CHAIRPERSON HENDRICKS: If not, we'll move  
20 then to our second speaker in this open public  
21 hearing. We welcome Dr. Larry Bassett to the podium  
22 from the Society of Breast Imaging.

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1 Dr. Bassett.

2 DR. BASSETT: Thank you.

3 The Society of Breast Imaging is the  
4 largest national organization specifically committed  
5 to the practice of breast imaging, and I can refer you  
6 to the SBI Web site for position papers on the IOM  
7 report. Simply [www.sbi-online.org](http://www.sbi-online.org).

8 Next.

9 We are addressing now the issue of  
10 improving breast imaging quality standards from the  
11 Institute of Medicine published 2005. The Society of  
12 Breast Imaging commends the thorough data finding  
13 efforts and analysis by the IOM in defining many  
14 issues that are confronting breast imaging practices.

15 However, some proposed solutions may have a negative  
16 impact on the goals sought by both the IOM and society  
17 at large.

18 Here I've kind of outlined the four main  
19 categories of the recommendations to improve breast  
20 imaging quality taken directly from the IOM report.  
21 One is to improve mammography interpretation; the  
22 second, to revise MQSA regulations and inspections and

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1 enforcement; and next to insure an adequate work force  
2 by breast cancer screening and diagnosis; and the  
3 fourth, to improve breast imaging quality beyond  
4 mammography.

5 Next.

6 So starting with the first of those,  
7 improved mammography interpretation. This addresses,  
8 first, to revise and standardize the required medical  
9 audit component of MQSA and, two, to facilitate a  
10 voluntary advanced medical audit with feedback.

11 The SBI has found a concern about this in  
12 that increased regulations, while aimed to improve  
13 breast health care, have to deal with also the work  
14 force shortages and low reimbursement that will be  
15 aggravated by implementation of such measures.

16 Dr. Lee has indicated the crisis in the  
17 work force for breast imaging. This is something that  
18 has been identified and reported in at least three  
19 papers in the literature in peer reviewed journals.

20 Why is this happening? I think we heard  
21 that there's not new people coming into the field.  
22 There are people dropping out of the field and people

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1 retiring, and some practices simply do not find it  
2 financially feasible to have a strong breast imaging  
3 component.

4 We do feel that if we're going to increase  
5 regulations we need to have sufficient incentives to  
6 create an infrastructure that will support the  
7 improved delivery of care before these go into  
8 implementation rather than have them occur  
9 concurrently with the imposition of additional  
10 regulatory burden on a work force that's approaching  
11 crisis level shortages.

12 We see this every day in my practice. We  
13 train many breast imaging fellows. We've trained 64  
14 to date since we started that endeavor. I had two last  
15 year. Both of them had about ten job offers in the  
16 first month of their fellowship. There's a real need  
17 out there, and it's not being filled.

18 Next.

19 We are concerned that increased medical  
20 audit requirements may scare off other current breast  
21 imagers.

22 Next.

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1           The new audit recommendations are time  
2           consuming and require more paper work. No payment is  
3           included for this, although to date the facilities  
4           have used their own resources to pay for all of the  
5           requirements that they have to fulfill. This is  
6           another one that may just be the one that broke the  
7           camel's back.

8           In our own facility in order to try to do  
9           this kind of medical audit which we have been doing,  
10          but it's an academic institution, we had to hire a QA  
11          coordinator who keeps track of the zeros and so on and  
12          the fours and fives.

13          We couldn't do it as a radiologist because  
14          we're already working the work of two people because  
15          we're short staffed. We can't get someone to take the  
16          open position that we have in breast imaging, and this  
17          is true of most facilities that are academic  
18          facilities in the United States.

19          Small, rural facilities may not have the  
20          same kind of resources, may not be able to accomplish  
21          this. And the other thing that Dr. Lee referred to is  
22          that we know that the results of medical audits depend

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1 largely on your patient population. So we're not sure  
2 there's a real standard that we can arrive at that  
3 will be uniform across all practices.

4 Next.

5 In addition, there was a recommendation to  
6 establish breast imaging centers of excellence and  
7 undertake demonstration projects and evaluations  
8 within them, and further study of the effects of CME,  
9 reader volume, double reading and computer aided  
10 diagnosis and detection.

11 The Society of Breast Imaging supports the  
12 concept of centers of excellence and thinks this  
13 should be pursued.

14 In terms of the other recommendation,  
15 there's a lack of evidence that variables such as  
16 reader volume are related to interpretation quality  
17 and requiring greater volume would further reduce the  
18 number of physicians that are qualified to interpret  
19 mammograms.

20 Next.

21 The next issue was modifying regulations  
22 to clarify their intent and address current technology

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1 and to streamline inspections and strengthen  
2 enforcement for patient protection. And the Society  
3 of Breast Imaging agrees requirements should be  
4 reviewed to determine which are the effective ones in  
5 determining the quality of mammography and perhaps  
6 remove and eliminate those that are not effective.

7 And the SBI strongly supports streamlining  
8 the process.

9 Next.

10 In the next group to college and analyze  
11 data on mammography work force and service capability,  
12 to devise strategies to recruit and retain highly  
13 skilled breast imaging professionals, and to make more  
14 effective use of breast imaging specialists, the  
15 Society of Breast Imaging supports any way to reduce  
16 burden on the current breast imaging work force.

17 However, the use of radiologists to assist  
18 us to interpret breast images is controversial,  
19 remains to be proven in effectiveness, and does not  
20 reduce the medical legal responsibility of the  
21 interpreting physician who is overseeing them.

22 We do want to improve output. We want to

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1 do that without sacrificing quality.

2 Next.

3 Finally, to mandate accreditation for non-  
4 mammography breast imaging methods that are routinely  
5 used for breast cancer detection and diagnosis, such  
6 as ultrasound and breast MRI.

7 Also, we want to include the issue that as  
8 an X-ray examination of the breast, stereotactic  
9 biopsies should by law be included in MQSA  
10 regulations.

11 And as was mentioned, there's already an  
12 accreditation program that's set up. So this would be  
13 an easy one to implement.

14 High quality ultrasound is crucial in  
15 breast imaging today, but there is variable  
16 performance and equipment, and this also merits  
17 mandated accreditation, and again, there is an  
18 accreditation program already in process so that it  
19 could be easily adapted.

20 And, finally, breast MRI accreditation we  
21 feel should occur, but this will have to come later  
22 because we don't know what the proper standards are

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1 yet today.

2 Thank you.

3 One more slide.

4 Thanks for your time and service to the  
5 field of breast imaging. We appreciate this very much  
6 from the Society of Breast Imaging.

7 Thank you very much.

8 CHAIRPERSON HENDRICKS: Any questions  
9 related to Dr. Bassett's presentation from the  
10 audience or the panel?

11 (No response.)

12 CHAIRPERSON HENDRICKS: Then at this time  
13 we'll ask Dr. Finder to read two separate sets of  
14 written comments from public speakers who are not  
15 present today. The first is a set of anonymous written  
16 comments related to the IOM recommendations.

17 the second is a set of written comments  
18 submitted by Dr. Richard Ellis related to the IOM  
19 recommendations.

20 Dr. Finder.

21 DR. FINDER: For those in the audience,  
22 these comments are a part of the packet of materials

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1 that you have.

2 The first one, as mentioned, was sent in  
3 by a person who wishes to remain anonymous and wanted  
4 this read into the record. It says, "I am" -- and  
5 I'll try and go through as much as I can in ten  
6 minutes. It's a rather long statement here.

7 Okay. "I am a registered nurse of a  
8 woman's diagnostic center. As a patient advocate, I  
9 am aware of the advocacy of other nurses, such as Judy  
10 Wagner. I have some great concerns about the practice  
11 of mammography and other breast imaging modalities if  
12 we do not make some changes in educational  
13 requirements and tracking of competence.

14 "Screening mammography still provides the  
15 best defense against a death from breast cancer.  
16 However, this is only true when the quality of  
17 radiologists' reading accuracy is highly proficient.

18 "As you may or may not know, studies  
19 indicate that doctors need to read minimally 2,500  
20 films each year to stay sharp. The government,  
21 however, only requires 480 per year. It is ridiculous  
22 to think that anyone can be proficient reading this

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1 few per year.

2 "At this time the government does not  
3 require regulatory agencies to monitor these levels of  
4 proficiency. Having the radiology groups monitor  
5 internal performance is quite like having the fox  
6 watching the henhouse. Most radiology department  
7 directors have neither the time nor the staff to go  
8 back and find the false negatives.

9 "A run a small center, and makes it a  
10 priority to go back with each new cancer diagnosis and  
11 see if it fits into the false negative category. This  
12 is time consuming, but very necessary.

13 "To date I have discovered 18 false  
14 negatives read primarily by two radiologists within  
15 the past two years. I work closely with the medical  
16 director of the center who has been very supportive.  
17 He has helped me get this information to the Physician  
18 Quality Committee and has made recommendations to  
19 remedy the situation.

20 "While we have discovered the actual cases  
21 of missed diagnosis, I can only wonder how many more  
22 patients that were given a benign or negative outcome

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1 may have a cancer already.

2 "Several months ago we had a fellow  
3 trained mammographer join the practice. She quickly  
4 spotted the above problem and stated that there were  
5 two other physicians in the group who should not even  
6 read mammography. She stated that this was more of a  
7 problem than just the need for a few CMEs in  
8 mammography. The cancers that were being missed were,  
9 for the most part, not small, difficult to see  
10 cancers. It seemed clear to her that there was a real  
11 problem identifying what cancer looked like in its  
12 early stages.

13 "We have the R-2 image checker which is  
14 used, and still we have this many missed diagnoses.  
15 She left the group after only a few months to go to  
16 practice in a large hospital breast center. As with  
17 the majority of community hospitals, the radiology  
18 group has the hospital radiology contract. They are  
19 very good at many things. They rotate several  
20 physicians through our center to cover mammography.  
21 They do not enjoy reading mammography, and clearly,  
22 are not going to spend time and effort to even go to a

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1 visiting fellowship in mammography as recommended for  
2 correction of deficit.

3 "My problem is that once you have a really  
4 good mammographer and see what quality looks like, you  
5 can't go back. I have insisted that they find us  
6 another mammographer, and so far the administration  
7 has backed me up. They, of course, are dragging their  
8 feet because this new person will not generate the  
9 same amount of revenue that other physicians in the  
10 group generate.

11 "My feeling is that there needs to be a  
12 new paradigm in the way radiology groups think about  
13 practice recruitment and development. Because the  
14 average radiologist would prefer not to do mammography  
15 and other women's imaging, the group should be willing  
16 to subsidize salaries for those who are willing to do  
17 this kind of practice.

18 "Women deserve this vital service even if  
19 reimbursement is terrible. It should be of some value  
20 to a radiology group to have one well trained,  
21 passionate person take all the heat in this highly  
22 sued specialty. This mammographer could help raise

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1 the bar for all radiologists in the practice.

2 "Mammographers should be allowed to just  
3 do mammography and should not have to keep skills up  
4 in other areas as well. Breast imaging is changing so  
5 rapidly that it is no longer just mammography. A  
6 breast imaging specialist has to be able to read  
7 breast MRI, do minimally invasive breast biopsy  
8 procedures, talk to patients and the public in  
9 general. He or she should not be expected to take  
10 general radiology call as well.

11 "When I confront our radiology group with  
12 their individual statistics for all BI-RADS  
13 categories, false positive, false negative, true  
14 positive, true negative, and when I provide percent  
15 recommendations, they tell me that they should not  
16 have to be held to the standards. They say they don't  
17 read as many per year as mammography experts and can't  
18 be expected to reach the same level of proficiency.

19 "I say this is bunk. If I go to a surgeon  
20 and have my colon removed, should he be able to say to  
21 me, 'Well, I missed some of the possible cancer  
22 because I don't do as many of these as some others

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1 do'? May it never be.

2 "At the last NCBC conference this past  
3 February I voiced my desire to see minimal reading and  
4 CME standards improved.

5 "One, additionally we must improve  
6 reimbursement for breast imaging. We must find a way  
7 to provide incentives for bright, dedicated physicians  
8 to go into breast imaging.

9 "Two, we should encourage radiology groups  
10 to recruit breast images and be willing to subsidize  
11 their salaries.

12 "Three, regulatory agencies must find a  
13 way to do more than measure accuracy of equipment in  
14 their surveys until such time as physicians can  
15 adequately police themselves. In lieu of this,  
16 hospitals should be required to have non-physician  
17 personnel or consulting physician personnel monitor  
18 statistics for reading accuracy.

19 "Four, the MQSA needs to become more  
20 comprehensive. I am in favor of expanding it to  
21 Breast Imaging Quality Standards Act.

22 "Six, with regard to stereotaxic

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1 qualifications, I have no problem with surgeons doing  
2 stereotaxis in our center. If the radiologist has  
3 done a good job of marking the recommended area for  
4 biopsy, our technologists have no problem locating the  
5 lesion on the computer and preparing everything for  
6 the surgeon. He then reviews the mammogram. The  
7 stereo is set up and marks the area for biopsy.

8 "I think when surgeons get into trouble  
9 doing stereotaxis is when they interpret the  
10 mammograph which was done perhaps in their office,  
11 then expect an aide other than a registered mammo  
12 technologist to set up the equipment and position the  
13 patient.

14 "Recently I read in the Mammography  
15 Regulation and Reimbursement Report that the American  
16 College of Radiology would begin calling the false  
17 negative a sentinel event for the hospital. This  
18 would have a big impact on hospital accreditation.

19 "I will now be attempting to track our  
20 cancer patients to see if they die of breast cancer.  
21 If so, the sentinel event repercussions for the  
22 hospital are significant. I can see if this happens,

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1 the individual hospitals will begin demanding better  
2 quality readers of breast imaging.

3 "I am only one voice, but I am a thorn  
4 under the saddle. Each time I find another false  
5 negative, I see the patient's face. I am the person  
6 who will counsel them prior to their first surgical  
7 visit. I am the nurse who gives out her phone number  
8 to them for questions and comfort. I am the nurse who  
9 runs the women's cancer support group. None of them  
10 know that their cancer should or could have been  
11 caught earlier.

12 "It is my job to market our center as a  
13 center of excellence. We meet that goal in every  
14 single way. We have very high customer service  
15 scores, and people rave about the quick and  
16 compassionate service they receive. Indeed, we are a  
17 center of excellence in so many ways. It is the  
18 physician component that lets us down.

19 "In order to keep my job, I must fight  
20 this battle quietly within the Physician Quality  
21 Improvement Committee. It has been of little value to  
22 me. Recommendations for improvement are just that.

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1 The radiology group has little incentive other than my  
2 constant nagging to do much about anything."

3 And then she lists some percentages and  
4 indices for evaluation. I will say that this person  
5 reported that she had no financial interest, conflict  
6 of interest.

7 CHAIRPERSON HENDRICKS: Any questions or  
8 comments related to the anonymous statement?

9 DR. FINDER: Okay.

10 CHAIRPERSON HENDRICKS: Next we move to  
11 the comments from Dr. Richard Ellis.

12 DR. FINDER: Dr. Ellis is from the  
13 Gunderson Lutheran Medical Center. He also reported  
14 that he had no financial conflict of interest to  
15 report. We'll give him the full ten minutes.

16 He says, "I appreciate the opportunity to  
17 submit a statement for review and consideration by the  
18 FDA concerning the Institute of Medicine Committee's  
19 recommendations for improving MQSA.

20 "For over nine years I have practiced as a  
21 clinical breast radiologist, subspecializing in the  
22 early detection and diagnosis of breast diseases.

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1 Listed below are the issues that need to be reviewed  
2 and addressed both by the FDA and IOM committees as  
3 you prepare recommendations for reauthorization of  
4 MQSA.

5 "If the intent of screening mammography is  
6 to reduce the mortality and morbidity of breast  
7 cancer, then early interruption of the disease is  
8 paramount. Over the past 100 years we have seen  
9 advances in surgical techniques that have  
10 significantly improved patient morbidity but not  
11 mortality. Likewise, we now have chemo and hormonal  
12 therapies that have allowed moderate improvement in  
13 patient mortality.

14 "However, it is the advent of early  
15 detection and diagnosis which interrupts breast cancer  
16 early in its natural history that has resulted in the  
17 greatest reduction in mortality from breast cancer.

18 "Since the initiation of MQSA we have seen  
19 improvements in the technical aspects of screening  
20 mammography given the standards required for  
21 certification. However, even if we have the best  
22 equipment, X-ray film screen systems, technologists,

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1 quality assurance programs, and viewing conditions,  
2 but lack high quality interpretation of the screening  
3 mammograms, we severely limit the potential of early  
4 detection.

5 "This is clearly demonstrated in the  
6 randomized clinical trials for screening mammography  
7 as tumor size and stage at detection drives subsequent  
8 mortality rates. In order to insure high quality  
9 interpretation, a performance audit must be obtained,  
10 reviewed, and action taken when deficiencies are  
11 noted. A screening mammography interpretation  
12 performance audit should include one average size,  
13 mean and median size of the screen detected invasive  
14 carcinoma for women participating in 12 or 24 months  
15 screening intervals; two, total screening volume per  
16 year; three, recall rate; and four, positive  
17 predictive value for BI-RADS 4 and 5 categories. In  
18 order to help achieve acceptable screening performance  
19 standards, radiology residency, and breast imaging  
20 fellowship training as well as postgraduate training  
21 programs that properly instruct high quality screening  
22 interpretations are critical.

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1 "Although there are many  
2 mammography/breast imaging programs offered for CME  
3 each year, unfortunately many simply do not provide  
4 the type of education that will allow direct  
5 improvement in screening mammography interpretive  
6 skills.

7 "Two, many will argue that if physician  
8 performance standards are set to insure a high  
9 standard of care, then access to women in many  
10 communities will be lost as many general radiologists  
11 may not be able to achieve and/or maintain the  
12 required standards.

13 "This issue can and has been successfully  
14 addressed by other countries including Sweden and the  
15 United Kingdom. Although the total number of  
16 screening mammograms interpreted per year may serve as  
17 a surrogate performance marker, Items 1, 3, and 4  
18 listed above provide an objective measure of  
19 performance. If inappropriate low interpreting  
20 physician performance standards are set by MQSA to  
21 simply afford greater access, mortality rates will  
22 likely not be reduced, and overall cost of care will

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1 increase.

2 "Reasonable and preferable high  
3 interpreting physician performance standards need to  
4 be instituted. An exemplary model of postgraduate  
5 training success can be found by examining the  
6 interpreting physician performance improvements  
7 achieved by private practice, radiologists in  
8 Albuquerque," and he talks about Linver's practice  
9 there.

10 "Similar models of postgraduate training  
11 with proven success need to become a fundamental part  
12 of physician CME for screening mammography breast  
13 imaging.

14 "On a similar issue, communities and  
15 medical institutions of sufficient size should strive  
16 toward creating interdisciplinary breast care teams  
17 which help provide improved overall care, efficient  
18 use of resources, and substantial reduction in medical  
19 costs.

20 "Third, with the use of screening  
21 mammography, the majority of breast cancers are  
22 initially detected in the preclinical phase,

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1 nonpalpable. However, other imaging modalities,  
2 especially breast ultrasound, are frequently used in  
3 the diagnostic evaluation of screened detected  
4 abnormalities to further segregate which patients may  
5 require a biopsy for definitive tissue diagnosis.

6 "Given the advancement in training and  
7 technology, most breast biopsies can be performed  
8 under image guidance to include ultrasound and  
9 stereotactic guided breast biopsies. In 1996, through  
10 the joint efforts of the American College of Radiology  
11 and the American College of Surgery, we have the  
12 stereotactic guided breast biopsy accreditation, but  
13 which remains under voluntary accreditation.

14 "However, breast ultrasound and ultrasound  
15 guided breast biopsies have multiple guidelines and  
16 accreditations from various institutions and agencies,  
17 to include the ACR, the ACS, the American Society of  
18 Breast Surgeons, and the American Institute of  
19 Ultrasound in Medicine.

20 "Both the FDA and IOM members need to  
21 investigate why they're on multiple and varied  
22 physician training guidelines and accreditations for

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1 breast ultrasound examinations and procedures. The  
2 FDA and IOM should insist on a single universal  
3 standard for ultrasound examination and procedure  
4 training guidelines and accreditations so that  
5 multiple standards are not propagated.

6 "Even amongst radiologists there is a wide  
7 disparity of performance and interpretation for breast  
8 ultrasound. The universal accreditation program will  
9 help insure that not only mammography, but also other  
10 breast imaging examinations and procedures meet an  
11 acceptable MQSA standard for accreditation. If the  
12 FDA and/or IOM through the MQSA does not require and  
13 enforce the universal practice standard for breast  
14 ultrasound examinations and procedures, then the  
15 qualification for breast ultrasound will simply fall  
16 to whomever can afford the equipment regardless of  
17 prior training and performance level.

18 "In the very near future universal  
19 standards and accreditation should also be established  
20 for breast MRI and imaging guided breast tumor  
21 obliteration.

22 "Four, although not directly related to

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1 MQSA, a major issue to be considered is the dwindling  
2 number of radiologists and training residents that  
3 have a desire to provide mammography/breast imaging  
4 services. Relatively low reimbursement rates and high  
5 exposure to malpractice litigation must be addressed  
6 and appropriate incentives need to be provided to  
7 prevent radiologists from abandoning  
8 mammography/breast imaging services. Creative  
9 solutions, to include providing graduated  
10 reimbursement rates for mammography/breast imaging  
11 services based on physician performance and creating a  
12 balanced, knowledgeable national committee to review  
13 and arbitrate medical malpractice suits, along with  
14 placing caps on punitive damages, tort reform will be  
15 important.

16 "Should you have any questions or need  
17 additional information, please contact me. I  
18 appreciate your review and consideration of my  
19 recommendations."

20 CHAIRPERSON HENDRICKS: That ends the  
21 submitted comments from the public speakers for this  
22 portion of the session.

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1                   Based on the itinerary, I'd move to a  
2 break, but may be we should move into the next speaker  
3 because we are ahead of schedule.

4                   The next item on the agenda are some  
5 comments to be made by Dr. Michael Divine, who is  
6 Chief of Inspection and Compliance Branch, to comment  
7 on inspection observations.

8                   Mr. Divine, welcome.

9                   DR. DIVINE: My name is Michael Divine.  
10 I'm the Chief of the Inspection Compliance Branch,  
11 Division of Mammography, Quality and Radiation  
12 Programs.

13                   There will be two main topics for this  
14 particular discussion. One will be similar to the  
15 inspection results from the MQSA inspections for the  
16 last three fiscal years. The fiscal year for FDA runs  
17 from October 1st to September 30th, and I'll also talk  
18 about from follow-up actions involved regarding things  
19 we can do when we find serious problems.

20                   Okay. The inspection results I'm going to  
21 be discussing for this fiscal year, which started  
22 October 1st ran through August 26th of this year. All

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1 of our inspection observations from inspections are  
2 broken down into three different levels. The first is  
3 level one, which we consider the most serious. This  
4 is the most likely one that might result in us taking  
5 regulatory action or conducting a follow-up inspection  
6 or warning the facility if they don't have a history  
7 of problems.

8 The next level which we consider moderate  
9 but still significant is level two, and the last one  
10 is level three, which we consider minor. No  
11 significant problems.

12 This is probably the most important slide  
13 I'll give for this presentation because it shows the  
14 overall performance of facilities over time. If you  
15 looked at a chart like this spreading back to 1995  
16 when we started inspections, you would also see that  
17 it has been continuously improving since the beginning  
18 of the program.

19 The level one observations has been very,  
20 very small, for several years now almost nonexistent  
21 on this slide. You also see a drop in the level two  
22 and the level three problems over time, and you're

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1 seeing that the top line, the blue line is where  
2 things have gotten to we're about at 70 percent of  
3 facilities that have a clean inspection.

4 Starting with some level one problems for  
5 initial qualification of personnel, the first set of  
6 bars has to do with the physician either having board  
7 certification or the alternative of having two or  
8 three months of training in mammography. This number  
9 has been dropping.

10 To give you an example of the perspective,  
11 we do about 9,000 inspections. So this is way less  
12 than five percent of facilities that have this  
13 problem. The license problem, we still see some of  
14 that. Mostly we think that's an issue of allowing the  
15 license to expire and not getting it renewed, which is  
16 mostly a technical problem and not really related to  
17 quality, or that they don't have any documentation at  
18 the facility during the inspection.

19 For the medical physicist, pretty much has  
20 just gone away. We don't see too many problems with  
21 the physicists at all anymore. We still see some  
22 problems with the technologists. Once again, this is

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1 a very, very small number of facilities considering  
2 the number we inspect every year, and that has also  
3 been dropping.

4 In the QC area, once again, we have some  
5 problems, but they're not that significant in terms of  
6 overall numbers. We have an observation for if they  
7 have failed to do processor QC for five consecutive  
8 days or more, that will get them a level one, and  
9 that's around 30 to 40 facilities. Processing out of  
10 limits, when they're outside the actual limits on  
11 their processor charts.

12 The third category is where we look at the  
13 number of days in a month, the percentage. That is  
14 also very small, and the last column is when there's  
15 standard QC missing.

16 The first few charts on this, these are  
17 tests that are done during the inspection. All of the  
18 ones that are very low are relating to test  
19 inspectors. As you can see, it's much less than 20  
20 facilities for any of those phantom tests, either the  
21 spec groups, the fibers or the masses that are broken  
22 down individually. So there's a very small number of

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1 problems that we're finding with phantom image  
2 testing.

3 Under processing, which is a test we do,  
4 it's called the step test, which is a test of  
5 sensitometry where we actually run a film through the  
6 processor and compare it against a standard. We find  
7 very few problems with that these days. The  
8 processing has gotten much better.

9 We do find a certain number of problems  
10 with fog when we go in to test the fog in the dark  
11 room, but once again, we're talking about much less  
12 than five percent of facilities.

13 These are problems relating to the survey.  
14 The first column is where there's more than 14 months  
15 between the annual survey. Even though they're  
16 required to have an annual survey, we allow up to 14  
17 months between surveys before we consider it to be a  
18 problem.

19 The next column is when we go into the  
20 facility, and the last survey was more than 14 months,  
21 but they haven't had a more recent survey during the  
22 inspection. So it's a much bigger problem when we go

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1 in because of the timing. We usually see the last  
2 survey and the one before that being more than 14  
3 months.

4 The next set of columns has to do with an  
5 incomplete survey where there's either a problem with  
6 the tests that were done or there were missing tests  
7 from the survey. So the survey was done, but there  
8 was a problem with it.

9 The next column has to do with the X-ray  
10 unit. When they installed a new X-ray unit or they  
11 have a major repair on the unit, they have to have  
12 mammography equipment evaluation done by a medical  
13 physicist, and this column has to do with -- these  
14 were not done -- once again, this is a very small  
15 number because if it's a unit, they have to go through  
16 accreditation. So they're going to have to have it  
17 done anyway. So this is a fairly rare occurrence.

18 The next one is where they install a new  
19 processor or they have a major repair on the  
20 processor. Once again, they have to have the medical  
21 physicist come in and do an evaluation, and we're  
22 seeing very few problems in that area.

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1           These are testing that are done by the  
2 inspector during the tests, and I added this slide for  
3 comparison purposes because we're going to be talking  
4 about what things we do during inspections and  
5 streamlining inspections during the next discussions.

6           The first column is zero, and there's an  
7 asterisk there to point out that we have not seen a  
8 dose value exceeding 300 millirad in an inspection  
9 since 1997. It has basically gone away as a problem.

10           So we're still doing the testing, but we  
11 haven't found any problem since 1997. Exposure  
12 reproducibility, almost nonexistent. It looks like  
13 about ten facilities out of about 9,000 inspections.  
14 This is a test to see that shooting the X-ray beam  
15 several times with the phantom in the beam produces  
16 the same level of radiation. Beam quality has  
17 basically gone away as a problem.

18           We still see a certain number of  
19 facilities with the alignment tests, but this involves  
20 several different tests we do in the inspection. One  
21 is oversizing of the X-ray beam on the film. It also  
22 involves where the compression paddle is in relation

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1 to the film and the chest wall of the X-ray. So there  
2 are several different problems that can get a facility  
3 here. So it's not just one test.

4 But even taking that into consideration,  
5 there's still a small number of facilities, less than  
6 five percent.

7 Getting into some interpreting physician  
8 qualifications, radiologist qualifications, and level  
9 two, one is the initial CME. That's either having 40  
10 hours of training in mammography or 60, depending upon  
11 why the physician qualified. Once again, that's a  
12 small problem and has been decreasing. The initial  
13 experience is the 240 mammograms read within a six  
14 month period. That's very small.

15 We see more problems with continuing  
16 experience, continuing education, but those numbers  
17 have been going down over time, and as you can see,  
18 the continuing education has been dropping, too.

19 Technologists qualifications. The  
20 mammography training is that they have to have 40  
21 hours of training in mammography with supervised  
22 examinations. Once again, we're almost seeing no

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1 problems with that. As with the physicians, you're  
2 still seeing some problems with continuing experience.

3 The continuing experience is to have read 200  
4 mammograms in a 24-month period, and the continuing  
5 education in a similar position. I still see some  
6 problems, but they are decreasing.

7 Medical physicist, initial training or  
8 initial experience requirements. Once again, we're  
9 seeing almost no problems at all in that area. Also  
10 having some problems with the continuing education and  
11 experience, but as you can see, it's almost  
12 nonexistent compared with 9,000 inspections a year.

13 Getting onto medical records and reports,  
14 we have a problem. The facility has a problem with  
15 sending out patient letters or mammography reports  
16 within 30 days. They can get a level one for that.  
17 We consider that a very serious problem. Once again,  
18 this is just a small number of facilities. Way less  
19 than five percent of facilities get this problem. So  
20 it's pretty much a non-problem these days.

21 We do see some problems with the  
22 assessment categories. A lot of that has to do with

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1 wording. We're still seeing problems with that, but  
2 we don't consider that to be a significant problem,  
3 but it is decreasing, and reports without the  
4 physician being identified, that's almost gone away  
5 altogether.

6 the first one has to do with the X-ray  
7 unit. When we first went in with the final regs. in  
8 1999, requirements that, for instance, they have to  
9 have two film sizes for each mammography unit to do  
10 the 24 by 30 and the 18 by 24. Most of those problems  
11 have gone away, almost nonexistent problems these  
12 days.

13 We still see some problems, though very  
14 minor, with the procedure for consumer complaints, and  
15 that has been going down, I think, as the facilities  
16 get better educated as to exactly what we're  
17 expecting, and the procedure for infection control,  
18 once again, that's a small number of facilities. Once  
19 these procedures are in place we usually don't see it  
20 from year to year. So a lot of these could be  
21 facilities that are new or have changed their  
22 procedures and we find problems with them.

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1           This has to do with the medical outcomes  
2           audit. The first one has to do with not all of the  
3           positive mammograms are entered into the system. Once  
4           again, this is a very small problem.

5           The second one, even though it says no  
6           biopsy results, what we're actually talking about is  
7           they haven't gotten all of the biopsy results for all  
8           of their positive mammograms or they can't document  
9           that they have made an honest attempt to get all of  
10          those results.

11          The third one has to do with they have not  
12          identified an audit interpreting physician for -- this  
13          is an annual audit. The third one is, which we've  
14          seen more problems than the last three categories, but  
15          still very small. The analysis is not done annually.

16          They're required to do an annual analysis of the  
17          results.

18          The last one is that they haven't broken  
19          down the analyses by each interpreting physician,  
20          which they're required to do, and the last one is that  
21          they haven't done an analysis for the entire facility.

22          They may have broken it down by each physician, but

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1 they don't have a complete analysis for the whole  
2 facility or they haven't done it at all.

3           This one has to do with just if they have  
4 any problems, and if you go back to all of those other  
5 problems where we talked about qualifications of  
6 personnel, if they have any problem, they get cited  
7 for this, and there's also a situation where -- and  
8 it's a good time to mention this -- if they go in and  
9 there's something missing from the file, but the  
10 facility can justify that the documentation exists and  
11 they can obtain it within five days after the  
12 inspection and they can provide that to the inspector,  
13 either fax it to the inspector or get it to the  
14 inspector before they send the inspection to us. We  
15 allow the inspector to remove that observation from  
16 the inspection, but they will still get cited for this  
17 thing because they have to have their documentation,  
18 their paper work ready for the inspection.

19           So we consider it a problem, and we want  
20 to track these problems. Of all the things I've show  
21 today, this is going to be the highest because, you  
22 know, there's always going to be something at a lot of

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1 facilities that they're going to have a problem  
2 somewhere, and so this is still less than about ten  
3 percent of facilities, but still more. And once  
4 again, it's still been something that is decreasing.

5 Okay. The next part of the talk is I'm  
6 going to be discussing actions that we can take after  
7 inspections and for facilities that have ongoing  
8 problems, once again, most of what you saw in the  
9 previous slides have to do with problems that aren't  
10 going to result in these kind of things. It's just a  
11 very, very small number of facilities that have  
12 problems over and over again, and that we've decided  
13 we've warned them and they still have problems.

14 The types of things that we can do, the  
15 first thing we would probably consider is a follow-up  
16 inspection, and the follow-up inspection would be  
17 done, let's say, for a level one problem at a  
18 facility. Let's say the facility had responded to the  
19 level one. Well, we knew the facility had some  
20 problems in the past, and even though they're telling  
21 us what they're going to do to correct the problem,  
22 because of their track record, we want to go back in

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1 there to see that everything has been corrected  
2 permanently. So we might go in. Since we're doing an  
3 annual inspection, we might go in about midyear, about  
4 six months and go in and check to see if everything is  
5 okay.

6 Another thing that we can do which has to  
7 do with evaluating whether the problems at a facility  
8 could affect clinical image quality is we can do  
9 additional mammography review. In the vast majority  
10 of situations the facility's accreditation body would  
11 be done the additional mammography review, but our  
12 regulations allow for us to have somebody other than  
13 the accreditation body do the review, but that would  
14 be under very unusual circumstances where that would  
15 occur.

16 Should the results come back from that  
17 additional mammography review that the patient's  
18 facility's mammography quality represented a serious  
19 risk to human health, we have the authority to require  
20 patient and physician notification about those  
21 problems so that the patients are aware that there's a  
22 problem or a potential problem with their mammogram.

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1 Another thing we can do if we have a  
2 facility that has a lot of problems is something  
3 called a directed plan of correction. This is a list  
4 of conditions in addition to what's in the regulations  
5 for them to operate. This is something we can do  
6 instead of shutting the facility down. We think we  
7 can work with the facility. It requires a lot of  
8 monitoring.

9 For instance, a typical thing they might  
10 require would be that they would have to send in  
11 records to FDA, let's say, on a monthly basis, for  
12 instance, quality control records or any other things  
13 that we think requires the requirements to be put in  
14 the facility so we are assured that they are operating  
15 in compliance, and it also could involve additional  
16 inspections where we go into the facility and  
17 requiring them to come up with more detailed  
18 procedures than would be required of the regulations  
19 so that we know that they're keeping track of things.

20 Civil money penalties is pretty self-  
21 explanatory. This involves fines that we can levy  
22 against a facility that is in violation.

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1           The next one is if these other things have  
2 not worked, if we've tried to work the facility.  
3 We've given them warnings. We've even put them under  
4 a directed plan of correction or we believe that they  
5 have a serious risk to human health, let's say, from  
6 an AMR, additional mammography review.

7           We have the option of suspending their  
8 certificate. If we suspend their certificate, they  
9 have to stop doing mammography until we lift the  
10 suspension, and another option, which we have yet  
11 used, is revocation. This would be a much more  
12 serious version of suspension. They would have to  
13 stop doing mammography, but the owner-operator of the  
14 facility could not own or operate a facility for two  
15 years if this occurred.

16           The last one is injunction. This is the  
17 only one on this list that would actually go to  
18 federal court. We consider this somewhat of a last  
19 resort because we have all of these other tools. We  
20 usually don't have to go to court. We can deal with  
21 facilities in that, but up to this point we have not  
22 used injunction.

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1           Injunction basically is a court order that  
2 would shut the facility down. There are only two  
3 conditions under which we can use this. One is that  
4 the facility's mammography is a serious risk to human  
5 health. Since we usually suspend the certificate if  
6 we find that to shut the facility down, we would only  
7 go to court if they continued to do mammography after  
8 suspension.

9           Another one is if they were performing  
10 without a certificate. Once again, usually when we  
11 find a facility that's performing mammography without  
12 a certificate, after talking to them they usually shut  
13 down until they can get reinstated or apply to an  
14 accreditation body to get a certificate. So most of  
15 those are not real problems, but if a facility just  
16 decided they were going to continue without a  
17 certificate even after warnings, we would have to go  
18 to court to shut them down.

19           Follow-up inspections. We checked on  
20 corrective actions for serious problems. Usually it's  
21 a level one, though it could be repeat level two.  
22 Usually if a facility has recent problems, if they

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1 haven't had problems in the past, we probably will at  
2 least evaluate their response, and if it looks  
3 adequate we probably won't need to do a follow-up  
4 inspection. So it's usually a facility that has a  
5 level one or a repeat level two, but now they have  
6 more problems in the past. So we can't really take  
7 their word for it as far as their corrective action,  
8 and it's usually limited to certain specific problems  
9 because something we believe we can monitor without  
10 actually having to go in the facility.

11 Additional mammography view, as I  
12 mentioned, it's usually done by the accreditation  
13 body. It can be anything from two mammograms all the  
14 way up to 30 mammograms, and if there's a serious risk  
15 found in the review, we would require patient and  
16 physician notification.

17 Some examples, if we find a level one  
18 phantom image failure at inspection, we do a limited  
19 review, usually two mammograms to check everything is  
20 okay with the clinical quality. The level one for the  
21 interpreting physician, we theoretically could do  
22 that; in most cases is related to qualifications. We

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1 usually are able to resolve those problems without  
2 having to do an additional mammography review, and in  
3 many cases it's more practical. If they can't  
4 document that they meet their initial qualifications  
5 at a level one, we may actually have the facility,  
6 have another qualified interpreting physician rereview  
7 all of the mammograms read by that interpreting  
8 physician. So sometimes that works better than having  
9 to do an AMR, and that assures that all of the  
10 mammograms are read by a qualified interpreting  
11 physician.

12 If we have problems, we from time to time  
13 have complaints about clinical image quality that need  
14 to be investigated, and really the only way to do that  
15 is to have the accreditation body look at clinical  
16 images to assure how bad the problem is or if there is  
17 a problem.

18 Overall, quality assurance failures,  
19 generally when we find a lot of problems in that area,  
20 we're usually taking some other action, and because we  
21 found these problems, we have to have some assurance  
22 that they haven't affected clinical image quality. So

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1 we usually do additional mammography review in those  
2 cases.

3 And with fraudulent record keeping, which  
4 relates to some of these other areas, we usually do --  
5 we have to be able to assure that the clinical image  
6 quality has not been affected by the fraud.

7 Once again, if the AMR shows a problem  
8 that's a serious risk to human health, we require  
9 patient and physician notification. This provides the  
10 patients and the physicians an explanation of the  
11 problems that were found, how they were found, and  
12 some follow-up actions that the patient may wish to  
13 have another mammogram. The patient may wish to have  
14 another physician evaluate their mammogram to see if  
15 their mammogram is bad enough that they do need  
16 another mammogram.

17 And we try to use plain language as much  
18 as possible. In the early days we did some focus  
19 testing and found that we have to make sure that  
20 everybody understands what's being included in the  
21 letter, and we try to make it as readable level for  
22 all possible patients that could be notified.

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1 Directed correction imposes additional  
2 requirements in the facility and allows us to monitor  
3 what's going on in terms of them sending letter into  
4 us, and it could include additional inspections.

5 We only use suspension for very serious  
6 violations. Under the act we can suspend for a  
7 variety of serious violations. However, we usually  
8 have to give the facility a hearing in advance for  
9 them to contest our intention for suspension. So they  
10 have the option for a hearing.

11 We usually do this when we've tried to  
12 work with the facility. Usually if it was rated with  
13 the quality assurance program, we would usually put  
14 them under a directed plan of correction before going  
15 to this or we would use, you know, some other method  
16 before threatening to close them down.

17 And if we find a health hazard which is a  
18 serious risk to human health, usually found through  
19 additional mammography review, the law allows us to  
20 shut them down immediately, and that's usually our  
21 standard procedure for doing that. If we find a  
22 serious risk, they're shut down immediately, though

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1 they do have the option for a hearing after the fact  
2 if they want to contest the fact that we shut them  
3 down.

4 Just to give you some idea of the numbers  
5 of actions we have taken over the course of the  
6 program, this goes back to 1994 when MQSA started.  
7 Sixty-four additional mammography reviews, 17 patient  
8 and physician notifications, four directed plans of  
9 corrections, three civil money penalties. The six  
10 suspensions include we have another option under the  
11 law that if the accreditation body revokes the  
12 accreditation of the facility, the facility  
13 certificate will remain in effect until FDA decides  
14 that it should not remain in effect because of the  
15 problems that were found.

16 In many cases we have taken actions  
17 directly from a serious risk to human health finding,  
18 an additional mammography review, which also resulted  
19 in the accreditation body revoking the accreditation  
20 of the facility, and then we remove their certificate  
21 pretty much immediately.

22 As I mentioned in my earlier talk or

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1 earlier slides, revocations and injunctions have yet  
2 to be used.

3 CHAIRPERSON HENDRICKS: Thank you very  
4 much.

5 Any questions for Mr. Divine? I had one.

6 DR. DIVINE: Yes.

7 CHAIRPERSON HENDRICKS: Carolyn Hendricks,  
8 panel Chair.

9 In your opinion, which aspects of the  
10 current routine facility inspections could be  
11 completely eliminated without impacting the quality of  
12 the inspections that are currently being performed?

13 DR. DIVINE: Well, one of the things that  
14 we have been considering removing because, as I  
15 mentioned, we do a dose tester in each inspection on  
16 each X-ray unit, and we haven't found any problems  
17 since 1997. So it's very hard to justify doing that  
18 test every year if we don't find any problems every  
19 year. That would be one I would mention.

20 And if we eliminate that, we would also  
21 probably be eliminating the reproducibility test  
22 because that's all done in conjunction with it, and

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1 the beam quality test also because we find very few  
2 problems, but those are the things that stick out in  
3 my mind.

4 CHAIRPERSON HENDRICKS: Questions? Mr.  
5 Passetti.

6 MR. PASSETTI: Bill Passetti.

7 You mentioned that you haven't seen  
8 anything exceeding the dose limits and how long. do  
9 you know what the current average is that you're  
10 seeing throughout the facilities?

11 DR. DIVINE: I think it's about 1.7  
12 milligray, which is about 170 millirad. That's my --  
13 1.7, 1.8 I think. It's been going up a little, but  
14 that doesn't result in any problems with the dose  
15 testing.

16 I think the reason it has been going up is  
17 that there has been a preference for darker  
18 mammograms, and usually that's achieved through using  
19 a little higher exposure to the patient, but that  
20 hasn't resulted in any noncompliances by going up in  
21 the last few years.

22 CHAIRPERSON HENDRICKS: I have a follow-up

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1 question. Would those changes that you propose  
2 related to elimination of those steps in the  
3 inspection significantly reduce the inspection time or  
4 expense of the facilities in your estimation?

5 DR. DIVINE: The inspection time depending  
6 upon how many units at the facility and the particular  
7 inspector. I think if we eliminated the radiation  
8 exposure test, that might reduce the inspection time  
9 maybe half an hour per unit. That's just a guess off  
10 the top of my head. I don't know how much that would  
11 affect the fee. I couldn't really comment on that.  
12 It certainly would be something we could consider, but  
13 I don't know. I don't have any data on that.

14 CHAIRPERSON HENDRICKS: Yes.

15 DR. WILLIAMS: This is Mark Williams,  
16 University of Virginia.

17 Just a follow-up comment on the question  
18 of dose. I wonder if it wouldn't be interesting to  
19 look at not just the average in the recorded doses  
20 during inspection, but also look at the dispersion  
21 around the average to see what kind of spreads they  
22 are, maybe in conjunction with data from the ACR to

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1 see whether or not it might be useful considering a  
2 different upper limit. If there is a fair amount of  
3 spread around that average, then it may be that even  
4 though we don't see violations above 300, it may be  
5 useful to consider other thresholds.

6 DR. DIVINE: Yeah, one thing I would  
7 mention, since you brought that up, is that there's an  
8 article. I think it's still available on our Web site  
9 where we have a spread of the dose data that we found  
10 during inspections, and so we do have that available.

11 One thing I will mention is that we're  
12 going to be looking into this issue, and we're going  
13 to be recording the dose values that are found by the  
14 medical physicists during the annual survey to compare  
15 against the values that we're finding during  
16 inspection so that we have some idea of how close we  
17 are to that and also, you know, if we're finding any  
18 problems. We're looking to that also

19 DR. FINDER: Dr. Finder.

20 I just wanted to add that in addition to  
21 the fact that currently we aren't measuring the dose  
22 every year, the medical physicist measures it every

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1 year at the facility and the accreditation body  
2 measures it every three years.

3 CHAIRPERSON HENDRICKS: Other questions  
4 from the panel, the audience?

5 I have another question. Related to your  
6 slide with the very high proportion of facilities that  
7 do not have any violations or any findings a tall,  
8 that would be a global lack of any findings in their  
9 audit, including the other CME documentation,  
10 requirements with --

11 DR. DIVINE: Yes, they get an inspection  
12 report that says all items in compliance.

13 CHAIRPERSON HENDRICKS: And that  
14 represents just about 70 percent of all the  
15 facilities?

16 DR. DIVINE: Yes. It has been continually  
17 increasing over the course of the program.

18 CHAIRPERSON HENDRICKS: So in your view  
19 then, would those facilities then benefit from less  
20 frequent screening if it's those facilities which are  
21 operating at such high quality levels that it might be  
22 okay for them to be screened at a less frequent

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1 interval and still maintain that high quality of care  
2 as determined by the inspections?

3 DR. DIVINE: Yeah, that's a possibility.  
4 One thing we discussed at the last meeting was the  
5 results of the inspection demonstration program and  
6 what we found was that there seemed to be an increase  
7 in the number of problems when facilities skipped an  
8 inspection, but you know, there were problems with  
9 that study, but that's what we had found.

10 Yeah, we are open to suggestions on that.

11 DR. FINDER: Yeah, this is Dr. Finder.

12 I just wanted to enhance what Mike said  
13 about this. For those new members on the committee,  
14 in the last reauthorization, Congress asked us to take  
15 a look at that exact issue about whether good  
16 facilities could be inspected less frequently and  
17 asked us to do a demonstration project or program on  
18 that.

19 We did evaluate a number of facilities  
20 that had been basically significantly citation free  
21 and had them inspected every other year, and the  
22 results of that were placed on our Website, and what

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1 they tended to show is that even the good facilities  
2 in the second year of inspection were found to have an  
3 increased number of citations compared to even the  
4 standard facility.

5 So it has been looked at at least to some  
6 degree, and at least the preliminary results were not  
7 very conducive to the concept of having every other  
8 year inspections.

9 CHAIRPERSON HENDRICKS: Thank you very  
10 much.

11 Any other questions from the panel  
12 members, the speaker or the audience?

13 (No response.)

14 CHAIRPERSON HENDRICKS: In that case, I  
15 think we'll move to the break. We're scheduled on the  
16 agenda for a 30 minute break or for a 15 minute break.

17 So we'll reconvene -- I just doubled the break -- so  
18 that we'll reconvene here in 15 minutes.

19 Thank you very much.

20 (Whereupon, the foregoing matter went off  
21 the record at 10:24 a.m. and went back on  
22 the record at 10:45 a.m.)

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1 CHAIRPERSON HENDRICKS: To start the next  
2 discussion, I'd like to invite Dr. Helen Barr to the  
3 podium. She's the Director of the Division of  
4 Mammography Quality and Radiation Programs, and she's  
5 going to lead a discussion of the Institute of  
6 Medicine recommendations.

7 Dr. Barr.

8 DR. BARR: Thank you.

9 Good morning, everyone. First and  
10 foremost, I'd like to thank you all on behalf of the  
11 division as well as the office, and indeed, all of FDA  
12 for being here, taking time out of your busy lives and  
13 schedules to come and give us your thoughts and  
14 opinion.

15 And as you'll hear when I tell you a  
16 little bit about my background, I have been out in the  
17 real world. So I do know what it's like to come from  
18 there, and I can't tell you how much we appreciate you  
19 all being here.

20 First of all, before I start, I wanted to  
21 make just two minor corrections. Mr. Divine mentioned  
22 that we will be in the process of collecting dose data

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1 that the physicist supplies to compare to dose data  
2 that the inspector actually measures during the  
3 inspection.

4           Actually we are already doing that so that  
5 we can make a comparison because one issue we've heard  
6 is that there's possibly a disparity between the  
7 measurements a physicist makes and the measurements  
8 the inspector makes, and I wanted to indicate that we  
9 will be doing that, but we already are underway doing  
10 that, and we'll be able to compare those results as we  
11 along.

12           Second, Dr. Finder mentioned that the  
13 inspection demonstration program was in the last  
14 reauthorization of MQSA. That was actually in the  
15 first reauthorization of MQSA. There has been a  
16 reauthorization since then. I just want to make that  
17 minor correction.

18           In the interest of transparency and so  
19 that you know a little bit about me because obviously  
20 my background informs naturally the way I work here in  
21 the federal government. I graduated from George  
22 Washington University School of Medicine and did my

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1 internship and residency in diagnostic radiology  
2 there. I did a fellowship there and stayed on there  
3 on the faculty for two years before I moved to Kaiser  
4 Permanente here in the mid-Atlantic region where I was  
5 the Director of the breast imaging services, including  
6 interventional procedures, for nine mammography  
7 centers throughout the mid-Atlantic region that  
8 performed well over at that time 60,000 mammograms a  
9 year.

10 We have the second stereotactic unit in  
11 the Washington metropolitan area. So I have  
12 experience in that area since the very beginning of  
13 the modality.

14 I came here to FDA -- I was just counting  
15 on my fingers -- I just passed my sixth anniversary  
16 here at FDA, and I came on as a Deputy Director of the  
17 Division of Mammography Quality and Radiation  
18 Programs, and in I guess about a year and a half -- I  
19 don't know how long -- became the Director of the  
20 program.

21 So that's who I am. Dr. Finder asked me  
22 before we start on the subject at hand to just mention

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1 to you a little bit about what we're doing about what  
2 was one hurricane and now is two hurricanes in  
3 relation to facilities and personnel throughout the  
4 Gulf Coast who may have been affected by the  
5 hurricane. We have a significant amount of  
6 information on our Web site related to what facilities  
7 can do in natural disasters and, in particular, what  
8 facilities in the Gulf Coast can do.

9 Probably the biggest thing that we're  
10 doing is helping personnel who are moving to other  
11 states be able to get employment at other facilities.

12 We here at FDA are looking at the last inspection  
13 that the personnel would have been involved in, and  
14 based on findings from that, providing personnel with  
15 letters so that they can document other initial and  
16 continuing requirements so that they can go other  
17 places and obtain employment right now.

18 These are folks that have had records  
19 destroyed in the wake of the hurricane. So Dr. Finder  
20 just asked me to mention briefly to you that we were  
21 hopefully doing good things.

22 I'm sorry. This microphone keeps -- if I

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1 lower it to where it needs to be it keeps tipping.

2 I also apologize in advance that I am a  
3 great seasonal allergy sufferer. So I've got my  
4 tissues and my sneezing and everything else up here.  
5 So I do apologize for that. Even though I am Dr.  
6 Finder's boss, my constant begging of him to schedule  
7 this meeting after the first frost doesn't seem to  
8 have gotten me anywhere.

9 (Laughter.)

10 DR. BARR: What our job -- you can imagine  
11 what the rest of my days are like.

12 What I'm going to lead us through here for  
13 the bulk of today and tomorrow is actually marching  
14 step by step through the Institute of Medicine  
15 recommendations. There's a lot of material here, and  
16 we want to get as much of your input as we can on  
17 these recommendations.

18 Some of them my guess is will require  
19 basically no discussion. Some of them may engender a  
20 fair amount of discussion, particularly when we get to  
21 the part on modification of MQSA regulations. What  
22 I'd like to do is perhaps not get stuck on the wording

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1 so much as the spirit of what is being recommended to  
2 be changed because I personally think that some of the  
3 new recommended wording is perhaps as confusing as  
4 some of the old wording. So rather than get bogged  
5 down on wording, you know, perhaps we can agree on the  
6 spirit, and then if something needs to be changed in  
7 regulation then, you know, experts on writing that  
8 can take our thoughts and put it down in the proper  
9 language.

10 Any questions before we begin about  
11 anything or shall we just dive right into it?

12 Okay. Here we go.

13 The background for the Institute of  
14 Medicine report is that over the last three years, and  
15 particularly the time of the last reauthorization, a  
16 lot of questions regarding the quality of imaging  
17 interpretation in mammography have been floating  
18 around, you know, through articles, through public  
19 opinion in Congress, and Congress struggled with a way  
20 to perhaps look at what the problems in image  
21 interpretation might be before putting anything  
22 specific in the law or taking anything out of the law

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1 and regulations.

2           The Institute of Medicine is a part of the  
3 National Academy of Sciences, and Congress  
4 commissioned a study from them in preparation for the  
5 last reauthorization -- excuse me -- at the time of  
6 the last reauthorization of MQSA in reparation for the  
7 next reauthorization of MQSA in hopes that the  
8 information from the IOM report could be used in the  
9 next reauthorization to improve particularly image  
10 quality interpretation.

11           Congress at that time also commissioned a  
12 GAO report on access to mammography and a couple of  
13 other issues, and although I know GAO is busy working  
14 on that report because we've been working on it  
15 actively with them, we do not have the results of that  
16 report yet, but luckily we do have the IOM results.  
17 So we're going to go ahead and get started with those.

18           The Congress' intent that, based on  
19 commissioning a study, for the IOM to look at a step  
20 to increase of interpretation, whether current  
21 regulation should be modified, the effects of  
22 recommendation on access to mammography, and

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1 identifying steps to insure safe and effective use of  
2 other screening or diagnostic tools.

3 The report is called improving breast  
4 imaging quality standards, and it was done  
5 specifically by the Committee on Improving Mammography  
6 Quality Standards of the National Cancer Policy Board  
7 at the Institute of Medicine.

8 There were four major areas of  
9 recommendation that the IOM came out with, and as I  
10 said, this is a very long, comprehensive report. So  
11 we've tried to take their four major areas of  
12 recommendation, and we'll be marching through them  
13 step by step.

14 Now, one was improve mammography  
15 interpretations.

16 Two, revise MQSA regulations, inspections  
17 and enforcement.

18 Insure adequate work force for breast  
19 cancer screening and diagnosis, and improve breast  
20 imaging quality beyond mammography.

21 I'm going to start with the first of those  
22 major categories, improving mammography

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1 interpretation. The recommendations within this  
2 category from the IOM were to revise and standardize  
3 medical outcomes audit, to facilitate voluntary  
4 advanced medical audit with feedback to establish  
5 specialized breast imaging centers of excellence; to  
6 study the effectiveness of continuing medical  
7 education, that should say. I know we had that slide  
8 changed, but somehow it's here wrong again. That  
9 should be continuing medical education.

10 Reader volume, double reading, and  
11 computer aided detection. So I'll go through the  
12 first of those recommendations to revise and  
13 standardize medical outcome audit.

14 This is just a lot of information about  
15 the different forms of positive predictive value, and  
16 if I can skip ahead here, I'll know which one we  
17 should concentrate on, which looks like PV-2.

18 The proportion of all women recommended  
19 for biopsy after mammography, Category 4 or 5, that  
20 are diagnosed with breast cancer. So particular note  
21 is that value.

22 And also different definitions for

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1 different forms of false positive.

2 IOM recommends that the medical audit  
3 should include the calculation of three core measures:  
4 the positive predictive value two, the proportion of  
5 women recommended for biopsy after mammography,  
6 Category 4-5, or are diagnosed with breast cancer;  
7 cancer detection rate per 1,000 women; and the  
8 abnormal interpretation rate, women whose mammogram  
9 interpretations lead to additional imaging or biopsy.

10 The rationale that they include in the  
11 report is that MQSA currently does not require  
12 calculation of specific performance statistics; that  
13 all of these three things together would be more  
14 useful than PPV-3. It's easier to calculate. PPV-3  
15 is easier to calculate than PPV-1 or -- excuse me --  
16 PPV-2 is easier to calculate than PPV-1.

17 That additional imaging assessment not  
18 included in the MQSA audit. I'm not sure what that  
19 means. Let me go back to that. I don't know. I  
20 can't speak to that specifically.

21 So I guess we'll discuss those first. So  
22 I'll go back to the slide that has the overall

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1 recommendations.

2 (Pause in proceedings.)

3 DR. BARR: Not only is Charlie Finder a  
4 great Associate Director, but he's the best  
5 administrative assistant I've ever had.

6 (Laughter.)

7 DR. BARR: Which I tell him all the time.

8 So here is the medical outcome audit, and  
9 I'm going to turn over to Dr. Hendricks and Dr. Finder  
10 if you have any discussion on this matter.

11 DR. FINDER: Yeah, it's Dr. Finder.

12 Basically as reported in the IOM summary,  
13 we do not require any specific statistics as part of  
14 the medical audit. We do require that the facility  
15 identify and track all positive mammograms, and we  
16 identify those read as suspicious or highly suggestive  
17 of malignancy, the fours and fives. They have to make  
18 a reasonable attempt to find out what happened to  
19 those patients and include that in their audit, but we  
20 do not tell the facility what specific statistics they  
21 need to do, whether they need to do any calculations  
22 at all, in effect.

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1           And the IOM is recommending that these  
2 three measures be included as part of the regulation  
3 that all facilities must do, and we're interested in  
4 hearing from the committee on what they think about  
5 this approach.

6           CHAIRPERSON HENDRICKS: We've got a couple  
7 of radiologists on the panel. If we could solicit  
8 your opinions first on how these recommendations would  
9 impact your practice, for example.

10           DR. FERGUSON: Scott Ferguson from  
11 Arkansas.

12           I see no need for adding increased  
13 mathematical calculations. It would be a burden on  
14 the system and I don't think would add anything to the  
15 system to increase the number of calculations that you  
16 have to make.

17           Where is that information going? I mean,  
18 who's using that information? What good does it do I  
19 guess is my question.

20           CHAIRPERSON HENDRICKS: Thank you. I  
21 think we'll move along a little bit and maybe part of  
22 your question will be addressed as to what the IOM

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1 thinks about who should be using this information.

2 DR. FINDER: Any other comment?

3 CHAIRPERSON HENDRICKS: The next  
4 recommendation under this category is performance  
5 measures should be stratified by screening and  
6 diagnostic mammography. Rationale is difficult to  
7 interpret and compare performance with current  
8 literature or established databases.

9 Any comments? Discussion? I know we  
10 heard some in the ACR. Dr. Lee gave some opinions on  
11 this.

12 DR. MONTICCIOLO: This is Dr. Monticciolo.  
13 I'm a radiologist.

14 Yeah, I agree with the comments that were  
15 made earlier. I think it's very difficult to start  
16 discriminating between screening and diagnostic when  
17 there's differences among practices, what somebody  
18 considers a screen versus a diagnostic.

19 And so, like Dr. Ferguson next to me, I'm  
20 not sure how useful that discrimination will be and  
21 how that will help anybody. And I'll just add burden  
22 where I don't see much gain.

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1 DR. BARR: Thank you.

2 MS. MOUNT: Carol Mount.

3 I agree. Within our facility we have a  
4 number of satellite facilities, and every one of those  
5 facilities also call screening and diagnostics  
6 different. So I think it would be very difficult to  
7 differentiate.

8 CHAIRPERSON HENDRICKS: I'd just add a  
9 comment. I think I'm a medical oncologist. So like  
10 the majority of my patients have breast cancer, have  
11 been diagnosed and treated for breast cancer.

12 I actually think that this may be a very  
13 important point. I think that just the fact that  
14 amongst the panel members out there is a great  
15 difference, and it has been the definition of a  
16 screening and diagnostic mammogram doesn't mean that  
17 we don't need to establish one. I think the  
18 facilities in this community -- and I practice in  
19 Bethesda, Maryland -- are really overburdened right  
20 now from women who are seeking out diagnostic imaging,  
21 and they just don't have the resources for the  
22 radiologist to read those films in prime time.

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1 I think that if the public could be  
2 educated, the word well, the women that we are  
3 targeting for screening could be educated on what the  
4 true definition of a screening mammogram, which in my  
5 clinical practice is the screening of a woman age 40  
6 or older with no breast symptoms at the time  
7 examination is done.

8 I think this is a very important public  
9 health issue, and I think it could really lessen the  
10 burden that certainly the facilities in this area are  
11 overwhelmed with women seeking out diagnostic imaging  
12 when really they are more appropriate for screening.

13 So I don't think that we should abandon  
14 this idea that we could level the playing field and  
15 create a definition of a screening patient that all  
16 facilities could accept. But I'd welcome other  
17 comments about that.

18 DR. MONTICCIOLO: Well, I think the  
19 problem comes in, just the variations of practice. I  
20 have one surgeon who wants all of his patients with  
21 cancer to be diagnostic, and so we fight this battle  
22 every year, and we have another surgeon when I was at

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1 Emory. The main surgeon, who was a well known, a  
2 nationally known cancer surgeon, said, "I want my  
3 cancer patients to be screened because I want them to  
4 feel as normal as possible."

5 Now, you have the implant patients. You  
6 know, should they be screening or should they be  
7 diagnostic? And I think you're right. It would be  
8 nice to have a standard, you know, who falls in where,  
9 but some facilities can't respond to those standards  
10 very easily. So we have to keep that in mind. We put  
11 more restrictions on facilities about what they can  
12 and can't do.

13 For example, implant patients. We now  
14 can't do them as screening. So we have women that  
15 have to drive 40 miles -- I live in central Texas --  
16 to get their diagnostic mammogram and they have no  
17 breast complaints, but they happen to have implants.

18 So there's all of these variations, and I  
19 think you're right. If we had something more  
20 standard, but when we do impose that standard it's  
21 going to have implications. So I'm a little concerned  
22 about access and the difficulty of putting more layers

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1 on what we do.

2 CHAIRPERSON HENDRICKS: Yes, ma'am.

3 MS. PURA: Linda Pura.

4 We use simple terms as asymptomatic,  
5 symptomatic, and then special views for the implant.  
6 It could be as simple as that, and then, of course,  
7 you have to start subdividing, but those are simple  
8 terms that can be utilized.

9 CHAIRPERSON HENDRICKS: Also in response  
10 to the issue one of our tasks is to try to decrease  
11 the burden that inspection and mammography has placed  
12 on the system economically and clinically for the  
13 imagers. The concern about my patients who seek out  
14 or are continually in this diagnostic mode is the  
15 frequency with which they should be studied.

16 So a very high proportion of women are  
17 seeking mammography at intervals more frequently than  
18 years. Whereas if we could establish some standard or  
19 some period of time beyond which mammography more  
20 frequently than yearly could be performed in women who  
21 are long term survivors of breast cancer, for example,  
22 I really do think that the burden would be decreased

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1 significantly.

2 DR. BARR: Thank you.

3 DR. FINDER: Would they be screening or  
4 diagnostic?

5 (Laughter.)

6 CHAIRPERSON HENDRICKS: In my community  
7 here in Bethesda, the women are used to having -- what  
8 has become quite commonplace is women want face-to-  
9 face interaction with their radiologist. They'll call  
10 and they'll schedule because they know that a certain  
11 physician is going to be reading that day. Basically  
12 they want an appointment slot, you know, to meet their  
13 mammographer after their imaging.

14 And, of course, when you look at flow  
15 through a mammography unit, that can really cripple  
16 the flow and decrease the number of high quality  
17 images that the facility can read and the radiologist  
18 can interpret.

19 So, again, it's more of a public health  
20 issue to educate women and their families and their  
21 physicians on high quality breast care, you know, at  
22 the expert level because there are experts in images,

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1 of course, who understand the requirements and which  
2 women would benefit from more frequent imaging and  
3 which women require screening and diagnostic  
4 approaches.

5 DR. MONTICCIOLO: I agree with you. I'm  
6 in favor of increasing education. I'm just not sure  
7 that separating out audit data is going to help. To  
8 me that seems like an extra burden, but I like the  
9 idea of getting a more standardized approach to who  
10 gets screening, et cetera.

11 DR. BARR: Thank you.

12 C under recommendations option, that  
13 facilities should have the option of combining audit  
14 measures for physicians at multiple facilities. Their  
15 rationale in the report is that the data would be more  
16 meaningful or is more meaningful when larger numbers  
17 of exams per physician are analyzed.

18 Charlie, do you want to comment on what's  
19 currently the --

20 DR. FINDER: It's Dr. Finder.

21 I just want to kind of provide some  
22 background of where we are right now. Under the

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1 current regulations, each facility is required to do  
2 its own audit. So the data has to be done. Whatever  
3 data they do or whatever calculations they do, and  
4 again, we don't require any specific calculations, has  
5 to be broken down by facility and by individual  
6 physician at that facility.

7 Part of the reasoning behind that is we  
8 have authority over facilities, not over individual  
9 personnel, and that's the entity that we can hold  
10 responsible for making sure that that happens. Once  
11 you start expanding out to other facilities, it  
12 becomes more problematic.

13 Another issue was that since we did not  
14 require that the audit be done, either broken down by  
15 screening or diagnostic, we felt that if we could at  
16 least keep it to the facility level, then all of the  
17 physicians at that facility would basically be in most  
18 cases looking at the same populations, and they would  
19 be able to compare whatever analysis was done at that  
20 facility with the other physicians at that facility,  
21 and that was our purpose basically for the audit. It  
22 was not for a national collection or anything like

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1 that, but just so the physicians at the individual  
2 facility could compare themselves with the other  
3 physicians at that facility.

4 So in that sense, our regulations talk  
5 about these analyses being done facility specific.  
6 Now, we have adjusted to that. We actually have  
7 approved an alternative standard which allows mobile  
8 facilities in which their mobile units are each  
9 individually certified so that their own facility, but  
10 where the physicians are the same and these mobile  
11 units all go kind of round robin to the same  
12 populations.

13 We have allowed them to combine their data  
14 into one audit, but we have not done that yet for  
15 fixed facilities, and part of the reason is we  
16 couldn't be -- one, we didn't even get an alternative  
17 standard request for that specific issue, but the  
18 other is we do have concerns about how you're going to  
19 combine data from different facilities to make a  
20 cogent analysis.

21 If, for example, one facility is screening  
22 basically and another one is primarily diagnostic,

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1 what happens to the data when you combine those two?

2 But that's why you're here, and we want to  
3 hear what you have to say about this issue because it  
4 is being constantly brought up. As part of our  
5 guidance, we do suggest that even though according to  
6 our regulations you must base this on a facility,  
7 individual facility, we do recommend that practice  
8 groups that practice at multiple facilities combine  
9 their data and do a second analysis to get their data  
10 and look at that also because we do believe that the  
11 increased numbers can supply additional information.

12 But again, our current standard is the  
13 audit has to be facility based and then broken down by  
14 individual physician at that facility.

15 CHAIRPERSON HENDRICKS: Any comments?

16 DR. FINDER: Comments, thoughts? Do  
17 people think it would be a good idea if we allowed  
18 multiple facilities to combine their audits and just  
19 produce one set of data?

20 DR. MONTICCIOLO: It seems to me as a  
21 radiologist that what you're interested in is how the  
22 physician is performing. So if they read at multiple

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1 facilities, I see no problem with that. I would be  
2 strongly in favor of allowing them to combine data  
3 because the larger your numbers are, the larger the  
4 sampling and the more accurate look you're going to  
5 have at that person.

6 CHAIRPERSON HENDRICKS: I have a comment.

7 In this area, in this geography, there is multiple  
8 satellite offices. So certainly I would support, you  
9 know, the data to be combined for multiple satellite  
10 offices when there's one large clinical practice  
11 responsible for providing the mammography services.

12 DR. BARR: Thank you.

13 DR. FERGUSON: My question would be are  
14 you talking about mandating or are you talking about  
15 allowing them to combine their data?

16 DR. FINDER: It's a very good question.  
17 It could be either one, depending on what kind of  
18 advice we get.

19 DR. BARR: And I think maybe D speaks a  
20 little bit to that. The recommendation is that audit  
21 data collection and analysis be verified at  
22 inspection, but not collected -- I assume they mean

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1 collected -- by the FDA, and the rationale is no  
2 change in procedure one because regulator is not able  
3 to verify the accuracy of the data.

4 DR. FERGUSON: I guess my question goes to  
5 this data is for the physicians to judge among  
6 themselves how good a job they're doing. It's not  
7 used for any other purpose, right?

8 DR. FINDER: Well, correct. Under the  
9 current regulations, the information obtained from  
10 that audit is supposed to remain at the facility. We  
11 do not collect that data. We do not create a national  
12 database or use that data except to see that it has  
13 been done. That's all we do.

14 DR. FERGUSON: And so I would favor  
15 allowing rather than mandating because this is for  
16 physicians to improve themselves and see where they're  
17 shortcoming, and I think they should be measuring  
18 those standards against one another, and if someone  
19 needs additional training or whatever, they take care  
20 of it.

21 But as far as mandating it, it doesn't go  
22 any further than the group. I don't see where you

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