UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

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November 4, 2011
8:00 a.m.

Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, Maryland

PANEL MEMBERS:

CAROLYN B. HENDRICKS, M.D.	Chair
ROBERT M. FAULK, M.D.	Non-Voting Member
SARA J. FREDRICKSON, M.D.	Non-Voting Member
SUJATA GHATE, M.D.	Non-Voting Member
DANIEL B. KOPANS, M.D.	Non-Voting Member
CAROL H. LEE, M.D.	Non-Voting Member
DEBRA L. MONTICCIOLO, M.D.	Non-Voting Member
THOMAS G. RUCKDESCHEL, M.S.	Non-Voting Member
JAMES A. SEIBERT, Ph.D.	Non-Voting Member
JUSTIN P. SMITH, M.D.	Non-Voting Member
WEI T. YANG, M.B.B.S., FRCR	Non-Voting Member
MARLENA VEGA, Ph.D., M.S.W.	Patient Representative
MADELINE Y. LAWSON, M.S.	Consumer Representative
DEBORAH R. LAXAGUE, RN	Consumer Representative
CAROL A. PRICE, RN (Retired)	Consumer Representative
SANKAR SURYANARAYANAN, Ph.D., M.B.A.	Industry Representative
KATHLEEN M. WILLISON, RT(R)(M)	Industry Representative
SHANIKA CRAIG, MHA, M.B.A.	Designated Federal Officer

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FDA PRESENTERS:

CHARLES FINDER, M.D.
Associate Director, Division of Mammography Quality and Radiation Programs

MICHAEL P. DIVINE, M.S.
Division of Mammography Quality and Radiation Programs

INVITED SPEAKER PRESENTER:

ERIC BERNS, Ph.D.
University of Colorado Hospital
Denver Health Medical Center

OPEN PUBLIC HEARING SPEAKERS:

LYNNE FARROW, Breast Center Choices, Inc.
NANCY CAPPELLO, M.D., Are You Dense, Inc.
JOANN PUSHKIN, Are You Dense Advocacy, Inc.
MARC F. INCIARDI, M.D., University of Kansas Medical Center
MARSHA GLAZER
ELLEN GRUBER
HENDA SALMERON
STACEY VITIELLO, M.D., Montclair Breast Center
LISA WEINSTOCK, M.D., Women's Digital Imaging
KAREN HANDEL, Susan G. Komen for the Cure
TERRY TYLER, M.D., Owensboro Medical Health System
BARBARA MONSEES, M.D., ACR Breast Imaging Commission

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M E E T I N G

(8:00 a.m.)

DR. HENDRICKS: I'd like to call this meeting of the National Mammography Quality Assurance Advisory Committee to order.

My name is Carolyn Hendricks, the Chairperson of the Committee. I'm a medical oncologist in practice in Bethesda, Maryland. I'm a former member of this Committee from February of 2003 to January of 2007 and chaired in January of 2007.

I note for the record that the voting members that are here present today constitute a quorum as required by 21 C.F.R. Part 14. I would like to add that the Panel participating in the meeting today has received training in FDA device law and regulations.

For today's agenda, this Committee will provide advice and recommendations on the following issues: (1) proposed changes to the Mammography Quality Standard Act (MQSA) policies and inspection procedures; (2) accreditation body review of soft copy mammography images; and (3) reporting breast density on mammography reports and patient lay summaries. The Committee will also receive updates on the MQSA Program and the status of the Full Field Digital Mammography universal quality control manual.

Before we begin, I'd like to ask the Committee members and FDA staff seated here at this table to introduce themselves. Please state your

name, your area of expertise, your position, and your affiliation, beginning with Dr. Vega.

DR. VEGA: I'm Marlena Vega. I'm from the South Bronx. I think that says it all. I'm a psycho-oncologist, a three-time survivor of breast cancer, a third-generation survivor, and I have an organization called A Will to Live, where we work with underserved women and their families in order to keep them intact and together and where we just celebrated our 42nd year.

MS. WILLISON: Kathy Willison, Hologic, Incorporated, Vendor Representative, Manager of Clinical Research, Breast Health.

DR. SURYANARAYANAN: Sankar Suryanarayanan, Industry Representative from Philips Healthcare, from Andover, Massachusetts.

MS. PRICE: Carol Price, Consumer Representative, breast cancer survivor and registered nurse.

MS. LAXAGUE: Debbie Laxague, Consumer Representative from far northern California, from a small organization that serves people in our small county.

MS. LAWSON: Madeline Lawson. I'm a Consumer Representative, and I serve professionally as the President and CEO of the Institute for the Advancement of Multicultural and Minority Medicine, based here in Washington, D.C., and the focus of the institute is on addressing health disparities.

DR. YANG: Wei Yang, breast radiologist practicing in

MD Anderson Cancer Center, Houston, Texas.

DR. FAULK: Robert Faulk, a diagnostic radiologist, breast imaging specialist, and I'm in private practice, Omaha, Nebraska.

LCDR ANDERSON: Lieutenant Commander Sarah Anderson of the United States Public Health Service and the FDA.

MS. CRAIG: Shanika Craig, DFO for this Committee.

DR. KOPANS: Dan Kopans. I'm Professor of Radiology at Harvard Medical School and senior radiologist in the breast imaging division at the Massachusetts General Hospital.

DR. LEE: I'm Carol Lee. I'm a diagnostic radiologist specializing in breast imaging. I'm attending radiologist at Memorial Sloan-Kettering Cancer Center and Professor of Radiology at Weill Medical College, Cornell University.

DR. FREDRICKSON: I'm Sara Fredrickson. I'm a breast surgeon in private practice just outside Chicago.

DR. SEIBERT: Tony Seibert, Professor of Radiology at the University of California, Davis in northern California. I'm a medical physicist and work in digital imaging in mammography and other types of breast imaging.

DR. SMITH: Hi, I'm Justin Smith. I'm a radiologist in nuclear medicine and diagnostic radiology, and I'm with a private group in Washington State. I'm the founder and led the company of Confirma for

about 12 years. That's the company that made the first breast MR pattern recognition system.

DR. GHATE: And I'm Sujata Ghate. I'm Assistant Professor of Radiology at Duke University Medical Center and specializing in breast imaging.

DR. MONTICCIOLO: I'm Debbie Monticciolo. I'm Professor of Radiology and Section Chief of Breast Imaging at Texas A&M.

MR. RUCKDESCHEL: I'm Tom Ruckdeschel. I'm President and Certified Medical Physicist for Alliance Medical Physics, which is a group of medical physicists that oversee medical facilities in the southeastern United States and evaluate mammography programs for MQSA.

DR. HENDRICKS: Thank you.

And Dr. Finder.

DR. FINDER: I'm Dr. Charles Finder. I'm the Associate Director for the Division of Mammography Quality and Radiation Programs, and I've been with the MQSA Program since 1994.

DR. HENDRICKS: Thank you.

I just want to remind all the participants, if you have not already done so, please sign the attendance sheets that are out at the tables by the door.

And next, Ms. Craig, who is the Designated Federal Officer for the National Mammography Quality Assurance Advisory Committee, will

make some introductory remarks.

MS. CRAIG: Good morning. I will now read the Conflict of Interest and Deputization to Temporary Voting Member Statement.

FDA Conflict of Interest Disclosure Statement for a particular matter of general applicability, the National Mammography Quality Assurance Advisory Committee. Today's date is November 4th, 2011.

The Food and Drug Administration (FDA) is convening today's meeting of the National Mammography Quality Assurance Advisory Committee under the authority of the Federal Advisory Committee Act (FACA) of 1972. With the exception of the industry representatives, all members and consultants of the Committee are special Government employees or regular Federal employees from other agencies and are subject to Federal conflict of interest laws and regulations.

The following information on the status of this Committee's compliance with the Federal ethics and conflict of interest laws covered by, but not limited to, those found at U.S. Code 18 Section 208 and Section 712 of the Federal Food, Drug and Cosmetic Act (FD&C Act) are being provided to participants in today's meeting and to the public.

FDA has determined that the members and consultants of this Committee are in compliance with the Federal ethics and conflict of interest laws. Under U.S. Code 18 Section 208, Congress has authorized FDA to grant waivers to special Government employees who have financial conflicts when

it is determined that the Agency's need for a particular individual's services outweighs his or her potential financial conflict of interest. Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to special Government employees and regular Government employees with potential conflicts when necessary to afford the Committee essential expertise.

Related to the discussion of today's meeting, members and consultants of this Committee who are special Government employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of U.S. Code 18 Section 208, their employers. These interests may include investments; consulting; expert witness testimony; contracts/grants/CRADAs; speaking/teaching/writing; patents and royalties; and primary employment.

For today's agenda, the Committee will provide advice and recommendations on the following issues: proposed changes to Mammography Quality Standard Act (the MQSA) policies and inspection procedures, accreditation body review of soft copy mammography images, and reporting breast density on mammography reports and patient lay summaries. The Committee will also receive updates on the MQSA Program and the status of the Full Field Digital Mammography universal quality control manual. This is a particular matter general applicability during which general issues will be discussed.

Based on the agenda for today's meeting and all financial interests reported by the Committee members and consultants, no conflict of interest waivers have been issued in accordance with U.S. Code 18 Section 208 and 712 of the FD&C Act. A copy of this statement will be available for review at the registration table during this meeting and will be included as a part of the official transcript.

Dr. Sankar Suryanarayanan is serving as the Industry Representative, acting on behalf of all related industry, and is employed by Imaging Systems, Philips Healthcare.

Ms. Kathleen Willison serves as the Industry Representative, acting on behalf of all related industry, and is employed by Hologic, Incorporated.

We would like to remind members and consultants that if the discussions involve any other matters, products, or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record. FDA encourages all other participants to advise the Committee of any financial relationships that they may have with any firms at issue.

For the duration of the National Mammography Quality Assurance Advisory Committee on November 4th, Dr. Marlena Vega has been appointed as a temporary non-voting member. For the record, Dr. Vega

serves as patient representative to the Oncology Drugs Advisory Committee for the Center for Drug Evaluation Research. This individual is a special Government employee who has undergone the customary conflict of interest review and has reviewed the material to be considered at this meeting.

This appointment was authorized by Jill Hartzler Warner, J.D., Acting Associate Commissioner for Special Medical Programs, on November 1st, 2011.

Thank you.

Before I turn the meeting back over to Dr. Hendricks, I would like to make a few general comments.

Transcripts of today's meeting will be available from Free State Court Reporting, Incorporated, 1378 Cape St. Claire Road, Annapolis, Maryland 21409. The telephone number is (410) 974-0947. Information on purchasing videos of today's meeting can be found on the table outside of the meeting room.

The press contact for today's meeting is Erica Jefferson.

I would like to remind everyone that members of the public and the press are not permitted in the Panel area, which is the area beyond the speaker's podium. I request that reporters please wait to speak to FDA officials until after the Panel meeting has concluded.

If you are presenting in the Open Public Hearing today and have not previously provided an electronic copy of your slide presentation to

the FDA, please arrange to do so with Ms. AnnMarie Williams at the registration desk outside.

In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time that you speak. Finally, please silence your cell phones and other electronic devices at this time. Thank you very much.

Dr. Hendricks.

DR. HENDRICKS: We'll now have a brief Panel update from Dr. Finder.

DR. FINDER: On behalf of Dr. Helen Barr, the Director of the Division of Mammography Quality and Radiation Programs, I'd like to thank all of the members for coming to this meeting, and we're looking forward to your advice on the matters that are going to be discussed.

Dr. Barr wanted to be here, but unfortunately she encountered a medical emergency and is currently hospitalized and obviously was unable to be here. But I can assure you that she'd rather be here than in the hospital.

I think that we've got a number of very important and very interesting topics for discussion by the Committee, and I would just like to emphasize the fact that we would like to hear the advice and comments from every member of the Committee, to look at all aspects of the issues that are going to be discussed.

And, again, I do want to thank you for your participation in the meeting. I do notice that some of the members are returning members, and I want to thank them especially for being willing to come back and serve. So thank you all.

DR. HENDRICKS: We'll now proceed with the first item on today's agenda. This is a presentation by Michael Divine from the Division of Mammography Quality and Radiation Programs.

Welcome.

MR. DIVINE: My name is Mike Divine. I'm with the Inspection and Compliance Branch in the Division of Mammography Quality and Radiation Programs, and what I'm going to give is basically an update of what's happened since the last meeting, which was in 2010.

The first thing I'd like to discuss is some facility statistics. This information is also updated regularly on our website. But what I wanted to show you is a chart showing how things have changed over time, for the last fiscal years. Our fiscal year runs through the end of September.

And even though the total number of mammography facilities, which is the red line -- there's been a slight decrease over the last five years -- what is notable on this slide is how it's changed with respect to the number of facilities that are changing over into digital mammography. The total number of units actually has gone down a little bit. But as you can see, things are going in that direction, and that obviously is going to involve changes in

our program, which are going to be discussed later today.

The next thing I'd like to talk about is some changes. We always have a discussion during the meeting about how facilities are doing with regard to our inspections and how that's changed over time. The particular problems that we find are identified into three levels, Level 1 being the most serious and Level 3 being minor problems.

This is a trend that started right from the time that our current regulations took effect and has been continuing through time. The most notable line on this chart is the blue line, which shows the number of facilities that have had no problems during their inspection, and that's running over 80 percent of facilities and is continuing to rise. The number of them with serious problems has been small for quite some time, and I don't expect that'll approach zero, but it's now around one percent. And the number of facilities with Level 2 problems has shown a significant decline.

I wanted to point out some other things that we were trying to deal with, the problems with digital mammography.

For those who are familiar with our inspections, for most of the time we've had very detailed questions for each item that has come up during an inspection relating to equipment testing. The reason that was simple is that our regulations define what tests have to be done and what are the requirements for those tests. And so our software has always allowed us to identify specific problems and answer questions. So the inspection report is

very detailed in terms of the individual tests.

Unfortunately, for digital mammography, the tests that are on the particular equipment relates to the manufacturer's testing.

So our questions have really been limited to three questions, one question for the X-ray unit, one question for the review workstation, which basically has the monitors that are used in mammography, and the printer. And all of those questions basically are yes/no questions, and then the inspector writes into the inspection report details about what was wrong.

The problem with that is that where we have three levels for film systems, which are basically going away, we have a single Level 2 question for digital mammography equipment. And what that means is that a lot of the problems that are really minor in nature, if they were to occur in the film area, are now Level 2 for digital.

So what we decided to do was to take a look at how we assess problems in a facility with film and digital and try to sort of make them somewhat similar. We didn't want to use the same criteria in terms of deciding which tests were the most important, because the manufacturer has designed their testing program and they have different tests, and rather than trying to say, well, this test is more important than this test, we decided to just look at the frequency of testing because, basically, when you go to a facility and you're assessing compliance, you're looking at the behavior of the personnel, what are they supposed to be doing and when.

So looking at it from the frequency standpoint, which is a lot of -- which is pretty much how we're doing it with film, we decided to take that same approach.

So if the test program involves a daily test, which, for instance, processor sensitometry is what we do with film, in that situation, if there's one failure in a given month, we don't raise that as a problem with the facility. We consider that that's -- while it's not acceptable, it's not something we decided to raise to the level of putting it on the inspection report. So if it's a daily test, we advise our inspectors, one failure in a given month, we won't cite that on the inspection report.

We took the same approach with weekly testing. For film with our weekly testing, that would be the phantom image test. Currently one failure in a 12-week period is not yet cited. So we've decided to advise inspectors to do the same with digital equipment.

Monthly testing, one failure in a year would not be cited.

And the less frequent tests, we believe that it shouldn't be too hard for the facility to maintain that testing. So we would ask the inspectors to cite the facilities in those cases, which we currently are doing with film facilities.

The next thing I'd like to discuss is digital breast tomosynthesis. We consider tomosynthesis to be a separate and a new modality from digital mammography. One of the problems we always get when a new modality

appears, though, is it doesn't necessarily mean that there's an accreditation process immediately available. And that's true for tomosynthesis.

So the law requires facilities to be accredited, and without an accreditation process, that presented problems specifically when digital mammography came about.

And at that time we developed a process to deal with that, which you would call certification extension. The certification extension means that a facility must have accreditation on some equipment before they can enter this process. So in a case where a facility has an accredited unit and wants to buy a unit that doesn't have an accreditation process, this is the process that they would have to follow.

Now, when digital tomosynthesis came about, we decided to use this process, but we decided that the facility can get this by getting the unit accredited using the conventional digital mammography or, we might say, the two-dimensional version of that, and then we would -- they could apply for extension to use the tomosynthesis option.

The process is fairly simple, and it's been in place for many years. All the information is available on our website. They can download that and fill out the application and send it to our division.

This is basically a list of the equipment. There's some basic information about the facility; the unit they're using; the workstation and the printer; the phantom that they're using; the list of all personnel that are

going to be involved with tomosynthesis; an equipment evaluation on the unit, including a sample phantom image, of course, because that phantom image would be done under the conventional 2-D mode; the QC manual that they're going to be using, and an attestation by their lead interpreting physician that all of the personnel meet the qualifications to do tomosynthesis.

And the last thing I'd like to talk about is the fact that in tomosynthesis we're using the conventional phantom that was developed. Actually, it was developed for film systems and has continued to be used for digital. It has problems with the tomosynthesis capability, and we believe that there's a need for a new phantom.

And we know that there are a lot of people involved in this research. Dr. Chakrabarti, who's a liaison to IEC and AAPM committees, is working with our other scientists on developing a phantom that can be used with digital tomosynthesis. And we're working with universities.

The last thing -- I thought that was the last thing -- this is a list of the units that have been allowed for sale since the last meeting. The Carestream computer radiography system. The last column is the accreditation bodies that we've approved to accredit these units or, in the case of where there is an approved accreditation body, it's under certification extension. The Siemens Inspiration unit was approved. Of course, the tomosynthesis for Hologic. The Sectra MicroDose. The Selenia Encore. The

Inspiration. The Planmed Nuance and Nuance Excel. And the Senographe Care. The Planmed unit has not been approved through accreditation, so that is also under certificate extension.

Any questions?

DR. HENDRICKS: Thank you.

Do any Panel members have any brief questions? We will be able to deliberate on this topic in the afternoon.

(No response.)

DR. HENDRICKS: Thank you.

I have been asked to remind the public attendees that this meeting is open for public observation, but the public attendees may not participate except at the request of the Chair.

And next on the agenda, we'll have Dr. Finder reporting on an update on approved alternative standards.

DR. FINDER: It's Dr. Finder.

For those not familiar with Section 900.18 of the regulations, FDA may approve an alternative to a quality standard under Section 900.12 when the Agency determines that:

1. the proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace;
2. the proposed alternative is either too limited in its

applicability to justify an amendment to the standard, or it offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health;

3. the granting of the alternative is in keeping with the purpose of Statute 24 U.S.C. 263(b), which is the MQSA act.

Since the January 2010 meeting, the division has not approved any new novel alternative standards. It has, however, approved three alternative standards for the manufacturers of full field digital mammography units recently cleared by FDA for marketing -- and these include the Siemens Carestream and Sectra -- so that these units can apply 30-day corrective action periods to selected quality control tests similar to those already approved for earlier FFDM manufacturers.

In addition, we have approved several modifications to a previously approved alternative standard. These modifications deal with testing after software upgrades. And that current approved alternative permits the post-upgrade testing to be performed under medical physicist oversight. But in order for that to occur, the manufacturer needs to apply to FDA for each individual software upgrade.

Because we received a large number of requests for this alternative standard, we have generalized the alternative and allowed it to be

used by all manufacturers.

Under the modification, the testing may be done under medical physicist oversight, rather than have the medical physicist be on site, as long as a number of conditions are met. These include that the post-upgrade testing consists of tests that are normally done by the technologist are not required to be done by the medical physicist and that proper notification and instructions are given to the facility.

These alternatives that I've talked about are available in their entirety on our website.

Does anybody have any questions about alternative standards, why we do them? Anything like that?

(No response.)

DR. FINDER: Okay, that's it. Thank you.

DR. HENDRICKS: Moving along, the next item on the agenda, also from Dr. Finder, is a review of Guidance Document Number 13, also open for Committee discussion.

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

Regarding Guidance Document Number 13, the draft of this guidance was made available for comment in the *Federal Register* on October 9th, 2009. Four respondents submitted a total of 14 comments on the draft guidance.

In addition, the National Mammography Quality Assurance

Advisory Committee reviewed the draft guidance during its January 2010 meeting and provided additional comments.

FDA reviewed and considered all of the comments and in response FDA modified the draft guidance by:

1. providing the most current accreditation body and certification agency contact information;
2. clarifying that original or lossless compressed digital image files may be acceptable for record transfer;
3. clarifying the conditions under which an additional mammography review conducted by an outside entity would be acceptable to FDA;
4. deleting the question and answer dealing with image labeling;
5. modifying the section on the use of attestation to include a testing to the specific mammographic modality included in personnel initial training;
6. clarifying the guidance on the use of noninvasive kVp meters;
7. recommending the inclusion of cushion pads when performing AEC testing.

The document was published as final on November 16th, 2010, and at that point was incorporated into the Policy Guidance Help System.

For those not familiar with that system, it is a web-based, computerized searchable database that contains all final guidance issued by the FDA on complying with the MQSA Program.

Because this is the first Committee meeting since the document was published as final, it has been brought up to the Committee to see if they have any additional comments or suggestions that could be incorporated into a future guidance document.

Any questions on the guidance document?

(No response.)

DR. FINDER: Okay, thank you.

DR. HENDRICKS: Next, Dr. Finder again on proposed changes to the MQSA policies and inspection procedures.

DR. FINDER: Moving right along, it's Dr. Finder again.

FDA is in the early stages of revising the MQSA inspection questions to address issues that have arisen over the course of the last several years.

Specifically, we continue to hear from inspectors about the desire to have more specific questions regarding the inspection of digital units and the problems of trying to inspect these units by referring back to individual manufacturer quality control manuals.

These new questions, which we're going to be talking about, are our attempt to deal with both problems. Our goal is to develop questions

that are applicable to all units, whether they are film screen, FFDM, tomosynthesis, or even some other technology that hasn't been approved yet. Unfortunately, due to the inherent differences in technologies, this is not possible, but we are trying to get as close as we can.

In order to achieve this, we are focusing on what we believe are the most important quality assurance issues. That necessitates removing a number of a questions that are no longer felt to be of primary importance or a link to technologies -- and by that I mean screen film mammography -- that are decreasing in number. Screen film units now account for only 19 percent of the total units out in the field. With few new screen film units being produced, that percentage is expected to continue to decrease over the next two years.

FDA will begin to phase out supporting the inspector equipment, sensitometers and densitometers used to perform certain screen film tests, to reflect the smaller number of existing units.

By the time the proposed inspection questions are implemented in the next 18 to 24 months, screen film technology should make up only a tiny percentage of the operating units.

Just as in the current inspection questions, we don't have a question for every requirement or quality control test that a facility could be held accountable for. We've tried to limit the questions to those that have the most impact on quality and can be enforced consistently by the

inspectors.

The document containing the inspection question was sent to the Committee members prior to the meeting, and we look forward to their comments on these proposed changes.

In addition -- well, let's start with that. I assume that people have looked over those questions. Anybody have any issues, comments, thoughts, additions, subtractions?

(No response.)

DR. FINDER: Well, I thought we did a good job, but I guess we did better than -- oh, I guess not.

DR. SEIBERT: Tony Seibert.

With respect to the questions themselves, you decided to take -- you took a lot of things out that were for screen film. And I'm looking at it right now. Some of the things that I think maybe should be re-included is the AEC performance. You've taken that completely out. And, in fact, the AEC is actually available on the digital systems as well, and it seems to me like that should be tested. I don't know why it was just taken out carte blanche. Correct? That's the way I see it.

DR. FINDER: I'd have to check. Let me see. Well, there is some testing that remains involved, on page 6, in terms of focal spot, in terms for the AEC mode. But you're right, some of the testing has been taken out.

DR. SEIBERT: And I also note that --

DR. FINDER: But it's being done, I believe, for -- as part of the physicist survey.

DR. SEIBERT: Okay. In the FDA form that we have to fill out as physicists, the AEC only -- in fact, you say, Does it apply to screen film and digital, or screen film only or digital only? And the AEC, in that document, says screen film only. And I think that that should say screen film and digital as well.

DR. FINDER: All right. We'll look into that.

DR. SEIBERT: And it's just -- the appearance of the image doesn't change, but the signal-to-noise ratio certainly will, with variations in steps that you -- that the technologist would apply for the AEC.

DR. FINDER: Okay.

DR. SEIBERT: So I'd suggest that we take a look at that, that you'll take a look at that.

DR. FINDER: Okay, good comment.

Anybody else have any other comments? Thoughts? Tests that we should've taken out or that we should add back in?

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

DR. FINDER: Yes.

MR. RUCKDESCHEL: I agree with Tony. One of the things I've noticed is that there is a lot of inconsistencies in the manufacturers' QC, and some of them don't address performing AEC and some of them do. And that

might be the root of why maybe it wasn't so explicitly discussed in the revised or proposed changes.

Another one of the things I was looking at, I noticed that you have CNR and SNR listed there, and there's a lot of inconsistencies in what the manufacturers are asking for. Some don't even address SNR or CNR. While all can be performed on these units in one way or another, they're not actually described in the manufacturers' QC manual. So I don't know how that can be addressed. Would the inspectors' questions --

DR. FINDER: This is Dr. Finder.

You've brought up one of the excellent points that we are dealing with or trying to deal with. Under the current regulations, each manufacturer decides its own testing procedures and there are a lot of inconsistencies.

And one of the presentations you're going to hear is about a universal QC manual, which we hope, if it's finished and becomes available, can be used as a model to bring more consistency into the program, and we're hoping that that is going to occur by the time these questions actually go into effect. And at that point facilities will have the option of using that manual rather than go to individual manufacturer QC manuals.

We have the alternative standard process, which I talked about before. It could be used to allow that universal QC manual to be accepted and used in all facilities. Not that they have to use it, but that they could.

And our expectation would be that since it would make life easier for physicists, for inspectors, for facilities, that a large percentage of facilities would go over to that and use the universal QC manual. And in that sense, we'd be able to use our questions and focus them into a greater degree on just inspecting those areas.

But you're quite right, the inconsistencies and differentiations between QC manuals that currently exist is a headache for a lot of people. And one of the questions I would have for the Committee is, do they have any suggestions on what we can do in the interim, besides waiting for the universal QC manual, to try and bring some consistency to these QC manuals?

And if I don't hear an answer immediately, I know why, because we've been thinking about this, and I'm sure the physicists have been thinking about this because they are probably the most impacted by working in multiple facilities and having to deal with different units.

DR. SEIBERT: Yeah. Tony Seibert.

With respect to the inspectors' need to determine whether it's a Level 1, Level 2, Level 3 type of offense, are we going to go through some of those, Dr. Finder, in terms of -- you had suggested some. Well, what are we going to do for CNR and SNR? And I have some suggestions. I don't know if we take that up now or later. I'm not quite sure when we do that.

DR. FINDER: Sure, you can suggest, at this point --

DR. SEIBERT: Okay.

DR. FINDER: -- where you think that should lie. I mean, you've got three choices, Level 1, Level 2 and Level 3.

DR. SEIBERT: Well, I do note -- this is Tony Seibert again. I do note that in some of the tests, for instance -- I'm going to be bumping around here a little bit -- the laser printer tests, where you say, level to be determined, I think that some of the things that you've done in other areas -- for instance, if you have two to three instances of problems where the sites didn't do those types of tests, that would be a Level 2, and I you had greater than four or more, four plus, that it would be a Level 1. And I think that that holds also for CNR and SNR.

And I don't know, Tom, if you took a look at that. But certainly some of those things need to be a little bit more elucidated for the inspectors and for us when we're actually checking the technologist procedures as well.

DR. FINDER: Okay, it's Dr. Finder.

In the current software, as you point out, we do have these kind of levels, depending on how many times the test is missed. That involves a fair amount of software manipulation, but it's built into the system right now. And one of the issues that we're considering right now is whether to establish that same type of software for these new questions, or whether to just go with a simpler version that says, as Mr. Divine was talking about, if you miss 1 out of, you know, 12 or 1 out of a month, that you would be cited and have that.

We haven't made a decision yet. We're certainly interested in hearing from the Committee, how they think it is. I know our software people would be more than happy to spend a lot of time developing all of these things, but we also want to be kind of cost effective in terms of how this goes.

So I agree with you that we can have some levels within the levels in that sense, or we could go with a more simpler -- kind of just instructions to the inspectors and to the outside community because whatever we decide here will be published on the web, will be available to facilities and physicists and the public in general.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dan Kopans.

I'm curious. And this may be beyond the scope of what we want to discuss today, but my sense is that radiologists have been increasingly removed from the quality control issues because the digital technology is beyond what we can change. It's all done by the manufacturer. In the past, we could adjust the film processors and so on and work with our technologists and quality control folks.

Who is establishing, for example, the signal-to-noise that's being allowed? My sense is that the manufacturers have been turning down the dose in, quite frankly, I think, below levels that they should be doing, and yet we really seem to have -- the radiologists seem to have no say in that. So

how is it being determined?

I think the images are getting noisier and noisier. I'm not sure that's translating into missing things, but I'm concerned.

DR. FINDER: That's actually going into -- it's Dr. Finder. We have limited control over what the manufacturer -- my division, the Division of Mammography Quality and Radiation Programs and the MQSA Program, have limited authority over the manufacturers in terms of what they say in the quality control manuals.

The way it's written -- and again, these regulations were written in the beginning of 1996, even before there was a digital unit. We rely on the manufacturers to specify the testing and the testing requirements and the action limits.

All of those units have to go through another area of FDA to be cleared or approved for use, and those testing procedures are part of that review.

If the feeling is that some of these limits that are being applied to some of the units are not appropriate, I think we would like to hear about that, and we can always go back to the manufacturer and make suggestions. I'd like to hear from some of the industry reps on the Committee about this. But there are ways to deal with it. And I can tell you that when we have gone back to manufacturers, they have been receptive to suggested changes and issues like that.

So while we don't have a regulation that necessarily allows us to require that they make changes, in the past, they've been very receptive to things like this.

DR. SURYANARAYANAN: Sankar Suryanarayanan, Philips Healthcare.

So, Dr. Kopans, in order to address your point on manufacturers setting the dose levels, so we go through a rigorous quality assessment test and protocols to establish a sufficient level of signal-to-noise ratio and contrast-to-noise ratio in our systems. And one of the tests, for example, the accreditation phantom is used as benchmark, a scoring of that as passing criteria. That'd be to ensure that the thresholds that be set today meet those passing criteria.

But we are open to suggestions, and if there's any other clinical input that you can provide us, I think we'll be happy to consider it.

DR. KOPANS: And Dr. Kopans again.

I think we can talk about this off line, but my concern is that are we comparing the new level to the most recent old level, so that small changes which may not be picked up in testing between the old techniques and the newer techniques, if you go back to the original techniques, would you not see a major change?

And I'm a little concerned that, by incrementally reducing dose, we may be incrementally reducing our ability to see things. But we can talk

off line about it.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

Our experience is, is that -- the crux of Dr. Kopans' question is that in reality, I don't know if there really is any basis for what some of these criteria are set at and that they are getting quite low.

I'll see similar technologies that have evaluations that are at completely different criteria. Some people will just signal values and some will have acceptable tolerances, while others will just have a minimal tolerance. And so that does make it a little difficult, and I think that this universal QC manual will really help to focus that, and I'm hoping that's where it goes. But it will make it very difficult for the inspectors to really try to get a hold of this because they are all over the map.

So that's why I think, at this phase, keeping these questions rather generic is probably a good idea until we have focused into some more concrete acceptable values.

DR. FINDER: It's Dr. Finder.

I think the ultimate will be when we have new regulations that address the digital sphere that we're now in, similar to what we had for film screen. And, you know, that took decades to develop the standards. Before the program actually started, there was plenty of time for people to work out all the kinks. We've now had over a decade of time to start looking at digital. All the problems obviously haven't been solved yet, but I think it's -- we're

getting to the point where we can actually start to consider regulations that would establish certain requirements.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

One of the questions that I've had for a long time is that FDA originally required two-sized bucky systems and two-sized films, which I thought was actually a reasonable thing because body habitus is not one standard size.

Why was that dropped in the digital realm? Was it just because it's too expensive to have those, or was there some study that said you don't need it?

We actually went with two different manufacturers when we first went digital, so we'd have a large detector and a small detector.

DR. FINDER: I think you have to go back 10, 12 years ago when the first digital units were approved and those were the only units that were available. They only had fixed receptors. There was no way to have a dual receptor in that time. And the question was, Do you prevent that technology from getting out, or do you deal with what is available and what is possible at the time?

Personally, I would hope that in the future there are a lot of modifications to the systems improvements. I think there's a lot of possibilities in terms of digital that haven't been explored yet, in terms of

making improvements in the quality of the mammograms. But you have to deal with what the manufacturers come in. You can't magically wish for something and tell them to do it and hope that they're going to come in with it. You have to deal with what's available.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

I'm wondering, I don't know if it's appropriate, but is it possible to get a comment from a physicist, Eric Berns, in the audience, for the discussion or should we wait until he presents?

DR. HENDRICKS: I defer to you.

DR. FINDER: Okay, I would say let's wait to hear what he has to say, and you'll have a chance to ask questions of him. And I may even ask him a question or two.

(Laughter.)

DR. HENDRICKS: Yes.

DR. FAULK: Robert Faulk.

If the goal is to have a universal set of standards and we expect traditional film screen to be, in two to three years, probably less than five percent, it would seem that now is the time to get radiologists, industry reps, and physicists on the same page to develop that universal set of standards, since it sounds like that's going to take a reasonable amount of time.

And I agree with Dr. Kopans. I mean, the radiologists clearly

need to have some input because I do think there's been changes over the years, and that needs to be addressed and it can't be addressed unilaterally by one group.

DR. FINDER: It's Dr. Finder.

Well, the good news is that there are groups that are working on that, and at some point proposals will be brought before this Committee to decide changes in the future to regulations, to talk about taking what are consensus standards or the universal QC standards and incorporating them into regulation.

But at this point people have been working on this process or this problem for, I'd probably say, close to 10 years. Maybe that's a little bit long, but somewhere in that ballpark. And I'm hoping to hear, in an hour or so, what's been developed by groups involved with the ACR, in terms of this QC manual.

Remember that before the program -- before the MQSA Program, the ACR had come out with their QC manual for film screen, and that was used basically as a standard for our interim regulations. That went on for several years, at which point we developed final regulations which codified many of those same standards and put them into regulation so that we had more basis for enforcement. And I would hope that the same thing would happen with the digital standards.

One of the issues that we have to keep in mind, though, is that

once you put something into regulation, it is there for a long time, and we want to try and get it right, and that's why we are looking and working with other people, other groups, to develop these standards.

DR. HENDRICKS: Any other questions from the Panel?

(No response.)

DR. FINDER: Okay, this Dr. Finder again.

If there are no questions about our proposed questions, I do have just one other issue that I'd like to hear from the Committee on, and it basically goes like this. In screen film systems, failures of the X-ray field, light field, image receptor, and compression paddle alignment tests require a correction within 30 days. That has been extended to FFDM systems through the use of approved alternative standards.

However, some manufacturers have added a test called the missed breast tissue on the chest wall side. And although the test can vary in how it's performed by the different manufacturers, we're basically asking the question, Should a failure of this test require a 30-day corrective action period or an immediate correction action period before further imaging is done?

I'd like to hear from people who are familiar with this test, especially the physicists who may be involved with it.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: Tony Seibert.

With respect to the missed tissue, most of it is due to either beam alignment or the compression paddle misalignment that will extend too far beyond. And I don't know all manufacturers, but many manufacturers, it is actually a very simple thing that you need to do. It's two screws that you undo and you redo and then you can retest. Typically what happens, however, is that you have to call in the service engineer from the company or if you have on-site service to be able to do that.

I think it's an important thing. The missed tissue is something that the radiologists don't want to see happen, and I think that, in my opinion, 30 days is too long to correct that issue, and I think it should be immediate, if in fact you see it. Because, of course, we only test periodically and it might be miscalibrated for a very long period of time, and when you do find it, you need to correct it immediately, in my opinion. And that's what I would like to see happen.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dan Kopans.

I would completely agree with that. I mean, I think that missed tissue at the back of the breast is a huge volume of tissue that's actually being missed. So I think it should be corrected as soon as it's detected.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

We actually have a lot of experience with this, and even though

there's 30 days, we always tell the site that they should correct this before they proceed. It would be in their best interest to do that because I think that's very vital to finding cancer in screening.

So I would support getting corrective action prior to clinical use for missed tissue.

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: Robert Faulk.

I have a question and that is, how often is this actually tested for?

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

It's different with every manufacturer, but we do it for every manufacturer anyway, and we do this on equipment evaluations, which, one thing we've noticed with digital, we are there more frequently than for film screen. There seems to be a lot more corrective actions that require follow-up with equipment evaluations and a lot of these -- if you replace a detector, if you replace a tube or adjust a column leader, it usually will require you to retest that X-ray light field.

So it's a minimum of -- once every 14 months would be the minimum that it would be tested, but it is tested more frequently on some units.

DR. FAULK: I guess that would be my -- this is Robert Faulk -- that would be my question. If it's such an important issue that needs to be

corrected immediately, then is once-a-year testing of that adequate?

DR. HENDRICKS: Dr. Lee.

DR. LEE: This is Carol Lee.

I just have a question concerning film screen. If misalignment, you get 30 days to correct that problem, shouldn't we change that standard also to say that it should be immediate correction? Because it's the same problem, you're missing some breast tissue.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: I again agree with Dr. Lee. And I would just point out that missing the chest wall tissue is far more important than the edges of the image being out of alignment because there's no breast usually out at the other edges of the image.

So I think for both film screen and digital, immediate corrective action should be taken once it's determined. And I think, quite frankly, the testing should be more frequent in terms of chest wall loss.

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

Just to address some of the points that have been brought up, the issue came up because manufacturers, at least some of them, have established a separate test outside of collimation. It's true that with film screen, that a portion of the testing for collimation includes a testing that can address the issue of missed tissue along the chest wall.

And the 30-day period was put into regulation after discussions

with the Committee, as I said, in 1996, '97. And I think the reasoning at that point was that if there was a significant missing of chest wall tissue, that it would be picked up on the clinical exams and that people who are looking at those exams would know what's a good clinical image or not, and that they would be able to recognize the fact that tissue is being missed and they would stop doing clinical exams at that point. So that was the rationale behind it.

This issue has come up again because some manufacturers have separated out the test and have a separate test, and it's done in different ways and it measures different things now. The tests for film screen systems involved basically the compression paddle alignment. Some of the tests that are now being talked about don't even involve the paddle at all. They're testing the receptor in a different manner. So there are different issues that are being brought up, and the testing is being done in different ways.

I agree that, obviously, the issue of getting the most amount of tissue is one of extreme importance, but the issue also has to go to the fact that every single exam is being reviewed, and irrespective of whether the equipment has a problem or not, you have to get all of that tissue on. And most of the problems are not with the equipment. They're with the technique done with the exam, and those shouldn't go through.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

I would just, for the record, point out that radiologists can't actually tell whether there's more tissue that could be imaged that's being missed. That may have been the discussion back in the '90s, but certainly now none of us can look at a mammogram and say, Oh, there's another -- there's always more tissue than we see on a mammogram anyhow, so we can't tell how much is being missed.

And we've all seen a number of cancers where the only way you detected it was a few little wispy densities just at the edge of the film, and when the breast was pulled further in the machine, you saw the lesion.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: With respect to the question about frequency, it seems to me that, in terms of practicality -- oh, this is Tony Seibert -- in terms of practicality, the test probably should be done by a technologist, it would seem.

And I'll be really interested to hear Dr. Berns talk about whether or not that has been addressed in this universal phantom, and whether or not we can encourage all of the manufacturers to develop some sort of methodologies -- the digital manufacturers -- that could provide this type of test that would be simple and straightforward so that it could be done on a frequent basis such as once a week, it seems to me.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

In relation to the fact that this has really been a specialized test for a specific manufacturer versus others, it is really implied in the testing and the others, you know, the X-ray field cannot be within the chest wall, and therefore if it is, then you are missing excessive breast tissue.

So that is evaluated even though it's not explicitly described as missed breast tissue. And so that's done on the annual evaluation by the physicist or on the equipment evaluations.

The factors that would affect this pretty much would be things that would require -- would be changes that occur following some kind of corrective action that was done to the unit, which would require a physicist to come and do an equipment evaluation. So I think that it would be caught at that time.

The other things that could happen is if you start losing detectors along that line. But that would become obvious to the technologist when they're doing their routine QC or the radiologist -- you would start to see that there is, you know, a white line, or something like that, where there should be an image, that type of thing.

So I think that it is covered, but it could very easily be introduced through the technologist's routine, to pick this up, because the one thing that might not be caught would be the paddle, if that becomes loose. But that's supposed to be part of their visual checklist, which they

perform at least monthly. Some require weekly.

And if they evaluate their compression paddles to make sure that they aren't loose, that they haven't changed their position relative to the detector, if they're doing that part correctly and they follow up on any errors that they find, then it could be caught. But it can be introduced into the structure, and I think it would be something that would be rather easy to introduce and for the technologist to perform.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: I would just second the suggestion that this be done on a weekly basis and something that a technologist can do. It will also make the technologist more aware of the issue. And sometimes, you know, things that change gradually are not appreciated until there's a sudden -- somebody realizes a lot of tissue is being missed. So I think it should be done on a weekly basis.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: Thank you. Kathy Willison, Hologic.

I agree with the discussion. I question how often this issue, this particular issue comes up, how often on an annual survey do you find that. I would have to say that this is not a frequent issue. I would put it to you -- put that to you first.

Actually, I would say that it seems to me that putting it in the hands of the technologist should be fine. I mean, there's a phantom that they

put, that has an edge that is measurable. You could put something in the phantom, a fiduciary or something that says, you know, this is how close you are to the chest wall, and certainly taking into account dead space at the chest wall, between the grid and, you know, the edge of the detector and so on and so forth.

So I don't see this as a big stretch. I see it as more of an issue for the sites rather than the manufacturers or -- you know, this is added work for the technologist, and I wonder whether weekly is just too much. And perhaps monthly or bimonthly or something like that. I think I'd like to understand the frequency of problems such as this.

And the very fact that you mentioned that there's a single manufacturer out there that added this single test also raised a question in my mind as to whether this is a single -- specifically related to a single manufacturer's equipment design.

And having said that, again, I'll just point -- ask for Tony or any of the physicists to -- or Tom, yourself to speak to the frequency of such issues.

Thank you.

DR. HENDRICKS: Yes, Dr. Seibert.

DR. SEIBERT: Tony Seibert.

We get in there once a year, and that's probably not enough to be able to figure out whether or not once a week is frequent enough or not.

What I say is that you do a test in terms of its frequency. As the likelihood of that you'd find a problem.

So my recommendation would be to do it pretty frequently, and then maybe, perhaps after a certain period of time, that we could back it off to once a month or something like that.

But those compression paddles in particular get loose quite often, and it's up to the technologist to see that. And the radiologist is not going to have -- I don't think they're going to be -- they're more interested and more concentrated on the mammography content rather than the fact that there's maybe a little bit of a hint of a compression paddle or something in the beam and/or whether or not there's any tissue missed. They can't consider that. There needs to be a test that needs to be done at some frequency.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: Well, I would just add, if the paddle is pushing out, you probably -- let me think about how -- there's two ways you could lose tissue. One is if the paddle is pushing out, extending over, but also if the paddle is in front, you could not be grabbing tissue. And, of course, that would show up as an artifact on the ACR phantom.

First of all, I just want to say that I think, as a vendor, I think -- or you could also comment here -- that I don't think -- I'm not opposed to -- I don't think we're opposed to more frequency of this test. Again, I think the

burden will be on the site as opposed to the manufacturer. We would have to put it into place, you know. But also, if you're going to include a test, it probably would -- I would think, as the phantom, you know, whether it be weekly or biweekly.

And then I think, Tony, what you said is appropriate. I know that when we were doing QC testing of the processors, you do a five-day test. Maybe you do this test for, you know -- but I'd have to say I don't think that that would work in this particular case, that only reducing the frequency after you realize over a year's time with the country, you know, doing this sort of thing, that you realize this only happens, you know, a certain percentage of the time, therefore, you know, quarterly is fine or something like that.

DR. HENDRICKS: Mr. Ruckdeschel, then Dr. Monticciolo.

MR. RUCKDESCHEL: To speak to the -- this is Thomas Ruckdeschel. As far as the frequency of the occurrence of missed breast tissue, I think it was -- the question is that we don't see it that much. When we do see it, it has been after there has been a major repair or during installation. And so you know, when we're there, of course that's when we're there. I have not seen it on annual, routine annual surveys, at a very high frequency. When I do see it, it is because of the compression paddle.

And so that's the approach that should be done because the physicist is required for an on-site survey for major reassemblies or repairs, and so therefore it can be caught at that time, when you replace a tube,

because they're playing with alignments when they're replacing the collimator assembly, depending on the unit. That will definitely affect things. And if they replace the detector, there could be a misalignment when that is done, but that is always checked after that is done.

So I think, as far as the -- the frequency of occurrence is not that high. But at the crucial times where it can occur, I think it would be caught, and I think introducing a small test into the technologist QC program would be an excellent benefit. And that could be addressed either through the universal program or just recommended by the manufacturers.

DR. MONTICCIOLO: Debbie Monticciolo.

Well, I certainly don't want to miss any breast tissue, but I'm looking for some clarification, I guess, from the physicists because it seems to me that mostly this is going to be detected by the current tests that we do and with the phantom.

And I think I agree with Ms. Willison that, you know, if there's one manufacturer that's introducing this, I'm not sure what the motivation is for that.

But I think it sounds like we detect most of these problems already with what we're doing, and although I don't think it's a bad thing to test for, just doing it every week when we think it's a very low likelihood situation, you know, the techs have a lot to do already. And so even adding one more thing, even though it sounds innocent to us, that's another burden

they have to bear, and I think we should really think about whether it's worthwhile introducing an additional burden for something that seems like, number one, we already test for. I think we'd see it in the phantom and, you know, like you said, maybe monthly or quarterly, but I'm a little hesitant to move forward based on what I've heard.

MS. LAXAGUE: Debbie Laxague.

Without knowing the technical details, I hear quite a discrepancy between the original question of, is it okay to correct it in 30 days or immediately? And I heard immediately. If it's that important, it seems like an interval of as much as 14 months to test it is too long. There needs to be some correlation there.

DR. HENDRICKS: Yes, Dr. Seibert.

DR. SEIBERT: Tony Seibert.

With respect to the frequency, we do the phantom test every week right now. And I don't know what the universal phantom is looking like, whether or not they have some missed tissue capabilities. Hopefully we'll find out. It just seems to me like that would just be another simple check and you could do that at the same time as the phantom, as we've discussed. But it would require an extra look. Right now, the technologists don't even consider missed tissue. That's not part of -- it's not in their mentality.

So it seems to me that this discussion is really important to bring to rise -- to keep this concept up high in terms of the fact that it really

could have a detrimental impact to the patient.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Dr. Monticciolo.

I have to say, Tony, I respectfully disagree that technologists don't have it in their mind that they might be missing tissue. I think that's what they focus on completely.

Now, I'm not against saying, make sure you look at this when you look at the phantom. But I think when they look at a phantom, they absolutely look at what they've imaged. So I think the techs are highly cognizant of that. At least my techs are.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: Certainly some techs are and some techs aren't, and the fact that we don't even discuss missed tissue in that particular line item of different tests that the technologists have to do. I do know that, clinically, yes, they look -- at least our techs do, too -- they look to make sure that they've captured all the tissue they can. But they don't really understand, I don't think, the concept of the loss of tissue possibility when they're doing the phantom test. And I think that if there were some sort of methodology to indicate that, hey, there are some areas that are missed, and then they would perhaps understand why it was really difficult for them to get all the tissue that they want to get when they're doing the exam.

DR. HENDRICKS: Dr. Fredrickson.

DR. FREDRICKSON: In my area, I don't understand all the technical aspects of it, but I agree with Dr. Monticciolo that, you know, the techs are overburdened a little bit.

My question would be, if you're already doing the phantom, how much extra time would be involved in looking at the missed tissue issue?

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: So I just want to point out that if the problem truly is the paddle extending over the edge of the detector, in most cases that probably would be more of a visual checklist because, you know, truthfully you have to -- it's, you know, impinging on the breast and, of course, the phantom isn't being impinged on by the paddle at all. So, in fact, you'd have to put the paddle up. It wouldn't show up or not show up in the image. Clearly, you don't know what you're not missing or what you're missing when you see that final image.

So, truly, it's got to be some sort of visual. If you're not going to make this a physicist test to show beam alignment and everything else, just as it has been and probably why it's been relegated to the physicist, then it has to be some sort of visual checklist. And that's fairly subjective. You know, is it millimeters? How is the tech going to manage that?

Does that make sense?

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Yeah, I agree with what you're saying. I think

that I have to say we've had this sneak up on us, and it wasn't until it became dramatic that something was wrong. And then, as you said, it usually is the paddle.

But I think the point that's been made is that if we don't at least test more frequently for a period of time -- and I don't know if there's any way of FDA, you know, mandating a short period of time to collect data on this to see what the frequency is -- you don't really know what the frequency is. And the technologist may have gone in and discovered that the paddle was loose and corrected it, and we as radiologists never knew it was even out of alignment.

So, you know, I agree with Dr. Monticciolo, the technologists have a huge burden. But it seems to me that there should be some creative way. It's not a complicated issue. I mean, we used to put a quarter on the edge of the bucky to, you know, see how much of the quarter was missing. I mean, it's not a sophisticated study, but it seems to me that it should be looked at and at least try to get an understanding of what the frequency is so then you can have a more reasonable approach.

MS. LAWSON: Hi. Madeline Lawson. I'm the Consumer Representative, one of the Consumer Representatives.

Certainly any missed breast tissue is risky and is a concern. And so I will leave it to the experts to determine how we do this. I certainly am saying that there should be immediate corrective action.

DR. HENDRICKS: Yes, Dr. Vega.

DR. VEGA: Marlena Vega.

I'd like to take it for a moment to a very different point of view, and that is for patient education, particularly for non-speaking women who come in -- non-speaking-English women, I'm sorry -- come into an office. If you ask women -- and I have done this regularly in Boston, all over, okay -- where your breast tissue is, okay? They tell you, right here, the breast. And when you suggest to them that breast tissue extends to the wall and under their arm, et cetera, they have absolutely no knowledge of that. And I'm wondering -- I think this is really a major issue.

I understand that the techs are really overwhelmed and have a lot of work. But even a simple statement that's read or put up in an office or given out that suggests that breast tissue and the breast wall is extensive, and then you would get the cooperation of the patients rather than fear based.

Many people, including some nurses that I know, avoid mammographies and tell their patients that, you know, it's not so important, you can wait awhile because the thing that they talk about is the pain, okay? And when I explain to them that some pain is a lot better than their life, whatever.

So I perfected the Macarena, which is to do self-exam underneath the side of the arms, okay? And yes, it desensitizes so women can touch themselves. It also does -- that it shows the circumference in the

areas.

So I know this sounds perhaps not as relevant as a lot of the technical information, but I think it's very important to have the cooperation and reduce the anxiety of the patients, and that this might be something very easily done.

DR. HENDRICKS: Thank you.

Any other questions or discussions? Again, returning to that issue of whether this would or should lead to either immediate correction of the problem once it has been identified or that a 30-day correction period be permitted, acknowledging that we don't have a good idea on the actual incidence or the significance of it across various sites.

DR. YANG: Wei Yang.

I'm actually supportive of all of the recent discussions that this should be corrected immediately. And I think what I've heard this morning is that we really feel a need to collect data, and whether it's biweekly or monthly, in terms of phantoms studies, I propose that we move forward with collection of data through phantom testing either biweekly or monthly.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: I would argue that the point isn't that it takes people or a site 30 days or a manufacturer 30 days to correct a problem. I do think the issue is detection of the problem sooner. I would venture to guess that if you called the manufacturer and said, We have a misalignment, we

need to get this taken care of right away, that happens fairly quickly.

And so I think the issue really is frequency, how you detect it, and detecting it before it becomes -- you know, before it sneaks up on you, as sometimes you don't know these things are going to sneak up on you. So until it does.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

I don't think the response to service is the issue. I think it's shutting down a mammo center until -- you know, a little extra time is really more the issue. But unless it's written in the rule, then they're going to wait. So I think an immediate -- you know, before clinical use is a good way to go.

DR. HENDRICKS: Yes, Dr. Faulk.

DR. FAULK: A question for the physicists. As it stands right now, without a universal phantom that can check for the chest wall, is it reasonable that the technologist can accurately check for this?

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

This is a very simple test that can be done when they're doing a weekly phantom, and for most methods that have been proposed for the digital, it would be very simple to test with placing some kind of fiducial marker on there to see that it's done. It would take an extra minute of their time to do that. And it's important.

And just to address, most technologists, you know, they already

notice these things, but there is a sample of the technologists that will not. You'd be surprised how -- you know, I don't know how to say this, but what's going on out there in the field.

And so you know, I've come in, you know, where paddles have been crooked and misaligned and then I've had to point out that and I hadn't been there in a year and that's -- and you know it just didn't happen that day.

So it's just something that if you bring it to their attention, if you give them, Is your paddle -- you know, Are you missing any breast tissue? that will be on their list and it will bring it to their attention. If it's not there, they are busy and they have a lot to do and they just won't mentally notice that, unless they're an excellent technologist, as would be at most of the facilities that we're affiliated with.

DR. HENDRICKS: Yes, Ms. Willison.

MS. WILLISON: Kathy Willison.

Dr. Finder, I guess I would put this question to you, as to who would establish how this test is done. Is this something each of the individual manufacturers would yet again establish their own tests on how this should be done? Or would this be a uniform implementation?

DR. FINDER: This is Dr. Finder.

Under the current regulations we cannot require a test. We just can't develop a regulation to say you have to do it. It would have to come from the manufacturers.

Now, the other way to do this would be, if there was a universal QC manual that we would approve under an alternative standard, then the facilities would have the option of following that, you know, set of procedures. And if that procedure called for a certain type of test, they would have to do it as part of that alternative standard. But at the present time, it would have to come from the manufacturer in their QC manual.

DR. HENDRICKS: Thank you. Dr. Finder, are there any other questions you'd like to put before the Committee, related to these issues, before we take a break?

DR. FINDER: No, I think we've gotten a good discussion on this matter, and I appreciate the Committee's input. Thank you.

DR. HENDRICKS: Thank you.

Then we will take a 15-minute break. Please, Panel members, please, I want to remind you that you're not to discuss meeting topics during the break either amongst yourselves or with any members of the audience. And we will resume in 20 minutes.

(Off the record.)

(On the record.)

DR. HENDRICKS: Welcome back from the break.

We have two agenda items between now and lunch. We're going to start out with accreditation body review of soft copy mammography images and Committee discussion led by Dr. Finder.

DR. FINDER: This is Dr. Finder again.

In January 2000, FDA approved the first full field digital mammography unit for commercial use in the U.S. The first accreditation body began accrediting full field digital units in February 2003. As part of the accreditation process, clinical and phantom images are reviewed by the accreditation body.

Since 2003, all the accreditation bodies have required their facilities to submit their clinical and phantom images in hard copy. FDA is requiring all accreditation bodies to modify their procedures so that facilities can submit their images in soft copy form for accreditation review.

All accreditation bodies are up for renewal of their status in 2013, and the goal is to have the new procedures in place at the time of their renewals.

Soft copy review of full field digital images will also serve as a prerequisite and a learning experience for future clinical image review of tomographic images.

Those on the Committee that deal with soft copy images are aware of the general problems associated with the transfer and display of soft copy images. FDA would like the Committee to discuss these general problems, as well as one specific to the accreditation review process for clinical and phantom images, and offer its advice to the FDA and the accreditation bodies on these matters.

So with that I would ask the Committee to kind of start their discussion about their own problems, their own experiences with soft copy images and their transfer between different facilities and how this might play with the accreditation bodies.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

It's my experience that it's very difficult, and I wouldn't say impossible, but at this point, to review outside digital images on CDs or whatever is being sent, that we really at this point still require hard copy images from the outside for review.

I know there's a lot of work that's been going on to try and correct this, but the manufacturers at this point, or at least the ones that I've dealt with, don't allow a good display of the other manufacturers' images. And I think part of the problem is that, although there are manufacturers that will display the other companies' images, they don't go out of their way to optimize that display the way they do for their own images.

So even in the clinical realm, looking at one company's images on a universal workstation, for example, at least in my experience, is still far from optimal. And certainly getting outside images is very difficult to do.

So I think if you're going to review for accreditation, and so on, soft copy images, those problems need to be eliminated.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

First of all, I completely agree with what Dr. Kopans said. We have a heck of a time when we get disks at this point. But Charlie, if we're going to go to soft copy review, which I think is inevitable, I think it's imperative that we have a mechanism to do it on, you know, a standard PC. Because if you require it on a workstation, I mean, that's virtually impossible to get those disks onto a workstation, at least currently. You know, we give them to our file room and they spend days trying to get them onto PACS, and then we pull them off PACS to do the soft copy review.

But as a reviewer, I'm -- I don't know if any of the other radiologists here review for the Mammography Accreditation Program, but I've reviewed for the program for more than 20 years, and I can say that I don't think we need exactly the same requirements as we do the resolution for our workstation because we're not making diagnoses when we do accreditation review. We're looking at specific issues on the images, and the exams that they send us are normals.

So I think if you made the requirement that we have to look at the disks on workstations, which are more manufacturer specific and have a lot more issues, yeah, you're going to bring accreditation review to a screeching halt because the burden would be tremendous.

And right now our workstations get immediately filled by all the images getting dumped in directly from our digital units. There's very little

space on them, they're very inflexible, and getting a variety of different disks and putting them in a direct workstation I think would be -- right now it would be completely impossible.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: Well, I'd like the discussion in my mind to center around maintaining the integrity of the original intended image, the manufacturer's image. And I know there's been a lot of work with the IHE working group and manufacturers voluntarily complying.

It seems to me that we have come a very long way, and this is a similar issue only in that all workstations should be able to display other vendors' workstations as a patient care issue, not just a quality control issue; and that in terms of reading on a PC, I am very concerned about the proper representation and maintaining that image integrity, including skin line, nipple, density of the breast tissue, which are all things that are evaluated.

Thank you.

DR. HENDRICKS: Dr. Monticciolo and then Dr. Kopans.

DR. MONTICCIOLO: Debbie Monticciolo.

Yes, I agree that we have to have all of the information on the image. There's no question about that. But even though the manufacturers say that the workstation should work for everyone, the question is how much time am I going to spend trying to get that disk to get on that workstation? It's a matter of efficiency.

Now, I can get on a PAC station, I can have it loaded on PACS and we can look at it with PACS with fairly high resolution. But on the individual, everyday workstation, you've given me a disk for a patient that I didn't do on my own digital unit, and it'll take me an hour to get that case up.

So even though the manufacturers say they're compatible, I can get the images by pulling them down off PACS. So I'm not talking about looking at them on a little tablet, but I'm talking about looking on a PACS monitor. That's doable. But doing it on the individual workstations, I think doing accreditation review on those would be extremely onerous.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Yeah, Dr. Kopans.

I agree with everything Dr. Monticciolo has said, and I want to just emphasize what I said earlier, and that is, even workstations that have been approved by the FDA as universal workstations, the images by the manufacturers that are selling -- if it's an acquisition manufacturer as well, their images are displayed as well as I assume they can possibly be displayed. The competition's images are not displayed as well because I've looked at the competition images on their workstations, and they're much better than they are on the universal workstation.

So we're still not at the point where there's an ability to take images from one manufacturer and display them on another manufacturer's workstation. And PACS has a lower resolution to begin with. I think, quite

frankly, that -- and I'm not a reviewer, so Dr. Monticciolo has much more experience than I do in this. But it would seem to be that, as a reviewer, I would like to be able to say that I think their spatial resolution is up to snuff in terms of reviewing, and I don't think you can do that without a workstation.

So I think some -- you know, you can look at small areas on a PC and blow them up. I think that's problematic. So I think if you're going to go to soft copy review, it needs to be high-quality soft copy review.

DR. HENDRICKS: Dr. Smith and then Mr. Ruckdeschel.

DR. SMITH: Pardon me. Hi. Justin Smith here.

One thing that I have noticed, and it's been brought to my attention by technologists asking the question, is, Dr. Smith, are they using these images from another hospital that we have to review on soft copy? They just don't look as good or they don't look the same.

Which leads to the question, if I then looked into and found that, for example, one vendor was using fractal compression, another was using a different kind of compression, I am not -- I don't know enough to say that one is different. Or we have some manufacturers that send a CD with lossy compression and with lossless compression.

Then also the question comes up about what goes on between acquisition and the computations necessary to turn it into something we can look at with an appropriate gray scale. And then what filter and what

smoothing for our eye? What's the conversion from between, say, the acquisition bit depth and the display bit depth? What kind of a curve -- I'm forgetting the name of the curve, but --

UNIDENTIFIED SPEAKER: Barton curve?

DR. SMITH: Yes, thank you, thank you.

UNIDENTIFIED SPEAKER: Barton curve.

DR. SMITH: Yeah, sorry.

But, anyway, those are the sorts of things that I think make it challenging to say this is the same as this. And they've noticed it also in the background noise, what they call the background noise, that haze, adding to a bit of a haze, they think. So that's really one of the things that I've seen as an issue. Maybe not a problem.

Also the horrendous size of these things and transferring them from a slow CD onto our network, which is fast. But the problem is the nature of the data transfer is physically slow, and I've advocated for why aren't we using flash disks or why aren't we using, you know, embedded chips? But the medium of a CD or even a DVD, even 48 times speed, is very slow.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

I agree with Dr. Smith about the speed. That's another issue that adds to the inefficiency. Because if we are talking about accreditation

review and we have to download every CD, we're going to shoot ourselves. That's when I'll have to retire as a reviewer.

(Laughter.)

DR. MONTICCIOLO: Because I'm doing that for MR right now, and I think Dr. Lee has, too, and just waiting for those disks to load, I'm getting old doing that. So, you know, I think it's another limiting element for doing this for accreditation.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: Thomas Ruckdeschel.

Just some of my experiences out there. We have experience with a lot of the different vendors, and some of our facilities have mixed vendors that are there, and what we've seen is that some of these have post-processing that they apply and they don't transfer to some of the vendors, and so there can be a problem with that. So you've got to be cautious on that. Supposedly they're working on that concept, but so far, they have to kind of limit it to the vendor-specific type of thing.

And then another thing I've noticed is that, for the longest time, we've been doing QC and, you know, the nightmare is all the combinations that are possible for evaluating image quality on review workstations and printers when you have a huge network of a hospital system where any radiologist can read at any review workstation. And we have a lot of experience with that, and we noticed that this looks good, it looks like the

image I see here is the image that's here. But recently, the images that we see here are not what we're seeing at other review workstations.

So there are some problems where these lookup tables are not being set up properly for displaying images. So there are some issues that need to be addressed before we have some kind of uniform application.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

Yes, I again completely agree. And you were actually verbalizing it better than I was. All of these images are highly processed and much of the processing, I suspect, is proprietary. Some of the vendors have extreme edge enhancement, for example, that makes things look like they're jumping off the page.

I think the reviewers -- and again, not being a reviewer -- need to see what the radiologist is seeing to be able to say that this is, you know, an appropriate system and image chain and so on. And I think that's a real -- a very difficult problem for soft copy, unless you have the same workstation with the same processing characteristics and so on. So I think it's a very complicated issue, and I agree, I don't think it's been solved.

DR. HENDRICKS: Dr. Sankar.

DR. SURYANARAYANAN: Sankar Suryanarayanan.

So one of the other issues I see with soft copy is data de-identification. When you said film for review, it's easy to tape up what

slide it's coming from and it can hide the information. In a soft copy, I think the burden is a little more on the site to make sure that they properly de-identify. And it depends on the manufacturer and how this process goes forward. So that's something to take into account.

The other issue on image display, I think I would like to second my colleague's thought here. We feel that images of appropriate quality can be displayed on the manufacturer's provided five-megapixel workstation versus on a PC, because when you look for things like artifacts and noise, I think it manifests very differently when you go to a clinical grade versus a conventional PC, unless it's a real high-quality PC. So I think that is the other thing to take into account.

Regarding the display of different manufacturers or vendors on various workstations, the question I have to the Panel is, when you try to display for-processing images -- so this is after the proprietary image processing each manufacturer applies, this is the final image -- when you display it, it's a DICOM image on any other workstation. Do you still feel the quality is different when the same image is displayed on the manufacturer's own workstation versus other?

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: Robert Faulk.

With regards to transferring outside soft copy images, we have not particularly had a problem. Now, we get the CDs and DVDs, and quite

honestly, I don't deal with that. I have directed our IT people to do that, and our IT people load it onto our PACS and I'm not -- we actually have very few problems with that.

Now, in terms of the quality of the image on our universal workstation, that's a different issue, and I do think the quality of the images on a universal workstation, that is an issue to be dealt with.

Lastly, in terms of reviewing for an AB, I do think it would be important to review these on the highest quality workstation available and preferably a mammography approved workstation rather than a PC.

DR. HENDRICKS: Yes, Ms. Willison.

MS. WILLISON: Kathy Willison, Hologic.

I just wanted to -- I agree very much with what Sankar said about the de-identification. There's also the re-identification of electronic images. Right now it's very easy to map ID on images on film, but not so much with an electronic image. And so that would a burden really on the manufacturer side of things, I think, to implement something that allows that re-identification of an image.

I also want to point out that in terms of importing priors, that we are dealing with legacy images as opposed to the most current images, where, with the ACR or accreditation images, if you will, these are the most current images that you're dealing with. And legacy images will have a lot of DICOM header issues, and probably not so much on the current. That

actually probably could be argued one way or the other, I guess.

Another point I'd like to make is to Dr. Finder, as to the potential to centralize upload of digital images, such as into ACR TRIAD and what that would take. And that certainly makes sense to -- not only from the sites uploading, although probably onerous at the very beginning, it might be useful, but also for readers who would be doing it at the other end, that you could bulk transfer these images from one site to another.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

That's a good point because I'm obviously familiar with ACR TRIAD. But you can't get those downloaded into a workstation. I mean, that's my point. Workstations are usually connected to the digital machines, but they're not connected to the outside and nor do we want them to be.

So that's why I'm saying there's a real barrier there to do accreditation review on a specific workstation. Maybe on a PAC system and if you have good high resolution monitor. I mean, I know people who read mammography on PACS, so the resolution is sufficient for diagnosis. That's probably more doable. It's still going to be onerous, I think, because there's still download time. You have to get the image to your PACS, and that takes time. It's not going to magically appear quickly. But the workstations generally are not connected to the outside.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: Kathy Willison.

I agree with what you just said. And so two more points. If you're going to do this kind of soft copy read and you want the same integrity for all reviewers across the board, then, in fact, the accreditation body should provide workstations that are of equal quality across the board, that resolve the image quality in such a way that there's equality.

And in terms of transferring from TRIAD to another workstation or to another thing, I think that that's electronics, IT, and I think that that's likely workable in this electronic world. Although I'll add that it's not happening tomorrow. This would take some time to develop.

DR. HENDRICKS: Yes, Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

Yeah, please, come talk to our IT people.

(Laughter.)

DR. MONTICCIOLO: Oh, my God. It took them three days to hook up my printer.

Okay. But you know, really, I think there isn't a security issue for hospitals. The reviewers that review the clinical images for accreditation are people who work in mammography. You know, we're physicians, we have clinical practices, and if you tell my hospital they want to hook -- I want to hook our workstation up to some outside source, they're going to have a real problem with that, even if they can do it, which I bet they can't. I mean, they

can if they were -- never mind, I'm not going to talk about their quality. But I think that's going to be an issue.

DR. HENDRICKS: Yes, Ms. Willison.

MS. WILLISON: Kathy Willison.

I agree with the whole security issue with having your reading workstation hooked to the outside world. What I was suggesting is perhaps a segregated workstation specifically for the review of images.

DR. HENDRICKS: Yes, Dr. Monticciolo.

DR. MONTICCIOLO: Ms. Willison and I are having a private conversation here. This is Debbie Monticciolo.

Yeah, that's a great suggestion, and if you have $75,000 that you can give us for each workstation, I would be happy to. I'd love an extra workstation, and I'm trying to get one, but it's really, really expensive.

MS. WILLISON: The point was more to say -- Kathy Willison here -- more to say that if the FDA is considering centralized or electronic reading, that it has to be equal across the board.

DR. HENDRICKS: Yes, Dr. Monticciolo and then Dr. Kopans.

DR. MONTICCIOLO: Debbie Monticciolo.

I agree with you. I think it's a real problem that if we're going to go to soft copy review by 2013, a lot of these issues haven't been solved and there won't be parity. And also, if they're going to mandate this, then somebody's got to fund that because, you know, there's hundreds of

reviewers, there's thousands of units that need to be reviewed, and if we're all going to get new workstations that are dedicated to this, it's going to cost an awful lot of money and there's a lot people that cannot bear that expense.

I will also point out -- and this is something Dr. Kopans said. You know, right now, when someone sends us a printed copy, even though on digital the contrast and exposure can be manipulated by the reader, the radiologist surveying those films are forced to show me what they're looking at, how they are viewing that image. And I am concerned, with soft copy review, that I'm going manipulate the image so it looks good, but that's maybe not how the radiologist read it, so that they're not -- we're no longer forcing the radiologist to demonstrate that they know how the film should look, what the optimum is for that image.

DR. KOPANS: Dr. Kopans.

I agree with everything Dr. Monticciolo has said. I think the bottom line is soft copy review is a real problem at this point. But I think Dr. Finder is well aware that you've got to figure out these problems because tomosynthesis images cannot be done with hard copy review. So the soft copy review has to be figured out.

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

We didn't bring all you people here to deal with simple questions.

(Laughter.)

DR. FINDER: We have to keep in mind we're almost 12 years out from the original approval of FFDM. We're hearing from facilities that are all soft copy, and they're having problems with the hard copy and the idea of sending in hard copy images for accreditation. And I think the discussion here has brought up some of the problems and they are extensive, and as I said, it's not an easy problem to deal with.

What I'd kind of like to try and go in the next direction is, well, what can we do to help the accreditation bodies in this process? Are there mechanisms that can be thought up that wouldn't cost a fortune, that would allow accreditation bodies to not only -- we've kind of focused here on the clinical images, but there's also the phantom issues, and I'd like to hear from some of the physicists about this.

And the other thought to keep in mind is these are for accreditation body purposes. They're not for final interpretation. And this was started by Dr. Monticciolo, about all the standards have to be the same, or are there mechanisms that can be thought up that would allow perhaps maybe the majority to go through one type of process, the passing ones that are clearly of good quality, and then reserve some of the high review workstations, high, you know, resolution workstations for those problematic images?

What we're asking the Committee to do is kind of come up with some thinking out of the box to try and come up with some solutions here,

because this is a tough problem, but it's one that has to be solved because of new technologies that are going to be coming down the road and which, unless we develop some type of soft copy evaluation, they will never be able to be accredited.

DR. HENDRICKS: Dr. Kopans and then Dr. Seibert.

DR. KOPANS: I'm going to be a little naive here, but it seems to me that the burden should be on the manufacturers to make their images compatible with a non-proprietary workstation.

And as you say, this has been going on for a long time, and I know there's a group -- I've forgotten the acronym -- that's been looking at this forever, and I know radiologists who are in the group, and they're incredibly frustrated that the manufacturers aren't getting together to do this. And then that's, I think, the only solution. You've got to get the manufacturers to make compatible displays. And, you know, they may be able to hide their proprietary algorithms. It's just the ultimate image that needs to be displayed the same way the radiologist looks at it.

DR. SEIBERT: Well, one thing -- I think Kathy mentioned it right at the beginning -- is the IHE mammo profile and you need to require compliance to that profile. I think there has been a lot of work in being able to display these images and ultimately what you need to do to -- I'm not quite sure how to solve the problem with respect to what the radiologist visualizes versus what the accreditation inspector looks at because that is a big problem

and that's where film does a really nice job.

I think it's solvable. I think that you can use a relatively -- you don't need a $70,000 workstation to view these images. I think you can do some things with a relatively low-cost PC and two to three megapixel monitors with, you know, a certain format. Of course, it's going to take a little bit more time, and I do believe that the accreditation issues are not the same as trying to do a diagnosis.

Maybe, Debbie, you can talk to that.

But the problems, I agree with Dr. Finder, in the sense that we do need to get away from film, I think, and hard copy and ultimately somehow go to soft copy, and the first step is the IHE mammo profile and getting the users as well as the vendors linked into this need to send for-processing and for-presentation type data so that you can ferret out some of these issues and differences.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

Yeah, Tony, I agree with you on several of these points. You know, I'm not -- I would prefer, obviously, to always review on the five-megapixel monitor on my workstation. I just know that from experience, that trying to load disks on that or open it to an outside source like TRIAD is not really a viable solution.

Now, I do know that folks read on PCs through a PAC system

with a three-megapixel monitor for diagnosis, and they seem to do well. I think it's probably doable. That's probably the direction we have to go because those systems are more available, they're open to the outside, and then there comes the problem of disk compatibility. And even the IHE has been around for a long time, they have not solved all the issues.

And as Dr. Kopans pointed out, you know, if they were pushed, maybe, you know, the manufacturers need to come to the table a little more flexible and get this issue solved because we still do have problems with disks.

DR. HENDRICKS: Any other comments?

Yeah, Mr. Ruckdeschel. Thank you.

MR. RUCKDESCHEL: Thomas Ruckdeschel.

I am a phantom reviewer, and so I do look at films and there really is -- it facilitates the process, being able to look at films. If we started putting them on disks, it would slow down the process.

Since I don't do that with -- you know, electronically with mammo at this time, I do it with other modalities, and there seems to be a lot of different viewers and a lot of different formats, and that complicates the process sometimes, depending on how that comes. You can get straight DICOM images from the facilities. But on the other end, that becomes a difficult process, trying to just get it in that format to get it to the ACR so they can review it on a standard DICOM viewer that all the reviewers have. So

that's potential problems there.

However, as a medical physicist for my clients, you know, I look at images through the whole imaging chains, and I do save them on disks, and I don't know if anybody's tried to use a flash drive in front of an IT person, but you will be quickly ejected from the facility because they have this huge fear for introductions of viruses into their systems, and that's really hard to do. While the flash drives do work better for transferring data, they have always directed us to save them to disks. So these are just some of the issues I wanted to bring to head.

But the quality of the images for phantom images that I've seen on disks have been where I think they're reviewable and have acceptable image quality for accreditation purposes.

DR. HENDRICKS: Other questions or comments from Panel members related to this issue? And if not, Dr. Finder, do you want to move to the other questions that we had posed?

DR. FINDER: Well, I'd like to stay on this -- Dr. Finder. I'd like to stay on this topic because we're not finished yet.

(Laughter.)

DR. FINDER: A couple of questions. And just to give you a little bit of background, by regulation, clinical hard copy images are evaluated in the accreditation process on eight attributes, and these are stated in the regulations, and they are positioning, compression, exposure level, contrast,

sharpness, noise, artifacts, and image identification.

And my question to the Committee for discussion is, are these eight attributes still appropriate when you're evaluating in the soft copy environment? And if so, which ones still are and which ones aren't? And how would we or should we modify what we've got in the regulation here?

Now, the good thing about it is the regulation is written in such a way that we can use other attributes, other than these eight, without having to go through a regulatory change. So we'd like to hear which ones are important, which ones make sense, which ones we might want to add or whatever. So if the Committee could discuss those items.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

I'll stick my neck out first since I'm a reviewer and I use all of these. I think obviously positioning, compression, sharpness, and noise are going to be just as important and similar in a digital environment as they would be on a hard copy. And artifacts.

But exposure level and contrast are the only two that might be given some consideration. They're equally important. But when you get a soft copy, you really can't tell how the radiologist looked at the contrast, so you can manipulate it. And the exposure levels, to a large extent, also can be manipulated to make an acceptable image. There's just more latitude with digital than there is with film screen. So the positioning and compression

have to be there. But it's harder to judge somebody and probably harder to fail them on exposure level and contrast.

Now, having said that -- I mean on soft copy. Having said that, you know, if they really have a totally crappy exposure and you can't fix it with windowing or you can't fix the contrast, you'd still want to have the ability to flunk them for that attribute. So we probably have to give the reviewers, the accreditation reviewers, additional training on how we would approach that on soft copy. But it seems to me they would still be important to include.

So I don't think I would change the attributes much. I think there just needs to be education for, in particular, exposure level and contrast for the reviewers, if we go to soft copy review.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: Kathy Willison.

I just have a question for the physicists. Would the SNR and -- CNR and SNR measurements sort of replace those noise and contrast evaluations with that state, if they were within limits that you were actually getting decent images?

DR. SEIBERT: Certainly, Kathy, that's a good point. I think that, from the perspective of how much processing you can do to an image, it's going to be dependent upon how much noise is in that image. You can't process as strongly when you use too low of an exposure, for instance. Or on

the other hand you can do the reverse. So the contrast and noise and signal-to-noise probably would be good attributes that should be evaluated. But to do that in a non-soft copy environment, you can't because it is not possible, unless you would require the individuals to do those measurements.

Now, with that being said, the signal to noise and contrast to noise are done in for-processing images as opposed to for-presentation images, and that's because they're going to be completely different if you don't do it on the for-processing type images.

DR. HENDRICKS: Dr. Monticciolo and then Dr. Kopans.

DR. MONTICCIOLO: Debbie Monticciolo.

I think what you're talking about, though, Ms. Willison, is the physicist review and this question was regarding the clinical review of images. And I think it's important for the physicists to have input and to tell us what they think, but we're going to assess noise on how it affects visually what we see, and I think it needs to stay in there. And even if the physicist tells me this is an acceptable signal-to-noise level, if I think the image is too grainy and non-diagnostic, I'm going to fail it, and I think the reviewers should be able to fail it independently with the clinical review.

DR. KOPANS: Dr. Kopans.

It seems to me -- and again, I'm not a reviewer, but the reviewer should be seeing the images the way the radiologist reviewed them originally. And it's my experience with multiple vendors that the way the

images are presented on the vendor's workstation is optimized, so that it's very rare -- I'd be interested in my colleagues' experiences -- very rare that I window and level any image.

And so what's needed, I would think, for the accreditation review is how was this image presented to the radiologist at the time it was reviewed so that the reviewer can see what the radiologist was really looking at.

Again, I don't know if you do this, Deb, but if you're window and leveling to bring out a soft tissue density that really is hard to see without window and leveling, we have no idea whether the radiologist actually ever did that.

So it seems to me that the accreditation groups should get the image the way it was presented to the radiologist and then go from there.

DR. HENDRICKS: Yes, Dr. Lee.

DR. LEE: This is Carol Lee.

I just have a question. How would you do that with soft -- would the indication of the window and level be consistent across different monitors?

DR. SEIBERT: It depends upon --

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: This is Tony Seibert.

It depends upon the manufacturer's bit depth display, the way

in which the information is, whether they're using value-of-interest LUT, lookup tables, or standard LUTs. It's the Wild West out there when it comes to displaying images.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

Again, that's why I was saying I think this is really a manufacturer's issue. I mean, everything is electronic, so there's a file that says how that was displayed to me on my monitor. Now, we may have different monitors and that's certainly a problem, but the image should be fixed, at least at some point, so that it's the way the radiologist was given the image. That's all quality assurance. If you can window and level an image and make it look really nice and it's higher quality for interpretation but that's not the way I saw it and so I'm missing things because I'm not seeing it that way, that's the problem.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

One thing I've experienced -- it gets a little frustrating out in the field -- is there are these upgrades out in the field, and there may be similar units, but if one unit got an upgrade and the other didn't, there are different LUTs for the images. That can be frustrating. And then I have to work with the service and we usually work it out, but I need to apply certain factors to my results, based on what lookup tables that they're using. So that

can start to interfere with some of these images. So that's a potential complication.

I know for the phantom portion -- I know we're not really talking about that -- you might be able to do snapshots or some kind of JPEG or something like that if you wanted to really get a snap, but I think you might lose something on the clinical side if you started going in that direction with JPEGs or TIFFs or some kind of snapshot format.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

But once the lookup tables have been applied to the image, which is what I get to look at on my workstation, it would seem to me that the manufacturer could save that in a file, and it seems to me that that should be the file that then gets accreditation review.

There's no question that there's no way that anyone is going to be able to have all the manufacturers' algorithms in some standard review workstation. They won't give them to you.

And this is again going to become increasingly a problem with tomosynthesis because the processing algorithms to synthesize the tomograms are proprietary and they're all over the place.

So it's a huge problem, it's not trivial, but I think the manufacturers have to be involved in the solution because they're the ones that are processing the images in the first place.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: I just want to offer that, you know, the IHE mammo profile has been out there for some time now and is always in development, and that is a compilation of the manufacturers working with the physicians, working with other groups as well. And I think as compliant as you can be with IHE is what's going to get you to that next step for interoperability, if you feel that there is a next step to go.

I'm also hearing a couple of different things. I'm hearing that you want to maintain the integrity and see the integrity of that original image, but I'm also hearing that we can use lower resolution PC-type monitors and computers that don't allow you to window and level and don't allow you the workstation things. So to me that sort of -- those two things oppose one another.

So I think there's two issues here. One is I hear complaints about radiologists not being able to see other vendors' images on their own workstations in their daily practice. I think that needs attention.

I think the issue of reviewing images for ACR accreditation is another issue, and what I'm hearing is I don't think that you can maintain the integrity of an image from a soft copy review down to a PC.

And I think that those are two very different things and for two very different reasons. I'm not opposed to the PC solution. I just think that we're talking about two different things.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

I appreciate that, and I don't think we're talking about doing things on a low resolution monitor laptop or something. You're not going to get the resolution unless you look at the image this much at a time.

But I do think that it is more likely that we're going to be able to roll out something like this, allowing PACS on a three-megapixel monitor in a hospital system. It is lower resolution, but not tremendously lower than the five-megapixel workstation for accreditation purposes. I think that's just from a practical standpoint.

Now, you know, it would be optimal to have the five megapixel and have it in the same way that the person reviews it. But, again, there's a barrier to having that provided, and if it can be done, that's fine. But there are people who read on PAC stations for diagnostic purposes. I'm not talking about the real -- I'm talking -- we're not talking about a huge difference in resolution. We're talking about something that's a little bit tighter.

DR. HENDRICKS: Dr. Kopans and then Ms. Willison.

DR. KOPANS: Yeah, Dr. Kopans.

It seems to me that the hard copy film screen review is sort of the standard that we should be aiming for. Those are the images that the radiologist read. And it seems to me that what we should be trying to do in accreditation and in comparing one vendor's images to the next year's, if you

have a new vendor or whatever, it all comes together, is how was that image presented when it was interpreted? That's really the key.

So I think I disagree. I think that having all of the parameters of high resolution and the same window and level and contrast and lookup tables and all of that, need to be in the image that's going to be reviewed. Then we can discuss -- and I think Dr. Monticciolo has some good points -- that then you can review it maybe on a different kind of workstation. But you, I think, need to have the fundamentally same image that the radiologist was reviewing. Otherwise, you know, there's all kinds of things that can enter into it.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: So I'd have to point out that I'm not sure that a printed image -- and I certainly defer to all of you as well -- that the printed image is what the radiologist is actually reading on a soft copy review workstation. That's one point.

The other point is that mammography workstations, if I'm not wrong about this, are accredited. Mammography should be reviewed on an FDA-approved workstation with five megapixel monitors, is that correct?

DR. FINDER: This is Dr. Finder.

That is not correct.

MS. WILLISON: Okay.

DR. FINDER: What the regulations state is that the monitors or

the stations being used have to pass the quality control standards. But the regulation does not specifically state that the workstation has to be specifically approved or cleared just for mammography.

MS. WILLISON: Um-hum, um-hum.

DR. FINDER: So you can use other systems as long as they meet the quality control standards.

MS. WILLISON: Right. And I would say that there are PACS workstations out there that are specific for mammography. That's very different than a PACS workstation that you'd read chest or whatever else that gets reading on. And those mammography workstations, in fact, comply with all of those IHE interoperability standards that have been worked on so hard over these last 10 years.

So to take it down to a PACS workstation, I'm not saying it's impossible or shouldn't be done. I'm just saying that you have to admit that the mammo workstations, whether it be a PACS mammo workstation or a vendor-specific workstation, they all strive to achieve the IHE standards.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

So let me answer a few of your questions. The first one -- Ms. Willison. The first one was I'm not sure that the images that are sent in are what the radiologist sees. They're supposed to be. The idea is that the supervising physician that sends in those images checks the images and says,

This is what I read. This is what we believed is optimum quality for this image. So that's what we ask them to do for the accreditation images. So it absolutely is judged that way and they're told that's how we're going to judge it, that this is what you say you're looking at as your best images.

So, in fact, the fixed printed images we get are supposed to represent and are judged as representing what the radiologist reads. And that's one of our concerns with soft copy and the manipulation by the reviewer.

The second is -- and I know you're not a radiologist, but I can tell you that there are very few PAC stations just for mammography. We started out reading our mammograms on our PACS because we were asked to do it by our administrator, who didn't want to buy the workstation, and that lasted about a week because I really enjoyed it. So we went ahead and spent the extra money.

But we review cases for wire localization and things like that on the PACS. You know, it's the resolution of the monitor. As long as you have enough, if you have that quality image, these monitors, the three megapixels, are very, very high resolution and they are certainly acceptable for accreditation review. I'm certain of that based on my experience.

DR. HENDRICKS: Yes, Ms. Willison.

MS. WILLISON: Kathy Willison.

So I agree with you. I think, again, it's two distinct issues. One

is the review of images in a clinical setting and maintaining all of those qualities and the integrity of the original image, as is intended, and the needs of the ACR reviewer. I think they're two different things and maybe perhaps that's where we should start, is what are the needs of the ACR reviewer, and then how do you meet those needs?

DR. HENDRICKS: Dr. Finder.

DR. FINDER: Dr. Finder.

A couple of points I want to make out. First of all, we're not talking about ACR reviewers. We have three accreditation bodies that do clinical image review. It is not just the ACR, although they are the biggest. But the states that are involved in clinical image review have some of the same problems and have some different problems, which I want to get into at some point in the discussion.

The other thing is that this is not a new problem for digital. We had the same complaints or issues brought up about hard copy review for screen film systems, and the issue there was, well, the radiologist who looked at it, looked at it on a different view box that was brighter, less bright, different viewing conditions. Those issues came up 15 years ago.

The differences with digital, we've got even more of that type of thing. Viewing conditions are obviously very important. The monitors are very important. The differences in the software. So it raises the complexity of the issues that we're dealing with, but it's the same issue.

And one of the other comments that we've been getting from facilities, basically come back, you're looking at a hard copy, this is not how I read mammos anyhow. So it's not the best way to evaluate my facility. And there is some truth to that.

Now, there are also the issues about if they send in an image, they supposedly have looked at it, and you get some insight into what they think is a good image, and there is information to be gained from that.

The other thing to keep in mind is that, at least in my experience looking at the clinical image review processes, most of the failures that come in are due to positioning and that you can see on virtually any type of a monitor.

So I think it's very important to think about the question that we've got right before us, which is accreditation body review and what's necessary for that. Because if we don't push at least through this process, I'm not sure that you're going to get much push for the, you know, routine clinical images that also have these same type of issues. So if we can kind of stay on this.

I do have a question again about the phantom image because I think we're shortchanging that a little bit. And an issue has come about whether, in the soft copy environment, artifacts should still be subtracted. And I'd like to hear from the people that looked at this and have -- you know, do they feel that the typical artifacts that one would subtract out for it in a

hard copy system should also be subtracted out in the soft copy environment?

DR. HENDRICKS: Dr. Kopans and then Dr. Seibert.

DR. KOPANS: I'm sorry. When you say subtracted out, you don't count off for it or you don't deduct for an artifact?

DR. FINDER: That's correct, that's what I'm asking. Do you just go by the raw score or do you subtract out for artifacts? And we're basically -- for those who are not familiar with it, the American College of Radiology has a scoring system for phantom images, and basically it involves looking at the number of items or fibers, speck groups, or masses, and then subtracting any artifacts that resemble those fibers, speck groups, or masses, so that you get a total -- a final score after you subtracted out the artifacts.

And some of the issues that come up are, if you start changing window settings and levels, that you can pretty much create artifacts all over the place, and how do you deal with that in the soft copy environment? So that's where we're going to.

DR. KOPANS: If I can just pick up that. Dr. Kopans. That goes back to my point. Certainly the phantoms aren't images that the radiologist sits down and diagnostically reviews, but it should be the way the image was acquired. And I would argue that we should keep window and leveling out of the review because there's an infinite combination of windows and levels. So where do you start?

That's why it seems to me, again, that the way image is obtained and the way it's displayed to whomever is reviewing it is the way the accreditation body should see it. And at least that way. And then I would argue that they shouldn't be window and leveling at all.

DR. HENDRICKS: Dr. Seibert and then Dr. Monticciolo.

DR. SEIBERT: This is Tony Seibert.

I think that if there are any artifacts, if a physicist reviews that type of accreditation phantom, you get a pretty good feel for what is there and what's not because you know it's there. And I think that you should still actually account, in my opinion, for artifacts that appear. For instance, a dead pixel that might look like a microcalcification.

And even if you do window and level -- and I agree that perhaps you shouldn't -- maybe you can magnify or whatever, take advantage of the way it is, because I do know that some of the manufacturers have more stringent needs to meet to be able to pass accreditation.

But with respect to those artifacts that are obvious, they do need to be subtracted, and they might look like a mass or a fiber or a microcalcification as a result of some potential defect in either the monitor or the acquisition device.

DR. MONTICCIOLO: Debbie Monticciolo.

I agree that artifacts should be taken into account. I just wanted to mention that one of the possible ways to do that is to have a

separate category on the phantom for artifacts in the review. Rather than subtracting them out, maybe now with digital we can have a separate category for artifacts, whether it passes or fails.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

I agree that what may need to be done on the evaluation of the images, perhaps either prescribe what window and level settings that it should be evaluated at, or that a site chooses what window and level that they reviewed their phantom at and then that can be reproduced by the reviewer. And then if there are artifacts that are in that image, then it should be subtracted from the image quality evaluation; and that if there is further window and leveling, which I think there should be, because sometimes there are some artifacts there and if they haven't picked it up, it would be good to pick that up and let them know about it and have a separate category, as Dr. Monticciolo said, so that they can be aware of that, because there are artifacts that you don't see in the actual initial clinical window and level settings. But that might be slightly out of the window that they're using.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

I like the idea of a separate category and your point about window and leveling bringing out artifacts, I think, is an important one. There was a major artifact that was being created on one manufacturer's images by

another manufacturer's workstation, that got the name of the screen door artifact, that was incredibly compromising to interpretation but subtly in the background and was not appreciated for a long time and then there was a lot of dispute as to whose fault it was. It turned out it was the processing going on in the universal workstation that was creating the artifact.

But I think artifacts are very, very important. I mean, they're almost more important in digital than they are in film because in film it may be dust between the film and the screen and, you know, that usually gets cleaned off at some point and they go away. But if there's an electronic artifact, it's there always. I mean, there may be some intermittence, but I don't know what they are.

So I think it's very important to keep track of artifacts, and I like Dr. Monticciolo's idea of maybe making it a separate category.

DR. FINDER: It's Dr. Finder.

I just want to get this clear. Are you saying that a facility sends in an image, somebody looks at it on a workstation or some other monitor that isn't being used at the facility, but that transfer created an artifact and that facility then should be cited or failed accreditation because that artifact shows up because of that?

DR. KOPANS: Dr. Kopans.

You're suggesting that the artifact is in the review workstation. Is that what you're saying?

DR. FINDER: Well, it could be, but we don't know where it is.

DR. KOPANS: And that's important to know, too, because the review workstation needs to be fixed.

DR. FINDER: No, no, it's the review workstation of the clinical image reviewer or the phantom image reviewer that is different than what's actually going on at the facility. And that would again go against your thought about we should try and make it, as much as possible, what the facility is actually looking at.

What I'm getting at is the facility doesn't have that artifact. It's only because it was transferred over to the reviewer as part of the accreditation process.

DR. KOPANS: Oh, yeah, clearly that shouldn't count against the facility.

DR. FINDER: Right. Well, how do we figure that out?

DR. KOPANS: Well, Honeywell.

DR. FINDER: Right. As I said, no easy questions here, otherwise we wouldn't bring you in for this.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: I'd have to agree with the separate artifact evaluation because I think if the site -- if it's reported back to the site, the site will have to go back and figure out where that artifact is coming from, whether it's coming from their monitor, whether it's coming from the imaging

chain, a dead pixel, you know, whatever. I think that that's wholly reasonable.

And I'd like to just comment on something that Dr. Finder said and also just bring up the point again that if it's possible to evaluate exposure level -- maybe not exposure level -- contrast, sharpness, noise, artifacts through phantom, then it leaves the actual clinical images to be evaluated by positioning and compression and perhaps exposure.

And so I'm only offering that as a suggested method to deal with this potential issue of having to print or not print.

Is that something that perhaps we beef up the phantom image or put something on the clinical image that allows you to know where things are? I'm just making a suggestion to try and simplify that. What is easiest to be done and evaluate, across the board, electronically probably would be compression and positioning.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: I would like to defer her question to -- Dr. Monticciolo, I think, was ready to do that.

But in relation to Dr. Finder's question about the artifact on the reviewer, there are two reviewers that look at it. So it would have to be, you know, a repeated artifact. And so the chances of that being -- showing up on both of the reviewers, and if it did, there would be an appeal process that's in place, that the site could appeal to say that, No, we don't have artifact that

they reported here. But I think that the process of the two reviewers or if there's a disagreement between two of them, there's a third reviewer who takes care of that artifact problem for the reviewer.

DR. HENDRICKS: Dr. Monticciolo and then Dr. Kopans.

DR. MONTICCIOLO: Well, I didn't have my hand up, but sure, I'll just jump in.

(Laughter.)

DR. MONTICCIOLO: This is Debbie Monticciolo.

I don't think you can regulate exposure assessment of the clinical images to the physicist. It makes a huge difference. That's why we ask for a dense and a fatty breast, because there's a lot of variability in the anatomy and you have to make sure that the exposure is good clinically to the eye. So you're not going to assess that from a phantom block.

DR. KOPANS: Dr. Kopans.

Again, I would absolutely support Dr. Monticciolo in that statement and add to it that a phantom is fine. It's one thing, you can compare one system to the next. But breast complexity is another part of the whole image interpretation.

And what we're seeing with digital, which is one of its advantages, is the manipulation of the primary information, the processing, if you will, of the information. That kind of comes out with completely different images of the same breast, depending on which manufacturer you're looking

at.

And there are processing algorithms that, quite frankly, lose information -- very high contrast, edge enhancement and so on -- that you can't even window and level because the fundamental information has been so manipulated that you can't do it. I think the reviewers need to be able to appreciate that and you can't get that out of a phantom image.

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: Robert Faulk.

I'm going to digress a moment because I think that the main issue here is soft copy review of clinical images and phantom images, and until that can be instituted, I think everything else is sort of a moot point.

So I think the real issue is can -- is there a way that we can come up to accurately judge, on a soft copy basis, clinical images and the phantom images?

So I would submit that the question is, given that it's an imperfect world and we have vendor-specific algorithms to deal with and a host of other issues, is there a way to come up with a set of common denominators, such as a set window and level, agree upon a set resolution monitor, agree upon, for instance, a display bit depth, and perhaps universal software, to get this accomplished? Because until that can be accomplished, nothing else can really be done.

DR. HENDRICKS: Yes, Dr. Sankar.

DR. SURYANARAYANAN: Sankar Suryanarayanan here.

I think the set window/level is a good idea in concept, but the potential problem is what everybody has been describing here as, at the radiologist's workstation, you may choose to set up specific window/level. You could even communicate it to the accreditation radiologist, the reviewer, while they're reviewing it. But unless the LUTs match, the meaning of that particular window/level setting may not translate to exactly what it was intended for.

But having said that, we could potentially explore a method where we could do something similar to a screen capture, where what you see is literally what you get, and hopefully that transmit to the reviewer and therefore you maintain the same integrity.

The other point my colleague here was mentioning, Kathy, is conformance to IHE. I think that's the way to go. I mean, if you're conforming to IHE profiles, then a lot of these inherent disadvantages are taken care of.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: From the research perspective, I think that there is a possibility. You would have to normalize for-processing images. Those are the raw, unprocessed images that if you could normalize them to a specific and standardized bit depth, for instance, and have them all be done in that way, then there might be a chance.

But after hearing this for the second time now, I think the screen capture might be a viable alternative, at least in terms of a temporary way in which we could start to do some soft copy review, if you could do a screen capture at a high enough resolution. And maybe that would be the way to go.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Yeah, again I mean, I think that was what I was trying to suggest, is that you've got the electronic image on the screen, you have all the data there, and it's a lot of data. But it seems to me that's what should be captured and that's what the reviewer should have the opportunity to review. You get into problems of, well, does the reviewer's workstation show it exactly the same way as the radiologist? But that's the closest you're going to get to what the radiologist used to make a diagnosis. It just seems to me that, aside from the volume of data, that's the only way really to do soft copy review.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: This is Tony Seibert.

Of course, with screen capture, then you have the issues of standardizing the screen capture tool that would be able to acquire every single bit of information that you're trying to capture and you'd have to some sort of standardized method. But that, I think, would be the way to getting -- if you really needed to get to 2013 and have that soft copy capability, that's

where we should probably be putting our efforts.

DR. HENDRICKS: Yes, Ms. Willison.

MS. WILLISON: I just have a question for the physicists. With a screen capture, do you have to worry about various LUTs that different manufacturers use, like sigmoid LUT and linear LUTs and all of that? Screen capture is screen capture. You know, you don't have to -- because that really, I think, is part of the issue, is the various LUTs that are used.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: Yeah, this is Tony Seibert.

It depends upon the screen capture tool. But what you see is what you get with the screen captures, from the screen capture tools that I am aware of. And they're pretty straightforward and trivial implementation.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: I just want to add that I agree that we see quite a few different systems and we do use screen capture. I do a lot of nickel medicine, so I use snapshots sometimes. But we use screen capture, and as he says, you get -- you see what you get. So it should be a good method to use. I'm just a little concerned about the -- I haven't looked at enough clinical images to know if the resolution is sufficient for what the radiologists need.

DR. HENDRICKS: Dr. Fredrickson.

DR. FREDRICKSON: I had a question about, if you use screen

capture, will the images be able to be uploaded electronically or will they still have to be on a disk for submission?

DR. HENDRICKS: Mr. Ruckdeschel or Dr. Seibert.

MR. RUCKDESCHEL: You could do it any way. They just become files that you can transfer.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: One issue, however, would be to actually reproduce the mammographic image that you're displaying at true size or regular. That's going to be another issue, depending upon how -- and you'd have to standardize that, as well. If you're going to use a screen capture tool, you're going to have to -- you can't have fit-to-viewport because the viewports are going to be different and you have to have true size, I believe, in terms of how you would display that image during the screen capture.

Even though screen capture seems to be oh, yeah, this is a really simple thing to implement, there's a lot of details that you have to make sure are taken care of so that you're ultimately going to be comparing the images as they were displayed in that particular view.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

Yeah, I agree that the screen capture issue is going to be -- it's got to be lossless and you've got to get all of the data, so it's going to be a humongous file, but so would the images that you submitted for digital. So,

you know, it's going to be the barrier.

DR. FINDER: It's Dr. Finder.

Well, now that we've solved all of those problems --

(Laughter.)

DR. FINDER: -- I do have another question, and this was done earlier. We tend to focus in on the largest of the ABs and their issues. But one of the problems that the state accreditation bodies would have is that they avoid conflict of interest issues by masking the facility that they're looking at, while ACR does it by sending it out to the people in other states who have no relationship.

What about the issue about facility identification on the images? Is there a way, an easy way to mask that and then also have it come back in? Because they do have to evaluate that as part of the review process for facility identification, but the actual clinical image reviewer can't see it.

So anybody have any -- if we solved the first problems so easily, I think this one shouldn't be really that tough.

DR. HENDRICKS: Dr. Seibert

DR. SEIBERT: This is Tony Seibert.

That's an informatics issue, if in fact you're -- for instance, during a screen capture -- and it depends upon what type of screen capture you're talking about. But if you have a software tool that will be able to allow you to snapshot the image, there is a way that you can turn off the overlays

and de-identify and then re-identify.

And actually in DICOM as well, there are methods in which you can run de-identification as opposed to anonymization, which are two separate issues. De-identification allows you to re-identify, whereas anonymization completely strips everything and you're no longer able to go backwards.

So there are methods to be able to de-identify the images through electronic means, and for screen capture it would actually require that the institution would have to push one of their buttons that would take off the overlay information, as an example, before you captured the image.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

Yeah, I agree with Tony, you could do it on the screen capture. Of course, you'd want to be able to prove that the site could appropriately label their disks. So what you might have to do for those accrediting bodies is have somebody separate confirming that issue, which is really just a check box. You know, is the site able to -- you know, maybe they can send an image with the appropriate overlay and somebody checks that box off before it goes to the clinical reviewer and only the kind of denuded ones go to the clinical reviewer.

DR. FINDER: This is Dr. Finder.

The state ABs do it with hard copy. They have their state

person evaluate the identification issues, and then they mask it over with a piece of black tape, basically, and send it off to the clinical image reviewers, who, we are told, never pull that off.

(Laughter.)

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: Robert Faulk.

Dr. Finder just addressed it. I review for a state AB, and that's indeed how it was done. And no, we never have pulled back the tape.

(Laughter.)

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: I think the point about de-identifying is that, at some point, you'd really want to know where these images came from and be able to trace it back to the site, especially if you have a lot of images coming in in this electronic way. So either there's a way to de-identify and re-identify.

And often, at workstations themselves, the reviewers, similar to not pulling of the tape, can hide those attributes during review so that they don't see those reviews at all. I don't know if that's universal, whether that becomes an IHE sort of compliance type of thing.

DR. HENDRICKS: Dr. Monticciolo and then Mr. Ruckdeschel.

DR. MONTICCIOLO: Debbie Monticciolo.

Well, the issue is you don't want to send the images that have

the identification available and then count on the reviewer to remove it and put it back. But if there is a separate person who checks off the identification, then you can link the other images to their accreditation number and then you won't lose track of them if they're screen captured.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

And when you de-identify, the DICOM header still has all that information. So you could, you know, use the DICOM viewers to locate it, if we use DICOM images for the reviewing process. So even though you make it anonymous, if you had to identify that those were the specific sites, you could look it up in the DICOM header.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: I guess that the point is, is right now, with the hard copy, I think that there is a sticker put on with the map ID on the images themselves. Is that correct? And so how would you get that on in the electronic world? Would it be needed? I think that that's the point I'm getting to, is that there is a need to somehow identify those images by that map ID and know that that always correlates.

DR. HENDRICKS: Yes, Dr. Seibert and then Dr. Monticciolo.

DR. SEIBERT: Tony Seibert.

There's various ways. If you're going to do a screen capture, you could require that -- and this would be more of a level up, but a screen capture with the overlay data on it and then without and reroute it those two

ways. And then, for the ones that didn't have the identification on them, the file name would say the map ID, for instance, or the whatever. I mean, there are ways to solve that. I don't know if we're here to exactly figure out how we can solve that, but I do know that there are ways that could be done.

DR. MONTICCIOLO: Debbie Monticciolo.

Yeah, I was just going to say you just put it on the file name on the screen capture and then the number will follow the image.

DR. FINDER: Dr. Finder again.

Just one last question, and I know we've talked about it, but we've basically been focusing on clinical images. I want to go back to phantom images for a second, in terms of the monitors that would be necessary to review those, and to get the opinion of the Committee.

In terms of logistics and expenses for state -- especially state accreditation bodies, but I believe also it would involve ACR, would it be reasonable or acceptable for a phantom image to be reviewed on, let's say, a PC monitor? And if it passes, that that would be sufficient. And if it fails, then go to a more high resolution monitor to check that.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: Yes, I think that would be the appropriate -- Tony Seibert -- that would be the appropriate thing to do. I look at accreditation -- I don't go to multiple sites like Tom, so I'd be interested in hearing him, what he has to say as well.

But in our institution we have several mammography units. I look at the accreditation phantoms all the time on my PC. It's a four megapixel, 30-inch monitor, and it's just a matter of how much you're willing to sacrifice when you're analyzing the images to make sure that you're not limited by resolution, for instance, when evaluating microcalcifications.

So I would say that, personally, as long as it passes on a low resolution or, let's say, less than stellar monitor, then that's okay. And then if it doesn't pass for some reason, then you need to move it to a higher capable monitor. So I think that's a reasonable thing to do.

DR. HENDRICKS: Mr. Ruckdeschel.

MR. RUCKDESCHEL: This is Thomas Ruckdeschel.

I do look at digital mammo phantom images on a laptop, actually, and it's sufficient for passing. Just to put it into perspective, I do review for other modalities, and I review those on a laptop. But there are some times if there is something that's really kind of close that was subjective, such as low contrast or something that could've been affected, or resolution that was affected, you know, by the resolution of my monitor, I would take it to a higher resolution review workstation to do that.

So, you know, I have experienced that. And actually I never really saw a difference when I did that, but just so I felt better, I would do that for other modalities. But for mammography, I think it's sufficient.

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: A procedural question. If you do it under that proposal, if it fails on the low resolution, is that reported to that institution as a failure, then, and it's going to be subsequently reviewed, or is it reviewed automatically before it's ever reported as a failure?

DR. FINDER: This is Dr. Finder.

Well, since this is all hypothetical, I'll make up the answer.

(Laughter.)

DR. FINDER: And what I would say is that it would be transparent to the facility. They'd never know about it. Unless you want it the other way, in which case I'll come up with the other answer.

(Laughter.)

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: I think, just for the record, it's important to understand that the phantom is a very crude measure of the digital image and it's almost -- it's not black and white, but it's almost is it there or isn't it there, the different structures that are being looked at in the phantom? And I certainly would have no problem with physicists reviewing on a PC and then, if there's a question, going to higher resolution systems.

DR. HENDRICKS: Thank you.

Any other questions or comments on this topic, soft copy?

(No response.)

DR. HENDRICKS: Then we'll move to the next item on our

agenda. Thank you for your input.

The next item is the invited speaker presentation. From the American College of Radiology, we welcome Dr. Berns to address an update on full field digital mammography, the universal quality control manual.

Welcome.

DR. BERNS: Eric Berns. And I think I need some help unlocking the screen here.

Thank you very much. There we go. My name is Eric Berns, and I am an assistant professor at the University of Colorado and Denver Health Medical Center in Denver, Colorado, and I'm here and I've been asked to represent the ACR and provide an update on the status of our ACR FFDM QC manual.

So a little history which everybody knows. And at first, before I started this point, I was thinking, well, maybe I should've presented this first to sort of address some of the questions you'll be discussing. But after hearing all of the issues, many of which we will be addressing here, I think it's good to hear the discussion because actually now people are interested and so there may be some appreciation of what has gone into this, to this point.

(Laughter.)

DR. BERNS: So, anyway, I think everybody knows the history and the current situation where everybody in the field has to follow the latest manufacturer's QC manual. So there's nothing new here.

Everybody who uses digital mammography has to meet the manufacturer's performance standard. Currently, failures to meet these, most manufacturers have alternative standards which allow you 30 days or have to fix immediately, which we've discussed. So everybody's pretty much familiar with the current situation.

And so back in '99, in the screen film days, there was a quality control manual which sort of predated the MQSA and developed into the regulations, so everybody knows the history on that.

And I think people are starting to appreciate what has happened with digital, since there hasn't been an ACR QC manual, which is manufacturers are required to put out a QC manual and that each facility has to follow that QC manual.

And at the beginning, this was sort of okay because these QC manuals contained the beginning-to-end process, from the detector all the way to the workstation. Well, that has sort of expanded, and now there's QC manuals for X-ray systems, for monitors, for workstations, for printers, and so this has sort of exponentially gotten out of control.

So we have taken on the task of putting together a group of people to address this, at least from the ACR perspective. So we have a committee we formed a couple years ago that contains different groups of people. We have clinical representatives, we have MITA representatives, which are the manufacturers, and we have people from the ACR staff that are

on this committee.

And we have about, oh, 18 or so people, and they're listed here, and we don't need to go through each person's name at this time. But that's myself, I'm the chair of this committee. We have two technologists that work clinically on this committee. We have four radiologists that are on this committee, that work both in academics and clinically, and we have three medical physicists that are on this committee, and we have -- right now, currently, we have three MITA representatives, from the manufacturers, on this committee, two of which have since retired and rotated off this committee. And we have two people from the ACR staff on this committee. So that just kind of gives you the overview of who's on this committee.

And what we've been asked to do, there's two things. One is to design a phantom that is specific for digital for the accreditation body, and two is write the associated QC manual. So those two things have been our task.

And some of our goals were to standardize all of these QC tests for all digital manufacturers. So there's one set of QC tests, there's one set of frequencies for these quality control tests, and there's one set of performance criteria with some caveats, depending on what kind of detector you have.

So there will have to be some sort of -- a little bit more interaction between a facility and a physicist and manufacturers to sort of

understand the properties that each system may contain. But our goal overall is to sort of standardize these performance criteria much like the screen film.

We've drawn on a variety of sources for these tests. They've come from the MQSA Program, the old ACR screen film manual, ACRIN DMIST results, manufacturer QC programs. MITA has its own published QC recommendations. European guidelines have some QC recommendations. AAPM TG 18 talks about monitor quality control. And we also, last but not least, did not want to discount our clinical experience and common sense that comes from that.

So the point here is that we've really tried to encompass a variety of references, in terms of pulling together some quality control tests that make sense clinically.

We wanted to make sure that these quality control tests were clinically relevant and didn't get off into the obscure areas of academia. We want to make sure these are user friendly. We also wanted to design this in the hopes that manufacturers will freely adopt this manual and embrace it and replace their current systems, and hopefully that this manual may become the basis for new regulations over time.

We also realize that this is a very critical component of the ACR Mammography Accreditation Program, and so we have to keep in mind that we need to account for all past, present, and future digital units out there

because there's a large number of these already out in the system and they date back to the early 2000s.

We want to make this reasonable and appropriate for mass implementation, realizing what's out in the field already. We wanted to eliminate unnecessary complicated procedures and analysis. We wanted to maximize the user experience, especially for the techs, radiologists, and facilities, knowing that this is a very sensitive and time-consuming issue for them.

We also had a philosophy that we wanted to embrace, which was we wanted to make as many measurements, quality control measurements, with external equipment. We didn't want to rely on manufacturers to have to supply certain software or dosimeters or photometers. We want to make sure that we can do external evaluations on systems and not rely on other equipment or software. And in particular, contrast-to-noise and signal-to-noise measurements, we may have to have some better involvement.

So we are structuring the manual very similar to the screen film manual. We're having different sections, one for the radiologist, the clinical image quality section, a technologist section, a physicist section. We're also going to expand some sections for an educational section, guidance and troubleshooting sections, and of course some reference sections at the end.

So it's very similar to the screen film manual. Of course,

dedicated towards digital.

So what will be new? So I just want to highlight a few of the new things to sort of provide some exciting interest in what's coming.

So we're going to have a radiologist section that is going to -- and of course all of these are to be determined and we're still in the draft phase.

But we're going to try and address image identification regulations or recommendations, come up with recommendations for hanging protocols. We're going to try and get some guidance on monitor and viewing conditions because that's always a hot topic. We're going to include a section on diagnostic tools for analyzing poor images. We're going to give a section for radiologists on how to score the ACR FFDM phantom. And then, finally, sort of a guide for radiologists on what their roles and responsibilities are for overseeing a QC program.

So all of these are relatively new for digital and sort of come from our clinical experience and to try and address some of the deficiencies in the screen film manual that actually have some practical use in the digital manual.

For the tech section, we've expanded some tests, and we've expanded some other parts. We're going to have a sort of enhanced positioning and image quality section, which you would expect.

We have a new test that we are proposing at this point, which

should bring in the radiologist into the quality control program, where we're going to have the tech and the radiologist work together to do a monitor and image quality control test. We're going to have a dedicated facility quality control review test, so to speak.

We're going to revise the formatting for corrective actions so documentation can be improved. And we have a new document to help facilitate how facilities keep an inventory of their equipment, because we realize that no longer are we just sort of tracking X-ray units, but now we're tracking systems which include monitors, printers, X-ray units, and that can be over vast distances, as we all know, with teleradiology.

We're going to have improved quality control forms, which should go -- should be very welcome. We're going to have instructions on mobile mammography, and then we are going to do our absolute best for technologists to eliminate calculations because we realize that is a huge barrier. And so we're working on that.

For medical physicists we have a new theme, which is better documentation and communication to facilities. Old-school physics reports are printed Excel spreadsheets that basically look like a foreign language, and so we're going to try and help that facilitate communications, so that when a facility receives a report or an inspector looks at it, that it can be interpreted by most people.

So to do this we're going to design a single medical physicist

summary form that will work for the facility, for the ACR accreditation body, and for state inspectors and MQSA inspectors. So we're going to have a single summary form that will communicate the summarized results.

We're also going to have an action item summary. So we're going to have the physicists sort of provide better detail on what a facility needs to do once they get this report in their hands, so that there's sort of an action item list, because right now it's very open on how things are documented. So that's going to sort of fall into the medical physicists, but we're going to provide that format for them.

We're also going to have a specific form that comes from a physicist, that goes directly to the lead tech, sort of describing operating levels, if there's any, and any specific QC instructions. And you'll see where I'm going with that. But something that's sort of direct to their attention so they don't have to flip through pages of reports, they can look at one sheet and say, Okay, here's what I need to do to continue on.

For the physicists we're also going to have improved procedures for evaluating and documenting tech QC. Right now that's very vague about how do you -- how does a physicist evaluate how the technologist or a facility is doing QC? So we are going to be very descriptive on what the physicist does in terms of evaluating that.

We're also going to form a link between the physicist and the radiologist. We feel that there is sort of a gap between what goes on. Most

radiologists don't even know that the physicist comes in and does anything. So we're going to try and provide a format for the physicist to sort of, in letter format, kind of write a summary of what they did and eliminate things like -- no offense to collimation, but we're going to try and eliminate things like that are more of on the tedious technical side and just give them a summary on image quality and radiation dose and say, How is your system functioning? Is it where it should be?

So we're going to have sort of a letter and a link that can go to them and that way they can at least understand what the physicist is doing and hopefully be more included.

We're also going to sort of change the formatting of corrective action, where the techs and the physicists will be using the same corrective action form, so if a problem is discovered, that the physicist will initiate a QC form for corrective action that then they can hand off to the facility and the facility then can follow up on it.

So oftentimes there is a lack of communication between a physicist failure and the service person who ends up fixing that. So this way the technologist doesn't have to translate to the service engineer what was wrong and what needs to be fixed.

So hopefully this document can provide that way to provide the documentation to the service engineer and it can also provide a way that it can close the loop on open corrective action items needed. And it'll be the

same form that a tech will use and the same form that the physicist will use. So we're trying to consolidate that.

So what else will be new for the physicist section? We're going to provide forms in both PDF and Excel worksheets. So that's sort of just a practical thing for the physicists. And we're also going to provide guidance to physicists on how to deal with multiple units, with digital units, workstations, AWs, RWs, printers, et cetera. We're also going to have guidance on how to deal with multiple facilities.

So this, all of sudden, went from a small problem to a big problem, and it's part of the reasons why it sort of takes them time to work through these issues to find solutions that work because you have to account for all of these different systems. But I'll get to this in a sec, how this is going to kind of work.

We're also going to have some guidance for facilities on how to handle multiple units at multiple locations. So it sort of dovetails from the physicist into the facility. So managers, lead techs can kind of have some guidance on that.

We're also going to have guidance on what needs to be done when major and minor repairs are done, who needs to do what, when, how. That's always sort of been a mystery out in the field, about what happens, and oftentimes there's a lot of questions and not a lot of easy answers when it comes to what to do when there's repairs that are done or software

upgrades or detector replacements. So we're going to try and give some guidance on that.

We also have a new test that is what we're going to call the facility QC review, and this is going to be a quarterly test, and I'll get to this in a sec. But we're going to make people sit down on a quarterly basis within a facility. That will include a tech, a radiologist, and a manager, if there's a manager, and review quality control. Too often we find that radiologists and managers don't know there's problems until there's an inspection, and then they're discovered. So we're going to try and bring them into the loop and make them a little bit more involved in the process.

So this is sort of a small slide. It's difficult to see. But this is the list of where we're at with the technologist QC test of what we're proposing.

And so we have a list of 11 tests, and for each test we have what we're calling a test element. So for each test there's different parts to that test. And for our first test we're going to have the tech do a weekly ACR phantom, which I have, which I'll show in a second. We're going to have the techs do an acquisition workstation QC weekly. We're going to have them do a radiologist weekly monitor QC.

And for the phantom image, the first test, there's like five different subtests within that. All of these are very short, efficient tests. They're not long and lengthy, but there's five little parts. And accounting for

time, I didn't want to break out into the tedious details. We can later.

And for the acquisition workstation there's three subtests. For the radiologist workstation QC there's five subtests. For the laser printer QC there's five subtests. For monitor cleanliness there's one. There's a visual checklist. There's a repeat analysis test. There's a monitor QC for the radiologist. This is where the technologists and the radiologists will sit down together and do an evaluation. There's a facility QC review test, which is quarterly, which is, as I just talked about, where everybody's going to sit around and review QC on a quarterly basis. And then the standard compression force test every six months.

And then, finally, there's a monitor detector calibration test, which will come from -- if applicable, from detector manufacturers, where FDA will have some recommended calibrations weekly, daily, monthly. However, with the recommended frequency, if it's necessary, then we would account for technologists doing that calibration test.

We have two supplemental forms. One's a corrective action log, so it's a way for them to document the corrective action. And this will be a little different because we're not going to have corrective action for each little test. We're just going to have a single log that, for whatever occurs, you'll just start a new page, essentially, if there's problems. This way it's easier to say, Okay, what were your problems? You go to one section and you can find this easily.

And then, finally, for the techs we're going to have another supplemental form, which is the facility equipment inventory form, which is basically a record keeping sheet where we're providing them a way to document what units are within their system. Whether it's an X-ray unit, the monitor, a printer, we're going to sort of give them a place to put when it was last inspected so they can start to keep track of that. And this will also become handy when the physicist goes in and they can look at the sheet and say, Okay, I'm here to test this X-ray unit, but there's 35 monitors within the system and they've been accounted for in terms of their QC review. So this sort of centralizes and sort of puts our arms around their external equipment that is off site.

The physicist has 17 tests. We have an ACR phantom test and we have five or so or six image quality tests for that from the physicists. We have a ghost image evaluation. And these tests are all done annually. This is the typical annual inspection that a physicist does when they come and do an evaluation.

We have an AEC control system performance test, a collimation check. We have a kVp and reproducibility check. We have an evaluator check, which is used for dosimetry. We have a dose check, and there's a couple different tests within the dosimetry; a unit checklist where we look at the integrity of the unit. We're going to have the physicists look in more detail on their site tech QC program to make sure that it's being done

correctly.

And then, of course, there's the MQSA equipment requirements which we're incorporating into this QC program for the physicists. We have some computer radiography tests, if applicable. If you have CR tests, we've got a couple tests we recommend for that. And then, of course, we have an acquisition workstation review, a radiologist workstation. We have more tests that the physicist does for these devices, a laser printer, viewbox luminance.

And then we have other -- the last test is that the physicist, at least once a year, will have to evaluate off-site tech QC programs. If someone has monitors off site or a printer in the business office, they're going to have to look to make sure that that QC is done correctly. So at least once a year.

So one of the philosophies that we're taking with the way that these units are expanding in number is that we are basically writing our QC program in modules.

So we're going to have like X-ray unit sections, which is like the first 12 tests, and then an acquisition workstation QC as kind of a standalone document. So if you replace an acquisition monitor or you get a new one or there's some reason, you can just pull out the acquisition monitor QC and go do that QC. The same thing for the radiologist workstation because these are essentially their own devices now. They're systems in a sense, but they're also standalone.

So if you're doing -- if you've got 30 workstations in a system, you can just go around and do radiologist testing on each workstation and just pull out the RAD workstation QC. So it's a separate device.

Because nowadays these workstations and printers, they are changed and moved and upgraded and sold and lost all the time. So it's like chasing wild cats, these monitors. So you really have to have a standalone QC program for those. But we're certainly integrating them within the context.

The same thing with laser printers.

So we have a few supplemental forms, which are important to know, for the medical physicists. So we're also going to have a single summary report that's generated from this. We're going to have, as I was saying earlier, a technologist operating level or a QC instruction form. A medical physicist's summary letter that goes directly to a radiologist. We're going to have a single corrective action log.

And then we have put together something that's very supplemental, which is sort of a pre-inspection interview form, where there's so much information now you need to know before you walk in the facility. We're just detailing some of the items that a physicist may want to know before we get there, because oftentimes we do our work at night, over the weekends, when they're not using it clinically. So we're just trying to save some time and make things more efficient for the physicist.

And then, of course, a technique chart which we are going to

try and recommend from the physicist.

And then for the technologists we have some other educational example forms. So what we also want to do is provide ways to educate the techs and the facilities on how to -- well, we're going to provide a complete set of forms that are filled out so people know kind of what examples need to look like when you do something correctly. We're going to give a guide on how to score the ACR phantom. We're going to give guides on how to do calculations. Even though we are on the verge of eliminating that for the technologists, we still need to do that for the physicists.

We want to give a guide on how to do monitor test pattern evaluations because that can be an ominous task for someone who has never seen this or done this before. We also want to give a guide on how to do a printed film evaluation, a guide on how to evaluate a printed film. And then we also want to give a guide on how to sort of evaluate for artifacts from the phantom standpoint.

One of the things we're doing for the printers and the monitors for QC is we are going to take advantage of our -- for a variety of things that were said this morning, we're taking advantage of the ACR phantom, which we're going to get to next, and we're going to use that for the majority of quality control on monitors and printers and not necessarily trust all of the lookup tables and the image processing that may or may not be applied to test patterns, but we're going to look at the phantom.

So oftentimes, when you look at a phantom, you have some sense that the system is working properly, even though there's some algorithms that may or may not be applied to a phantom, but you know that you're not looking at a test pattern which could be very different than the native software that an image is displayed in.

So even though the majority of manufacturers utilize this now for a variety of reasons, we're going to try and eliminate most of that because you don't necessarily know if that lookup table applied to a test pattern is the same applied to an image. So we're just getting rid of that.

So the phantom. So we had some design principles that we wanted to maintain in designing this digital phantom, and we wanted to base this phantom on the ACR accreditation phantom, the current phantom. We wanted to maintain similar scoring to the current screen film phantom, and we wanted to be able to use the experience of the 8,000-plus facilities that are out there that already know how to use this phantom.

We want to be able to use this phantom on both screen film and digital, we wanted the attenuation to match between screen film and digital, and we wanted to be able to maintain the MQSA limit of three milligray for the dose limit.

We wanted the phantom to cover all or most of the detector on digital systems, with a single exposure resulting in all relevant information.

And so this solves a lot of the issues with what we were talking

about earlier, about window and leveling because, as you'll see, we've eliminated all of those controversies.

We wanted to evaluate for artifacts at one window/level, that is, the same window and level that you looked for test objects. So if you windowed and leveled optimally for your test objects, you now know that you can see all relevant clinical artifacts.

We also want to provide more enhanced details and specifications for manufacturers because in the current phantoms there's sort of some mysterious variability among phantoms, so we're going to be very specific on the details of the phantom. And, of course, this manufacturing will be open to all vendors. If you want to build a phantom, you submit a phantom to the ACR for some standardized approval process.

We also have some differences from screen film. We are proposing that we're going to eliminate subtraction for artifacts, which we talked about earlier. We feel that this is just too controversial. What we want to do is be able to add a fail for artifacts. So if you spot an artifact that you feel is clinically significant, then you can fail for accreditation. You're no longer sort of trying to subtract for artifacts. That's a whole different discussion.

When we have phantom reviewing courses, we spend hours, the physicists, about deciding if that dot is worth subtracting off of that calcification. And it is so subjective that that's just not the way to go in the

digital frontier. So we're eliminating the subtraction and we're going to add fail.

We're going to improve the rules for scoring. We're going to change the scoring criteria, but the objects are the same size or effective size as a screen film phantom, as you'll see, as the current thing.

So this is the picture of the phantom, and I'm going to pass this around so people can see the phantom and what it weighs.

And so we have a very small set of prototype phantoms, and it's about the size of a large detector. It's a little bit shorter in depth because it has to fit on the CR units and the smaller digital units. It's got to fit on the smaller bucky size. So if you compare this to the screen film phantom, it is significantly larger because we designed it to cover the whole detector.

We have three components. Well, four. There's a cover plate on the phantom. There's a wax insert which contains the test objects. And there's a very thin -- similar to a piece of Saran wrap, what we call a compensator, and what that does is it allows us to match the dose to this phantom to the dose to the screen film phantom and sort of normalize the background signal.

So this is a very noisy slide, but this is one of our sketches that details how proscriptive we are going to be in the manufacturing of the phantom, because we want every phantom to be identical, which is not the case in screen film.

We were very proscriptive in the design and build of the wax insert, in terms of placement and sort of very tight tolerances, so that we can have one phantom on one facility, and it's not going to give you different results from another phantom.

We were very proscriptive about dimensions. And one of the big improvements we have done to the test objects is we have switched out the material for the speck groups, from a variety of either luminous specks -- we're now using NIST traceable glass microspheres so that we can be very precise about what size these speck groups are.

This is what the phantom looks like when it's set on a large field digital unit, so it covers the whole detector itself. This is an X-ray image of what it looks like, and one of the things you'll notice about it is it's a nice, uniform background image. You can see that, to a degree, there's a wax insert in the middle. There's a little circle up in the very center of the object. This is a one-millimeter milled-out hole, so there's a little hole in there so that you can measure contrast and noise, at least the physicists can. And then the entire phantom covers the majority of the detector. So this allows you to look for artifacts.

So one of the key features about this is if you optimize for those test objects, which are sort of low contrast masses and fibers and the higher contrast speck groups, you're also optimizing for looking for artifacts. So this can also be printed out and sent to the ACR for review or it can be a

snapshot or any kind of image. But this is one of the advantages. We wanted to eliminate sort of the different edge processing that can happen.

Now, this is an expanded view of the wax insert. The lighting in here is horrible, but you can kind of see how across the top there's a row of six fibers, in the middle there's six speck groups, and in the bottom there's six masses. So these are the same general idea as the current phantom.

This is a better image, as it's just the wax insert. It's not the test objects. But you can see how the test objects are laid out on a wax insert. And you can see -- and some of you maybe won't appreciate this, but the glass microspheres, which are the speck groups, are very circular, they're very much the same within their group. So this is an improvement.

Yes?

DR. SEIBERT: The black dot underneath the --

DR. BERNS: The black dot is an air bubble in the wax. So that's just --

DR. SEIBERT: An artifact.

DR. BERNS: It's an artifact. Good catch, Tony.

(Laughter.)

DR. BERNS: So this is all prototype, of course. So this is an expanded view of the calcifications. You can see that they're very round and circular. This is the glass microsphere. So this is an enormous improvement. Physicists get very excited about this kind of thing because we've had to deal

with multiple phantoms over time. So this is a very good thing.

This is sort of where our pass/fail criteria will be. So if we see two fibers, three specks and two masses, going across, or better, that's equivalent to, in today's world on the screen film, of four fibers, three specks, three masses. So we're just shifting the numbers are little bit because we've made finer gradations of the test objects, and we've made them go smaller because in some of these digital systems we've maxed out the current screen film phantom. So that's what that looks like.

Then there's the little hole up at the top where we do our contrast to noise. This is sort of the electronic measurements where we're trying to see how the system's performing.

And then this is a side-by-side image of the digital phantom and the screen film phantom and one of the things you can notice here -- and this is one of the big successes of the phantom -- is that the large digital phantom, you can see, has no white -- the white banding around the screen film phantom, that's sort of electronic compensation that's being done at the skin line, so it's thinking that's a breast. And so what that does is it doesn't allow you to see everything on a single shot.

So we've sort of normalized that, we've gotten rid of that by some tricks with some of the materials, and now we can see the whole image without any real signal processing problems and we can look for artifacts.

DR. KOPANS: Are any of the test phantoms -- I assume --

DR. BERNS: Can you speak in a microphone?

DR. KOPANS: Dr. Kopans.

Are there any of the test objects that are beyond the capability of present-day digital systems to image? In other words, the present ACR phantom, with digital mammography systems, you can basically see all of the specks, almost all of the calcifications, and all of the masses. I think what you said is that you're going beyond that, so that -- I mean, digital is better from that perspective than film screen, and we're hoping that digital will get better still. And of course tomosynthesis coming along the lines.

Can this phantom go beyond, so that if contrast resolution becomes higher, you'll be able to appreciate that?

DR. BERNS: It goes beyond the current phantom. We had to draw sort of a cost/benefit ratio of how small to take the objects because, at a certain point, the cost of manufacturing and the cost of the objects just got too high. So we said we can go smaller, we can make it reasonably affordable, but we can't go beyond things that may not even be out there yet. So that's kind of our thinking on that.

So a couple of examples. So also we tested this and we still have some substantial pilot testing to go on this in the review process. But this is a current digital CR image and you can see that this phantom does work with CR, which is -- and you can actually see -- or on the perimeter you can see some artifacts from the positioning of the plate within the cassette.

So this is just an example of how this works for computer radiography.

Now, this is my million dollar example to my promotional material. This is an old screen film phantom, an 18 by 24. When we put the new digital phantom on the screen film unit, you can start to see all sorts of artifacts that the physicist would -- or even a technologist on the regular QC could evaluate a little bit easier in terms of seeing problems that are going on in the system. So this was the same system as before, a different cassette, but you can see that there's a myriad of artifacts going on. And so that's one of the benefits of the phantom.

We also did some electronic testing to verify that the dose or the signal values that the phantom would see are about the same from the digital to the screen film. So they do match up electronically.

So to summarize the phantom, about 50 percent of the tests for the technologists use this phantom, and a lot of it's visual. Most of it's visual. And so we feel that a very integrated and an important part of adopting the QC program would be adopting the phantom, too.

And about 41 percent of the physics tests incorporate some element of the ACR phantom, whether it's image quality, measuring dose, or other things like that.

So benefits of the new phantom. So it covers the whole detector, looking for artifacts, and as Dr. Kopans was saying earlier, we feel, from our clinical experience, that artifacts is probably the single most biggest

issue when it comes to failings in digital mammography. So we felt that putting our efforts into artifact and image quality was where we should really try and get some good evaluation benefit.

When we look at the window/level as optimized for the test objects, it optimizes for the artifacts. So you do it once, you can screen save it, you can print it, you can look at it. But that's how the technologist would know if they're windowed and leveled properly.

And the majority of the time this automatically happens. It's not like you take an image and you've got to window and level. But if you want to, you can window and level because it gives you something to reference when you're window and leveling. And this is particularly important for physicists because when you -- you can choose window and levels which hides a lot of artifacts.

And artifacts are very subjective, so we felt that this is like a starting point for looking for artifacts by looking at test objects. So relative to the test objects, are the artifacts significant or not? And then from there you can look around and change your window and level settings to look for very smaller other types of issues. But that's our starting point.

We improved the gradations for the test objects; we made them smaller. We made finer gradations, so they're tighter together so you can discriminate between units a little bit better.

We matched the doses so the dose for screen film is the same

as a digital phantom.

We have a single image now that gives us dose image exposure levels and image quality measurements on a single image with a single exposure.

We also recognize that this is saving on training the 25,000 or so techs that are out there with this current scoring mechanism. We didn't want to start over and reinvent the wheel.

And this also provides the basis using this phantom for both monitor and laser printer QC. So we're going to use the same image that goes through your imaging system to then become -- you'd be looking at that same image for your QC.

And then also this works for physics reviewers. And of course this was before the idea about soft copy review. But if you print this film on a single film, you can see artifacts and test scores on a printed image. So that's a benefit. And you don't need to really change the window width and window/level settings.

So our challenges in this QC program were accounting for and incorporating all the different technologies that are available now and are coming down the pike, handling off-site equipment has been a challenge, predicting for future systems, and ensuring all necessary tests are included, meaningful, and relevant. We've had a lot of tests that we've seen across different manufacturers, across different research studies, that we felt may

or may not really be of value, in terms that they might be interesting but they may not be as useful in terms of implementing in accreditation programs.

So what's next from here? We're very close to having a draft that we're going to send out, too, for sort of a pre-review, pre-pilot testing kind of thing. We're going to send a draft to the manufacturers, to the FDA, and to some select reviewers for preliminary feedback. We're then going to collect these back, these comments, we're going to edit it into a final manual, and then we're going to send that final draft to the FDA for applying for the alternative standard.

Here's my preemptive questions.

Cost to the phantom. Everybody has this question, besides when are we going to be done? And so the political answer is we don't know, but we do have reason to believe that it will be affordable. It's not going to be outrageous like some of the other phantoms.

Implementation and rollout. The ACR will work on developing a plan to include some sort of training, because obviously this is new. It's not the ACR that's going to do applications with all of these facilities, so that's going to have to be developed.

And then, finally, when? So hopefully preliminary review will be sent out December-January for our first wave. We'll get that back, then we'll send it out for the final review.

So with that, thanks very much.

(Applause.)

DR. HENDRICKS: I guess we'll take questions for Dr. Berns. First, Dr. Sankar.

DR. SURYANARAYANAN: Sankar Suryanarayanan.

Two questions. Are you sure of the CNR target in the phantom? So is the plan to -- how do you plan to mandate that? Are you going to have a standard CNR benchmark that all manufacturers have to pass to establish that threshold? So that's the first question.

The second question is the design of the phantom. What are your thoughts on using this with detectors with curved surfaces versus flat?

DR. BERNS: Eric Berns.

The first question is, for CNR, we plan on -- before our final iteration, we've got some pilot testing where we're going to collect data on all the available units out there. We're going to see how that data comes back. We realize that that's a very tricky situation. And so it might be one of those areas -- at least our preliminary thinking is it's going to be one of those areas where physicists or a facility will have to talk to a vendor to get some certain feedback on how their systems are supposed to perform. That would sort of expand to the AEC, some of the other AEC testing. So that's kind of where we're at that. It's very difficult to choose one number and say that's it for everybody.

And then the second question was on --

DR. SURYANARAYANAN: Sankar again.

Have you taken into account considering --

DR. BERNS: Oh, curved.

DR. SURYANARAYANAN: -- curved detectors?

DR. BERNS: We tested it on some old Fischer units, and it seems to work fine. We've yet to test it on some of the newer that are more recent. One of the problems is getting access to units that aren't even in this country yet. So it's hard to say. But on a preliminary testing, it worked great.

So anything else?

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Not to be the Grinch, but we finally caught up with the digital. Now, we already have tomosynthesis. What's the plan to make a phantom for that?

DR. BERNS: A good question. We have taken this into consideration. We feel that the majority of our tests can apply, can just be rolled over for tomo for a lot of that. Some of the issues with the image quality portion, we've done some preliminary testing on current approved units and it seems to work and we just -- so I think that it's going to be a modification. I don't think it's a whole new start-from-scratch QC program, but we have thought about that.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: Tony Seibert.

Eric, how is a physicist going to measure dose and air kerma? Currently, what happens is the dosimeter is placed just next to the existing phantom, underneath the compression paddle. What are your committee's thoughts on that issue?

And then the other issue was what we talked at length at, was the loss of information at the chest wall. I know, I'm familiar with the DMIST phantom that you probably looked at, and they had some really nice indicators, millimeter indicators that would give you an estimate of how much you're not seeing that you should be seeing, as an example. Maybe that might increase the cost of the phantom too much. But your thoughts on those two issues.

DR. BERNS: As far as the dosimetry, what we were -- our initial thoughts were to take an AEC exposure using the phantom, like they would clinically, because that's another theme we wanted to do, is evaluate the systems like they use clinically, not testing separately in different modes and have to kick them into service mode, but we wanted to test how it's used clinically. So if we can find the techniques that would result from an AEC image, we could then measure mR for mAs, putting in the detector, replacing it and then do it by calculation.

And then the other question was about the missed tissue. One of the things about the missed tissue test is it's really a measurement of where sort of the detector cover starts to where the detector starts. So

you're measuring the distance from the edge of the cover plate to where the detector is. And that distance is usually very fixed. That's like a manufacturing distance.

And so I'm familiar with the DMIST, and I think that's where this sort of evolved from, was from a research study awhile ago. And so from our clinical experience and even looking at the DMIST results, that was something that never failed because it's a manufacturing thing about the distance from the plastic cover to where the detector starts. So that distance doesn't change, necessarily.

And so taking it to the next step further as well, why don't we measure it with the current phantom? The committee felt that that failed so infrequently, basically never, that it wasn't worth the time, the cost/benefit ratio of what it takes to do the measurement and then the benefit you would get from doing that.

Now, with our phantom, one of the things we had to deal with was actual cost of the phantom versus putting in test objects. And so instead of getting very elaborate and fancy test objects, we thought, Well, it's not worth the extra dollars because one of the things we were very sensitive to, the first question is -- I mean, no one cares about the QC. They say, What does the phantom cost? That's the big thing. And if we make it too high and put in test objects that just doesn't have the bang for the buck, we're not doing a service to facilities. They're paying for extra test objects in a

phantom.

So we could theoretically use this phantom sort of in a backwards way, to measure the distance, say, electronically, from the wax insert back to the chest wall. And that may be something that's reasonable for a physicist's acceptance.

But since this is sort of a manufacturing thing and it's difficult for us, the ACR, to say, Well, we're going to tell the manufacturer that the distance from the detector to the plate is X millimeters, that's just maybe an unreasonable thing. It's like telling them what their pixel size needs to be on the detector. So we're just kind of measuring sort of what that is.

But it was good to hear that discussion this morning, and I will take that back to the committee.

Anything else? Yeah.

DR. HENDRICKS: Dr. Seibert.

DR. SEIBERT: In the acquisition of the image, do you specify a specific AEC location? And for those detectors -- I only work with one system.

DR. BERNS: Yeah.

DR. SEIBERT: But there's other systems that use different methods of figuring out. In fact, our system you could go into this auto mode where it would select, apparently, the highest value. What is the recommendation of the committee for AEC?

DR. BERNS: Well, we've got a couple of different ideas. And

one of the advantages of sending this out to all the manufacturers is we're hoping for input back from them when they test this out in the sort of pilot phase, to say, Hey, it didn't work in this mode; it does work in this mode.

Concurrently, we are going to take our committee and go out and test these on the same systems, and so we will see if there's any sort of negative effects of choosing fixing it or not fixing it.

One of the things we don't want to do is get too prescriptive on setting the AEC because we want to use what they use clinically. So we're hoping that if we say just do a clinical exposure, they may or -- if we're telling them to set things special for the phantom, it may give us phantom-specific results. So we want to shy away from that if we can. But hopefully that'll come up in the pilot test.

DR. HENDRICKS: Other questions from the Panel?

(No response.)

DR. HENDRICKS: Thank you very much, Dr. Berns, for your presentation.

DR. BERNS: Thank you.

DR. HENDRICKS: Now, we're going to take a break for lunch. But before we break, I do want to remind all the participants, please do not discuss the content of this meeting during lunch among yourselves or with any other member of the audience. We will return to this room in one hour, but please take any personal belongings that you need with you at this time.

This room will be secured by the FDA staff during our break so no one will be allowed to return to this room until we reconvene at one o'clock.

Thank you.

(Whereupon, at 12:00 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(1:00 p.m.)

DR. HENDRICKS: Good afternoon. And welcome back to the National Mammography Quality Assurance Advisory Committee meeting.

We need to resume the Panel meeting at this time. We're going to proceed with the Open Public Hearing portion of the meeting.

During this portion of the meeting, public attendees will given the opportunity to address this Panel, to present data, information, or views which are relevant to our meeting agenda. Ms. Craig will now read the Open Public Hearing disclosure process statement.

MS. CRAIG: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the Open Public Hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the Open Public Hearing speaker, at the beginning of your written or oral statement, to advise the Committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, this financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the

meeting. Likewise, FDA encourages you, at the beginning of your statement, to advise the Committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

I will pass the meeting back over to Dr. Hendricks.

DR. HENDRICKS: We have a number of public speakers today, and so I want to go over the process to make this a smooth transition from one speaker to the next.

Speakers will be given five minutes for their remarks. When the speaker begins to speak, the green light on the podium will go on. A yellow light will appear when you have one minute remaining for your comments. At the end of the five minutes, a red light will appear and the microphone will then be switched off.

I would like to remind the public observers at this meeting that while this meeting is open for public observation, public attendees may not participate except at the specific request of the Panel Chair.

Our first speaker in this portion of the meeting is Lynne Farrow, Director of Breast Center Choices, Incorporated.

MS. FARROW: Good afternoon. My name is Lynne Farrow from Breast Cancer Choices. Our organization is in New York. The principal mission of our organization is to provide informed consent for breast cancer patients when it's available. We do this by determining if the disclosures are

in place so the patient can make educated choices.

You'd think getting disclosure would be a no-brainer. But getting disclosure has been a tough task. I used to be a college professor who believed experts in their fields had the right to make decisions because they had oversight. Even though my academic training revolved around asking questions, I never applied that rigorous questioning to the medical profession or asked about disclosure.

I've traveled here today to voice a big regret in my life, and I hope my story might help others learn from my mistakes. I should've asked more questions from the beginning. I should've used my mind before I turned over my body no questions asked.

From the time I turned 40, I had yearly mammograms. Every year, the mammogram reports came back clear. I would do a little dance in my head and I would thank the universe. Then six months after the fourth year of mammograms, I felt an unusual thickening and was directed to have, next, a diagnostic mammogram. That film also showed nothing.

Because the doctor could actually feel the mass, she ordered a needle biopsy, which came back positive for cancer. Even after they knew exactly where to look for the cancer on the film, the mammogram did not reveal it. By the time I had surgery, my diagnostic came back DCIS with an aggressive invasive component.

If I could have had access to a more reliable diagnostic

procedure earlier, my cancer would've been caught much smaller and treatment recommendations would've been less aggressive.

I didn't know what to do with my knowledge of mammography's dirty little secret, and the crude X-ray is practically Russian roulette in its ability to detect cancer, especially in dense breasts such as mine. We'll never know how many aggressive treatments would be avoided.

What I didn't receive was informed consent. Why not? Why wasn't I told that my dense breasts made them pretty much mammogram-proof?

Mammography disclosure, even a few sentences, creates and asks questions, call to action for cancer patients who have a long line of procedures ahead of them. We need disclosure before doing anything with high stakes, right? If there is no disclosure, we can only assume the nondisclosure has something to hide. How can anybody ethically make a case for covering up the facts?

As I've had more time to review the facts of mammography, I realize that the women need a much stronger remedy than even disclosure. We need a clear disclaimer that mammography can be completely unreliable. When a diagnostic procedure doesn't work for a huge percentage of women, that negative outcome crosses the line from disclosure and plants itself smack in the middle of disclaimer territory.

If a company manufactured an oven that was unable to roast

chicken, they would issue a disclaimer because so many oven users roast chicken. My point is that mammograms are the ovens that don't work on dense breasts. Should the mammography industry hold itself to a higher standard than oven manufacturers? Okay. What about the mammography industry holding itself to a higher standard than used car salesmen?

My state, New York, mandates a lengthy 500-word legal disclosure when you buy a used car. In California, the governor recently vetoed a measly 64-word mammogram disclosure, where a woman's life is at stake. I ask you, Why does New York care more about honesty for used car buyers than California cares about honesty in breast cancer screening?

Breast cancer patients are the stakeholders. Please hear us. Let the breast cancer community work with you. We won't stop until the right disclosure or disclaimer is made law.

After the dense breast disclosure was vetoed in California, one of the reasons given was disclosure would cause anxiety in women. I can tell you what causes anxiety in women. Being lied to causes anxiety. Not disclosing that mammography is severely limited in its diagnostic abilities causes anxiety. Not being offered other means of detecting cancer causes anxiety. We are grown women. Our lives are at stake. We don't want any bureaucrats or insurance companies denying us information because we might get anxiety. We'll be the judge of what causes anxiety.

My question to the FDA is how can you help us find approval

for better diagnostics and guarantee us full disclosure about mammography, especially for the dense-breasted? After all, disclosure only means telling the truth. If oven manufacturers and used car salesmen are regulated to provide disclosures of their products, how can the FDA require any less from mammograms?

Thank you.

DR. HENDRICKS: Thank you for your comments.

Our next speaker is Dr. Nancy Cappello, president and founder, Are You Dense, Incorporated.

DR. CAPPELLO: My name is Nancy Cappello. My remarks are on behalf of the board of directors of Are You Dense, a nonprofit public charity.

November 25th, 2003.

Dear Ms. Cappello,

We are pleased to inform you that the results of your mammogram are normal.

This sentence from my lay letter, or what I would refer to as the happy-gram, greeted me for more than a decade. For me and for more than one-third of women, this letter is misleading and sometimes with fatal consequences.

I first learned about my dense breast tissue two months after my normal mammogram, when my physician felt a ridge in my breast. While

the subsequent mammogram saw nothing, the ultrasound revealed a 2.5 centimeter lesion, which was later determined to be Stage 3C breast cancer, which had metastasized to 13 lymph nodes.

What confused me at first and later outraged me was the fact that my cancer was diagnosed at such an advanced stage. I questioned my surgeon why my years of mammography did not find my cancer. You have dense breast tissue, and for women like you mammograms miss cancers. Dense breast tissue? What is that, I replied. After her explanation, I asked why no one ever informed me of this fact. Her response, It's not the standard protocol, still haunts me today.

I searched for information about dense tissue on cancer organizations' websites to no avail. I turned to medical journals and, to my amazement, I uncovered mounting scientific evidence, for decades, of the masking and causal risk of dense tissue, study after study concluding that breast density is the strongest predictor of the failure of mammography screening to detect cancer, and that high tissue density is a high-risk factor for breast cancer.

The American Cancer Society lists high tissue density as conferring four to six times risk and as equivalent as having a first-degree relative with premenopausal breast cancer.

Women with dense tissue are at risk for having a cancer detected when they are large or have a greater likelihood of recurrence,

present fewer treatment options, have poorer prognosis, and are far more costly to the healthcare system. All of these facts make breast dense tissue of great importance for screening for breast cancer.

Outraged that this information was seldom shared with women, but well known in the medical community, I was propelled to action. Through my advocacy, the Connecticut legislature passed three laws relating to dense breast tissue, two for expanded insurance coverage for adjuvant screening using MRI and ultrasound, and standardizing the communication of breast density to the patient.

I founded Are You Dense and launched a corresponding website to educate the public about dense breast tissue and its significance for early detection.

Other than Connecticut and Texas, there are currently no mechanisms in place to standardize the communication of breast density to the patient. Individual state efforts and a recent federal bill are progressing, yet cancer does not take a time-out while legislatures debate these bills.

A radiologist representing the Connecticut Society of Radiologists publicly opposed the density notification in Connecticut, the legislation. In fact, her public testimony included the same points that the ACR postulates in its position on state legislation.

She collected her outcomes to enable her to return to the legislature with evidence that the law did not achieve anything material. She

revamped her office routines, trained her staff, educated referring physicians, and yes, communicated the meaning of dense tissue to her patients. When her data were compiled, she discovered that her cancer detection rate had doubled by adding whole breast ultrasound for women with dense tissue who had otherwise normal mammogram. In fact, similar to ACRIN 6666, all except one had cancers that were detected at an early stage with negative nodes. A paper outlining this experience has been submitted for publication.

Teresa from New York contacted me a few years ago when she was diagnosed with advanced cancer within months of a normal mammogram. Her story represents the many stories on our website, advanced cancer, metastases to lymph nodes, years of normal mammogram, and never told of the limitations of mammography because of dense tissue until after diagnosis.

Teresa, a passionate crusader, designed cards about the best-kept secret of dense tissue and would hand them out to anyone who glanced at her.

In memory of Teresa, who passed away last week, and thousands of women like her, you have an obligation to demonstrate leadership by being transparent about the limitations of mammography screening for women with dense tissue.

The board of directors of Are You Dense supports an amendment to the MQSA reporting requirements in both radiologist reports

and patient lay letters, to include individual patient breast density information and its meaning as it relates to the accuracy of mammography. This information will give women an opportunity to discuss their risk factors and personalized screening surveillance with their physician.

We believe that your affirmative action has the potential to reduce later-stage breast cancers by 50 percent and alter the tragic destiny of women like Teresa.

Thank you very much for this opportunity.

DR. HENDRICKS: Thank you for your comments.

Our next speaker will be JoAnn Pushkin, Director of Government Relations, Are You Dense Advocacy, Incorporated.

MS. PUSHKIN: Thank you.

My name is JoAnn Pushkin. I'm with Are You Dense Advocacy, and I'm an unpaid advocate.

I think most people would agree that there isn't too much you don't know about yourself once you hit your forties. Six years ago I learned two things: I learned I had breast cancer and I learned I had dense breast tissue. Tragically, I learned them both the same day.

The palpable lump did not show up on a diagnostic mammogram. Why? Oh, said the tech, because you have dense breast tissue. That's a very hard find for us.

When I finally reviewed all the annual reports that had been

sent from radiologists to referring doctor, I was shocked to learn that dense breast tissue was a term I should have been very familiar with. It was mentioned every single year in the report sent from radiologists to referring doctor. My radiologists knew I had dense breasts. My referring doctor knew I had dense breasts. The only one who didn't know was the one with dense breasts.

And despite the fact that my breasts were extremely dense, despite the fact that due to density there was at best a 50/50 shot that that tumor was going to be found, and despite the fact that I had a higher risk of breast cancer and a greater likelihood of recurrence, despite all of that, based on language suggested by the American College of Radiology to satisfy the current federal requirement of a summary in lay language, the letter I received said normal negative, no evidence of cancer. Six words.

What I know now is that my letter stated no evidence of cancer, not because cancer wasn't there and not because the radiologist knew with any reasonable certainty that cancer wasn't lurking behind dense tissue; it said no evidence of cancer because he simply couldn't see anything.

When I read the words normal negative, I never imagined the screening I was recommended to go for had a find rate no better than a coin toss because of my density. That's not screening; that's Russian roulette.

Are You Dense Advocacy was born out of the frustration of sick women, all with later-stage cancers, who had diligently followed the

screening protocols recommended by medical professionals. These women connected through Are You Dense, Inc., founded by Dr. Nancy Cappello, who spearheaded the nation's first breast density informed law in Connecticut. The second density informed law was passed in Texas, fought relentlessly for by Henda Salmeron.

State efforts continue to spread across the country. There is no shortage of women with missed cancers due to breast density, and due to the growing media coverage of the issue, no shortage of women seeking change.

New York's bill has passed its senate unanimously and is headed towards its assembly. The California bill will be reintroduced in January. Four other states will be introducing legislation this upcoming session, and 11 other states are considering sponsoring bills.

The growing number of state initiatives has resulted in proposed federal legislation. Federal Bill H.R. 3102 was introduced last month, a copy of which was supplied for you.

Each bill seeks to correct the fatal flaw in the post-mammography communication to patients. The FDA requirement that a radiologist issue a patient a post-mammography lay letter is, of course, laudable. An informed patient educated about her own risk factors is now an aware participant in her health surveillance. Otherwise, a woman not told the realistic limitations of a screening tool can hardly be considered an informed patient. No letter would be better than one which purports

mammographic findings to be something they are not.

In the interest of public safety, a single national standard for the notification of breast density to women must be developed.

We thank the MQSA Committee for including this critical topic on the agenda, and we look forward to the thoughtful consideration of the issue and would welcome the opportunity to offer input on draft language.

Are You Dense Advocacy strongly supports an FDA amendment to include, in the report to both patient and doctor, mention of a woman-specific density rating, what that rating means in terms of her personal risk factor, and the effect her density might have on tumor detection. Armed with that information, women will now have the opportunity to advocate for and protect themselves.

Thank you so much.

DR. HENDRICKS: Thank you for your comments.

The next speaker will be Dr. Marc Inciardi, Assistant Professor of Radiology, University of Kansas Medical Center.

DR. INCIARDI: Members of the Mammography Quality Assurance Advisory Committee and Panel, I appreciate the opportunity to appear before this Committee and discuss this important issue of breast density and its ramifications for women with regard to breast cancer.

Dr. Rachel Brem has yielded her time to me, so I'll be speaking for both her and myself.

As far as disclosures, I have become -- I am part of a research trial that's been funded by U-Systems for automated breast ultrasound, and I've been a physician trainer for their FDA reader study, and I have paid my way here and home.

So I'm an assistant professor at the University of Kansas and section of breast imaging. I'm speaking on this important topic as a researcher in breast density and breast ultrasound, on behalf of Dr. Brem, who was the principal investigator on this research project in screening asymptomatic women and dense breast with automated breast ultrasound.

As the principal investigator for the study at the University of Kansas, I've had the opportunity to be involved and fully understand the ramifications and challenges of screening women with dense breasts. I will describe this research in more detail, including some preliminary results of the study from the University of Kansas.

Radiologists have known for at least 16 years that mammography misses cancers in a significant number of patients with dense breasts, and the use of ultrasound can indeed detect additional cancers that are mammographically occult.

Dr. Paula Gordon authored one of the first articles in 1995, published in *Cancer*, showing an additional rate of 3.5 cancers per 1,000 detected by ultrasound that were not seen on a mammogram.

Indeed, there have been a total of nine studies published in peer-reviewed journals, the most recent of which in 2009, which show remarkable similar detection rates of mammographically occult cancers by ultrasound, averaging 3.5 per 1,000.

At the University of Kansas, we have been fortunate to be asked to be part of a multicenter trial to evaluate a new automated breast ultrasound device for the detection of breast cancer in patients with dense breasts. The device is called automated breast ultrasound, or ABUS for short.

The SOMO-INSIGHT clinical study is the largest breast ultrasound screening study to date, enrolling greater than 16,000 patients nationwide. This scientifically important and possibly landmark study was designed to compare the breast cancer screen detection rate of full field digital mammography to full field digital mammography combined with automated breast ultrasound in patients with greater than 50 percent breast density.

This study has been accruing patients for about two and a half years and is scheduled to close accrual later this year. After data collection ends, the trial findings and multicenter analysis will be submitted for peer review publication.

I'm able to share some of our single-center data from the University of Kansas that we have collected over the past two and a half years.

We've enrolled 1460 patients. All subjects had screening digital mammography followed by automated breast ultrasound. Again, we were comparing the breast cancer detection rate of full field digital mammography to the combination of full field digital mammography and automated breast ultrasound.

We have diagnosed a total of 12 breast cancers, including both invasive and DCIS. Of these 12, 8 were detected by mammography and 7 by automated breast ultrasound. Of the 7 cancers detected by ABUS, 3 were also seen with mammography, but 4 cancers were mammographically occult.

The mammographic detection rate was 5.5 per 1,000. ABUS detected an additional 2.8 per 1,000, for an improvement of 50 percent over and above mammography.

Of these 4 additional cancers detected by automated breast ultrasound, 100 percent were invasive and all were 9 millimeters or less in size. The goal in screening is to detect small invasive cancers, which was met by our study site.

Of note, of the cancers detected by mammography, 75 percent were invasive and 25 percent were DCIS, comparing to 100 percent for ABUS.

I would like to compare and contrast the unique nature of the automated breast ultrasound device used in this research with current ultrasound technology.

Of the nine published studies to date, all but one were

performed with traditional handheld ultrasound or so-called -- traditional ultrasound or so-called handheld ultrasound. Handheld ultrasound is a type of ultrasound used exclusively in diagnostic ultrasound currently, whether for breast, obstetrics, or dental examinations. Handheld ultrasound uses a small probe and is performed by a non-physician sonographer, for the most part, who is usually registered or certified.

This current practice with regard to breast ultrasound has several limitations. When determining breast ultrasound, radiologists are dependent upon the skill and expertise of the breast sonographer to scan the breast and the pathology. Breast sonographers perform ultrasound examinations and make clinical decisions as to what they believe are important regarding normal and abnormal breast anatomy.

Radiologists are only presented with what the sonographer documents in the images. However, they are not trained as physician-radiologists.

Breast imaging, by its nature, is more difficult than ultrasound in any other part of the body due to this tremendous nature of variation of normal breast anatomy. The wide variation in the skill of the breast sonographer has been cited by radiologists as a major limitation of widespread acceptance of screening breast ultrasound. Specifically, there are concerns with false positives and false negatives.

Additionally, in the published data on screening ultrasound

performed so far with handheld ultrasound, the scans were performed by highly trained and, I might add, highly motivated breast radiologists. Therefore, the published results from handheld screening studies may not be directly applicable in routine clinical practice.

Automated breast ultrasound is a new technology that acquires images of the breast in a 3-D dataset similar to that of computerized tomography or MRI. The images are then reconstructed in three orthogonal planes for review by the radiologist.

As this is a complete dataset with no skip areas, essentially all of the breast is imaged and available for review by the radiologist. This overcomes a limitation of the handheld ultrasound screening as performed by the breast sonographer, as the radiologist now has full access to the dataset.

This device, which has been in development for a number of years, is currently FDA cleared for diagnostic ultrasound, and the data has been submitted to the FDA for PMA approval for an indication for breast ultrasound screening as an adjunct to mammography.

A second criticism of widespread adoption of breast ultrasound screening by radiologists is the time required to both scan the patient and interpret the exam can be lengthy. The automated breast ultrasound overcomes this limitation. The ABUS exam can be performed in about 15 minutes total room time, compared to about 30 to 60 minutes for handheld ultrasound exams.

Additionally, handheld ultrasound is performed by a certified or a registered sonographer. ABUS examinations can be performed by virtually anyone after a training period of about three days.

Physician interpretation time is quite acceptable as well, on the order of two to four minutes.

Another issue cited by radiologists is that of reduced sensitivity and specificity of handheld screening breast ultrasound.

The company that manufactures and markets the automated breast ultrasound device has conducted a series of feasibility studies, including one pivotal reader study under FDA guidelines. I've been fortunate to be involved as a physician instructor in all of these studies.

The readers in these studies received about eight hours of peer-to-peer instruction on interpretation of automated breast ultrasound, focusing on optimizing sensitivity and specificity. Although the results will not be made public until 2012, I can say from my perspective, they perform quite well after a relatively short training period.

Thank you.

DR. HENDRICKS: Yeah, we'll take questions from the Panel at the end of all of the open session. There'll be plenty of time. Thank you.

Thank you for your comments.

The next speaker is Marsha Glazer.

MS. GLAZER: Hello. I'm a patient advocate-survivor. My

purpose today is to be heard. If I speak out now, it may prevent an unnecessary health challenge for other women.

I have always taken good care of myself, exercising, eating the right food, no family history of cancer, going for yearly mammograms, which always came back normal.

Five years ago, after 15 years of "normal" mammograms, I felt a tenderness in my breast. My gynecologist, though insisting all was well, as a mammogram taken eight weeks prior was normal, referred me to a breast specialist to put me at ease.

My breast specialist sent me for an ultrasound, which immediately showed two substantial spots on my left breast. What a shock. It was then that I learned that I had dense breast tissue, which makes tumors hard to detect. I had never been told this despite going for mammograms for years. I learned this after my cancer diagnosis.

In addition to the two large tumors, I had, out of 20, 18 affected lymph nodes. This cancer was growing and missed by mammograms for quite some time. The result was a mastectomy, surgery, chemo, radiation, baldness, wigs, no eyelashes, and missed work.

I believe it is critical that all women be informed of their breast density. I believe the doctors should include density information in the reports women get after their mammograms.

I am smart now, but I had to learn the hard way. If I had known

I had dense tissue, I would've asked for an ultrasound earlier and this cancer would've been caught earlier.

Do you or your mothers or your daughters want to go through chemo and radiation and watch your hair fall out? My children had to watch me suffer this indignity just because no one shared this critical information about me, with me. You could all be heroes to the ones you love.

Dense breast tissue makes a woman at risk for breast cancer. I wish someone had tipped me off, had said to me, Be aware, be awake, be informed, be educated about your dense breasts. The big question of the day is why in the world would anyone object to sharing this vital information? There is no reason not to.

Thank you.

DR. HENDRICKS: Thank you for your comments.

The next speaker is Ellen Gruber.

MS. GRUBER: Good afternoon. My name is Ellen Gruber, and I'm from New Jersey. I'm not affiliated with any organization. I am a patient and a patient advocate.

When I first was told that I could speak today, I was happy and relieved to hear that I was "one of the success stories." After listening to some of the other women speak, my heart hurts for them.

I have been receiving mammograms for 12 years, and only in the last seven years have I had screening ultrasounds in addition, due to the

knowledge that I had dense breasts.

My current radiologist informed me of my dense breasts and the limitations of mammography as a diagnostic tool. It is through her scrupulous diagnostic techniques, including twice-yearly sonography, which I know is not often recommended, that my early stage breast cancer was found and treated prior to it spreading. My cancer was not identifiable on mammogram.

A colleague of my doctors looked at my mammography and declared I'm quitting, as my cancer was invisible on the film. Due to my early diagnosis, I received treatment early and have an excellent prognosis.

I'm working for equal access to assure that the other 40 percent of women with dense breasts receive the same excellent treatment that I was fortunate enough to receive.

I'm thankful that I was given the choice to pursue second-level screenings and was informed that my mammography was limited. I am so lucky that my breast cancer was caught at an earlier stage and that chemotherapy was unnecessary.

When my children found out that I had breast cancer, their first concern was, Mommy, are you going to lose your hair? They were so relieved to know that I did not have to go through chemotherapy.

I left my family and work to come here because that's how important this issue is to me.

Thank you for giving me this opportunity to share my history with you.

DR. HENDRICKS: Thank you for your comments.

The next speaker is Henda Salmeron from Texas. She was involved in the Texas breast density informed legislation.

MS. SALMERON: I don't quite sound like a Texan, so --

(Laughter.)

MS. SALMERON: My name is Henda Salmeron. I am from Dallas, Texas. I'm here as a patient, but more importantly, I am here as a recent breast cancer survivor. I'm here today to testify on the importance of informing women about their breast density and the limitations of the mammogram to detect a tumor in dense breast tissue.

I'm the mother of two young children, and two years ago breast cancer was something that happened to other people and older women. I was 42 years old and it was not part of my world. I was having my annual checkups religiously and believed that by having my annual mammogram I was doing my bit. And I believed that a mammogram was foolproof, as so many women do today.

In December 2008, I had another clear mammogram, the fourth one in a row. I had a baseline at 35, and I started having annual ones when I reached the age of 40.

The spring of 2009 I decided to get fit after many years of

working 18 hours a day, stretched beyond belief and really not exercising enough. After 8 weeks I lost 12 pounds. I'm kind of small, so 12 pounds made quite a difference. And I felt a very tiny little lump as hard as a pea near my breastbone in my right breast.

My doctor at the time reminded me that I had a clear mammogram four months before and that it was nothing.

That weekend I was at dinner with my mother-in-law and casually, as part of the conversation, I told her about this tiny little bump that I was feeling. She's a Ph.D. nurse from Oklahoma City, Dr. Lois Salmeron, and her advice probably saved my life because she said to me, Henda, don't let anybody tell you that a lump is nothing.

I called my doctor the next day and said to her, Please let it be checked again, and I went in for one more mammogram, which again was clear and they were going to send me home. But I don't have red hair for nothing, and I texted her and said I'm not going home because I think we need to keep checking, at which time they did a sonogram and then a biopsy.

On June 7th, 2009, at 8:30 in the morning, my life was interrupted when I got the call that I had breast cancer. It is the diagnosis one in eight of us will get, but none of us want to hear. But I had hoped that mine was found early and that it was small. I knew that our best chance today for breast cancer survival is based on early detection.

The next day, I transferred to UT Southwestern and had a

mammogram, a sonogram, and an MRI. And on June 9th, 2009, at 2:00 p.m., my life changed forever. My breast surgeon called me that day and she started the conversation asking me if it was a good time and if I was sitting down. We all know that that is not a good conversation starter. She told me then that my cancer was neither early nor was the tumor small and I had to come back for further tests.

How did this happen to me? How did I end up with a four-centimeter tumor that went undetected by mammography? And that was when she told me, Henda, you have dense breast tissue, which can hide a tumor. It is like looking for a snowball in a blizzard or a polar bear in the snow, as both dense tissue and tumors show white on a mammogram. My four-centimeter tumor was entirely invisible on my mammogram, and the sonogram only indicated less than one centimeter.

But what really got me that day was when she showed me that on every one of my mammograms, the radiologist had indicated that I had dense tissue. I was asked why I was never told. Why did no one inform me about this very vital part of information about my own physiology? I learned then that it was not required and not part of standard of care.

I did not sleep that night. I was very scared and afraid and anxious and nervous, and I was very afraid that I would not see my children, which are 8 and 10 years old, graduate from elementary school. And at sunrise that next day, I knew that I will do everything in my power to change

that status quo.

As women we have the right to know. We have the right for the best chance of survival when we are one of the eight women today that will be diagnosed with breast cancer.

I called my Texas state representative and begged him to help me draft legislation to inform all women in Texas about their breast density. Back then I didn't know that there was any other option or way to educate and create awareness and tell women about dense breast tissue.

I spent many days earlier this year in Austin educating and urging state lawmakers and organizations, including the Texas Medical Association, the Texas Hospital Association, the Texas Radiological Society, the American Cancer Society, Komen, and so many more, to support informing women about their breast density. And in May, the bill was unanimously passed in the Texas Senate, and there were only five noes in the House out of 150 representatives.

Governor Perry signed Henda's Law, House Bill 2102, into law on June 17th, 2011, exactly two years after my very first surgery. And as of September 1st, with full compliance by January 1st, the women in Texas now will be informed about the fact that dense breast tissue can hide abnormalities and they may benefit from supplemental screening. They will also now receive a copy of their mammogram report. I never knew that we could actually ask and see our own report.

But the bill was watered down and did not include the very important provision for insurance companies to cover supplemental screening. So therefore I will be back in Austin in 2013 as my work is not done.

I have high hopes that this Committee and the ACR will recognize the very importance of taking the lead on introducing consistent language in screening guidelines for women with dense breast tissue.

Again, we have the right to know and we need to know about our density. It is no longer good enough to think that it's a nonissue. The studies are there to support all the facts about the risks of not detecting a tumor early. Only 1 in 10 women may be lucky enough to know about her breast density. How many women have to continue to die before it becomes important enough for you to address this? In the end, my own ignorance about my breast density almost killed me.

I used to say that if I could save one woman with Henda's Law, then my cancer journey had purpose. I now say that that is not enough. We have to save as many as we can. I will not rest and will continue every effort I can to change the status quo, even if that means that I have to go state by state. And as you well know, there are many initiatives underway across the country.

I hope you will recognize the importance of this issue. The conversation is here to stay. More and more women are coming forward and

willing to take this on as a grassroots effort. We are not going to go quietly away. This is our life, and we deserve nothing less than to be informed on how to best care for our own breast health. It will be so much better to have density guidelines at your level, instead of ending up with 50 different density informed acts across the country.

And in closing, I want to personally address the issue that probably makes me more angry than everything else, the debate that is so large about the anxiety we may create by informing women about their density. Ladies and gentlemen, let me guarantee you, it can never compare to the incredible fear and anxiety that we have to deal with when we have a breast cancer diagnosis.

I appreciate your time.

DR. HENDRICKS: Thank you for your comments.

Just for the record, I need to state that those comments and Henda Salmeron, as part of the Are You Dense Advocacy group, may --

MS. SALMERON: I am not part of the Are You Dense Advocacy group. I am here entirely representing myself as a patient and a survivor.

MS. CRAIG: For the record, what we're saying is that you are part of the group that requested time to speak, which is why you were allowed to speak for more than five minutes.

MS. SALMERON: I appreciate that.

MS. CRAIG: So you are separate.

MS. SALMERON: Okay, thank you.

MS. CRAIG: Um-hum.

DR. HENDRICKS: Thanks for the clarification.

The next speaker is Dr. Stacey Vitiello from the Montclair Breast Center in Montclair, New Jersey.

DR. VITIELLO: Good afternoon. I'm Dr. Stacey Vitiello, a breast imaging radiologist in private practice at the Montclair Breast Center in New Jersey. I completed my specialty fellowship in breast imaging at Yale, and I have over 12 years experience practicing in my specialty field. I've read thousands of mammograms, breast ultrasounds, and MRIs and found hundreds of cancers.

As such, I can tell you from experience and from scientific literature that breast density is one of the strongest predictors of the failure of mammography to detect cancer. Even with the best digital technology and the most experienced reader, a cancer will not be detected in half the women with dense breasts when there's actually a cancer present.

When I give a woman with dense breasts a normal mammogram report, I am only 50 percent certain that there's no cancer in her breast. This is ineffective screening by any definition. And by not routinely informing women with dense breasts that their mammogram is limited and that they have a choice to pursue second-level screening with breast ultrasound, MRI, or another test, we are poorly serving many of our

patients.

Women who are diligent and come to me yearly for their mammograms expect to be effectively screened for cancer. They trust me to do that for them. We do not provide effective screening if breast density is ignored.

The FDA does not accept blurred films or images with dust or small artifacts on them. Why do we accept the huge limitations of breast density?

Some would argue that the definition of dense breast is too subjective and thus women shouldn't be informed, as they might be read as dense one year and not dense the next, depending on the center and the radiologist.

Yet so much of mammography and medical practice in general is subjective. One doctor might see a red throat and prescribe antibiotics and another might call the same throat mildly pink and send the patient on their way. Yet we don't recommend that doctors keep their findings secret from the patient because of the subjectivism of the physical exam. Why should mammographic density be any different?

And if a practice is truly concerned with this inter-observer variability, they can now buy software that will digitally determine breast density with a high reproducibility rate.

But as to this issue, most of us practicing in the real world know

a dense breast when we see it and we reliably call it.

An additional argument offered against patient disclosure is that there is debate in the scientific community regarding the significance of breast density as an independent risk factor for breast cancer. But across 18 studies in 8 countries, the literature repeatedly and clearly finds that increased risk to lie somewhere between 3.6 and 18-fold. How can this be thought to be the slightest bit controversial?

The FDA has already acknowledged that there's a limit to the effectiveness of mammography, as well as an increased risk for breast cancer in dense breasts, by granting approval to digital tomosynthesis, a tool that's been marketed to increase sensitivity in dense breasts.

You've already signed off on this as an important issue. Informing patients of their own medical circumstance is the next logical step to allow women to advocate for their own health.

Finally, we should not be afraid of market demand driving innovation and better outcomes. In fact, we should welcome it.

Thank you.

DR. HENDRICKS: Thank you for your comments.

The next speaker is Dr. Lisa Weinstock, founder of Women's Digital Imaging in Ridgewood, New Jersey.

DR. WEINSTOCK: Good afternoon. My name is Dr. Lisa Weinstock, and I'm from New Jersey. I have no financial relationship

with any companies or groups that may be affected by the topic of this meeting. In addition, this legislation will not affect me, my patients, or my facility.

I am here as a patient advocate and as an expert in breast imaging. I'm convinced that, in the year 2011, dense breast tissue warrants further screening and that, just as mammogram results are given to patients, the patients should be made aware of their breast density and be advised that additional imaging may be necessary.

I've always been a proponent of developing individual risk profiles for my patients, which include family history and whether or not they have dense tissue. With that knowledge, I selectively advise supplemental imaging in addition to the mammography.

As it has been stated with dense tissue, cancers big and small are often not visible on the mammogram but are visible on other modalities, including breast ultrasound, MRI, and molecular imaging.

Subsequent to 10 years working in various practices, I opened my own center to focus on individualized cancer screening for women. As the owner of a breast imaging center, I have the ability to practice medicine the way I feel it should be done, which includes full disclosure of results and limitations of the study to the patient.

In previous practice settings, it was protocol to allow patients to leave, following their mammogram, believing they were cancer free,

though I may have only been 40 to 50 percent confident. I find this to be unfortunate, bordering on negligent, when the radiology community knows that there are noninvasive, cost-effective imaging modalities, such as ultrasound, which may find these mammographically occult cancers.

I have successfully integrated ultrasound into my practice. I speak to every patient upon completion of their mammogram, and for patients with dense tissue, regardless of family history, I will recommend ultrasound. For patients who have a strong family history, I will recommend ultrasound or MRI even when their tissue is fatty or mildly heterogeneously dense. These exams can be performed immediately after the patient's mammogram during the same office visit.

I have excellent ultrasound technologists who perform the breast ultrasounds. Due to my low volume, I do have the luxury of scanning the patients myself, following the technologist. It is rare, though, that I find something that my technologist does not. They have been well trained and are registered in breast ultrasound.

Many of my patients are on an alternating schedule, meaning, if they have dense tissue but their mammograms are stable, ultrasound is performed as an interval screening in six months. This has the potential of finding a interval cancer at an earlier stage. Having the ultrasound performed at a six-month interval may be a way for high-volume practices to start integrating ultrasound into their practice.

Although the mammography reports that go to the clinicians do state the patient's density, most clinicians themselves are not educated about the implication of dense tissue. This is why educating patients directly about the risks of dense tissue and the limits of mammography is imperative. Giving patients the information directly also closes the loop in patient care and decreases the work and time of the clinicians, who are usually so swamped they may not have time to get in touch with the patient and explain the additional workup that may be necessary.

I have detected at least three cancers by ultrasound in the past four to six months alone, which were not seen on the mammogram. This includes a cancer in a friend who's here, as you have already heard from. Her cancer was found on an interval screening ultrasound. Even in retrospect, with a marker placed on the cancer and additional spot mammographic views, the cancer was not visualized.

I explain to patients who are at high risk and with fatty tissue, and even with patients who are not high risk, that mammography does not detect 100 percent of cancers. It has been my experience that women with fatty tissue who know that they are high risk do not forego additional imaging with ultrasound or MRI because of a false sense of security.

The issue of patient anxiety by additional imaging has been raised over and over again. It has been my experience that once educated, patients are less anxious and more reassured by a negative ultrasound than

by being only 40 percent sure they don't have a cancer when they leave the facility.

Yes, knowledge of breast density requires additional screening, despite the possibility of false positives. All tests have false positives, but this is how we find the early cancers. And all the recent talk about finding early cancer, that it will never do any harm, is misguided because at this time we don't know which cancers are harmless and which are potential killers until they are removed.

False positives can be a problem. However, as with anything else, with experience lesions which appear most likely benign do not need biopsies and can be followed. The ACRIN trial validates follow-up without biopsy in women with low-suspicion lesions. The malignancy rate has been proven to be less than two percent. If biopsy is needed, ultrasound-guided biopsy is inexpensive and a relatively noninvasive procedure.

There's also concern that unless supplemental screening were reimbursed by third-party payers, that there will be an "unfortunate disparity" between women who can afford the tests and those who cannot. A disparity is always unfortunate, and this is why I believe that everyone should be covered. However, does it make any sense to deny knowledge to those who can pay out of pocket, important information that may allow them to find their cancers early?

Thanks to the ACR and MQSA, mammography is the only test

where, by law, results must be given to patients. Let's continue this trend toward patient advocacy and education by giving patients the complete truth and not a partial truth. We can do this by supporting the breast density legislation.

DR. HENDRICKS: Thank you for your comments.

Next, we have Karen Handel, Senior Vice President for Public Policy for Komen.

MS. HANDEL: Thank you very much.

Madam Chairman, members of the Committee, thank you so much for this opportunity to talk with you this afternoon.

I think all of us would agree that a great deal of progress has been made in the fight against breast cancer. The five-year relative survival rates for breast cancer have improved from just 74 percent to 98 percent. Still, however, 230,000 women will be diagnosed this year, and sadly, 40,000 will die.

And that means, with one in eight women expected to be diagnosed with breast cancer in her lifetime, and because early detection remains a key to survival, continuing to ensure high-quality, effective, and safe breast screening is critical. And I want to commend you on your work to that end.

Equally important, however, is ensuring that the quality standards continue to evolve as new screening technologies come to market

and as science begins to provide us more and deeper insights into this disease, specifically in the areas of breast density. My statement today will be directed towards these goals in three areas.

First, the modifications to the direct patient report. Komen commends the progress that's been made as a result of the MQSA Program. However, scientific innovation and research findings do demand ongoing evaluation of how the goals of this important legislation can continue to be advanced.

We believe it is critical that women be aware of the breast cancer risk factors, including the risk factor that breast density presents, and that they also have access to the early detection screening tools that just may save their lives.

For this reason, Komen joins our advocacy colleagues with Dense in supporting, strongly supporting that reporting breast density on all mammography reports and patient lay summaries be enacted.

We believe that a woman needs to have as much information as possible about her own health, her breast health, and her test results so that she can make the most informed decision that she possibly can in consultation with her physician about her care. Doctors should inform women of their breast density, if their mammogram shows that they have dense breasts, and provide information about what that actually means and the risks that it may pose.

Unfortunately, as you've heard here today, most technologies -- no technology is foolproof, and so women also need to know about the potential limitations that technologies, such as mammograms, do pose and how this could affect them.

Traditional mammography alone may not be effective in detecting tumors in women, particularly women with dense breasts. Dense breast tissue can make abnormalities so difficult to find, even to the most trained eyes, as some of our other speakers here have experienced.

Compared to standard film mammography, digital mammography has been shown to be better at finding tumors in women with dense breasts.

Additionally, MRI and ultrasound, in combination with mammography, are under study as breast cancer screening tools for women with dense breasts.

Given that the body of science on breast density continues to yield more and more information, we believe that the most appropriate approach today is to definitely require that all mammography reports and lay summaries include information regarding the density of a woman's breast, and to include language in that lay summary that urges a woman to have a specific conversation with her physician about the risk and any potential additional screening that may be necessary for her.

Ensuring that mammography reports include this information,

and that patients have that information through the lay summary, will encourage that important patient-physician conversation about the risk factors and what should occur next. With as much information as possible, women can be in the best, most informed position to discuss her specific needs along with other breast risk factors that her physician may discuss with her.

Second, I want to speak a moment about collaborative strategies. We propose that there should be an interagency strategy to facilitate collaboration among the relevant groups within the Centers for Medicare and Medicaid Services, NCI, FDA, on MQSA issues.

This approach would involve working with other cancer patient groups, device makers, community mammography facilities and specialists to develop a consensus on the priorities as well as some specific proposals and recommendations that may indeed need to come back before Congress.

Interagency collaboration will also be important in effectively addressing questions that will arise as the evidence regarding breast cancer continues to yield more and more.

For example, as science provides better understanding of breast density, it will be important to determine how best to ensure that additional screening that's found to be clinically effective and medically necessary as it relates to breast density is indeed covered under health insurance policies, Medicaid and Medicare.

Quality improvement. Any modifications to the MQSA should continue to focus on ensuring quality and safety. The Committee must make certain that the MQSA standards are adapted and updated as necessary for effective oversight of new and emerging technologies and their specific applications in areas such as for women with dense breasts.

For example, while broad standards have been established for full field digital mammography and tomosynthesis, additional standards will also likely be needed given the potential of these new technologies in detecting cancers in dense breasts.

In conclusion, let me say that Susan G. Komen for the Cure appreciates and commends the work of this body, and we appreciate the opportunity to speak to you, and we hope that you will give favorable, favorable consideration to requiring that the mammography reports, as well as the lay summaries, have the information about breast density.

Thank you so very much.

DR. HENDRICKS: Thank you for your remarks.

Next is Terry Tyler.

DR. TYLER: Thank you, Dr. Hendricks and Committee members. I'm Dr. Terry Tyler. I'm a radiologist and chief diagnostics officer at Owensboro Medical Health System in Owensboro, Kentucky, and I wanted to share a little bit with our experience over the past year in helping and trying to promote additional screening for patients with dense breasts on

mammography.

We're a small rural community, so we're kind of limited on resources. I talked to the CEO about the problem of the dense breasts, and he and the board said we need to do something about it here in our community.

So initially we wanted to do breast MRI, but that's expensive in terms of per exam and capital equipment. So we turned to automated breast ultrasound. And so we've been promoting that for the past year for those patients with dense breasts. And what I wanted to share with you is the difficulty or the barriers that we have encountered.

We have gone out and talked to referring doctors and tried to explain this to them, because the group of people who know about the dense breasts are radiologists. I think everyone acknowledges that that's an issue. If you interpret mammograms, you know that.

The other group of people are the patients who have unfortunately had a mammography fail them.

It is assumed that primary care doctors also understand about the dense breast, but they don't. And I will tell you that my survey of some of our doctors has shown that they don't read the reports, and therefore they don't even know that the breast composition is discussed in the report. And I don't think they will read the report unless they have some impetus to do that.

So radiologists know. Referring doctors in our community really don't know. Women don't know. So what can we do about that? I think that this Committee has an opportunity, a great opportunity to take mammography, take breast imaging, take improvements in breast care a step forward in this country.

For the past few years we have been inundated by what Dr. Kopans has pointed out, very unscientific papers that have reached the media and discouraged women about mammography. Mammography saves lives, but it's not enough.

By recommending that the notification of breast density be in both the lay letter and the official report, this Committee can move us away from the past, an argument that needs to be -- enough is enough, as Dr. Kopans says. We need to move away from that and move to the future of breast imaging, and that can focus on the patients with dense breasts.

There's a lot of work to be done and a lot of research that needs to be done. What's the best modality? Is it breast MRI? Is it ultrasound? Is it all the other imaging modalities? There's a lot to be done.

But in the meantime, women deserve to know that there is a potential problem. So I urge you to recommend that the FDA require notification of breast density in both the lay letter and the official report.

Thank you very much.

DR. HENDRICKS: -- the open public forum is Dr. Barbara

Monsees.

DR. MONSEES: My name is Barbara Monsees. I'm a Professor of Radiology at Washington University. I'm here today to speak for the ACR Breast Imaging Commission. I chair that commission. They paid my way and I receive no salary from them. I am entirely paid by Washington University.

Let me tell you a little bit about myself, which also, I think, goes as part of the disclosure. I am a 21-year breast cancer survivor. My breast cancer was found on a mammogram, and I can tell you, we didn't grade breast density then, but I had extremely dense breast tissue. So I'm speaking on behalf of women that I take care of in my practice and radiologists that I represent for the American College of Radiology.

Breast imaging is my profession, and it is my passion. It is something that is extremely important to me, and fostering the good care of women and good communication with physicians and women is extremely important.

I can tell you, I heard some comments about cost, and this is a big issue for me in my practice. I have a very large outreach program in my practice for indigent women, and through philanthropic organizations such as Komen and local community people, I am able to offer screening to people without any regard to their ability to pay.

So with that let me just inject a word of caution and some of the things that are my worries regarding any sort of mandate that we have.

I'm here speaking on behalf of the American College of Radiology. I'm also on the executive committee of the Society of Breast Imaging, and I'm familiar -- and I've seen their statement. That's also been sent to the Committee here.

The ACR has been an absolutely vigorous advocate for quality breast imaging and communication through the years. Not only did they support MQSA, they had a voluntary accreditation program that antedated any sort of MQSA legislation. They also were big advocates of reporting to women. And when MQSA was reauthorized, ACR was with the program and wanted women to get results because we didn't want people to fall through the cracks.

ACR, of course, recognizes that breast density has an impact on mammographic screening. It's very well known that greater breast density results in lower sensitivity for mammography. We all know that. It's obvious.

For that reason the ACR has included in its BI-RADS lexicon descriptions of breast density, and there are four levels of breast density, and it asks physicians to include those in their reports. This has never been mandated by MQSA, and we believe that this is a slam-dunk, easy thing to require, that, in fact, it should be in mammographic reports. And the idea would be that the physician would know how hard it is for the radiologist to interpret that mammogram if they see that language in the report. So we do support that it be included in there.

However -- and this is where is the big however -- it's more complicated than simple. It's unclear how a typical patient is going to interpret that and understand the information in a lay summary.

So while we're not opposed to that and we think it's probably okay to put it in there, I think we need to proceed with caution and look at all of the things and what kind of language needs to go in there, and what are the benefits and the unintended consequences of reporting mammographic density to women.

In particular, we have certain things that we want to talk about and urge consideration of, and hopefully the Panel will discuss those things.

One -- and this has been alluded to earlier by an earlier speaker -- is that breast density is not reliably reproducible and it can result in some confusion. And what we're really concerned about is we don't want women who get different letters based on that, if they go to different facilities, perhaps, to be confused or to think that mammography is not a good technique, for what it's worth, because of any disparity in breast parenchymal reporting. So we don't want it to undermine confidence in mammography.

I believe that there still is some confusion as to, and some controversy regarding, the magnitude of the risk as a risk factor. And so I'm not sure it's as high as maybe some people have described, but it certainly is an undisputed risk factor. But the level of the magnitude is, I think, somewhat questionable at this time.

For women with fatty breasts, I really personally would like to make sure that they are not falsely reassured by having a negative mammogram that says that they don't have dense breasts. I don't want a woman with fatty breasts, who happens to have a strong family history of breast cancer, to think that she doesn't need supplemental screening. She may need it, based on her family history.

So the language and the way we report, I don't believe, should be linked to breast -- dense breasts and therefore get supplemental screening, and I think it needs to be more inclusive of talk to your doctor about your risk factors. And the Komen speaker made that point, and I would heartily endorse what she's saying.

The inclusion of breast density in the lay summary could result in additional non-mammographic screening requests. We all know that. People up here have been saying that, in fact, they would like to do that. And what technique we use, whether it's ultrasound or MR, is going to be made on the basis of science, hopefully.

So perhaps women who have a very strong family history, who have inheritable breast cancer in their family, they probably should forego ultrasound screening and go to MR screening. So some science needs to be used to determine who gets what.

And most importantly, as I mentioned, therefore it's more than breast density that we have to look at. Because breast MRI is more sensitive

than ultrasound, very high-risk women maybe ought to go to that.

I just want to put in, also, another caution in that there's never been a randomized trial that shows either ultrasound or MR, in fact, saves lives. We think that it probably does, but we have no scientific data to say that.

And I am concerned about payment disparity, if there's no payment linked to recommending supplemental screening.

So I think proceed with caution on the lay letter, on the lay summary, and let's craft the language appropriately. We're not opposed to it. I think we should review the data that came out of Connecticut, to look at the unintended consequences that may have emerged. And before any decision is made, I think we need to look at that, how much it's costing, what kinds of false positives are emerging, how many unnecessary biopsies may have been generated because certainly there will be people criticizing what we're doing.

And I also would leave you one more thing, and that is I urge caution regarding the logistics of any mandate. As science emerges with more data, we need to be able to change the language. So we don't necessarily want it in federal legislation. We want it in a way that we will be able to change the language as science gives us more information.

Thank you for the time to speak here.

DR. HENDRICKS: Thank you for those remarks.

Now, we have a few minutes specifically to invite the panelists

to ask questions of any of the speakers in the open forum.

MS. LAWSON: Madeline Lawson.

I have a question for Dr. Weinstock. Is she still here? You had mentioned that many clinicians are not well educated about the extent of dense breasts, and since most of the reports, mammogram reports, are sent back to the primary care physician, that's a little bit disturbing to know that many of them may not take it seriously.

And I just wondered if you have any suggestions on how the primary care physicians, and other physicians, could be better informed about the seriousness of the matter and how we can improve in that area. I mean, that's certainly the point of contact for most patients, is their primary care physician.

DR. WEINSTOCK: Right.

MS. LAWSON: So if they're not taking it seriously, then -- and they certainly could address with the patient the significance and certainly speak with them about the next steps, the next appropriate steps. So I'm a little bit concerned about the fact that this may not be taken seriously on the part of the primary care physician.

DR. WEINSTOCK: Yeah, it's quite disconcerting. I don't think that -- it's not that it's not taken seriously. I think that there are so many conflicting stories out there about, you know, if mammogram is enough, if mammogram isn't enough. The clinicians really just do not know, and I think

once the public is educated, the clinicians will be educated as well. They're going to be forced to be educated by their patients.

Once a patient knows that they have dense tissue and says to the clinician, Well, I heard that breast dense tissue, cancers aren't found on the mammograms, the clinician is forced to investigate this. Otherwise most clinicians, this is not their field. This isn't what they are -- they just do not have the experience and they don't have the education behind this, and especially with all the different studies that are out there, I think they just -- I don't think it's that they don't take it seriously. I think that they just need some education.

DR. HENDRICKS: Thank you for the response.

Any other questions of panelists, of specific speakers in the open forum?

(No response.)

DR. HENDRICKS: Then this concludes the open forum portion of the meeting.

Now, we'll take a break of 10 minutes and then reconvene.

(Off the record.)

(On the record.)

DR. HENDRICKS: Welcome back.

We have only two remaining agenda items. We're near the home stretch. We're going to start out with a report from Dr. Finder on

reporting breast density on mammography reports and patient lay summaries, and also invite Committee participation and discussion.

DR. FINDER: This is Dr. Finder.

At the present time, the MQSA regulations do not require that breast density be reported in either the mammography report sent to the referring physician or the lay summary sent to the patient.

As you've heard, some states have required or are considering requiring that breast density be included in the mammography report and lay summary, along with recommendations on actions that should be considered in patients with dense breasts. A similar bill has also been submitted in Congress.

FDA is asking the Committee to discuss the pros and cons of requiring reporting breast density in all mammography reports and lay summaries, and possible ways of presenting such information in a way that would be most beneficial to referring physicians and patients.

So with that as a background and what you've heard from the public, we'd be interesting in hearing from the Committee. And I would strongly recommend that everybody participate. And, you know, this is not a physics-type question where you've got to use calculations and equations. So we want to hear from everybody.

DR. HENDRICKS: Ms. Price.

MS. PRICE: Thank you. Carol Price, Consumer Representative.

I would like the Panel to consider different things before you make any kind of recommendation.

I feel that consumers nowadays are far more knowledgeable and informed, thanks to technology, than in the past 20 years or so. Now, whether they have correct information or know how to use that information is questionable. But I will tell you, there are groups of consumers, once they have a diagnosis, or a family member or a friend or a relative have a diagnosis, become very educated in the disease and the process. And I have from my medical experience seen these people sometimes be very more informed than some physicians that deal with the disease process.

The public very much wants transparency within the medical world. They are entitled to their medical records and should be able to get those.

When it comes to standards that are being developed in different states, I have concerns that if we don't have a standard across the board, that you're fueling consumers to fuel this debate even more because they're going to say, Well, how come in your state you've got something and I didn't get it and how come I can't get it? And it will just continue this battle line, I think.

I do see that consumers receiving a medical summary can be a safety net. And as mentioned by one of the presenters before, we all know we have busy practices and sometimes we don't fully look at the reports and

maybe see that it's normal and throw it in a patient's chart. And I can tell you from my own experience, that is what happened to me. And the only way I know this is through my breast surgeon, because all mine were normal.

But after my diagnosis, my breast surgeon was able to show me my mammogram reports from previous years. There was actually something in the report that jumped out at me, as a consumer, that I would've questioned immediately, that could not be true, saying that I had had biopsies before, and did not. My physician did not pick up on that, but I, as a consumer, would have and I would have brought it to his attention.

Now, whether that would've changed my outcomes or not, who knows. But I do see it as a safety net for women that are educated, that can look at those and something will jump out at them.

I also know there's a big debate as far as breast density and defining breast density and what scale can you use. But I also feel there's a very important person that is not at this table to help with that decision, and that is mostly the gynecologists. Because they are the ones that get these reports, they should be here today telling us what do they need, what do they need to see in those reports to help them guide their patients in their practice, to make decisions as to ultrasounds or MRIs? What do they need? They should be a part of this.

And I would urge that, in the end, a single report is made that includes both the medical summary and the lay summary, that it not only

goes to the consumer, but goes to the physician. When both parties have the exact same information, it creates a level of communication between the two. I think it's important that I know what you know and that you know what I've been told. And yes, I think lay summaries are important because you are going to have people that are not as educated. So you need to develop a piece in there to help them understand that. But I do think they need to be together.

Thank you.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

I've never done this before, so I may not do it very well, but I wanted to respond to some of the stories that we heard, and quite moving. And unfortunately, as a radiologist, I've heard many, many more of those.

I think what many people don't realize is the American College of Radiology, the Society of Breast Imaging, and breast imaging radiologists have been embroiled in a knockdown, drag-out battle for many years, highlighted over the past two years, since the U.S. Preventive Services Task Force guidelines came out, to try and preserve screening mammography for women in this country. There's a major effort to reduce access to screening mammography, and these two groups and the radiologists in general have been busy behind the scenes kind of trying to combat that effort. And the way we've been combating it is with science.

There was just a paper that came out from Dartmouth, saying that, well, women who say their lives were saved because of a mammogram don't understand that not many of their lives were saved because of a mammogram. First of all, it's a nonsense paper, but it was in *The New York Times*. I think some of you may have read it.

And this is reality, this is what's happening in our world, where science is actually being displaced by agendas. I will say, the agenda of the American College of Radiology, the agenda of the Society of Breast Imaging, is to do the best we can to save lives from breast cancer.

Mammography screening has been clearly proven to save lives from breast cancer. But it's never been said that it's the answer to breast cancer. In fact, I think all of us, certainly the radiologists at this table, are sitting, waiting, and hoping for a cure for breast cancer. We would all love to be put out of business. But the cure for breast cancer is not even on the horizon. I'm sorry to disappoint everyone. But the only way to save lives is early detection, and we certainly, I think, all agree in this room.

The question is, where there are forces to try and reduce access to early detection, and we want to suggest greater access with more technologies, we, at least in the medical community, have to argue from a scientific basis. We can't argue, unfortunately, from stories. And that's been written in the literature.

I mean, you know, when the U.S. Preventive Services Task

Force guidelines came out, the American College of Physicians journal, the *Annals of Internal Medicine*, turned down scientific responses and said that radiologists were greedy, we want to do mammograms, and our only arguments were emotional or anecdotal, the stories that we heard today.

So the discussion you're going to hear this afternoon may not be what you want to hear, but certainly from my perspective and, I suspect, from the other physicians around the table, we're going to try and stick to the science. So, you know, as you listen, please bear with that.

From my own perspective, I'm surprised we don't tell women they have dense breasts. It's never been a secret. I mean, you know, the material that we have saying, you know, it's the big, big secret, it's never been a secret that I've known about.

And, in fact, I wanted to ask the FDA when it first became a requirement that we would give patients reports. My recollection was that we had to translate the report that we were sending to the physician into lay terms.

And I remember we had a computer reporting system that I developed, and I remember translating every report in lay terms that included breast density. So that's question number one. Why was, you know, it that -- it then came to the FDA, who said, Well, you didn't have to have an extensive report, you just had to convey the important information. So I personally have no problem conveying breast density.

The two other points. One is -- and I think we're going to discuss this more extensively -- you need to know that although you can find cancers with ultrasound and magnetic resonance imaging that don't show up on mammograms -- and again, I apologize to women who have bad cancers -- there are cancers that never kill anyone. And so the big debate out in the world is finding those cancers is over-diagnosis and women get over-treated.

And so if we add another test on, where there hasn't been a scientific study, a randomized controlled trial, the other test being ultrasound and magnetic resonance imaging, we're going to find more cancers. And that's probably a good thing, but the arguments will be made, you don't know that. You don't know that the cancers you find are already too late, they've already metastasized even though they're small, or you don't know that you're not finding cancers that will never kill anyone, and so you're going to over-treat all of these women. And those are the kind of issues that we face.

And just one other point now, going back to the science. The risks. We heard a few issues -- points made about women with dense breasts being at high risk. I think women with dense breasts are at slightly higher risk. I reviewed this a couple of years ago and wrote a paper -- and unfortunately, for some reason it couldn't be distributed, but the FDA assures me that if people want to write in, it can be sent to them -- that explains that the literature -- and there's big literature on dense breasts and risk -- is all fundamentally wrong and it's fundamentally wrong because the physics don't

work, and the problem is that the people who are writing the papers didn't understand the physics.

I'm trying to do this quickly because I'm taking too much time.

If you're trying to figure out the volume of breast density, which is how we grade breast density, what percent of the breast volume is dense tissue? Then that equation is the volume of dense tissue divided by the volume of the breast. And all of these papers have done it based on a single-view mammogram. The majority of them.

And the point is that a single-view mammogram, number one, you can't assess what the three-dimensional volume of any -- of the tissue is on a two-dimensional mammogram. And the physicists can attest to that, if there's any question.

And number two, what's the denominator? How big is a breast? And it depends on how far in the technologist pulled the breast into the mammography machine. And all of the papers which, you know, suggest high risk don't take that into account. So there's a higher risk. It's probably not nearly the risk that's out there in the literature.

And just to give you an example. Which segment of our population has the highest percentage of dense breasts?

UNIDENTIFIED SPEAKER: Young women.

DR. KOPANS: Thank you. Young women.

Which segment of our population has the lowest risk of breast

cancer?

UNIDENTIFIED SPEAKER: Young women.

DR. KOPANS: Young women. So it's --

UNIDENTIFIED SPEAKER: Which is more aggressive if they do have it?

DR. KOPANS: What's that?

UNIDENTIFIED SPEAKER: Well, which is more aggressive --

DR. KOPANS: It is more aggressive when they're young. And we can talk about that offline. I don't think they -- that's a very important question.

But the point is, who else has dense breasts? Lactating women. Who else has dense breasts? Women who are in really good shape and run a lot, who are theoretically at lower risk for breast cancer because they have low body fat and so on. So it's not as simple as dense breasts.

The other point is that, at least in our practice, 65 percent of women have dense breasts. So it's not like -- at least heterogeneous to very dense breasts. It's not like this is a small group and we're keeping it a secret from the small group. It's a huge group. And so you need to keep that in mind as you hear the discussion.

And I apologize for taking so long.

DR. HENDRICKS: Thank you.

Any other questions or comments?

Dr. Frederickson?

DR. FREDRICKSON: Thank you.

My concern -- well, I should start by saying that in my practice I tell women they have dense breasts all the time, or not so dense breasts, as the case may be. I see a lot of women coming to me because of concerns about dense breasts.

One of the concerns that I have relates back to what Dr. Kopans alluded to with the preventive task force. When those recommendations first came out, there was a certain percentage of women that were relieved that they didn't need to have mammography as often as they thought or were told. And depending on, you know, if this -- if the FDA does make the decision to put density in a lay report, I think the wording is very important, and I would recommend that, you know, a statement about the density, I don't think, is unreasonable.

What I do think is not a good idea is some sort of recommendation about what to do about the density, short of discussing of it with your physician, because we don't have randomized controlled trials that say that screening breast ultrasound or screening breast MRI saves lives. And until we do have that data, I don't think that we can be recommending those tests as a blanket statement to patients with dense breasts.

So I'm concerned that there may be another body of -- you ladies are all very educated women, but there's a large percentage of the

population in this country that is not as educated, that would see a report coming back that says that they have extremely dense breasts and that mammography may not be as effective, and those women would maybe shy away from having mammograms in the future, which could be to their detriment.

DR. HENDRICKS: Yes.

MS. LAWSON: Madeline Lawson.

I highly recommend that the regulations be amended to include the information on breast density, and with a statement to discuss with your physician.

I think more information is better. We certainly need to focus more on prevention and saving lives. And so the fact that there are variables in the density issue should not preclude us from sharing information with the patient.

So I highly recommend that we put -- if that's going to create more dialogue between the patient and her physician and that she'll ask more questions, I think that we certainly should take a position to encourage that.

DR. HENDRICKS: Thank you.

Carol Price.

MS. PRICE: Yes, this is Carol Price.

I have a question for Dr. Henderson [sic], then. If you only are including maybe a statement about breast density in the reports, how do you

think we should address the primary physician and gynecologists that are not educated and know where to go with the information if there's no recommendations included in any way in the report?

DR. HENDRICKS: Dr. Fredrickson.

DR. FREDRICKSON: Well, I think that that may be a situation that the American College of Obstetrics and Gynecology may need to address, and I don't think that the FDA as a credentialing body can step in to educate primary care physicians.

DR. HENDRICKS: Dr. Kopans and then Dr. Lee.

DR. KOPANS: Dr. Kopans.

I think that one other point and -- well, why don't you go first, Carol, and then I'll come back.

DR. LEE: This is Carol Lee.

I think this discussion brings up a very important point. I don't think that it is a good idea or I don't think it's feasible to put in a blanket recommendation for everyone based on their breast density because everybody's history and everybody's condition varies. I do think that more information is good, and I do encourage and I've always encouraged dialogue between a woman and her physician or her healthcare provider.

One of the things that the task force recommended that I objected to was that women in their forties should have a discussion, but after you're 40 you don't need to have a discussion about, you know, the risks

and benefits of any particular test.

So having said that, I would love to see, for example, the Are You Dense Advocacy or the Are You Dense organization help -- or Komen or other societies, help educate the primary care providers because they are the ones who, in conjunction with women, are going to have to make the decisions.

And we as radiologists are very -- most of us are very aware of the data and of the science. We are seen as being self-serving, as self-referring, as benefiting from this sort of notification. So, you know, I really worry about that perception that, oh, the radiologists are out there trying to protect their own, you know, bottom line.

DR. HENDRICKS: Dr. Vega.

DR. VEGA: Hi. What I want to say is something my grandmother, who was a bookmaker in Harlem, taught me. Girl, you just never know enough. Okay. And it seems to me that we should not digest information for our patients and assume that if they do not have a college degree or a medical degree or a Ph.D. or QXR and ABC, that they are not necessarily informed. I have learned more from my patients than I did from school. That may tell you something.

But it also tells me that when somebody doesn't know where or what the report says, that they can get a navigator, which is what Komen calls it. I call it a comadre, which means another woman or another person who's

significant or a mentor.

People have resources if you allow them to express their anxiety and to make a decision about their own body, since it is our body. It's not just a Marilyn Monroe, nursing kind of thing. It is something that's very, very important. And I think that we should not -- and I really mean this -- condescend in any way because I understand that anxiety makes you -- when you're in someone's office, okay, I suggest that they take a comadre with them, as well as a tape recorder -- but give people the chance to say, Well, you know, what is this? I know my daughter has, you know, dense breasts. But what is it?

Let people question. I know it takes longer in an office, and I also understand that sometimes the questions may be not what we have been trained to deal with.

But, you know, it seems to me that we're dealing with human beings. We're dealing with not just the identified patient but we're dealing the family. And families now, thank God, have computers. My grandchildren know how to work them better than I do, and they're able to Google and goggle and do a lot of stuff, and I think that people can really get some very important -- garner information and then process it and speak to their physicians, speak to family members, speak to people who have had this experience, and that that will help them a great deal.

DR. HENDRICKS: Dr. Smith.

DR. SMITH: I'd like to thank all of you for reminding me how moving and what passion you bring to this, and I thank you for that. And don't lose that passion. I use it in the biblical sense of suffering because we need to better understand what it is like to be in the office on the other side of the desk or on the other side of the film, and I appreciate very much you bringing that up for us.

That said, I would incline toward Dr. Kopans, that I at one point in my career was an affiliated assistant professor of chemistry and, of all things, in analytical chemistry, so I really like numbers and seeing those things help.

One of the things that I would just offer to you is remember that the history of medicine is replete with well-meaning physicians, laity, and so on, that thought a certain treatment would be a very good thing, and it turns out it either wasn't a very good thing or it was neutral, except it ran up a lot of money and anxiety for people.

Another thing I'd like you just to keep in mind -- and I appreciate all the suffering you've gone through, and I mean in no way to lighten the suffering or the intensity of it -- is that when you do tests that you're uncertain of the -- we don't have the data to really know whether we're helping or hurting, and for every -- I don't know the data in any way, as well as many of the other people at this table. But for every one woman that we may help by doing breast ultrasound, there's a real possibility that we may

be hurting one, two, three others. What do I mean by that? Unnecessary biopsies, unnecessary anxiety, and a big bill.

I understand. For those of you for whom it was not offered or you were harmed because it was not told to you, I'm very sorry for that, and it will remind me how important these things are. But at the same time, remember that these tests have -- they're not always clear, number one. Number two, they can hurt people.

I offer you the example of prostate cancer, where it is a horrible thing to be told that your PSA level is up a little bit because now the man does not know what to do. What are you going to do? Are you going to watch it? Are you going to have your prostate gland taken out? Are you going to undergo therapy? It's not an easy thing. So I have some respect, from that perspective, of what you've gone through.

Thank you.

DR. HENDRICKS: Dr. Kopans and then Dr. Vega.

DR. KOPANS: Yeah, I think I also wanted to interject a little bit of history. The reason the American College of Radiology recommends in our breast imaging reporting and data system -- you heard the term BI-RADS before -- the inclusion of breast density, it is an indication that the sensitivity of mammography is somewhat diminished.

And, in fact, in a lot of our reports we may say the breasts are heterogeneously dense. This somewhat lowers the sensitivity of

mammography. It's not a secret, it's out there, and it's sent to the referring physicians. And the referring physicians have been taught, whether they've learned, that that means that if someone feels something, even though she had a negative mammogram last week, that you shouldn't ignore that.

Now, I've forgotten. You know, someone told her story about having a lump and her doctor saying, you know, don't worry about it. We've been trying to educate primary care physicians -- I've been in this for almost 40 years -- forever.

There were papers written, you know, about negative mammograms leading to a delay in care years ago, and the American College of Radiology has argued, you know, strongly that you can't ignore a clinical finding just because a mammogram is negative. Mammography is not perfect. It's been said forever and ever and ever that we don't find all cancers and we don't find all cancers early enough for a cure. So the reason for the inclusion of the dense pattern in mammogram reports is specifically for that.

And, again, you know, it seems to me there's no reason to not put it in the lay report. I think what I've heard from others, and I would completely agree, what do you then -- what's the follow-on to that? And I think, from a scientific perspective, those of us who argue on the basis of science can't say, Well, you should get an MR or an ultrasound because the scientific proof of efficacy is not there, and we've heard that there are

downsides to all of these tests.

So I did ask a question, though, earlier, Charlie, that you never answered. Why was it sort of taken out of the report awhile ago? Was there any good reason for it or just to make it easier to send a lay report?

DR. FINDER: It's Dr. Finder.

You have to back again to the 1990s, in front of a committee just like this, where the regulations involving reporting requirements were discussed.

And I think it's important to stress a couple of things. One is that while many reports, mammography reports, contain mentions of breast density, that is not required under the regulations. And I have seen many, many reports in which breast density is not even reported to the physician. If it's not reported to the physician, you can't put it in a lay summary because there's obviously no data to pull that off of and to make a decision in it. So if you're going to want it in a lay summary, it also has to be in the report. And that is not in the current regulations.

What was and what was discussed at these advisory committee meetings more than a decade ago was just getting the assessment categories in, in terms of that, to get some consistency in terms of reporting assessment categories to the referring physicians.

And, again, in terms of a lay summary, the main thrust there was to provide the patient with a summary of that medical report in a

language that they could easily understand, and to serve as a stopgap measure to make sure that things didn't get lost in transit because we'd been hearing at that time that a lot of reports that had gone to the referring physician mentioned something suspicious, required some workup, for whatever reason the patient was never informed about that type of exam, and a year or two later found out that there was something.

So the focus was not on breast density. And at the time that we were doing the regulations, there was really no alternative to what would you do with that information?

I think, a decade later, we're in a different world, and I think, as has been stated, there are other options now that didn't exist 10 or 15 years ago.

DR. KOPANS: But there's no proscription, you know, there was some reason that you couldn't put it in, essentially.

DR. FINDER: Oh no, no.

DR. KOPANS: Well, the other question I'd --

DR. FINDER: We can do anything we want.

DR. KOPANS: -- like to raise --

(Laughter.)

DR. KOPANS: Well, I'm going to suggest that maybe you can't.

(Laughter.)

DR. KOPANS: And the reason I'm going to suggest that is that

it's my understanding that magnetic resonance imaging and ultrasound are not FDA approved for screening. So can one arm of the FDA suggest using devices that aren't approved for that use?

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

I can't answer that in terms of certainty. I'd actually have to go back and discuss this. But I can certainly come up with ways to address the question that you raised, because what you're talking about is a screening procedure, and those devices are certainly used in high-risk patients, and depending on how you define breast density and whether you put them into a high-risk category, you may be able to still do that legitimately.

DR. KOPANS: No, I understand we can do it. We as physicians, I understand, actually can do anything we want, which is --

DR. FINDER: Right.

DR. KOPANS: -- kind of interesting.

(Laughter.)

DR. KOPANS: But that's off-label use. And I'm just curious. Can the FDA recommend or tacitly suggest off-label use of a device?

DR. FINDER: I think a lot of it would be in whatever wording comes up and in terms of how this is developed. I wouldn't preclude it. I wouldn't say that we could do it. I'd have to discuss that within FDA to see. But it is an interesting question because, as you point out, these devices have not been cleared or approved for screening. The question is how do you

define screening? And there are ways and words to address some of these issues.

DR. HENDRICKS: Yes, Dr. Laxague. Sorry, Deborah.

MS. LAXAGUE: Debbie Laxague.

I hear a little bit of the angst about this issue may be coming from being overconfident about mammography, perhaps because we tried to say more about it and we oversold it. We may be, initially -- we're overconfident in the information we gave to women. So I see that danger here, too.

I'm kind of assuming that we're going to give information about breast density. But as we put that in a lay summary, I want us to be careful that we're not overconfident that we know more than we do. I don't think we like to say we don't know for sure.

So we can give the information. We can say we suspect that it may increase risk and that it may decrease accuracy of your mammogram. But we need to be really clear to women, in that very simple lay summary, that this is an ongoing investigation. We don't have full evidence yet. And there's no reason that women can't hear that information. We don't know. It's still their right to hear the information, in my opinion.

But I don't want us to get overconfident and say you must do something. We could provide levels of more information. You can reference, you know, for the -- like most of us in this room, the information-hungry

people, you can reference websites and more research for people to investigate deeper without overwhelming the person who can't take all that in initially.

You also have to include the difference between relative and absolute risk when you're talking about something like a tenfold increase in risk. Women need to have that in the context of what that means to them.

And the discussion with providers concerns me, in particular, from a very rural area where no one pretty much has access to above a primary care provider who's a family practice physician. Perhaps not even an OB-GYN. That's putting a big burden on them to put language that simply says see your provider, discuss it with them. I'd like a little more in that lay summary, at least about what we don't know. I mean really emphasize this is information that may be useful to you as we learn more, but right now we don't know a lot.

And provide resources in that notification, where they can get more information, because there are a lot of women in my county, in my rural area, who are not going to get that from their family practice provider out there in the real world.

DR. HENDRICKS: Dr. Vega.

DR. VEGA: I was really going to -- I bow to, for the first time, my esteemed colleague from Massachusetts. What I was going to -- I don't know you well enough to call you Charlie, so I'm calling you Carlos. But

Charlie --

(Laughter.)

DR. VEGA: There you go. But I was wondering why it had been removed, very much what you talked about. And I was thinking that you have a wonderful sense of humor and that if you reframe things the way you do here, that we have chance to perhaps proceed.

And wouldn't it be great to go home on a Thursday late and then we know Friday we have -- and to say that we really did something that really roused some people and might have really accomplished something for all of those people out there, and all of our family members, that really is worthwhile?

So in advance, con tanto gusto, mi amors, I want to thank you, because I think it's a very important thing to consider, now that I put you on the hook.

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: Well, I'd like to share with the public and my colleagues here my experience in my practice, which is a very diverse practice. I live in a very rural state, Nebraska, but I live in a big city of one million. I have a breast imaging facility in the major city, but I also do outreach both physically and via telemedicine and telemammography. So I deal with rural women, poor women, middle-class and wealthier women.

We do offer adjunctive screening to our high-risk population

and women with dense breasts. But what I really want to do is share what some of my issues are with that.

Number one is, is that when we have these women, usually it precipitates a discussion between myself and them regarding everything we've just talked about. And that's usually anywhere from 5 to 15 minutes, and that's a discussion regarding breast MRI, breast ultrasound, the pros and the cons, the false positives of MRIs, and so forth.

That usually then leads to their question of, Well, why am I even having a mammogram, then, which then leads to another discussion of the benefits of mammography and its relative benefit compared to all other imaging studies and the science behind it.

That then leads to angst between my wife and I, who's a lawyer who specializes in med mal.

(Laughter.)

DR. FAULK: And then my discussion at the dinner table is, Well, are you telling these women about it? And well, if you tell them about it and then they don't do it, are you documenting that in your report? Which of course then leads to a whole other set of issues.

But the point is, here, it leads to a whole series of things behind the scenes that I think a lot of people don't appreciate. And I think the biggest thing to me that I've discovered in my practice is that, as it currently stands, the burden of -- if you're going to do this, the burden is on the

radiologist. I have very few referring physicians, OB-GYN, family practice, internal medicine (a) that maybe even read my complete report, which all my reports do describe breast tissue density; (b) would have the slightest idea of what to do about it or even the alternatives to offer women. They would have no clue about it, which leaves the entire burden upon us as the end-diagnostic radiology.

Now, the problem with that is twofold. One, you know, there's a decreasing number of mammography facilities, there's not enough breast imaging radiologists and specialists to go around the country. So if we take on this burden, we have even less time to devote to all the other issues and to all the other women. That's part one.

Part two is an interesting phenomenon that, when I was in university practice, I didn't really face, but in private practice, I really do face, and that is I have some referring physicians who point blank will call me up and say, Robert, I absolutely do not want you talking to my patients under any circumstances. And if you do, I will not be sending you any more patients. And I have other referring physicians who are 100 percent diametrically opposed to that and say, I will let -- Robert, just call me when you're done. Do everything you need to do and then call me.

So I have one set of patients, depending on the referring physician, if they have increased breast density, I really can't even go in and talk to them without risking the loss of the referrals from that particular

group and/or that physician.

So those are some of the problems that I face on a practical basis of implementing adjunctive screening.

DR. FINDER: This is Dr. Finder again.

The last issue that you addressed was one that we had to deal with when we had the issue about providing lay summaries, and there were a lot of doctors who did not want radiologists to be talking or giving information to their patients. And one of the advantages to the MQSA was that it was required of everybody. So now they couldn't take patients away from you and give them to somebody else because that other person also had to do it. So it kind of leveled the field in that one aspect. Everybody had to do the same thing, and it did address that.

DR. FAULK: Well, just an interesting point about that. When the lay letters initially came out, at least in my practice, and interestingly enough, particularly more out in the rural than in the city, the big issues the physicians had was sending out -- the referring physicians I'm talking about, had with regards to the lay letters, they wanted the lay letters to go through them first before going to the patient, instead of going directly from radiology to the patient. That was a big point of contention with many referring physicians at that point in time.

DR. FINDER: It's Dr. Finder.

And actually that was addressed specifically by Congress when

they passed the law, the amendment to MQSA, that specifically said that it was the radiology facility that had to have the contact with the patient because that was another option that was being considered. So it was part of the history.

DR. HENDRICKS: Dr. Wilkinson -- Dr. Fredrickson.

DR. FREDRICKSON: Sara Fredrickson. I think I've been called a few different names today.

I think it was Ms. Price who initially said that the primary care providers and the gynecologists aren't at the table to discuss this. And I think that as a breast surgeon, as a breast specialist, I sometimes put on that hat of a breast primary care provider, and sometimes put on the hat of being referred patients, and I kind of get a sense of what the primary cares and the gynecologists would think of a lay report that alludes to things like breast ultrasound and breast MRI.

And Dr. Faulk is what sort of stimulated that thought, is that the malpractice issue, in terms of liability if that is on a lay report and the doctor disagrees with using a breast ultrasound or an MRI, that may be a big liability issue for them. Or it may cause them to refer more patients for breast evaluation, which is going to either put more of an onus back on the radiologist or on practitioners like myself, as a breast surgeon, which I certainly wouldn't turn away business. But it's not something that -- you know, that I would, you know, want to spend eight hours a day talking to

patients about breast density and nothing else. I do that quite a bit.

But I think that would inundate a lot of specialists that -- the primary cares are busy doctors. They're not going to spend that 15 to 20 minutes going through all of the ramifications of breast density, if they know it. And so I see that as, number one, a liability issue, and number one, something additional that the primary care has to deal with.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: I'm just trying to digest all of this and try and think of something reasonable. In the interest of, you know, giving people information, I can't see a real argument against telling someone, you know, your breast tissues are dense, however, no abnormality is seen, and should you feel something -- and I can think of reports that would be fine, and giving out breast density is just part of the report, anyhow.

I agree though. I think there are huge tangential issues in recommending the next step, and I don't know what the answer to that is because again there's no, sorry, scientific support for doing ultrasound and MRI. Individual doctors can suggest it and there are data to say that we should certainly study it and find out if it saves lives.

I personally think MR screening will reduce the death rate in addition to mammography, but I haven't been able to convince people to do the large studies that need to be done. But I would certainly urge the FDA to, you know, include breast density in the report. But I think the whole issue of

secondary screening is one that I don't think we'll ever come to agreement on, and I would hope that that's not introduced.

And just to interject, the primary care doctors will then be all over your case, too. Not that you can't deal with it. I know, a piece of cake. But, you know, one of the things in this business of having primary care doctors talk to women about breast imaging is kind of a little silly because primary care doctors see maybe four or five women each year with breast cancer.

It's not a big issue in a primary care practice, and they actually resent radiologists because with mammography we find things and we suggest that they should come back for ultrasound or MR or something like that, and they, the primary care doctors, are upset because they have to deal with the patient before she comes back to us. So adding another level of screening, not that it's a reason not to do it, but I think that it'll be very, very complicated.

DR. HENDRICKS: Dr. Seibert and then Dr. Finder.

DR. SEIBERT: Yeah, this is an issue. From my perspective, I'm kind of outside of the whole sphere of the conversation. But from the perspective of being on the record, I think there's no reason why the breast density shouldn't be put in the report or mandated by the FDA, from my perspective. So I support that.

But, again, it is the law of unintended consequences,

sometimes, that will lead to secondary studies and the like that might not be an appropriate course of action. So we need more studies there.

And getting back to the breast density. Dr. Kopans said right at the beginning, you know, breast density, the volumetric breast density. We have a breast CT scanner at UC Davis, a dedicated breast CT scanner, and the actual breast density itself, everybody thinks it's 50/50, but it's really like about 15 percent dense breast when you look at it by volume, and downwards from there.

Now, if we could find some way to quantitate the breast density in a little bit more careful way as well, because it's really Dr. Kopans' opinion versus any other radiologist's opinion on what the breast density is, and we do need to look at those issues as well.

DR. HENDRICKS: We'll go to Dr. Finder and then Carol Price.

DR. FINDER: This is Dr. Finder again.

Going back to the point you just made, we've been talking about dense breasts. Anybody want to define that for me so I know? Because you haven't really gotten into --

DR. KOPANS: The Supreme Court did it.

DR. FINDER: No, no, no.

DR. KOPANS: Oh.

(Laughter.)

DR. FINDER: No. What system should we use and at what level

should we decide that somebody's dense or not dense? And I do think that there's a basis, at least a start to the discussion, from the ACR BI-RADS classification system of four levels.

Do people think that that's a reasonable approach to at least begin and then decide at what level do you say that this is a dense breast and this is not a dense breast, and where do you define things and where do you do the cutoff?

Because I'm not sure that -- or maybe you do want this. If you were talking about putting language in the lay summary, do you want terms like the breast is almost entirely fat versus there are scattered fibroglandular densities, which is from the BI-RADS. Would you want that in a lay summary or would you want something a little bit more generic that would be more understandable, let's say, to the lay public? I don't think that most people would understand that breast tissue is heterogeneously dense, per se.

So my first question is, is the BI-RADS system a reasonable approach in terms of documenting at least density to the referring physician? And then from the basis of deciding how you would describe that in a lay summary.

DR. HENDRICKS: Let's go to Dr. Monticciolo for that.

DR. MONTICCIOLO: Thank you, because I wanted to address that specific question.

The BI-RADS is going to change, and you're probably aware of

that. The percentages are going to be removed with a new BI-RADS, and the reason for that is, is because it's been so variable. Dr. Kopans made that point very nicely. You have two people reading it, and there's a lot of difference in what they call fatty. For example, fatty says 0 to 25 percent, and none of us at 25 percent or 24 percent are going to call it fatty. Usually you get over 10 percent and we move up to scattered fibroglandular tissue.

So many of us use the most extreme categories to constitute less than 25 percent of that population, and because of that subjectivity and variability, the BI-RADS is no longer going to attach those percentages. So that's going to be a bit of an issue.

I don't know if you want me to let someone else go next, because I think Carol was -- but I had some other comments about just our general -- you can come back to me.

DR. HENDRICKS: Carol Price, do you want to interject at this point?

MS. PRICE: Well, it's for Dr. Finder. Carol Price.

And my comments before, it wasn't intending to see that things were added into the summaries that talked about ultrasound and MRI, but more of how do we educate the physicians that would get these reports to talk to their patients, if we included something about follow-up with your physician, that you have dense breasts and you should follow up with your physician? That was my concern, is how that's done.

But I think Dr. Faulkner [sic] spoke to the radiologist being the one that spoke to the patient, and isn't that something that the FDA could mandate, instead of saying follow up with your physician, that the radiologist actually did it then, right then and there? And since they have more experience -- that's my question on that one.

DR. HENDRICKS: Yeah, we'll go to Dr. Kopans and then back to Dr. Monticciolo.

DR. KOPANS: Yeah. Just to specifically answer that, many screening mammograms, if not most screening mammograms, are done when the patient leaves and before a radiologist looks at the images. So the radiologist can't really -- I mean, that's very important to keep the cost down and make access for all women. So the radiologist really can't do that right then and there. I think it would have to be some kind of phraseology that would be in the letter that would make some sense.

DR. MONTICCIOLO: Debbie Monticciolo.

So just some comments on the proceedings. One is I think Dr. Kopans nicely laid out the battle that we face just getting mammographic screening established and the fights we've been fighting for that. And this has a proven lifesaving ability, and still we find the task force not doing us any favors.

Second is I will repeat what Dr. Faulk said. When I first started talking to patients, I got a lot of heat from family docs and OB-GYNs. Why are

you talking to my patient? And I actually got yelled at for sending a normal letter to somebody. Of course, being who I am, I told him to go jump in a lake. But still, it was a difficult battle. So it may help if the FDA supports this.

I have to say as a radiologist, I always put density in the report. I think it's a no-brainer. I kind of assumed everybody did that. It seems to me it would make sense, but you know, I believe you see a lot of reports without it.

That said, there is a lot of subjectivity, which makes it difficult. But still, I think asking for it in the report is reasonable and something that nobody would find too surprising. Putting it in a lay letter is also fine with me. Again, I'm worried about the unintended consequences of adding recommendations on top of that when you don't know the overall risk profile of the patient or the degree of density.

So, you know, I see a patient who's kind of, I'd call, heterogeneously dense, one of my colleagues would call scattered fibroglandular tissues. I think mammography is quite effective in that patient. But being forced into something like an ultrasound -- and even studies with high-risk women, that ultrasound shows that, you know, over 90 percent of the biopsies are benign. So only 1 in 10 biopsies are positive in those patients.

And I personally have seen an awful lot of unnecessary biopsy, and so I'm concerned about that. And also there is good literature to show

that MR is much more effective in finding cancers in dense breasts than ultrasound.

So I'm hesitant to be forced into one avenue or another until we have really good data to support it. But I really wouldn't want to recommend -- I heard supplemental ultrasound pushed here today, and there's a whole lot of women I'd like to see have an MR before they went to supplemental ultrasound.

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: Yes, Robert Faulk.

I'll just address the issue of the radiologist having a consultation with the patient. And while I think it's a great way to go -- because I agree with most everybody on this Panel that I think believes that radiologists are in the best position to discuss breast tissue density and adjunctive screening with the patient. In the current environment that we live in, it's not practical. And it's not practical for several reasons, one of the big reasons being time. I know of almost no radiologists who are going to have the time to do that with every patient in their practice that has greater than 50 percent breast tissue density.

Two is there will be a certain -- depending on your practice, a certain percentage of your patient population that you can't even talk to because of the referring physicians and incurring their wrath.

And then thirdly of all there's the issue of, if you do that, you

will be spending a tremendous amount of time doing that in your practice with absolutely no reimbursement, because under current CPT codes you don't -- there is no method of reimbursement for that.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Thank you. Debbie Monticciolo.

I would add to that, Robert, that my concern is that somebody needs to look at the overall risk for that patient, and that is best done by, I hope, the primary care physician or the OB-GYN, because they need to look at the whole family history, the patient's history, and they need to really know this patient.

And, you know, that's why I do favor telling the physicians -- I have no problem saying here's the density and in this patient -- and I already do this -- you know, you should look at the overall risk profile and consider what would be best for your patient. And then, of course, it's going to be up to us to educate and, you know, I think we can make some impact on that.

DR. HENDRICKS: Dr. Faulk and then Dr. Finder.

DR. FAULK: Yeah, just that I agree with that. In our practice we actually -- if we have a patient with increased breast tissue density, we actually do a risk profile. But, again, that gets into the issue of time, no reimbursement for it, and who's going to counsel the woman on that risk profile?

In essence, what I'm saying is that in order to do that, you

almost have to become a breast primary care specialist, as a radiologist, which is beyond the scope of practice for most of us, the way practices are currently set up in today's world.

DR. FINDER: Dr. Finder.

I just want to bring up two -- well, two points and a question. First is that we're always open to comments and suggestions about wording for things. So either from the Committee or from the public, send us your thoughts on, if we're going to have some type of wording, what it might look like.

Second, we're not alone in this. There are some states that have passed laws. They can serve as pilot projects and we can get information from that. And I expect to hear and learn from what's happened in Connecticut, especially how this has been implemented.

And my question goes back to a question that I had earlier, going back to breast density and what is it. Going back to the ACR BI-RADS, they have four classifications, 1, 2, 3, and 4. What do you consider dense? Is it just 4's? Is it 3 and 4's? Is it 2, 3's, and 4's? Because that changes the number of people that get involved in this.

And another comment that I had heard earlier was that maybe we shouldn't just be talking about the risk from breast tissue density but some statement about overall risk of mammography with an additional statement about maybe your risks are higher if you have dense breasts. And

what does the Committee think about something like that?

So those two questions, if you can answer that in the next few minutes, I'll be happy.

DR. HENDRICKS: Dr. Yang.

DR. YANG: Well, I'm not sure if I'm going to be able to answer both questions specifically, but I would like to share my experience. And I practice in a primary cancer center where the multidisciplinary effort is key, and I've heard a lot about communication of breast density and the onus being either on the radiologist or the patient or the physician. But I think that a multidisciplinary effort is probably going to be the best for the patient. Reporting breast density is something that we seem to all agree on at the table. Putting it in the lay letter is also important.

But I think the third prong that's missing is what do we do after that, and does it fall entirely on the radiologist or back to the clinician? And personally I think that the clinician, whether it's a primary care doctor or a gynecologist or a breast person or a well woman clinic physician, is probably the most important link, the third link, because he or she should be responsible for the woman.

And in terms of risk modeling, I don't think we are qualified to do this. So there are specific risk models throughout the country that are well calculated, and I think that somebody who's qualified to do it with the added capability of doing risk counseling is key. And I think all of these

factors have to be taken into consideration before recommending additional supplemental screening.

So I think that third link is very important, and that's something that perhaps should not belong to the radiologist alone.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Yeah, I think to try and answer some of this, I mean, first of all, Dr. Finder, there is no absolute scale. And, in fact, everyone is on a continuum. You don't suddenly go from, you know, 25 percent dense to 50 percent dense, or in the other direction. So it's sort of an arbitrary way of dividing women. So there is no answer to your question as to what's dense. It's in the eye of the beholder.

That said, first of all, I'm a little surprised that there are radiologists who don't put it in their report to the clinician. I thought that that was pretty standard, but you know better than I. The fact is that a lot of us do and, I would suspect, the majority, but I could be wrong. And when the clinician says, Well, what do I do with that, we talk to them and we, you know, explain and then you do that a couple of times and pretty soon they sort of get it.

So I think if you put it in a lay letter, there would be some early discussion. What does it mean? And I would say, for example, it means that you have to be more careful. If you feel something in your breast next week, don't feel that the mammogram, a negative mammogram, means you don't

have cancer. And we've said this in every patient. I like this quote. A negative mammogram does not mean that a woman does not have cancer, and whether it's fatty or dense.

So I think those can be handled, and there will be a lot of discussions to begin with. You know, what does this mean in my letter? And then eventually it'll certainly get out. It'll be in women's magazines. And I think it's already been there, quite frankly, but it'll be there again. I don't think that's an insurmountable problem.

I would want to bring up just one other reason to not push secondary screening, and that is that there are companies out there, it's hard to believe, who are entrepreneurial, and they're going around doing ultrasound screening.

Because a woman has been told -- I believe this is in Connecticut -- that she has dense breasts and she may want to consider secondary screening, there are companies that will do whole breast ultrasound screening, and then they give the patient her report, which has seven lesions, seven possible lesions in one breast and five in the other and she has to go find someone to take care of those.

And we haven't had that situation, but we've had the situation where people are doing whole breast screening with handheld systems and they come in with five in one breast and seven in the other and we have to figure out what to do with them. I would, quite honestly, if we could ever do

this, say, if you do whole breast ultrasound screening, you deal with the lesions and don't send them to someone else. You can't do that, but I just wanted to make people realize that that is a big problem.

DR. HENDRICKS: Ms. Willison.

MS. WILLISON: I just want to direct the conversation a bit to intra-variability, inter-variability, breast density subjectiveness and really point to year to year, when a patient has a mammogram and it's read by different doctors. I know Dr. Monticciolo brought this up sort of briefly. But one year she's told she has fatty breasts and the next year she's told she has dense breasts and the next year she's told she has, you know -- so I think that that's a question that hasn't come up yet.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Debbie Monticciolo.

I don't think it's the extremes that get confused, but I think it's hard subjectively to decide between 49 percent and 51 percent. So what we see is variability around that. And that's the biggest issue.

And I think it is hard, Dr. Finder, to say what is dense. I mean, we've talked about it among ourselves, and we kind of feel like it's 3½ to 4, if that helps you. I mean, certainly the people in the fourth category are dense. But when you get down to 60, 65 percent, 55 percent, you know, a lot of those patients, mammography is quite effective and I wouldn't be moved to want to do supplemental screening myself.

And, you know, I am directly concerned for the patients I care for, so I want to be able to find -- I don't want to miss anything. But there's two issues here. There's the tissue mask lesion. And we know, the extremely dense patients, you can see calcifications, but for masses it's more limited. And then the question is how much are they at increased risk? And that's an overall lifetime thing.

And I like Dr. Kopans' feel that that's been overstated in the literature. There is an increased risk, but I don't think -- I think the calculations in the literature have been quite biased and the risk -- real risk is about 1.5 to 2 percent, but it depends on what extreme you are in that spectrum.

DR. HENDRICKS: Dr. Faulk.

DR. FAULK: One additional complication with the breast tissue density paradigm for us is -- that we all run into, is the focally dense mammogram where it's less than 50 percent, but there's one area of the mammogram that is very dense. Now, what do we do with that?

DR. FINDER: This is Dr. Finder.

Yes, what do we do with that?

(Laughter.)

DR. FINDER: That's why you're here; you're to advise us.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

This is why the American College of Radiology doesn't put a lot of emphasis on density, except as an indication that there may be reduced sensitivity.

And so in a situation where a radiologist is concerned that there's a patch of dense tissue, it wouldn't surprise me if that radiologist would report the breast as heterogeneously dense, even though there was a lot of fat elsewhere, just to alert the clinician and the patient that the clinical exam or the self-exam or the self-awareness, I guess, now if you follow the U.S. Preventive Services Task Force, will be a little more acute, so that a lump that develops is not ignored.

Again, I think what you're trying to do is refine it to science. You know, what is a dense breast? Give me a number. The answer is there's no science. And the science of risk, you know, just -- I know the audience is sitting here saying, well, there all of these papers that say that the risk is increased. Papers are published because journals like them. You don't know all the papers that didn't get published because they didn't show any increased risk. And the journal says, well, then we've got to publish a paper that doesn't show anything. So I think we need to be a little bit careful there.

But, again, I think you could have a guidance document that explains, you know, density is in there because women would like to know and we think they should know. But no one -- there's no consensus on, you know, the importance of it and women should discuss it with their doctors.

DR. HENDRICKS: Yes, Ms. Willison.

MS. WILLISON: I would just also add that if you look at just the BI-RADS definition of density, the 1 through 4, and you put that sort of on a bell-shaped curve, you have fatty breasts, 1, very small and, you know, to the left. Everything else is kind of dense all the way to dense.

And so again I wonder about the quantification and the consistency over years, over mammograms, over reports, taking into consideration a woman's lifetime cycle from premenopausal through menopause, things of that nature which the radiologist could address better than I.

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

I think in some ways I may be asking the question incorrectly. But as Dr. Kopans and many of the radiologists have mentioned, they are already using this classification system and have been using it for a long time.

My basic question is, is this is a good one for us, if we had to go in this direction, for us to use or do we develop a new one? And my general consensus about that is, is creating new systems causes new problems. My question keeps coming back to, when we talk about dense breasts -- and I did get an answer of 3.5.

(Laughter.)

DR. FINDER: And that's the best answer I've heard so far.

DR. KOPANS: We use 3.2.

DR. FINDER: Okay.

(Laughter.)

DR. FINDER: So I'm going to kind of average that out to 3's and 4's and, you know, kind of calling that the "dense" breast. Is that a reasonable assumption?

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: Well, I've never been accused of being the voice of reason, but I'll answer that. This is Debbie Monticciolo.

I think 4's, for sure. The problem is 3's is a pretty broad category, and some on the lower end, I think, are not appropriately included, but I wouldn't want to miss those on the upper end of the 3.

So number one, to answer your first question, I think we should go with the system we have. People are used to using it, we know the pluses and minuses, it's familiar, and I can't see how you can tweak it significantly to come up with a new one. So I think using the BI-RADS system would be appropriate, to answer that first question.

And then the second question is, I don't really like to see all of the people in the heterogeneous category lumped together with those on the more dense end of the spectrum. But at the risk of missing those on the more dense end of the heterogeneous spectrum, I'd probably say we'd have to include those in the 3 and 4 category, given that system.

DR. HENDRICKS: Dr. Kopans.

DR. KOPANS: Dr. Kopans.

I would agree completely with Dr. Monticciolo. It seems to me that we should just think back to the days when you asked us to translate the report to the clinician into lay terms for the report for the patient. And, you know, radiologists should be able to do that. I mean, if you say to me, okay, you sent a report to the clinician that says the patient has heterogeneously dense breast tissue, this somewhat lowers the sensitivity of mammography, no masses or clustered microcalcifications are visible, conclusion, no mammographic evidence of malignancy, I can put that into lay terms.

I agree with you. I would probably still use heterogeneous. And I don't know how to get around that without insulting people, but you know, they can look it up.

DR. HENDRICKS: Dr. Fredrickson and then Dr. Yang.

DR. FREDRICKSON: At the risk of being too simplistic, which, as a surgeon, I'm not usually accused of, but I would agree with using the BI-RADS categorization. Why reinvent the wheel? But it's like Dr. Kopans said, it just needs to be translated for that patient.

If you take the numbers out, you know, you could use minimally dense, moderately dense, or extremely dense. That doesn't say anything about numbers. But I would vote for using the BI-RADS in some way, but translated for that layperson.

DR. HENDRICKS: Dr. Yang and then Dr. Faulk.

DR. YANG: Yes, I support everything that's been said, and I'm a proponent for using BI-RADS 3 and 4 as dense breast tissue, understanding its imperfections and the inter-observer variability. But I think that's the best that we have.

DR. FAULK: Robert Faulk.

I agree with BI-RADS 3 and 4. The only thing I have a question about would be, in the lay report, the use of the terminology "heterogeneous." I see that as potentially a problem with many women in interpreting that. I would suggest the possibility of using the word moderately dense.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: This is Debbie Monticciolo.

The way we do it in our letter is we say, for those women, you're on the lower end of the dense breast tissue, the patients with dense breast tissue, you're on the lower end of density for the patients that have dense breast tissue. So that's another -- there's other alternatives, I think, to make it simpler.

DR. FINDER: This is Dr. Finder.

DR. HENDRICKS: Dr. Finder and then Carol Price.

DR. FINDER: As I said before, we're always open to hearing suggestions about wording in these types of things, from the Committee, from the public.

Yes?

UNIDENTIFIED SPEAKER: Can we send them to you, Dr. Finder?

DR. FINDER: Yes, you can send them to me.

DR. HENDRICKS: Carol Price.

MS. PRICE: Yeah. My only recommendation would be that you involve lay people in the terminology and what is translated for the lay people. Just having been involved in research and research abstracts that are written by scientists for lay people, they're hard. But if they involve the layperson in their project, the abstracts for the layperson are far more understandable, and I think it applies in this same situation.

DR. HENDRICKS: Dr. Monticciolo.

DR. MONTICCIOLO: This is Debbie Monticciolo.

It probably doesn't need more said than that because that was very nicely said, Carol. But I would agree with you. I spent 10 years on my IRB, and you know, if you're trying to protect human subjects in research, you can't have a 10-page document with lots of big terms. It's just not -- you know, not everybody's doing that every day. So I would just reiterate what she said. It's very important to have a lay perspective.

DR. HENDRICKS: Any other questions or comments on this topic?

(No response.)

DR. HENDRICKS: Then that concludes that item.

One final item on the agenda. We're going to hear from Dr. Finder. He's going to review the previous meeting summary minutes and make final remarks.

DR. FINDER: This is Dr. Finder.

All I want to say about the last summary minutes is I hope you read them.

(Laughter.)

DR. FINDER: Anybody have any comments?

(No response.)

DR. FINDER: If not, we're done with that aspect of it.

In terms of a next meeting, I assume there will be one at some point. We don't have a date or a time scheduled at this point. A lot of it's going to depend on what we come out of this meeting with and also some other issues that are down the pike. But at this point we don't have any additional meetings scheduled.

I would say that, in the future, we will try and schedule them for nice weather times in Washington. Years ago we used to schedule them in the summer and winter also. That didn't turn out to be a good idea because of the snowstorms and the summer thunderstorms. So I would expect that our next meeting would be either in the spring or the fall of 2012.

Does anybody have any questions for me at this point?

(No response.)

DR. FINDER: If not, I'm done with my section, then.

DR. HENDRICKS: Thank you. I'd like to also thank the entire Panel, members of the FDA, the public speakers, and Dr. Finder.

And so this meeting of the National Mammography Quality Assurance Advisory Committee is now adjourned.

(Whereupon, at 3:50 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

November 4, 2011

Gaithersburg, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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