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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September 15, 2016
8:30 a.m.

Gaithersburg Holiday Inn
Grand Ballroom
2 Montgomery Village Avenue
Gaithersburg, MD 20879

PANEL MEMBERS:

ROBERT D. ROSENBERG, M.D.	Chairperson
CAROL H. LEE-FRENCH, M.D.	Voting Member
LORA D. BARKE, D.O.	Voting Member
MITCHELL M. GOODSITT, M.D.	Voting Member
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JESSICA TORRENTE, M.D.	Voting Member
WILLIAM R. GEISER, M.S., DABR	Voting Member
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M E E T I N G

(8:34 a.m.)

DR. ROSENBERG: All right, thank you very much for being here. I would like to call this meeting of the National Mammography Quality Assurance Advisory Committee to order.

I am Dr. Robert Rosenberg, Chairman of this Panel. I am a radiologist specializing in mammography and did research on mammography outcomes, and currently a member of the Radiology Associates of Albuquerque.

I note for the record that the voting members present constitute a quorum as required by 21 C.F.R. Part 14.

For today's agenda, the Committee will discuss and make recommendations on

1. Compliance Analysis. This presentation will be focused on Mammography Quality Standards Act (MQSA) current compliance trends, such as how most compliance cases originate. Input from the Committee on any trends seen in the analysis, why the trends may be occurring, and possible actions will be sought.
2. Inspection Enhancement Project. This presentation will describe a proposal to use the inspection program to enhance image quality. FDA is seeking Committee input on anticipated facility questions related to the proposal.
3. The approved alternative standard American College of Radiology Full-Field Digital Mammography Quality Control Manual. The manual will be presented so that Committee members have knowledge of this alternative QC manual that facilities can choose to use. (This is presentation only.)
4. Issues related to breast density. A presentation of current issues followed by a Committee discussion on how these issues might affect a possible MQSA

requirement for reporting breast density.

5. Future challenges for MQSA, such as the role for synthesized 2D images. FDA is seeking Committee input on this challenge, as well as what future challenges MQSA might encounter.

Before we begin, I would like to ask our distinguished Panel members and FDA staff seated at this table to introduce themselves. We'll just go around. Please state your name, your area of expertise, your position, and affiliation.

Ms. Davis.

DR. DAVIS: My name is Sandra Davis. I am a Professor of Biology at the University of Indianapolis, and I am a Consumer Representative.

MS. CHAUHAN: Cynthia Chauhan, Patient Representative.

DR. PORTIS: Natalie Compagni Portis. I am a Consumer Representative.

MS. URIELL: Diane Uriell, Industry Representative.

DR. GEISER: Bill Geiser, a medical physicist at MD Anderson Cancer Center. I am a Voting Member of the Panel.

DR. NEWELL: Mary Newell. I am a breast imager from Emory.

CDR ANDERSON: Commander Anderson, Sara Anderson. I am the Designated Federal Official for this meeting. Thank you.

DR. TORRENTE: Dr. Jessica Torrente. I am a mammographer at Staten Island University Hospital, Northwell.

DR. BARKE: Lora Barke. I am a breast radiologist at Radiology Imaging Associates, Invision Sally Jobe in Denver.

DR. BERNS: Eric Berns. I am a medical physicist at the University of Colorado, Denver Health Medical Center, and I also am a Voting Member of the Panel.

DR. LEE-FRENCH: I'm Carol Lee. I am a breast imager at Memorial Sloan Kettering

Cancer Center in New York.

DR. GOODSITT: Hi. Mitch Goodsitt. I am a medical physicist at the University of Michigan, and I am also a new Voting Member of the Committee.

DR. BARR: I'm Helen Barr. I'm the Director of the Division of Mammography Quality Standards at FDA, which administers the MQSA program. I am a diagnostic radiologist and breast imager by profession.

DR. ROSENBERG: Members of the audience, if you have not already done so, please sign the attendance sheets that are on the tables by the doors.

Commander Anderson, the Designated Federal Officer for the National Mammography Quality Assurance Advisory Committee, will make some introductory remarks.

CDR ANDERSON: Good morning.

The Food and Drug Administration 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 Representative, all members and consultants of this Committee are special Government employees or regular Federal employees from other agencies and are subject to Federal conflict of laws [sic] and regulations.

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

FDA has determined that members and consultants of this Committee are in compliance with Federal ethics and conflict of interest laws. Under 18 U.S.C. Section 208, Congress has authorized FDA to grant waivers to special Government employees and regular Federal 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.

Related to the discussions of today's meeting, members and consultants of this Committee who are special Government employees or regular Federal 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 18 U.S.C. Section 208, their employers. These interests may include investments; consulting; expert witness testimony; contracts/grants/CRADAs; teaching/speaking/writing; patents and royalties; and primary employment.

Based on the agenda for today's meeting and all financial interests reported by the Committee's members and consultants, no conflict of interest waivers have been issued in accordance with 18 U.S.C. Section 208.

Diane Uriell is serving as the Industry Representative, acting on behalf of all related industry, and is employed by GE Healthcare.

We would like to remind members and consultants that if the discussions involve any other 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 relationship that they may have with any firms at issue.

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. Thank you.

Before I turn the meeting back over to Dr. Rosenberg, I'd like to make a few general announcements.

Transcripts of today's meeting will be available from Free State Court Reporting,

Incorporated, telephone number (410) 974-0947.

Information on purchasing videos of today's meeting can be found on the table outside the meeting room.

Handouts of today's presentations are available at the registration desk.

The press contact for today's meeting is Tara Goodin, and she is standing up in the back, for members of the press. Thank you.

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 meeting has concluded. Repeating this: Please, reporters, wait to speak to FDA officials until after the Panel meeting has concluded.

If you would like to present during today's Open Public Hearing session, please register with Artair Mallett at the registration desk.

In order to help the transcriber identify who is speaking, please be sure to identify yourself each and every time you speak.

Finally, please silence your cell phones and other electronic devices at this time.

Dr. Rosenberg.

DR. ROSENBERG: All right, Dr. Rosenberg here.

Recently approved alternative update on alternative standards approved since previous NMQAAC meeting: presentation only. This will be presentation number one. We'll now proceed with the first FDA presentation. Timothy Haran will now present.

I will remind 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.

Mr. Haran, you may now begin your presentation.

MR. HARAN: As Dr. Rosenberg said, I'm Tim Haran, and I'm the Deputy Director of the Division of Mammography Quality Standards. My informational presentation this morning concerns the approved alternative standards, the standards that we've approved since the last NMQAAC meeting, advisory committee meeting.

First, an explanation of what alternative standards are. They're written into the 1999 final regulations under Section 900.18. FDA may approve an alternative to a quality standard -- the quality standards are 900.12 -- when the Agency determines that the proposed alternative is at least as effective in assuring quality mammography as the standard it proposes to replace; and the proposed alternative is either too limited in its applicability to justify an amendment to the standard, that is, to the regs, or it offers an expected benefit to human health that's so great that the time required for amending 900.12 would present an unjustifiable risk to human health; and the granting of the alternative has to be in keeping with the purpose of the statute, MQSA, U.S. 42 263b.

Since the last advisory committee meeting, we've approved five alternative standards to two quality standards. Four of them were submitted by manufacturers for the use of test results. One of them was an alternative standard submitted by the ACR for Quality Control Tests—Other Modalities.

Okay. The alternative standard for the use of test results under 900.12 says that if the test results fall outside of action limits, something needs to be done to correct them before any examinations take place or any further images are processed, and the corrective actions have to take place within 30 days of the test and the failure. Each one of the approved alternative standards for quality control has essentially the same paragraph attached to it, which is that the tests have to be equivalent for the quality control tests for screen-film systems, and it specifies the quality control tests whose failures require corrective reaction. If the corrective action has to deal with the acquisition of images, the

acquisition of images has to stop, but the interpretation can continue. If the quality control test failures deal with interpretation, then image acquisition can continue, but interpretation has to stop.

All four of those alternative standards have exactly the same wording. They're very long, several pages each one of them. So I have decided to spare you a listing of all of the quality control tests involved, except to say that they all deal with daily, weekly, semiannual, and annual testing. They were submitted by Planmed, by Agfa, by Giotto, and by Fuji, those four. I've put links up there for you, if you would love to go in and read what each one of them says and a listing of all of the tests, but I wasn't going to do that this morning.

The next one has a rather long title, so I put it on its own slide. It's the Alternative Standard for Quality Control Tests—Other Modalities. It's the "Approval of an Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems, for Systems without Advanced Imaging Capabilities." In other words just FFDM only, full-field mammography machines only.

We approved the alternative standard on February 17th of this year. It has no time limit. It's an alternative to the quality assurance program recommended by the image manufacturer, and we determined that ACR's quality control manual, about which you will hear more later, as required in 900.18 is at least as effective in assuring quality mammography as following the manufacturer's QC manuals. The original standard, 900.12(e)(6), says for quality control tests for other modalities: For systems with image receptor modalities other than screen-film, which is virtually every machine in existence today -- there are less than 250 screen-film units in use in the United States -- the quality assurance program shall be substantially the same as the QA program recommended by the

image receptor manufacturer, except, of course, it can exceed the dose limit of 3 mGy. The approved alternative is, for full-field digital mammography systems without advanced imaging capabilities, the quality assurance program shall be substantially the same as the QA program recommended by the ACR Digital Mammography Quality Control Manual when used with the ACR Digital Mammography Phantom. That's the sum total of the alternative standards that we have approved.

Are there any questions, ladies and gentlemen?

DR. ROSENBERG: Thank you, Mr. Haran. Oh.

MR. HARAN: Okay, I was going to say --

DR. ROSENBERG: Does anybody on the Panel -- Dr. Berns -- have any questions to clarify?

DR. BARR: This is Helen Barr, FDA.

Could I let Mr. Haran add two comments to his talk?

DR. ROSENBERG: Would you, please? Yes.

MR. HARAN: Yeah, one comment. One comment is -- it's not up there, but who can apply for alternative standards? Mammography facilities, accreditation bodies, equipment manufacturers, state governments and federal agencies, and accreditation bodies. They can all apply for alternative standards. We're not allowed to apply for alternative standards ourselves. And they can be used by virtually any mammography facility. Some mammography facilities will use them, some will not, which is why we stipulate that it's of limited applicability as part of our approval process.

Any questions? All right.

Thank you, ladies and gentlemen.

DR. ROSENBERG: Any questions from the Panel?

(No response.)

DR. ROSENBERG: Okay. Thank you, Mr. Haran.

All right, we now proceed to a presentation by Dr. Eric Berns. There will be no discussion afterwards.

Dr. Berns, would you please proceed? You'll make your statement before --

DR. BERNS: I will. My name is Eric Berns. I am a physicist, medical physicist at the University of Colorado and Denver Health Medical Center. I am the Chair of the ACR Subcommittee on Quality Assurance in Mammography and also was the Chair and lead author of the ACR Digital Mammography QC Manual, which I'm going to present today to the Committee. So that is my role and relationship to this document, and it follows nicely from the previous summary of what an alternative standard is because this document is the alternative standard which was approved last February for use clinically.

So what I'd like to do this morning is we have a broad group of Panel members, and I want to introduce everybody to what the quality control program and document is in its entirety. I want to talk about the digital mammography QC phantom, which is integral and a required element of this program, and describe to people what phantoms are. For people that are unfamiliar, I want to talk through some of the details of what the program includes, what the document includes, and then a little bit about what's forthcoming of the next steps of the ACR program.

So in February of 2016, the FDA approved this ACR quality control digital mammography manual as an alternative standard, and this allows facilities to use this new manual under MQSA, which was previously discussed. So this was a process that is relatively recent in the history of this document, but one of the important caveats is this manual only applies to FFDM systems without advanced imaging capabilities. So what's defined as advanced imaging capability is tomosynthesis or contrast-enhanced mammography or other types of imaging that's either still being developed out there, but

really what that means is it only applies to two-dimensional digital mammography, which is sort of the traditional way that the systems have been used, even though they're expanding into tomo capabilities primarily, and other. So it's just approved for 2D imaging. That's sort of the take-home message is that this manual only applies to 2D imaging, not to 3D imaging. So that's one of the distinctions we need to make of what this system or the manual is used for.

So this, the documentation or the details of what the alternative standard is, how it's defined and what its uses are, are sort of available on the FDA website. And I just wanted to highlight again that it's not used with advanced imaging capability. So it's detailed on the FDA website. So the details are there, and they're available.

So we have some highlight points of the manual. We designed this manual to be comprehensive, to include all manufacturers of digital mammography systems, all facilities. And this was one of the most challenging aspects is to be able to design a program that can accommodate everybody. That is not trivial because when you go from film to digital, things sort of exponentially increase in its complexity. I think we successfully achieved that task.

In addition to the manual, we developed a digital-specific phantom. And a phantom is a device that's used for quality control purposes, and I have some pictures and more information of what a phantom is, but it's a test object that is used to simulate some patient image properties on a machine so that you can get some standardized results and make measurements on imaging equipment, that you can use to quantitate and then compare for results purposes. So this new phantom was a major step forward in terms of being almost allowed to quantify and evaluate digital systems. I'll get to that more in a second.

And one of the elements we'll talk about is that, in digital, there are different things

that we now worry about in digital that are different than what we used to worry about in the days of screen-film. And one of the primary things that you want to monitor is artifacts which are specific to digital, not that there weren't artifacts in screen-film, but the equipment has evolved so much that there are different things that you want to monitor more closely than you do in previous generations of equipment. So the phantom is very important. So that's sort of what I'm getting at with the design element here.

So we also had to -- a lot of quality control started with the original MQSA requirements that came from the screen-film document, and so those were well understood and well entrenched in the minds of most of the mammography community. So these have been going on for decades until digital came along. When digital came along, there were a lot of legacy tests that were applied and sort of rolled into the digital mammography tests, and a lot of them are still very relevant, and some of them aren't as relevant. But this manual included the majority of those tests which are still deemed important, and some were modified and some were put elsewhere. So we did include a lot of those legacy tests for a variety of reasons.

We also surveyed all of the currently approved digital mammography manufacturers because they all had their own individual quality control programs, that when they came to market they got approval from the FDA, but they had to use their own QC manual. So now each unit had its own manual, and so that just expanded the amount of quality control products or manuals out in the field. So we had to survey all of those out there to make sure we evaluated what they do in their programs to see how they would apply to a unified program, which is what we came up with. So we did survey all of the unit manufacturers.

Now, when we say current manufacturers, that also includes x-ray unit manufacturers, film printer manufacturers, acquisition and display monitor manufacturers. So it's not just an x-ray unit anymore. It's display devices. So we had to take that whole

next layer of quality control programs because sometimes the programs are just the unit, and sometimes they're the monitors, and sometimes they're the printers. So there are multiple layers of quality control programs in the field, so we had to basically survey all of those to make sure we reviewed and included all the data and programs that are out there.

And we wanted to accommodate. So some systems have built-in quality control programs inherent in their systems, so sort of these internal calibrations or internal measurements. So we didn't want to dismiss those built-in programs that manufacturers would put in their systems to sort of self-check themselves. So we sort of have a generic way to allow those to continue and not exclude them because there are sort of decisions have to be made about, well, how do we make a unified test that applies to everybody? But then how do we also include sort of these very specific, manufacturer-specific -- because in film there was basically one type of display medium, which was a piece of film that you hang on a view box, and everybody did the same thing. But with digital you have different types of manufacturers that use different types of detectors. You have different types of display devices that have different properties in terms of luminance, in terms of pixel size. So you have a whole array of different technologies now about how a digital image is presented to the radiologist.

So we had to appreciate and include things that were going on specific to different manufacturers but also try and make it broad enough to include concepts and tests that would then just apply to everybody. So there's a balance in that. So we wanted to include those.

And we also wanted to make this program dynamic so that we could include growth. We didn't want to just have this sort of be a dead-end program that then would have to be started over in the future as things change, because we realized one of the take-home messages is watching new products get FDA approval and come on the market, you realize

that people, the manufacturers are doing things differently, and they're growing because you have different equipment and you have different technologies. You have different detector technologies, you have different display methodologies, you have different display locations of where images are read. And one of the things which is even more sort of evolutionary is image processing because now you have digital images and things can be performed on digital data that can actually improve and enhance the ability to present information to the radiologist.

So we wanted to make sure that we recognized that this is not a static sort of you're looking at a piece of film, but it's changing tremendously. So anyway, we wanted to make sure that this could grow, and we would be appreciative of the fact that this is now a moving target and that we want to be realistic.

So the final thing is we wanted this program to have a realistic way to be implemented. We wanted facilities to be able to implement this and not be overwhelmed, because when you acquire a new imaging technology in your clinic, there's a learning curve on how this is implemented for a variety of reasons, but one of the biggest impacts that you have on the staff at an imaging facility is a quality control program is mandated. And so whether it's the manufacturer program, the ACR program, we wanted to be very sensitive to the fact that people are going to have to use this, and there's lots of different opinions and feedback from all the various different programs that are out there. And so we wanted to learn from that and make this more welcomed by the mammography community.

So I have some data on the amount of facilities and units out there, but it's much larger than just, you know, what a single manufacturer has in their network. Nationally, there's a much larger user base.

So this is just a photograph of the manual that finally got published after it was approved. So it finally got published on July 29. So now there's actually a PDF document.

Previously the ACR would do hard copy manuals that would get distributed, and now we have tried to cut the tie of the paper product and move into the electronic age. After all, this is digital mammography. And so we provide a digital way for facilities to get this document. And so this document was put online, and I think it was distributed to all ACR-accredited facilities to make available, to make them aware, to say here's the alternative standard; this is something that we invite you to participate. The details are still forthcoming about how actually the nuts and bolts of transitioning to this program, but that's something the ACR is working on because it's a lot of paperwork, it's a lot of processing of documents that they're still lining up. So I'm not going to talk about that today. We're going to talk about the contents.

So the committee that worked on this document, we were very careful and specific about getting representatives from all different backgrounds. So we have probably a dozen and a half, two dozen committee members that have been on the committee, and they range from physicists to physicians, radiologists, to radiological technologists that specialize in mammography. So we've had a handful. We've got participants from NEMA or MITA, so the manufacturers have representation on the committee. We have phantom manufacturers, and we've got ACR staff, of course.

So we really wanted to make sure that we had everybody at the table throughout the process so there would be a two-way relationship. There would be communication and input from each group, and then there would also be a way to -- when we needed to query information from those groups, we have an avenue to get that information. So it was as diverse a group as we could put together.

So currently, or not so current in this slide, at least, you can see that there's still an increase in units, an increase in mammography facilities. So last year it looks like we had about 12,000 digital units out in the field, and it's probably closer to 13,000-plus right now.

And we have in the high 8,000s numbers of facilities. So that's the accredited landscape. So there's 8,000-plus facilities, about 13,000 mammo units, and then it was stated that there's about 250 film units. So the film units are on the way out; they're on the decline. And there's about 3-, 4,000 thousand digital tomo units out there. So these are the units that are starting to come online and transitioning to tomo. So we'll get to that later.

But the point here is that this is a relatively large number of facilities that the ACR, with this alternative standard, is really starting from scratch to have to implement an accreditation program. So this is a huge number of units and facilities.

Now, one of the things that is not on this slide is the estimated number of radiological techs that are at these facilities, and I think unofficially, there was assumed maybe three techs per facility work there. So there are 24,000-plus techs that also know the previous screen-film quality control program. So we wanted to really embrace the knowledgebase of those 24,000 people that will be using this program because really the technologists are the ones that interact mostly with this program on a day-to-day basis. The physicists and radiologists are sort of secondary in terms of their interaction. So the technologist is our most important person on the ground when it comes to QC. So that's just sort of the scale of what we're trying to work with in terms of numbers.

So here's the latest unreadable picture of how many current FDA-approved units are out there, and I think there was something in the high 30s of units that are out there that have been FDA approved for clinical use. So they started at one in 2000, and now there are 30-plus right now. So that's how many QC manuals are out there. And then on top of that, there are versions within that group of QC programs. So there's probably three, four, five, six times as many QC manual versions out there that are floating. So that's just something to keep in mind.

So what's our purpose with quality control? And when we go to meetings and we

talk to various stakeholders in the quality control program, there are always different opinions and different interpretations of what quality control is. And so we had sort of to define that for the scope of this project. And so one of the things I like to sort of start out with is what are we trying to do with the quality control program in mammography facilities? So one of the things is we want to reduce radiation exposure to patients and personnel, so safety. So that's number one. Number two is we want to ensure adequate and consistent image quality. So those are sort of two tenets, at least in the field of radiology, that everybody in sort of a different form will speak to, is radiation dose reduction, patient and staff radiation exposure, so safety and then image quality. So quality and safety, the two things that we start off with.

And then with a quality control program, we want to have ways to document the program as you go along. So you want to detect and correct for potential problems before they impact quality and safety. One of the ways we developed this is so that the way you keep your records and make measurements, you can hopefully preempt a problem that you see coming that could have an impact. You want to catch it before it happens. So that's the point of doing the documentation and the tests themselves.

And so what it's not -- so it sounds simple enough, right? You'd say, well, how hard is that? But what it's not is a detailed technical evaluation of units. So depending on who is involved in the discussion, you have different opinions on how detailed you want to track safety and image quality because you can draw the bar as high as you want to go or as low as you want to go. That's where we get the advice of all the stakeholders and we get the FDA's input on this. And so that's where you come to a consensus of where do you start to draw realistic lines in the sand about what you can and can't monitor. But at physics meetings, that's always a very exciting discussion because everybody has different opinions on how detailed you can analyze and document and describe a unit. And then you'd say,

well, what's the actual clinical tradeoff for getting that information? And then what's the expense in terms of man-hours and phantom costs and to get to that data? So there are tradeoffs about cost-benefit.

And this is so what our QC program is: It's not a detailed technical evaluation of a unit, and it's not a detailed measure of the limits of a unit because units perform differently and they will all have different properties. In digital there are more sort of finite limits on a lot of equipment just because of the nature of what digital and digital imaging is. So they sort of have stopping points of how far you can go, of how small things you can see, and so they're a little bit more precise, whereas in film, in analog, things were really dependent on film processing. It sort of has a different way you'd want to measure that versus in digital. So it's not a detailed technical evaluation, it's not a detailed measure of the extreme limits of a system, and it's also not an optimization of a unit.

So a lot of the work that physicists do, and researchers and manufacturers, is they figure out how to optimize their unit for clinical use. Well, that's a different task than quality control. But everybody sort of, you know, at some level, thinks that those items should infiltrate a quality control program. And so we kind of approached some of that indirectly, but it's not a direct optimization, let's try and do that. That's a different project that physicists and manufacturers sort of can work on and do separately.

So we had three goals. We wanted to standardize all the QC tests for all the manufacturers. So we wanted to make this applicable to everybody, and we wanted to standardize the test frequencies, and we wanted to standardize performance criteria. So this model kind of came from the screen-film model, but we wanted to translate that, because as soon as we had different manufacturers and different quality control programs, they had different everything. So then it became very confusing for the users if they have different manufacturers in the same facility because then they'd have different programs

and different tests and different frequencies. So we wanted to standardize everything for everybody. So that was our goal, is to do that.

So these tests came from -- and I mentioned this earlier. We surveyed everything out there. We surveyed the MQSA requirements, number one. We looked at the screen-film program. We looked at the ACRIN DMIST QC program that that study put together and what they did, and we read their conclusions, and we incorporate a lot of those results. We looked at the manufacturer programs. We looked at the MITA or NEMA manufacturer programs. We looked at the European and other international QC programs because other countries do things differently. And then we wanted to make sure we included the clinical experience because that's one of the feedbacks we got from a lot of users of quality control programs is that you could anecdotally hear their comments on the usability and the value of QC programs. So we listened to that, including on the committee but also including outside the committee because there are gems of information that come from people that don't necessarily come from organizations or QC programs. So we did not eliminate the human element to this.

We want to make sure it's clinically relevant. We didn't want to diverge away from turning this into some sort of science project. We wanted to keep it clinical so that people could intuitively understand what they're doing, both the tech, the physicist, and radiologist, because we wanted to make sure it could be understood.

We wanted to make it be friendly because the technologists use this most of the time. And so if they don't understand it or if they don't like it, they're not going to want to do it, and then you have problems. So we have to make it approachable.

We wanted to eliminate all the nonproductive tests that have sort of either come from the legacy tests from previous iterations of QC programs or manuals, and we wanted to get rid of them or move them to a different frequency or put them into some

troubleshooting categories. But we want to make sure that what people did had value. So that was very important to us, and we didn't want to just be testing things just because you can. There are a lot of opinions out there about what's valuable and what's not valuable, but that was why we had the committee to decide, as a group, of what is valuable and what's not valuable and eliminate things that weren't. There are a lot of things. You know, we're changing from screen-film, which was a completely different technology, to digital. And even as you kind of turn around the corner and you see what's coming next, you realize that a lot of these tests, just because they were designed for equipment that was 30, 40, 50 years old, so the tests that they were measuring for things nowadays are not a problem. So we had to be mindful of that. And so that's what our scope of the project was.

In the manual itself, we have three primary sections. We've got a radiologist's section, technologist's, and physicist's section, with some appendices at the back. So we have a section for each stakeholder in the quality control process. So each of these three people groups have roles within the process, so each of them have a giant chapter with their QC elements.

One of the things that we removed out of this project, this manual, which was -- sort of lived in the previous generation of the ACR QC manual was a clinical image quality section, which was the section that talked about positioning, compression, image quality. And this we decided to pull out of this quality control program, and it would be put somewhere else within the ACR purview because -- well, a couple reasons. One is other quality control programs for ACR for MRI, CT, ultrasound, they don't have sort of clinical image quality sections like the previous version of the mammography manual. So we thought that we wanted to be consistent with those programs, and we thought that this document would be better served with a committee that was probably more focused on clinical image quality and could put out a tighter, cleaner document on that when that was

ready to be put forth. So we just pulled that out and parked it on the side. That document is separate from this, just straight quality control.

So this is a photograph of the actual new ACR digital mammography phantom. So basically, for those that are unfamiliar with the word "phantom" that I'm throwing around casually, is basically it is, in this case, phantoms are used to sort of replicate and allow people to test imaging equipment with fixed test objects so that you can measure them in a reproducible manner and try and make quantitative and subjective measurements from the test object.

So in this case, for mammography, it's a piece of acrylic. It's about 4 cm thick, and in this case, it's a rectangular shape that's virtually almost the size of most detectors of a mammography unit, and in the middle there's a pink, about a half centimeter, 1 cm thick piece of wax that contains very small test objects that simulate objects of interest for mammography. So for CT and MR, they look at different types of test objects, but these are mammo-specific. And then in the middle, there's a little tiny circle, which is difficult to see on this projector, but it's used for a contrast measurement, much like optical density differences in film to look at inside and outside to look at contrast.

So this is a comparison of the new phantom on the left. It's much bigger. The old phantom for screen-film was small and square. This is much larger and covers the entire detector, and there are several reasons for that. But going back to one of the caveats for this program is that we have to -- if people are going to adopt the alternative standard for the manual, they also have to get this larger phantom because they go hand in hand, to use the new phantom with the new manual. So that's sort of a requirement that facilities use. And this is one of the forward steps that we're relatively happy about because this phantom provides much more information to evaluate an imaging system, just by the sheer size and some of the other things we did to the phantom to allow us to evaluate the imaging system

itself. And it seems obvious because it's bigger and it covers most of the detector size, but the majority of failures in digital mammography -- or not even failures, but there's a lot of artifact introduction with digital imaging systems that are still present, even though it's different than screen-film where they have their own set of artifacts.

So this is important both from a day-to-day operator use, because you can see your entire imaging area, and it's also important for accreditation because when facilities send in their images for accreditation, the reviewers get to see the entire detector. So it's not that they just see a little snapshot of the smaller size of the old screen-film. So it's important both for the facility and for accreditation. So it's kind of a two-for-one.

This is a digital mammo system, and this is a picture of the phantom placed on the imaging plate, and there's a paddle on top of it, and you can see it basically covers the majority of the detector. So this is what the setup is for acquiring a phantom image to do quality control evaluation.

So to summarize some of the design principles, we did base it on the old screen-film phantom because one of the requirements from MQSA is they have a dose requirement, and the dose requirement is written for the property, imaging properties of the small phantom. So we took that, and we maintained the dose properties on the new phantom so they're equivalent so you can -- we did not have to modify the dose requirement, and that's a pretty standardized requirement about a dose, radiation dose to the patient, but it's radiation dose to the phantom. So that can be used for either phantom.

We also wanted to base this on the 8,000-plus facilities and 25,000-plus techs. So now you can see that they're starting to use this phantom, so the users are now going to have to switch phantoms, and so we want to make this approachable.

The phantom could also be used on screen-film units. So it's not like this is digital only. It can go in both directions because of the dose properties. It's got similar thickness

and similar dimensions in one direction and also permits testing of the dose limit. One of the important things that we've changed from the previous evaluation methodology of this phantom, which is what technologists and physicists used to say: Is the image quality adequate, and is the radiation dose adequate?

There was a different way to document artifacts. So without getting into the old way of how you would document artifacts, what we have done is we've added a way for facilities and reviewers to fail for an artifact. So in the previous methodology, you would not be failing for an artifact; you would have to score things indirectly and write comments on artifacts. But now you can flat out say this unit should fail. There are artifacts that are -- and we define that as clinically significant. So artifacts, we don't necessarily have to identify them immediately, but if you see artifacts that affect the clinical image, you can say this fails and that needs to get fixed. This doesn't happen very often, but we give the power to the tech or the physicist or the physician to say we stop imaging until this gets fixed. That's a new thing.

We also changed the test object sizes within the phantom because we basically took the sizes a step or two smaller because some of the old phantoms, you could see all the test objects on the digital unit, so we wanted to make it have smaller gradations so you could get a better assessment of image quality and see finer detail. So there's different scoring. It's not important to this group at this point, but there's different scoring for pass/fail rates; that's important to the users.

So this is an image of what the new digital mammography phantom looks like on a 2D image, and what you'll notice is it's basically a large rectangle. You'll see a dark gray circle in the middle, which is where the signal-to-noise and contrast-to-noise measurements are made to basically look at contrast differences. So this is where you can quantify with using some signal values from the detector itself to say, well, what's the signal inside versus

the signal outside, and is it adequate? It's similar to with film. You'd say what's the optical density inside the little disk and outside? So you make sure you have good contrast. It's a contrast measurement. And then the small rectangle is the wax insert, and there are test objects across there. And I think I have the next slide.

So this is what it looks like when you just image the wax insert itself. You can see test objects across the top. There are six fibers, six speck groups, and six mass groups. So instead of putting them in a circuitous square, we stretch them out into a rectangle so that they're linear. And so this is sort of what the -- the users will look at this and score their images. And this is where the training of the 25,000 techs will come into play because they know how to score, and they will recognize these test objects, and they will know what to do, and they will know when something doesn't look right.

So one thing we did was we improved the manufacturing process of the phantom. We are now requiring that phantom manufacturers get approval by the ACR to manufacture phantoms, and they have to meet specifications on how these phantoms are made, and so we have very tight tolerances on everything so that phantoms from site to facility to facility should match. So there's no longer sort of this variability in manufacturing on phantoms. In this example, we are using glass microspheres for the speck groups so that they should be very well monitored and how they're manufactured.

So this is our new pass/fail criteria, so on the phantom. So as you can see, across the top there are fibers to simulate fibrous morphology. And so a passing score for the new phantom is two, and the previous phantom, it was four. But that size of test object is identical. So this is why you can use it on the screen-film or on a digital.

The speck groups, the passing score is three speck groups, and that equals three specks on a screen-film.

And then our passing score on this is two mass groups, which is the same as three.

Two here is three on the screen-film.

And then we go to -- on the far right we go to one or two smaller gradations so that as technology improves we'll have more information available to measure if things in the future get -- which they will -- are more able to visualize the smaller test objects.

So that is the phantom. One of the things we did to sort of make the phantom even more useful was if you compare the phantom on the right, that's the old screen-film phantom, and you can see there's sort of a bright white box around the wax insert. So you have a big contrast difference between the wax and the Plexiglas on the outside. So what that did was it didn't allow a user to look at a single image to evaluate for test scores and evaluate for artifacts. So what we did was we introduced a few design elements so that on the left, on the new phantom you could window and level or optimize for the test objects but also optimize for the artifacts. So the user could just say, well, here, let's make the image as clinically presentable as we can, and then we can evaluate everything, test objects and artifacts. We got rid of that image processing issue that's happening on the phantom on the right. It's now nonexistent on the left. So it's a much better design.

So this is just an unreadable slide about our design details, but you can see that we've got some pretty tight specifications. There are tolerances on every single measured piece within the systems. We are very prescriptive about where test objects are located, how they're positioned, what the thicknesses are. So we're very prescriptive on this because one of the weaknesses of the previous generation was just the variability within phantoms and phantom manufacturers. So we tried to eliminate that altogether. And then we have a process where manufacturers have a formal way to approach the ACR for approval to be able to manufacture and market their phantoms, where these are evaluated against some gold standard phantoms and against the specifications to make sure that they're manufactured properly. So we're hoping that that alone will help some of the

consistency for phantoms.

Another slide that shows some of the tolerance levels we have on all the different test objects and the comparison from the old and the new phantom. It's not important to go into details, but these are just some of the documents that go out to manufacturers about how to make the phantoms.

So to summarize the phantom. So the benefits of the new phantom is it covers the entire detector. So it seems obvious, but it's important.

When you window and level to optimize for the test objects, you also optimize your artifacts. So this benefits not only the technologists, because that's one of the questions you get with other versions, generations of QC manuals. Well, what do I do? There are a lot of questions about what do I do, what do I do? So this is an example of an intuitive way to evaluate a system is that you're allowed to use your system and optimize the system and then you evaluate your system. So we don't give all of these little details about how to do all of these little micro-settings and then evaluate. We say let's use it like you would clinically and then evaluate it. So that hopefully is intuitive, and we get a lot of people that have this big sigh of relief because they're like, oh, well, that make sense; finally, something makes sense.

So we have finer gradations of test objects as we go smaller. The dose limits are the same. We meet the MQSA, which is very important. This also provides for a single image exposure for evaluation, and we don't have to take multiple images, do it different ways. We can do this both for quality control or for daily, weekly, monthly. We can also use this for accreditation submission. It can be used for MQSA inspectors so they can evaluate together. And minimal training. So that's one of the questions as we were evolving this is what's it going to cost, and how much time is it going to take? Those are sort of the two questions you get from facilities. They say, well, what's it going to -- how is it going to

affect me? So minimal training or at least training that they can start off with some recognition.

This phantom also provides the basis for a monitor and printer QC or display QC, which is a whole other generation of technology past screen-film. And then also physics reviewers, physicists who review these phantoms for accreditation can also -- they can score it, and they can look for artifacts, and they don't have to worry about window width and window level settings. So they can use it clinically.

So the phantom approval process. The phantoms can be manufactured by any manufacturer that wishes to sort of get approval from the ACR. The ACR will provide them with all the specifications about what they need to do. The approval process includes that the manufacturer submits two phantoms to the ACR, and then a physicist will test against tolerances and performance criteria and then provide either an approval letter or feedback of why they didn't meet the specifications. So this is actually a very good process in and by itself.

And so far there are two manufacturers approved to date. CIRS and Gammex are both approved to sell phantoms, and they can and do today.

So here's another unreadable slide, but I want to just go through and summarize the two sets of tests because this is really sort of the nuts and bolts of the program. Starting with the technologist test, we have a list of tests that you can't read on the slide. We have a set of management forms. We have a set of tests for mobile systems because there are more and more mobile mammography out there. And then we have a list of equipment at the bottom. So this is sort of a summary page that sort of lists the tests.

So for the technologist, they have the ACR phantom test, and they do that once a week. So in our summary chart here, we have the tests on the left, and we have the frequency in the middle, and then on the right we have sort of a summary of what the

corrective action is. So these are the tests that technologists actually perform in a facility, on a unit, and it tells the tech how often they have to do it and what to do if there's a failure. So this is just sort of a summary table.

And then for the management forms, we've taken the next step, and we have provided some ways to help document situations. So these days there's a lot of different combinations of how mammography facilities operate, and what that means is that there are networks now, and there are systems now. So you have x-ray units and display devices and printers and PACS systems, and they all are not all under the same roof. So we are providing facilities a way to document that so that a facility understands how and where their quality control is being performed and how and where to monitor that quality control, because their quality control has to be reviewed internally, and it has to be reviewed by physicists, and then, of course, they get MQSA inspectors come through once a year. And so the inspectors follow the units, but they also follow workstations and printers and display devices. So then it just goes into this complex web, but what we've done is we've provided a way for facilities to document this. So we'll get into that in a sec.

So one of the things that is somewhat -- and I'm not going to get into too much detail here, but one of the things we did for the day-to-day operators of the quality control program, being the technologist and the physicist, is we've provided a set of improved forms, in other words, an improved way for them to do their documentation. So we think we've done a better job at allowing -- to lead them through a process on the same page.

So here's an example. So once a week a technologist will acquire a phantom image to evaluate the x-ray unit. So on their documentation form, at the very top they have their facility information, their map ID, which is their accreditation information. They have a descriptor of the x-ray unit, the room number, the make and the model, so that on a single form, this seems trivial, but on a single form it has all the identifying information so that if

this form needs to be reviewed by a physicist, an inspector, or to the ACR, that form can be pulled out and evaluated, and you know where it comes from. So in previous generations, sometimes this is not all there. So we tried to give basic ways to document things, so we want to improve documentation. So that's at the top of every page is sort of identifying information.

The second part of the form is sort of a data collection. So we give them a nice way to collect the data. So that's the second part.

The third part of the forms will have sort of the analysis information. So on the same form, we say write down your data, and now you can look on the same form and analyze it. So they don't have to be looking back into manuals, they don't have to look at other documents. It's all right on a single page. And then at the very bottom, they have the action limits. So then they'd say, okay, here's the results, here's how to calculate the results. Does it pass, or does it fail? And then what do I need to do, and when do I need to do it? So on a single page, we've tried to have all of that be self-standing and right there. And so that's the design objective behind our documentation.

Now, we've tried to do that on all the technologist forms and on all the physics forms because, as what you'll see here, there are different modalities within mammography now because you have x-ray units, you have display devices, you have acquisition display devices, you have film printers, you have light boxes, view boxes still. So now all of those are sort of independent players that we evaluate independent and as a system. So that was sort of -- that's as detailed as I'm going to get today. So that's as low as I'm going to go.

So here's an example of an image of an ACR phantom. So now I'm going to show a few pictures because this is about radiology, after all, and this is an example of an ACR phantom. So it's an image that has minimal artifacts. Now, what you will notice is there's a little tiny black dot in the lower left-hand corner of the wax insert, and that's an air bubble.

So that's supposed to be there. But this image is supposed to be an example of what a nice, clean, artifact-free image is, and that's one of the tests, that the technologist will acquire this image once a week and they'll look at it. So we don't want to have machines doing calculations on this completely. Now, that's fine if we get to some electronic automated analysis, and there's discussion about that elsewhere but not in this program, but we want the technologist to look at the image because you get a feel of how your system is performing by looking at the image. You see more than what computers can analyze.

So they look at this, and they'd say okay, great, I can see my test objects. I score them, which we won't get into, and there are no artifacts. So then you'd say here's an example of -- and it's difficult to see, these are not the best viewing conditions, but you can start to see how images can have artifacts introduced from various reasons. And I'm not going to go into detail as to what they are, but you can see, in this example, there are some very fine vertical lines, and then there are some horizontal white lines across the bottom, and then you can see that there are some image processing issues going around the white box. But this is where you start to say, okay, here are some examples of some artifacts.

Here's another example of a non-perfect phantom image. You can just see how sort of textury it is and blotchy it is in the background. So I just have a few examples of some artifacts just to kind of show. Now, these don't happen every day, but they do happen, and you can start to see some artifacts on -- here's a readout line dropout artifact. Now, this is on a long-ago generation digital unit. You don't see quite as dramatic as this anymore, but these are just examples of things, over the years, that has happened in the clinical setting, and this is what you want to look for.

So this is an example of another major artifact, but if your phantom doesn't catch that line that's creeping across and bisecting that image, then you're not going to see that artifact, potentially. So that's another reason why we wanted the phantom to be the entire

field of view because then you might miss something like that.

This is an example of some thickness or some -- the thickness equalization algorithm around the edge of the breast. You can see how jagged it is, and it's just not uniform. And so you start to see that there is some edge. So this is image processing software. So now you have another element which is different than film processing because a film processor is just chemicals and a film processor. But now you have what a computer can introduce. It's not just a detector or a monitor, but now you have what's happening to a digital image.

So one of the things that I forgot to mention is that when we do our quality control using this phantom, we want the facility to acquire the image in a clinical -- using a clinical technique, not some special phantom technique or some special way that vendors put things into sort of a phantom or a testing mode. We want them to use it like you would a patient because we want to catch problems like this as you would doing a patient. So we really want them to use -- test the system clinically like they use it clinically and not putting in these special modes which sometimes can be easier for a technologist or a physicist to kick into testing mode. And service does this a lot. They'll put it in the testing mode, and they test certain subcomponents, and they say, yes, yes, yes. But this really catches the entire image processing chain.

Here's an example of some ghosting artifacts. And so you can see these lines that are sort of left over from residual over-imaging, and a lot of these artifact examples, I sort of -- I help enhance them so we can see them. So they're usually much more subtle in the clinical setting.

And then here is an example of some sort of zebra striping in a very non-uniform way, but this is an example of just things that happen. They might be unexplainable, but they are a reason to say this is a fail, and we need to get it fixed. And then oftentimes systems can be recalibrated, and they come right back into order. But this is why you want

to do this on a regular basis to just check your system.

Here's another example that happens relatively often, which is we can see a little dot that's sort of white and gray. It's usually a piece of dust or some little material that gets calibrated into the calibration file, which sort of overlays the clinical image when you create a digital image, so that will carry on throughout all of the -- it'll show up in all your clinical images as this sort of white/black reflection. So these are the things that we check. And then on an annual basis, the physicist checks this completely, all different sort of imaging setup combinations, and then the tech checks this weekly.

Here's another example of -- maybe this zooms in. No. So you can see a very dark black dot in there. So there's another something that might be invisibly sort of stuck on the detector or on the paddle or something in your imaging chain, and it can be showing up as little white dots, little black dots.

This one is very hard to see in this viewing condition, but you can see some sort of vertical lines on the edge of the detector that shows up when the collimators don't open up all the way or close all the way. And so they're very small. And this is very hard to see, but there is some banding in there for some readout lines that aren't working properly. And you can see a little better there. This image actually has -- in between those two blue arrows there are some readout lines that aren't working properly, and then there's some ghosting. In the top arrows up top, you can see that this detector -- and these are all signs of either normal use sometimes or signs of age or signs of needing to be replaced. But at least with the quality control program, they are caught and they are evaluated. So that's what we're trying to get at here.

Here's an example of collimators that just don't open up far enough, so you can see the collimator blades right at the chest wall edge.

And then here is another example of the little white dot that appears for a variety of

reasons. But these kind of little subtleties can mimic clinical information, so that's why we want to catch them in phantom environment. So you want to catch it. You really want to have as clean of a -- of what you're looking at. So you say is it clean? So that's sort of one of the objectives of this.

This is some saturation. So this is when you overexpose a detector. So very thick, dense breasts sometimes drive the unit's dose and exposures to higher levels, and then you can actually see the detector because it can't handle that high of an exposure.

But anyway, these are some examples of artifacts, just to take a break from my word slides, but that's the importance of artifact evaluation is you start to see these things that can have a clinical implication.

So one of the new tests that we've introduced that I think will be a tremendous benefit is bringing the radiologist and/or the -- and the facility manager into a quarterly quality control review. So once a quarter we're asking that the facility meets as a group, mostly the lead interpreting physician and the technologist, to discuss the results of a QA. So one of the things we've always heard is that the physicians and the radiologists don't always know what's going on with their equipment, so we said that's great; we'll bring you in and have a quarterly meeting. So what we've done is we've provided basically a meeting agenda so they can sit down and go through each item, and then the radiologist knows what's going on and how their systems are performing. So that's the objective of our QC review. We give areas for documentation and provide them ways to review everything.

We also have given documents for how facilities monitor their offsite facilities because oftentimes now monitors are not all under the same roof. So now we say here's a list of all the locations where you have images read, and then we have a way to document that the quality control is being performed at those locations so that if an MQSA inspector comes in and says, okay, we want to look at all your records, you'd say, okay, here's where

they're all read, and here are the results that the testing has been done, so that we're trying to minimize sort of sending quality control data back and forth every time there's an inspection either by the physicist or by MQSA. So we're trying to sort of simplify and provide a framework, and the advantage to that is that everybody is not reinventing the wheel when this happens, both from the facility standpoint, a physicist standpoint, and MQSA because all of these people have to be reviewing these records, and we want to try and unify that because otherwise it's reinventing the wheel every time, and that's how mistakes get made.

So I think I might be running out of time, and I think this is a good place to stop, and I thank you for your attention.

(Applause.)

DR. ROSENBERG: Actually, you're doing just fine, Dr. Berns. So thank you very much.

Time for questions or clarifications for Dr. Berns. Not a discussion, but any questions from the Panel, please.

DR. PORTIS: How many facilities are not accredited? Do we know?

DR. ROSENBERG: Zero, right?

DR. PORTIS: Zero.

(Laughter.)

DR. BERNS: Zero.

DR. BARR: Yeah, this is Helen Barr, FDA.

In order to legally operate in the United States, you have to be accredited and certified.

DR. ROSENBERG: Good, thank you.

Other questions, clarifications for Dr. Berns?

MS. URIELL: Yes. Hi, this is Diane Uriell, Industry Representative, GE Healthcare.

I believe that with this new program, it's indicated that we're trying to have equivalence from this test to what the manufacturers are doing. And so I'm curious if you could explain a little bit more about how that was determined for equivalence. And for those tests that are not in the manual, you still have to test the manufacturers, if there are some differences or additive tests. So could you expand on that a little bit more?

DR. BERNS: Sure. Well, one of the definitions of an alternative standard is that if you elect to go with an alternative standard like this new QC program, you do not have to use the manufacturer's manual anymore because it was already deemed equivalent or better than by definition of what the alternative standard is. So you do not have to do the manufacturer testing. So through the process of developing the ACR QC manual, we did go through all the manufacturers' tests, and we had discussions, both within the committee and with manufacturers about the merits of the tests that we were going to modify, eliminate, add, and that's how we came to the conclusion of the tests we did include. I don't know if that answers your question, but --

MS. URIELL: Yeah, that's helpful. Thank you.

DR. BERNS: Okay.

DR. TORRENTE: Dr. Torrente, breast imager.

As far as rolling this out to facilities, it's going to be a requirement that facilities use it or -- I mean, you know, how is it going to --

DR. BERNS: Right now, it's an alternative standard; it's elective. So a facility can choose to adopt this manual, and then the ACR is in the process of working the paperwork out to sort of roll that out, to perform training, and then there's going to be a process where before you adopt the alternative standard -- and this isn't in writing yet, but they're looking at having the physicists do initial testing using the new program before a facility can

use the QC program on that unit. So there will be sort of steps to get there, but it will be elective, and then if there are various discussions about, you know, whether manufacturers are going to either use or support or not support that manual.

DR. BARKE: This is Lora Barke, breast imager.

I just wanted to clarify for those non-imagers in the room, you mentioned that this QC manual is related to 2D mammography and not digital breast tomosynthesis. So to clarify, the approximately 3,700 machines that are out there are not completely eliminated from this testing because those machines also perform 2D mammography as well as digital breast tomosynthesis. Can you just comment on that?

DR. BERNS: Yes. I think the short answer is that if you have a 3D tomo unit that has not yet switched to 3D use, so you're only using it for 2D, you can use the alternative standard. If it has the ability to do 3D and you're using it clinically but you're also doing 2D and 3D, you cannot use the 2D manual. You have to use the manufacturer's manual still. So if there's any 3D imaging going on with the unit, you have to do the manufacturer's QC at this point.

DR. LEE-FRENCH: This is Carol Lee.

Does that also pertain to contrast? If you have a unit that does 2D but then occasionally does contrast, you have to use the manufacturer's QC? Okay.

DR. BERNS: Correct. A lot of these questions are exactly what the ACR is fleshing out, both in their instructions and in their FAQs, about how to handle all of these different scenarios, because it's complex. But right now, anything that does advanced imaging cannot use this manual.

DR. GOODSITT: This is Mitch Goodsitt, medical physicist.

Do you have plans to make a manual for 3D, for the tomosynthesis since we're transitioning more and more to tomosynthesis, and it's been shown to be very effective and

more effective than mammography?

DR. BERNS: The short answer is yes, there is -- we're taking the approach of writing, for lack of a better term, an appendix to handle the tomo measurements because right now, just like everything, it's complex because some of these systems do 2D, some do 3D, some do a combination of both, and some units are used with 2D and 3D imaging. So we're trying to devise the documentation so that it can be used either independently for 3D testing or 2D and 3D. So the answer is yes, we're working on that. We're going to go through the same process where we get the manufacturers involved and the FDA involved with how we write and devise the tests and the phantom and the plans, and then we will go through the same approval process that the FDA will approve them.

DR. GOODSITT: This is Mitch Goodsitt again.

Have you tested this phantom with tomosynthesis? Does the phantom work well?

DR. BERNS: We have tested it. We have come up with ways to use it to do some tomo measurements because one of the things you want to do is use the current digital phantom and not have to have a tomo-specific phantom, but use the phantom and use some tricks with some additional physics test equipment for the physicists, and then maybe some ways that the technologists can use it so we don't incur another cost of a special tomo phantom. So that's where we're going with the tomo program.

DR. GOODSITT: Can I ask one more question?

DR. BERNS: Sure.

DR. GOODSITT: You showed an image of a jagged edge --

DR. BERNS: Uh-huh.

DR. GOODSITT: -- due to equalization. I don't see how a uniform phantom can find a jagged edge. It seems like you need an edge, you need a phantom that's more similar to a real breast to show problems with equalization.

DR. BERNS: Yeah, that is true. And the phantom is not perfect, and we cannot test absolutely everything, but the majority of things that we felt should be tested are tested in that system. Now, we do have some straight edges within the phantom, with the wax insert that sits recessed in there. So there are some straight edges. So if there are some things that could happen there, we might pick that up. And the phantom doesn't go all the way back to the chest wall edge. It still pulls forward a little bit, so there is an edge that you'll see that will drop off the air. So those are just some of the decisions we had to make with designing a phantom.

One of the things that we were challenged with is if you could design a phantom to do everything, then it would cost more than the unit itself. So we had to sort of have some design limits, because otherwise if we had a phantom that cost X amount of dollars, nobody would adopt it because they'd say we can't afford a phantom. So we had to make it -- we had to take those into consideration.

DR. GOODSITT: Thank you.

MS. URIELL: Hi, this is Diane Uriell again.

I have a follow-on question. What is the timeline that is being worked on for the 3D portion?

DR. BERNS: Well, that's one of the things I'm probably not allowed to give a solid date, but I know that we're very close to finishing the internal draft. That draft will then circulate through the manufacturers to get their input and then go through some sort of preliminary review at the FDA and their group and then come back to the committee. So it's closer than not, how about that?

DR. PORTIS: Natalie Compagni Portis again.

I just wanted to clarify something that was said before. So this would be elective, and if that's true, how would consumers know if a facility has elected to use these

standards and go through these tests or not?

DR. BARR: Helen Barr, FDA.

You could ask a facility what QC manual it uses. These tests have to be done regardless of whether you use the ACR manual or whether you use the manufacturer's manual. You still have to go through QC testing. Right now the standard is -- before we approved the alternative, the standard was that you had to follow the manufacturer's QC manual, which has these tests and sometimes other tests. Now you can choose to follow the ACR manual or the manufacturer's QC manual, but the QC tests still have to be done. I'm not sure. Maybe you could comment more. I don't understand. How would it be relevant to a consumer? I mean, the QC tests have to be done anyway. I'm not sure of its relevance, of which one a facility follows.

DR. PORTIS: I guess my question has to do with -- the idea is to standardize this so we know that all facilities are doing the same thing the same way and having the same procedures to check their quality control, and if it's elective and it is variable -- no. Dr. French is saying no.

DR. LEE-FRENCH: They're equivalent. This is Carol Lee.

The QC tests are equivalent, no matter which one you use. And so by saying elective, it doesn't mean that a facility can choose to do it or not. They have to do one or the other, and they are judged to be equivalent in their efficacy in judging image quality.

DR. BARR: This is Helen Barr.

Yeah, we wouldn't have approved it if we didn't think it was equivalent, at least as good as the manufacturer QC manuals.

DR. PORTIS: Great. And one other question. So on a later slide, Dr. Berns, you mentioned that you're developing training for techs, and what's the timeline on that to know about the continuing education and training of the techs?

DR. BERNS: So the short answer is that the ACR is developing, as we speak, different training modules specifically for how to implement for the techs, whether that's in-person training or webinar training or online training. So there will be different methods of access for that kind of training. I don't know -- and that's what the triage -- how the ACR will be doing any other requirements. I don't think there are any sort of requirements coming, but they can be offering training in different formats.

DR. PORTIS: So right now, just so I understand, it's not required that there's any continuing ed?

DR. BARR: This doesn't refer to --

DR. ROSENBERG: That's unrelated. Yeah.

DR. BERNS: Yeah.

DR. ROSENBERG: Thank you very much.

DR. BARR: Thank you. This is Helen Barr, FDA.

Remember that these are clarifying questions on the presentation itself. Thank you.

DR. ROSENBERG: Dr. Barr, anything else to add?

(Off microphone response.)

DR. ROSENBERG: Anything else from the Committee?

Thank you. Oh.

DR. GEISER: Yeah. This is Bill Geiser, medical physicist.

I know that there are also states that are out there that are considered accrediting bodies: Iowa, Arkansas, and Texas. Are they going to be able to rewrite their regulations to go and use the new ACR accreditation program and the phantom? So, you know, if people want to adopt this program but they still want the state to be their accrediting body, will they be able to do that?

DR. BARR: This is Helen Barr, FDA.

Any facility can elect to use this, whether they're accredited by ACR or not. Whether the state accreditation bodies are going to accept that or not, we haven't gotten that far. But a facility, even in a state, has a choice of whether it wants the state to accredit it or ACR to accredit it.

DR. TORRENTE: So not to belabor the point about elective versus whatever, I'm assuming that the ACR took on this project and believes that it's going to have some benefit or else you wouldn't have undertaken something, I assume, of this magnitude. So from the facility point of view, what would you say might be some of the benefits, you know, of having a facility undertake this, I mean, what I'm assuming to be a fairly major change with retraining and stuff?

DR. BERNS: So the benefit would be that it will standardize their tests across the facility. It will unify their documentation process. It will unify the personnel training on how they do their quality control testing, and it simplifies their documentation requirements for maintaining one program versus multiple programs for different units. It will facilitate a more unified evaluation experience by MQSA inspectors because they can look at one thing instead of multiple things. And then from a technical standpoint, we think that there's an improved phantom that gives you probably better -- it gives you equivalent or better results than the previous phantom.

DR. TORRENTE: Thank you. Yeah, I agree, it looks better. I hope that that's translated to facilities so that they will want to adopt the process.

DR. ROSENBERG: I assume that if a facility has more than one machine, then they would have more than one quality assurance program for each machine they would currently have to follow, and that part of the advantage would be that there's now one process for every machine.

DR. BERNS: Correct.

DR. ROSENBERG: Anything further?

(No response.)

DR. ROSENBERG: All right. We are on time.

Dr. Berns, thank you very much. And thank you, actually, to your committee. It's very, very important that we appreciate that.

DR. BERNS: Thank you.

DR. ROSENBERG: We will now take a 15-minute break. Panel members, please do not discuss the meeting topic during the break amongst yourselves or with any member of the audience. And we'll resume at 10:25. Thank you very much. 10:30.

(Off the record at 10:08 a.m.)

(On the record at 10:30 a.m.)

DR. ROSENBERG: I thank everybody. It's now 10:30, and I'd like to call the meeting back to order. Dr. Berns had one clarification before we move on to the next topic.

DR. BERNS: So I just had one clarification that I wanted to point out, which was that the ACR QC manual does include any reference times within the program, that they may reference manufacturer's calibrations that might be built in, that are manufacturer specific. So we did not want to exclude valuable quality control tests that were sort of manufacturer specific, which are more calibrations than they are tests. So those, I think, will be one of the FAQ points that the ACR will address very clearly. So there are certain tests and calibrations. You don't want to mix those up, but there will be times when you do refer to the manufacturer's materials to do certain tests, or should I say calibrations instead, which are different than tests. But anyway, there are times when you'll be referring back to the manufacturer's materials to do some calibrations or tests.

DR. ROSENBERG: Thank you, Dr. Berns.

Now Rachel Evans of the FDA will give her presentation. This will be followed by a

Committee discussion.

Ms. Evans, would you please begin?

MS. EVANS: Good morning. My name is Rachel Evans, and I am the compliance team lead for the Division of Mammography Quality Standards, and today I'm going to talk to you about some analyses that we recently did on compliance cases and inspection citations.

So in 2015 we undertook an analysis of compliance cases from 2001 to 2015. We looked at various imaging modalities. We looked at mammography facilities that had varying mammography procedure volumes. We looked at accreditation deficiencies and compliance actions. Then in 2016 we took a look at inspection citations, and we have correlated information regarding that.

So what we've learned from that analysis is that our compliance cases are coming more often from clinical image reviews than from the inspection findings. We have also found that equipment is no longer the major issue in compliance cases or in imaging problems that we note. Facilities with low volume appear to be a factor in compliance issues, and screen-film imaging also appears to be a factor in compliance imaging. But more importantly, positioning has become the Achilles heel of image quality.

This slide shows that when we look at additional mammography reviews -- and for those of you who don't know what an additional mammography review is, whenever FDA or an accreditation body believes that the clinical image quality at a facility poses a serious risk to human health, we take a sample of the clinical images from a facility and analyze them for clinical image quality, and that's what an additional mammography review actually is. But we see that in 46% of the additional mammography reviews performed between 2009 and 2015, image quality was the primary reason for deficiencies that were noted. Twenty-eight percent of those AMRs noted deficiencies for other reasons, and those other reasons

include things such as compression and --

(Off microphone comment.)

MS. EVANS: Yeah, so other clinical image quality factors other than positioning. I'm sorry. All of a sudden I just drew a blank. And then only 26% of the additional mammography reviews are the direct result of inspection findings, and those types of things might be a facility that has large gaps in their quality control program where they fail to perform required QC tests and therefore had no indication as to whether or not the clinical image quality was intact.

We also took a look at facilities that have had accreditation deficiencies that were noted during their first attempt at accreditation. And during 2015 we see that 74% of those initial accreditation deficiencies are the direct result of positioning issues, 19% come from other clinical issues, 6% come from a phantom image quality problem, and 1% come from dose.

So when you look at accreditation failures during 2014, 93% of the ACR unit accreditation failures were for clinical image quality issues, and of those failures, 63% were for positioning. In 2015, 84% of the ACR unit accreditation failures were for clinical image quality, and of those, 79% were for positioning. The accreditation bodies of Iowa and Texas have also seen similar clinical image quality failure rates for positioning.

This graphic shows you that when you look at the inspection data and you look at equipment violations from 1998 to 2015, you can see that initially in the program many of the violations were equipment related. But as we have moved forward, and as digital technology has been implemented, equipment violations are less of an issue than they were in the early days of the program.

So then we took a look at volume: How many mammography procedures does a facility do during a given year, an annual rate? So nationally the average number of

mammography procedures performed per year is 4,480. Of the 117 facilities that have had AMRs since 2001, we see that those facilities have a lower number, a lower average number of mammography procedures performed. Their number is 2,756. For the 35 facilities in 2001 that were ordered to perform a patient and provider notification, their average annual number of procedures was 1,852. And for those of you who may not know what a patient and provider notification is, when a facility undergoes an AMR and if that AMR determines that the clinical image quality poses a serious risk to human health, FDA or the state certifying agency may require the facility to notify patients and their referring healthcare providers of the clinical image quality concerns at that facility. So a PPN is a post follow-up to additional mammography reviews. And so of the five -- only five facilities that were ordered to perform a PPN met the national average number of procedures. So low volume does seem to have an impact on compliance action.

So of the 24 facilities that were ordered to perform a patient and provider notification in 2009, 13 of those facilities did not have any inspection findings or inspection citations during that year that the PPN was ordered. And from 2009 to 2015, 38% of PPNs involved screen-film facilities. In 2015, 33% of the PPNs involved screen-film facilities, but keep in mind that by 2015, screen-film facilities only accounted for about 3% of certified facilities. So they are represented at a significant number in all of the PPNs that we performed.

We also decided to take a look at our inspection citations and to evaluate whether or not, you know, what citations are being issued by inspectors, which ones are issued at a higher rate, lower rate. And so we saw that some questions, some inspection questions are being cited at a lower rate, and we thought about what should we do with those specific questions? Do we have a situation where we should consider removing that question from the inspection process because facilities appear to be complying with that requirement on a

regular basis? We also looked at should we elevate some questions where we see maybe a higher citation rate and to address the issue of facilities submitting responses to those violations?

So keep in mind that for any inspection question where a decision was made to remove that question from the inspection process, the regulation that supports that inspection, that underpins that inspection question remains intact and that all facilities are required to comply with all requirements of the MQSA, whether we inspect against that requirement or not. So removing an inspection question would not eliminate the need for a facility to comply with that requirement of the regulation. But if we were able to remove some of those inspection questions, we could claim some time for perhaps addressing other issues that are emerging.

So after looking at the inspection citation rates, we decided that these two questions -- is there an SOP for infection control, and are required personnel documents available -- would be removed from the inspection process.

Now, removing the question regarding SOP for infection control should not create any level of risk for the patient, given that most facilities have higher-level SOPs regarding decontamination of equipment, cleaning of equipment, and any equipment that comes in contact with patients or bodily fluids. Those higher-level procedures are routinely reviewed by state programs and other federal bodies and by private accreditation firms. And so we thought that in addressing decontamination of mammography equipment, it would be fairly easy for facilities to roll those procedures into their higher-level procedures and to also address, you know, documenting that disinfection occurred through those higher-level procedures. And so the decision was made to remove the no SOP for infection control from the inspection process. Again, keep in mind that that requirement still remains in the regulation, and the facilities must continue to comply with that.

The question regarding required personnel documents available. This question was created as a reminder to facilities to gather their personnel records prior to the inspection so that the inspector would be able to review those records in a timely manner. So if a facility did not have records present on a given inspection and by the end of the inspection the facility could not produce the personnel records, then this Level 3 citation would be issued as a reminder to the facility that next year you should prepare ahead of time. The facility always had 5 days after the date of the inspection to provide the required documentation, but the Level 3 would remain.

What we have decided to do is to remove that Level 3 violation. Facilities will still have 5 days to produce the required documentation. However, if the facility does not produce the documentation, the facility will be cited with the Level 2 violation for the appropriate missing personnel documents. And this really is no different than what was being done, what is being done at the current time. The only difference is that the facility will not have a Level 3 warning on their report if they produce the document within 5 days.

We also looked at elevating some MQSA questions from the inspection process that are currently cited at a Level 3. But because Level 3 violations are followed up during the next annual inspection, we deemed that these violations, should they repeat, they should be elevated to a Level 2, and thus, if they repeat a second time, they really should be addressed at a Level 1. So in order to do that and to have the facility submit written responses to FDA to address these noncompliances, we have elevated these citations to Level 2 citations. The facility, if they receive a Level 2 citation, they will then be required to submit a response to FDA within 30 days to address that Level 2. And if in the following year's inspection that Level 2 repeats, it becomes a Level 1 requiring a written response to FDA within 15 days.

So the questions that will be elevated to Level 2 include whether or not -- the

question is the QA program inadequate, is the compression device QC adequate, is repeat analysis QC adequate, were there corrective actions taken when called for by the medical physicist's survey report, and questions related to the medical physicist's survey report being incomplete because tests were not done adequately or were not done at all.

So those are our proposed changes to those inspection questions. Dr. Barr will give you a presentation a little later on about what we intend to do to address the clinical image quality concerns. And are there any questions?

DR. ROSENBERG: Thank you, Ms. Evans, for your presentation.

So does anyone on the Panel have any brief clarifying questions for Ms. Evans? And again, speak clearly so we get this transcribed properly.

MS. EVANS: Dr. Rosenberg, there's a question.

DR. NEWELL: Yeah. Mary Newell, breast imager.

My question would be it appears that the percentage of cases where positioning is an issue has increased, but sometimes percentages can be a little bit of a confusing issue. Is it possible that it's just that the pie of issues is getting smaller, so it appears that positioning is a more important concern than it is? Has the absolute number of cases where positioning is a problem actually increased, or it's just that there are so few other concerns that it appears to be an increasing issue?

MS. EVANS: I think what we're seeing is that there are far more AMRs where there are positioning issues.

DR. NEWELL: So the absolute number has increased or the percentage?

MS. EVANS: Both. I mean, I think we're seeing more AMRs, more PPNs at the present time, and those AMRs are showing positioning issues. Our compliance volume has gone up.

DR. NEWELL: Do you have that data that you could show us where the actual

number of AMRs, the absolute number has increased over time as a result of positioning?

MS. EVANS: I don't have that in a slide to show you today.

DR. NEWELL: Okay.

MS. EVANS: No, I don't.

DR. ROSENBERG: Yeah, because I think the question -- and those of us who are reviewers would comment that because of digital, there are some things that are already taken care of that were film-screen problems that we noted a lot -- artifacts, contrast, the optical density -- and that those are no longer a problem unless a physicist is not doing their job. And so positioning and compression remain the two that are causes that relate to the technologist and the radiologist review. I think I understand the question, and that's where it's coming from, percentage versus absolute numbers, because I think that's an important question Dr. Barr is going to bring up: Is positioning becoming more of a problem, or is it just being recognized as more of a problem?

DR. BARR: This is Helen Barr, FDA.

We concluded that either case, it certainly could be that the pie is shrinking and positioning is becoming, you know, the remaining thing that's problematic. Our view is that it's a problem whether it's the shrinking pie or increasing. You may be perfectly right, but it's existing, and the accreditation bodies can tell you -- and I've seen some of it. It's pretty astounding, so a good question. Ultimately, in our plans moving forward, I'm not sure it matters which it is. We can certainly try to piece out that data and get it to the Committee at a later time.

DR. ROSENBERG: So it's a relative problem or a relatively increasing problem, whether it's an absolute increasing problem -- yeah, okay.

Other questions?

(No response.)

DR. ROSENBERG: Time for Committee discussion on these proposed changes. Anybody have opinions on this?

DR. BARR: Yeah. This is Helen Barr.

We need to show the questions that we want discussed. Thank you.

DR. ROSENBERG: Can everybody see the questions?

MS. EVANS: Would you like me to read them? Okay, all right.

DR. ROSENBERG: Yeah, please.

MS. EVANS: So we would like to propose the following questions for discussion by the Committee:

- Does the compliance case analysis reflect what is seen in clinical practice of mammography?
- Are there any other inspection questions that could or should be eliminated from the inspection process?
- And how do you think the elimination of Level 3 violations will be received by mammography facilities?

DR. ROSENBERG: So we'll take it one question at a time from the Committee. Comments on compliance analysis and clinical practice?

(No response.)

DR. ROSENBERG: Seeing none, any other questions that the Committee thinks could be eliminated?

DR. GOODSITT: This is Mitch Goodsitt.

Do you have statistics on the questions, on how many facilities fail for each question? And maybe there are certain questions. I think you must have that to decide which ones -- facilities never fail or had 5% or something.

DR. ROSENBERG: Yeah, Ms. Evans.

MS. EVANS: I don't have that data for you here, but we did pull the data by inspection question to look at which questions were cited at what level. And, for instance, the Level 3 violation regarding personnel records not being available, that was cited at a fairly high rate during inspections. In fact, we noted that some facilities had repeat violations of that particular question. And so that's one of the reasons that we decided to eliminate that question and just cite at the Level 2. When you cite a personnel issue at a Level 2, the individual employee's name who is deficient in whatever personnel requirement is not being met appears on the report. So we're trying to encourage facilities to address and to obtain their personnel records, you know, in advance of the inspection. Personnel should be qualified when they're interpreting or performing mammography or performing surveys. So that's just one example.

DR. ROSENBERG: Dr. Barr.

DR. BARR: Oh, I can't see you. Sorry. I'm sorry. Helen Barr.

I'm only a radiologist, and I can't see.

(Laughter.)

DR. ROSENBERG: It's in color.

DR. BARR: So Dr. Goodsitt, I would actually pose a question back to you: Does that matter? So in our analysis, we took away some questions that were cited at a high rate but don't have much of a public health impact, and we can deal with other ways. Some we took away, like the SOP, which is cited at a very low rate. It seems to me, surmising from your question, that you might say that those numbers matter. If it's at a low rate, it should go. If it's at a high rate, it should stay. We have all of that. I mean, we have minutiae data on that. Do you think that that matters, the rate, and whether you would consider eliminating something? We were sort of looking for your clinical experience of using things and inspections, that you say that's just ridiculous, why do they waste my time checking that?

DR. GOODSITT: Okay, this is Mitch Goodsitt again.

This should be clarified. I'm not an M.D. Okay, first I'm a Ph.D.

DR. BARR: Well, you're still a doctor.

DR. GOODSITT: I know.

(Laughter.)

DR. GOODSITT: I think you have to weight them by the seriousness, that is, like you said, if something is very important and it has a very -- it should have a higher weighting. Even though it's not cited very frequently, it would still be important, and we shouldn't eliminate it. But something that's not very important and is almost never cited, we could eliminate.

DR. BARR: So this is Helen Barr.

So what we did is kind of make one of those foursquare things, you know, important but not cited, important but -- and looked at that. So thank you for your comment.

DR. TORRENTE: Jessica Torrente, breast imager.

So basically the personnel, I guess, failure -- the gist of it is that's being elevated as an issue, like it's going to carry a higher degree of consequences basically by eliminating the Level 3, or is it the opposite?

MS. EVANS: It still has the same level if someone is deficient and is missing the required training and for required experience and that document is not presented within 5 days of the inspection. So that was always a Level 2 violation --

DR. TORRENTE: I see.

MS. EVANS: -- and that will continue to be a Level 2 violation.

DR. TORRENTE: Okay.

DR. BARR: This is Helen Barr. I'm not very good at this. This is Helen Barr, FDA.

For full disclosure, to tell you actually why the question we're eliminating was

originally put in is our inspectors were getting sick and tired of showing up at facilities who have a year to get their stuff together -- and I said stuff just for -- to clarify, I said stuff.

DR. ROSENBERG: Stuff happens.

DR. BARR: Yeah, stuff happens. And we did that, and we're finding that facilities have kind of gotten the message. So it's not that seeing if you have a medical license and seeing if you've done your CME, and if you're a tech, if you've done your exams, are going away. That's all there, and it will be cited through that mechanism. What's going away is us dinging you for not having it ready and making me wait 5 days for you to send it to me.

DR. TORRENTE: Okay. So it's not the severity of the repercussions or whatever is changing. It's more just how -- okay, I understand.

MS. EVANS: Right. That Level 3 was there originally kind of to be a little broad to encourage you, for the next inspection, to have everything ready.

DR. TORRENTE: Right.

MS. EVANS: And, you know, most facilities are very good at that. There are some facilities who, no matter how many times you remind them, you know, on the day of the inspection, there are still records that are missing or not present.

DR. TORRENTE: Okay, thank you.

MS. EVANS: Um-hum.

DR. ROSENBERG: Further questions? Any further discussion?

(No response.)

DR. ROSENBERG: Okay. And then, yeah, elimination of Level 3 violations, how do you think the facilities would view that change?

MS. CHAUHAN: I'd like to bring up an alternative or an addition to that.

DR. ROSENBERG: Please.

MS. CHAUHAN: Cynthia Chauhan. I'm sorry.

I'm not so concerned about how they view it as that they implement it, because I think this addresses patient safety and well-being. So I think that they need to learn to view it in the best interest of patient care, to view it positively in the best interest of patient care.

DR. ROSENBERG: Yeah, thank you. I mean, it seems to me that we've actually -- we've gotten rid of the Level 1's and made many of them Level 2's. No?

DR. BARR: No. This is Helen Barr.

So what we've done is, just to reiterate, the Level 3's are the lowest --

DR. ROSENBERG: Level 3's.

DR. BARR: -- Level 1's -- levels. And what happens is that's something that, when MQSA was written, was considered so minor that we could come back next year and check it. The problem is those kind of never go anywhere, and people repeat them, and we took a look at them and we said, well, it's either important or it's not. You know, either it should go away because we don't need to be dinging people for it and coming back in a year and checking it, or it's important enough to elevate to a Level 2 where if it keeps getting repeated, there are serious consequences. And thank you for your comment. That's at least a positive way to look at something. Thank you.

DR. ROSENBERG: So we've raised the level, yeah.

DR. BARR: Um-hum.

DR. ROSENBERG: Yes, Dr. Lee.

DR. LEE-FRENCH: This is Carol Lee.

I'm sorry, I'm just a little confused. For the personnel documentation, currently, if it's not available, a facility gets a Level 3 violation, has 5 days to produce the documentation, but it doesn't get revisited until the next year's inspection?

MS. EVANS: No. Okay, so what currently happens is when the inspector comes in

for the inspection, if there are missing personnel documents, the inspector will tell the facility that you have 5 days to get that record to me. The facility will receive a Level 3 violation for not having all the records available on the day of the inspection, even if they provide the document within 5 days. What we have decided to do is to eliminate that Level 3 violation. Any missing personnel record under the current inspection or future inspections will be cited at a Level 2 if that document is not provided within 5 days.

DR. LEE-FRENCH: So currently, if a facility does not have the documentation but then -- and does not produce it within 5 days, then they at that point get a Level 2 currently?

MS. EVANS: Right.

DR. LEE-FRENCH: Okay.

MS. EVANS: They get a Level 2. A Level 2 citation will require that the facility submit a written response within 30 days to the FDA, and at the time that they submit that written response, they should include whatever personnel documentation was missing.

DR. PORTIS: So it looks like most of the -- Natalie Portis. Sorry.

So most of the deficiencies have to do with positioning, and so that looks at human error. And then there's this issue of not having the records if people are doing their CMEs. And so again, I guess my question is like my prior one, which is how does the consumer know if a facility is regularly having these kind of deficiencies and whether or not they've corrected them?

MS. EVANS: I guess, as a consumer, you would not know that directly from anything at the facility per se. Of course, the inspection reports are always available through FOI. Keep in mind that personnel issues, especially the continuing education and continuing experience, if someone is a trained interpreting physician or a trained technologist, the fact that they did not obtain, you know, 15 CME or 15 mammography education units within a

36-month period doesn't necessarily mean all of their skills go away. You know, it's an ongoing training program, and we know that the more someone interprets mammograms or the more someone practices positioning patients, usually the better they are. So there are in the regulations these minimum requirements for continuing experience or continuing ed that we enforce. But that doesn't mean that on today, if Dr. Smith doesn't have 960, he has 940, that he is an unqualified interpreter. The skills don't go away at the drop of a hat because you reach that milestone. So just keep that in mind; it's our process of trying to get people to maintain their skills.

DR. BARR: This is Helen Barr, FDA.

I'd like to at least respond to that, too. So you as a consumer would know because if the positioning issues are so severe -- and that's not an inspection issue. That's from looking at images in one of a number of ways, which I'll talk a little more about later. If they were so severe, we would take that facility's certificate away, they would be shut down, and they would be sending you a notification that we said they have imaging problems and they need to fix them. As Rachel said, it doesn't mean all the knowledge of a technologist or a physician goes away. But if they don't meet those continuing requirements, then they have to stop and get requalified. You may not know that, but there are mechanisms in place that protect you in that we make them requalify under supervision and things like that.

DR. ROSENBERG: Okay, further questions?

(No response.)

DR. ROSENBERG: All right, I'd like to thank you for your presentation. We're on time. So Dr. Helen Barr of FDA will now present on the inspection enhancement program. This will be followed by Committee discussion.

Dr. Barr.

DR. BARR: I need a tutorial in advancing the slides.

DR. ROSENBERG: Is that a quality assurance or a training issue?

(Laughter.)

DR. BARR: Is this on? Can you hear me? In my case it could be either.

So, first of all, this is Helen Barr, FDA. I'm the Director of the Division of Mammography Quality Standards. I'd like to take this opportunity to thank all of you for serving on the Committee and your contribution to the work that we do. So you contribute to the public health, and we very much appreciate that. I'd like to thank Dr. Rosenberg for serving as the Chair. I've had the pleasure to see him chair other committees, and when I heard he was going to be our Chair, I was quite thrilled because he does an excellent job. I'd like to thank Commander Anderson, our Designated Federal Officer, for the yeoman's work pulling this meeting together; and all of my staff, too numerous to count. But I can guarantee you that in the MQSA program, you have people who are extremely smart and dedicated -- an exception is me; they make me look that way -- and really put their hearts and souls into this program. So thank you all for being who you are.

So I'm going to talk about -- and I think some of the -- this is sort of a carry-on to Rachel Evans's talk, so I think some things may become a little clear about where we're taking some of these issues.

And so the Mammography Quality Standards Act was signed into law on October 27th, 1992, by President George Herbert Walker Bush, and so this October 27th begins the 25th year of the existence of MQSA. It's almost hard to believe. So I wanted to talk about what have we seen in that first quarter century? What have we learned and what are the next -- how do those things inform the next steps of the 25 years going ahead?

So some of this will be a repeat of what Rachel told you, but we've seen a sharp decline in equipment issues. We've seen a decrease in dose and a rise in phantom image

scores. And, in fact, dose was so little of a problem that we actually don't check it at the time of inspection now. It's checked for accreditation, and it's checked by the medical physicist. So we're lucky that dose isn't a problem and phantom image scores have been going up as a measure of image quality. We've seen a relative decrease in breast cancer mortality. Certainly, MQSA cannot take full credit for that, but we believe it plays a role, along certainly with improved treatment, increased awareness, and a number of factors. And as you've heard, screen-film mammography is heading the way of the dinosaurs. When we wrote this slide, which has to be weeks ahead of time, it was 266. Probably Tim Haran's number is more accurate at this point. But be that as it may, there are not many units left in the United States.

You saw this slide from Rachel. That blip was when the final regulations took effect and people were getting used to it. And then you see where FFDM was approved and DBT was approved, and the point being that equipment violations are shrinking. And, you know, what's left -- actually, I had Tim Haran look at some of those. I said, well, what's left? You know, what are we seeing? And a lot of it is the medical physicist's -- I hate to ding you off -- report wasn't done within the 14 months, things like that, and not truly equipment issues.

And this is why I talk about dose and image quality. As you can see, way back when I started, I was at the -- you know, while zero mammography was fading out and screen-film was coming in. So we saw that big drop there, and then you can see the phantom image score slide. I don't know if I have a pointer or not, but you can see the phantom image score going up as the dose has rapidly come down. You can peruse this study and see the different modalities and where they stand in relation to the black line, which is all modalities. This doesn't include DBT, tomosynthesis.

So this is just some SEER data that is the point that the relative survival rate is increasing even as some -- you know, we were actually at a period where we were finding

more cancers or the incidence of breast cancer was going up, the deaths are going down. The bottom line, I don't know why it only went up to 2008, but now it seems we're about approaching 99% 5-year survival for breast cancer that is confined to the breast, and about 85% for breast cancer that is locally spread to the lymph nodes. So we've clearly made progress. Will it ever be enough? You know, we would like it to be more, but the improvement has actually been pretty dramatic.

So what else have we seen? We've seen new technologies come into play. We've seen DBT be approved by FDA. There's automated breast ultrasound, which we approved that specifically for -- the indication for use is for women with dense breasts and a negative mammogram. We recently approved a dedicated breast CT unit for diagnosing breast cancer. So we've seen new technologies. By everything that I've shown you up to date, particularly the phantom image score, and we hope part of the decreasing morbidity and mortality we've seen, we can conclude that we think image quality has certainly improved over the years.

But can it be improved even more? Can we do better? We've seen 25 years of MQSA. Where do we go from here? Wherever we go from here, it seems MQSA is what we have right now, and we should maximize its potential while people are looking at perhaps better ways to detect and diagnose breast cancer. But what we continue to see, which are some of the things we talked about, are what I call the human factors. And I think actually Dr. Rosenberg might have mentioned that. I guess I stole your thought.

So what are we seeing? We're seeing things like QC tests that aren't performed at the required frequency, that appropriate corrective actions are not taken and the effectiveness of those actions aren't assessed. Positioning we've talked about a lot, inadequate compression, physicians accepting suboptimal images for interpretation, and certainly that's subjective. Sometimes you have to -- you know, sometimes they pass the

big bucks to be able to read suboptimal images because that's what we can get for the patients that we're doing. But, you know, we do see images that we're wondering why they were ever accepted for interpretation -- lack of feedback and corrective action for poor image quality.

We've seen lately, even when we put -- and this is another thing that the accreditation bodies can help us do is put facilities under corrective action plans to correct problems. And when we reevaluate after that, we're even seeing some of those corrective action plans aren't doing a lot of good, particularly in the area of positioning. We're not sure why that is, and just some confusion about who's responsible for what and who has the ultimate responsibility.

So as Rachel Evans said, we found that -- well, as you saw, what was really sort of a surprise to us was that when we looked at facilities that were performing mammography poorly enough that they had to notify their patient population that that was the case, and we looked back at their inspections, and they were okay. So clearly there was a bit of a disconnect there. The inspection program was written heavily concentrating on equipment, when equipment was a big issue in mammography. It's one of the reasons MQSA came to be. Now we're seeing, in multiple ways we have been looking at images, that that's where most of our issues come from. And some still come from an inspection. If you don't perform your QC at the required frequencies, we'll go ahead and look at a sample of images to see if that lack of QC is translating into poor image quality or not.

So, in general, and in the beginning when the sun and the moon and the stars aligned and MQSA came to be, image quality was sort of put in the purview of the accreditation bodies. That was sort of their domain, and things like equipment and dose and QC were put in the purview of the yearly inspection, and sort of never the twain shall meet. So we said, well, what's available to us? What ways do we have currently that we

might address some of the issues we're seeing? You know, whether they're -- a very good point, whether they're because of the shrinking pie or because of a relative increase, there are still these problems that we see.

So we have the current method of accreditation where clinical images are looked at every 3 years. Facilities have to be reaccredited every 3 years, but the limitation is that's every 3 years. The accreditation bodies are required to perform random image checks on a certain percent of the facilities they accredit, but that's a small percentage. It does give us some random insight into what facilities are doing, but it's a small portion. And then we said we have the inspection program. We're in every facility every year. So is there something we can do through the inspection program that might help to improve image quality?

And we had some sort of what I'll call "aha" moments. And for those of you old enough, I'm not referring to the Norwegian or Swedish band A-ha of the '80s, was it? I don't know. So we looked at these cases we get, and we said why did 11 weeks or 3 months go by with no QC? How can that be? It's pretty clear what you have to do. Where's the oversight? Who's checking this? What's going on? And then we said, you know what? We've got regulations that address image quality that we don't inspect against, and we'll go through some of those.

And we thought, you know what? The current inspection program, besides the focus on equipment, which isn't really the problem anymore, focuses a lot on the technologist's and the physicist's responsibilities, and we said where are the interpreting physicians and in particular the lead interpreting physicians in this process? Granted, a medical audit is checked, and that's in their purview, but in other places it was kind of like, hello, where are you? And we said can we use the inspection program to improve image quality, and could we use something like the medical audit as sort of a model possibly to build on? And we

said, yes, good idea.

So what can we do? Well, we started out saying we'll teach inspectors how to measure from the nipple to the pectoralis muscle, and if that doesn't cut it, they'll have a discussion with the facility. We said, no, this isn't going to work. No, forget that. We said, okay, there are two breast imagers at FDA. We can just take images from a facility and look at them, or we can hire new radiologists, and we'll get the images at inspection and look at them. Well, that, you can imagine, was shot down. We could collect images at inspection and ship them off to the accrediting bodies, so they'd be looking at images every year instead of every 3 years, and with the volume of facilities, that seemed like a lot of burden when for most of these facilities we didn't have any evidence, if you will, that the image quality was a problem. So we kind of nixed that idea.

And then we said why don't we add inspection questions related to the imaging quality responsibilities that are outlined in the regulations? And as Dr. Berns pointed out, that the ACR has that idea, too, that you should have regular quality image review and a mechanism for feedback from physician to technologist.

So we designed a program which we lovingly named EQUIP, which is Enhancing Quality Using the Inspection Program, and the goal is to equip facilities to address image quality on a continuing basis, and as you'll say, that's what the regulations say, and emphasize the lead interpreting physician and interpreting physician's responsibilities.

So images will not be looked at during inspection because -- not that I was here in the very early days, but my colleagues who were said, you know, that's a big heyday thing of NMQAAC that we're not going to have inspectors looking at images. So we're not going to look at images, but what we're going to look at is the facility's processes for ensuring that there are mechanisms to assess image quality. That's what we're going to inspect against. And we added questions to the quality assurance part of the inspection procedure. And

let's see. And there will be violations for processes that are missing to ensure image quality.

So these are the regulations under most of the quality -- well, not most. The quality assurance regulations are under 900.12, and these are some of the regulations that we went back to: All interpreting physicians shall follow the facility's procedures for corrective action when images they are asked to interpret are of poor quality. The lead interpreting physician shall ensure that records, meaning all records, the QC tech's records, what the physicist submits, and including employee qualifications, meet the standards and are properly maintained and updated, and that clinical images produced by a facility -- and I outlined in the red, which I can see -- must continue to comply with the standard set by the accreditation body. And those of us who practice know that there's generally eight attributes of image quality which images are assessed against and are the image quality standards that the accreditation bodies use.

So we added three questions to the inspection program, and the first one says, does the facility have procedures for corrective action when clinical images are of poor quality? And there are two questions under that which have to be answered yes in order that this won't turn into a citation, and that is do the procedures include a mechanism for providing ongoing feedback on image quality to RTs or other designated personnel, and do the procedures include a mechanism for documenting any needed corrective actions and documenting the effectiveness of the corrective action? Now, it doesn't mean the inspector is going to say your corrective action wasn't effective. What you're going to do, what facilities are going to do is explain to the inspector how we provide continuing feedback on image quality and what our procedure is for documenting and assessing corrective action.

The second question is does the facility have procedures to ensure that clinical images continue to comply with the standards established by the accreditation body? And

again, there are two components to that to get a clean bill of health on this, and that is do the procedures include a mechanism for regular review of image quality attributes of a sample of mammograms performed by each active RT and accepted for interpretation by each active IP, and is there documentation of such review since the last inspection? So the inspector, again, is not going to look and say show me, you know -- well, they have the list of RTs and physicians at the facility anyway, but they're not going to say you didn't include so-and-so in your review. This is do you have a mechanism in place to, on a regular basis, do this quality assurance process?

What you will need to produce is a documentation that that review takes place. Now, such documentation could be, say, forms that are provided in a QC manual, it could be meeting minutes, it could be a signed statement from the lead interpreting physician that we do this at X frequency, and this is what we do. It could be memos to technologists, feedback forms, here's what we use to give to our techs, and things of that nature.

Now, by default, we're looking for once a year because the inspection is done once a year. In reality, we would certainly encourage that that review take place more often, and we're not talking about the -- so there's the regular review, and then there's kind of the ongoing, maybe quarterly review of a sample of images, and that's what we're looking for the documentation for. So the default would be that you've done it at least once since the last inspection, and as we said, we hope that it's more frequent than that.

And the last question is does the facility have a procedure for the lead interpreting physician oversight of the records, the QA and QC records, and corrective action? And to answer these questions, the LIP can be present at the inspection and verbally answer them. We're going to be providing an attestation that could be signed ahead of time and left with whoever is going to be there at the time of the inspection. There can be a written SOP, if one would choose, that is signed off on by the LIP and could be presented to the inspector.

And the sub-questions here are does the procedure include LIP oversight, including review of the frequency of all required tests, and the other is does the procedure include LIP review to determine whether appropriate corrective action was performed?

And again, we're not saying, LIP, you didn't review these frequently enough. We're saying, what mechanisms do you have in place to do it? Where it will come through that, here, she might be not overseeing them frequently enough is in the existing inspection questions that relate to QC missing. So if there's missing QC, that will be cited, and the inspector will say you might want to look at your procedure for overseeing this because you're missing 2 months of QC, but the actual violation for the missing QC will be the QC violations that currently exist. The additional violations would be if you didn't have any process in place to evaluate -- to carry out your responsibilities for quality control.

So how are we going to measure this? Well, as we said, we have a number of mechanisms where images are looked at, and those are the images submitted at the time of accreditation, the random image checks, a small percentage required that the ABs have to perform, and any other ways that we might look at images for missing QC, if it's a certain amount of time we look at images.

So we would look to see is there less of a need to do that? Right now we seem to be inundated with reasons to look at clinical image quality, and perhaps that will go down if we raise awareness and inspect against some things that could improve image quality. When we do look at images, are there fewer that fail? And that would lead to fewer compliance cases, which, in turn, means fewer numbers of facilities and patients put through a notification process or us putting out a safety notice about a mammography facility. So we have some things we can look at to see if either -- you know, in reality or in percentage of the pie, this is decreasing.

A possible carrot, we're hoping, is that can this clinical image review required in the

inspection and the LIP oversight of QC meet the practice quality improvement requirement of those IPs certified by the ABR and subject to these requirements? And we're going to be discussing that.

And timeline: What we would like to do is on October 27th, beginning our 25th year, I've asked our brilliant IT people to have these questions ready to go in the inspection program. What we're working on now, through each -- FDA is divided into regions out in the field, which is the rest of the world aside from us here at headquarters, who do all the inspection work and other great work for us. And each region has a radiological health representative, and through those amazing people -- and they really are amazing; in fact, Rachel Evans used to be one, and I stole her -- through them, we're going to get the inspectors up to speed and what we hope to do -- and there's actually a typo. This calendar year, sometime before December, we'd like to start beginning inspections with these questions in place. However, the questions will not generate citations. This would be a learning year for everybody, for the inspectors to get used to it, for the facilities to get used to it.

So say I'm an inspector, and I'd say, okay, let's go through these questions, let's see how you would do right now. Maybe not so good or maybe great, you're in great shape. So when I come back next year, this is going to be why, and if this or this happens, you know, this is what the consequences would be. So everybody would have a learning year.

What we would also do is during that time, see what comes back from the facilities. We ourselves have developed FAQs for facilities and inspectors and sought input, see when inspectors are actually in facilities, what people are saying about this, what did we miss that people are asking that we didn't include, and yes, there are FAQs that we've developed and would put out there. We would continually try to update those as we learn more once people are out in the field.

So the compliance strategy is the grace period, educational year. Then it would be a Level 2 citation if these processes weren't in place. And that requires, as you've heard, a response to the FDA district with a corrective action plan. And Year 3 and beyond, if you repeated it, that would go to a Level 1 citation. And this is kind of the new part where we came out.

So instead of taking all facilities and collecting images at inspection and sending them in, it's kind of like mammography screening, you know, taking a huge cohort and trying to find cancer. We said if facilities can't do these regular reviews and provide feedback, we'll give them -- you know, after the educational year, we'll give them a chance. Then if they do it again, we have at least some reason to suspect that there might be clinical image problems because nobody seems to be paying attention to some things that might indicate that. So we take a sample from those facilities and send them to the AB. Or we wouldn't really do that. Actually, the AB would request them, and the facility would be told that if you get a Level 1 violation, your accreditation body will request two random images from you to see whether this lack of procedures is translating into any image quality issues. And we talked to the ABs, who are totally on board and very supportive. We told them they can use existing procedures that they already have. They could design a new procedure.

Some of them charge. That's allowed as long as the charges are reasonably acceptable, and we review those. We said we want it to be random, we want it to be images already obtained. You know, you're not going to get a letter that says next Tuesday take images and submit them to us. We're going to say, you know, from a date 3 months ago, send us your images. And we told them that FDA sets the parameters for the random image review, the percentage that's required, and we said that they could count that towards the random reviews so that they don't get overburdened with all the work that they have to do on many, many facilities.

So we're trying to focus on enhancing image quality. We're trying to optimize the inspection by including quality assurance elements. We want to increase the attention and the awareness that's paid to image quality standards and evaluating them. We want to increase awareness of, at least as an LIP myself, where I think that the responsibility ultimately lies. We want to increase awareness of those responsibilities, and then who knows, we're going to have a discussion later today about some things in the future.

So first, I'll ask for any clarifying questions, and then I'll put up some questions that Dr. Rosenberg will ask you.

DR. ROSENBERG: Please.

MS. CHAUHAN: Cynthia Chauhan.

I have a naive question. I think you answered it, but I want to be sure. On the yes/no questions that you ask at an inspection, you don't just take their word; you have to see documentation?

DR. BARR: In this case, there is one question where we're requiring documentation, and that is of the regular image review where a sample from each technologist and each interpreting physician is evaluated and talked about. And the others are that we need to know that a procedure is in place. Yes. I mean, as I said, the physician can sign an attestation, they can do certain things. But we're putting the onus on the facility, which is where this belongs. So in some cases, yes, we are taking their word for it. You know, Dr. Rosenberg, if I'm the inspector and he explains to me exactly how his system works and it makes sense, then yes, I would take his word for it.

MS. CHAUHAN: So it has to be an explanatory yes.

DR. BARR: Exactly, exactly.

MS. CHAUHAN: Okay.

DR. BARR: No, we're not going to just say yes and check the box. No, you have to

give it. But documentation for review occurring at least once a year is a required documentation.

MS. CHAUHAN: Thank you.

DR. BARR: Um-hum, sure.

DR. GOODSITT: I would think you'd want more frequent communication between the radiologist and the techs than a quarterly review. Wouldn't you want a daily review almost, or a listing by week to see if someone is mispositioning and needs a refresher?

DR. BARR: Yes, I do. That's why there are two components to this. So maybe I didn't make this as clear as I could have. So there are two components to this, and if you can just kind of keep in your mind the two forms that were shown for the ACR manual.

I kind of liked everybody's mechanism of waking people up by banging the thing.

(Laughter.)

DR. BARR: And that certainly isn't the only mechanism. But keep in mind that we're talking about, yes, every time an image is presented to me, if it's not positioned properly, I need to feed that back or something's wrong with it, and I can either call the tech over and re-discuss it, I can either, you know, fill out -- lots of facilities have a form they fill out of what's wrong. You know, not in the pectoralis, the pectus is concave, the inframammary fold is missing. And yes, that's the ongoing, everyday feedback, and that's one of the questions.

Then there's another question that is a yearly, hopefully more frequently, like a quarterly, more formal review of images, that every tech has taken a sample, images that every IP has looked at for interpretation. And that can be done a number of ways. You know, we can sit down in a meeting and go through it, put them up, talk about them, and I write up meeting minutes. There are a whole bunch of ways to do that. But yes, you're absolutely right. There's the ongoing feedback on a regular, almost daily or case-by-case

basis, and then there's the more formal overview of the facility's QC as a whole and where it is.

DR. NEWELL: Mary Newell.

I think the intent of this is excellent. One concern or question I would have, it's essentially done by attestation to some degree, and my concern is, is this kind of the fox watching the henhouse? So as being a film reviewer with the ACR, it's clear that sometimes when images are sent in, the lead interpreting physician and the chief tech or whoever is in charge clearly just does not get it. So if that person is the one watching the henhouse, how effective can we expect this to be?

DR. BARR: I think that's really a good question, and I don't have an answer. I mean, I'm sure, as a reviewer for ACR, you don't have an answer either. You know, we expect facilities to comply with the regulations and do the best work that they can, and I really don't -- I'm sure there's going to be the rare case where the LIP maybe is the problem and is the one attesting. But we also hope that our inspectors are savvy enough to appear reasonable. I mean, I'll certainly be talking to all of them and explaining kind of what we look for.

This is sort of the oversight of that. There are still the violations for the exact things, like missing QC, no repeat analysis, different things like that. And if those are problematic, then clearly the procedures, as good as you're telling me they are, aren't working. So it's not like you can say, yeah, I have a procedure in place. That will sort of be borne out in the other violations of whether you really do and it's working. But there's no perfect answer.

DR. NEWELL: So as a follow-up, then, are we adding anything? If the objective data is going to shake out some of this anyway, is this attestation process, which essentially at this point it is, going to add anything?

DR. BARR: Well, it's really more than an attestation. One mechanism is an

attestation, if you can't physically be -- if the LIP can't physically be at the inspection. And there are certainly holes. This is in no way the be-all and end-all. This is a beginning to raise awareness, to raise consciousness, to make people realize that there are regulations about ongoing quality, and this isn't a perfect way to check it. This is an early start, and your questions are good. And I think at that point, why don't we go to the -- is that okay, Dr. Rosenberg, to go to the discussion question, because it seems like we're kind of getting there?

So do you believe EQUIP has the potential to improve image quality? And I think you touched on that. And how do you think it will be perceived by the mammography community?

DR. ROSENBERG: I guess I had a clarifying question, too. I think one of the issues we see as reviewers is that even the lead interpreting physician, or at least the lead tech that submits images, is not aware of adequate --

DR. BARR: Um-hum.

DR. ROSENBERG: What the standards are and what an adequate image is, which this doesn't directly address. So it almost seems like another QI issue may be making sure people are informed of what the standard is, in addition to the random film check. And I guess I had a question. Do you have a mechanism for the sample for each tech? Is there going to be 5, 10 --

DR. BARR: No, we're leaving that, at this point -- that doesn't mean all of this can't change. At this point we're leaving it up to the facility to design a mechanism that's appropriate for its particular situation, its number of technologists, its IPs that are off site. So at this point we're leaving it up to them.

And the other point you brought up is really a good one. Where we will catch this -- I mean, this is kind of like, all right, we raise the awareness, and we tell you to have these

processes in place. If you can't even get there, then we're going to look at a sample of images and see, and that's where it will be caught. But I think what you're saying is, in addition, there might need to be some sort of more outreach to facilities about what the standards are, what the quality is, you know, what we're --

DR. ROSENBERG: Because I think that there are two issues. One is raising the average, which is a little separate from getting rid of the lowest, which is, I think, what you're also saying.

DR. BARR: Yes, I agree. And if you have any ideas, I would love to see it because, you know, when we do the -- when Dr. Lerner and I do the oversight of the accreditation bodies and take a look at images that are submitted to them, sometimes, as you well know, those of you who are reviewers, you're like what IP laid eyes on this? You know, what QC tech thought that these were -- so how do you get to them sort of before? At least this is a mechanism to eventually get to them. It would be nice to have some sort of more proactive mechanism, but as I said, this is a start, and certainly we'll need to hear any ideas. It's a mechanism we had, since we're in the facility every year, to at least begin.

DR. TORRENTE: Jessica Torrente.

Perhaps incorporating something -- and I don't know if this is the right forum to put this out there, but as an idea for the LIPs to have, in the CME requirement, can there be some form of requirement to have to do with clinical image quality, you know, that there is some sort of a check for that, that it's not just the other things that most people do for CME? But if you are specifically a lead interpreting physician and your name is going on the MQSA paperwork, could there be something incorporated that, you know, we can check that box? You know, there might be some minimum bar for review.

DR. BARR: I think that's an excellent question, and this is the forum to bring it up in because I'm wanting to hear all ideas. And we are actually looking both for LIPs and

technologists at this point, if we should more specifically define what the continuing education has to include, and particularly for physicians. In discussions with the accrediting bodies, we think maybe this is why some of the corrective action plans aren't working, because the physician -- you know, right now, a lot of it is read the positioning manual. Should we be more stringent and say you have to do X or Y or Z to sort of get to that point? I think it's a great question, and we're definitely looking into those possibilities.

DR. TORRENTE: And just another comment I want to make. I echo the concerns of the other Panel members about the fox watching the henhouse, but I think -- I also really think it's important to roll these things out somewhat slowly and -- you know, because we don't want to impose very harsh regulations quickly that may have negative unintended consequences in the result of closing a facility. Particularly in rural areas, for example, we've seen that volume is obviously an issue, but those communities still need access to mammography.

DR. BARR: Yes.

DR. TORRENTE: So we don't want to do anything, you know, too quickly that's going to result in decreasing access to mammo.

DR. BARR: And you're absolutely right, and that's one of the mandates of MQSA is that we need to take that into consideration, and that's why we decided, of many ideas that floated around -- and you can see we started all over the place -- to start slowly and see if we can make some improvements this way without going -- and also using what we have. As you will hear when we talk about breast density, we have proposed, written and proposed amendments to the MQSA regulations that we expect to address breast density reporting issues, and that's been years. I mean, writing regulations is a glacial process, which is good and bad. It's frustrating, but it's there for exactly the reasons you said. Do we impose on people regulations at the highest level of government without a lot of

thought? So we wanted to use things we already had in place, too. But I think you're right on, and that's why -- you know, I practiced for a long, long time, but I haven't been out there for a long, long time, so I wanted to hear from all of you.

DR. LEE-FRENCH: This is Carol Lee.

Dr. Barr, you may have gone over this, but what struck me in your presentation is that there is a training process for the inspectors, but what about for the facilities? I mean, is this going to be sort of -- have facilities been -- will they be notified and given sort of some direction? You know, as a practicing mammographer, we deal with image quality in every single case we see. And so this is an ongoing -- as Dr. Newell mentioned, if the interpreting radiologists don't understand what is good image quality, then all of the attestations in the world aren't going to fix the problem. I see, in terms of how this is going to be perceived by the mammography community -- and I may be way off base, but I imagine that it could be perceived as an additional burden that is not going to go very far in correcting the very, very important deficiency that it is intended to address.

DR. BARR: And I share your concern. So to go back to the first part of your question, yes, we are looking at ways to reach out to facilities. We may use part of this lecture type where I explain the process and how we got there. We may do webinars, we may do -- we're looking at a number of mechanisms for that. Also, that being said, and the FAQs and everything we're going to be putting up, a lot of this is going to be done through the inspector-facility interaction during that first inspection where nobody gets dinged for anything and explaining what we expect by the next year. Does all of this get to the root of the problem? Only time will tell. Do we end up like we did with other inspection questions, saying this isn't working? I mean, this is going to be a continual evaluation process to see whether this makes an impact.

But I do hear, again, the echo of -- and I think we're all in this, not just FDA, but the

ABs, how do we -- you know, this is sort of the back end of it. How do we, on the front end, improve image quality? I know when the AB reviewers look at images, they give a lot of feedback to facilities on what's wrong, and then they give ideas for a corrective action plan of how to correct that. What I'd like to explore further is what more we can do in that regard, because some of the corrective action plans don't seem to be working, despite the feedback and despite the direction.

DR. ROSENBERG: Diane.

MS. URIELL: Yes. Diane Uriell, GE Healthcare, Industry Representative.

I think the industry shares the concerns that are being raised, as well, of it could be perceived as an additional burden to those facilities, as well as could lead to violations unwarranted that could then not allow access to some of those rural areas. So a question that I have is during the first year that -- no, it's the wording of the education part of it. What are the plans to take the learnings or assessing during that first year to understand and get a gauge of is this going to work, is it not going to work, or improvements? Could you share more?

DR. BARR: Yes. So as I said, I don't have it completely blocked out yet, but part of this will be connecting on a frequent basis with the inspectors and saying what are you hearing from facilities? What are they saying? What questions are they asking that we didn't enlighten them on? You know, what's going on out there? So I don't have the nuts and bolts worked out yet, but we plan to do a frequent assessment during that learning year to see what's really happening out there. Doing surveys is a little hard because we have a lot of restrictions in doing that. So it's probably going to have to be through the inspectors.

MS. URIELL: Yeah. So I was thinking qualitatively it sounds like that, but what about quantitative data?

DR. BARR: That's the nuts and bolts that we're going to -- and the quantitative data will not be in Year 1. Year 1 will be what questions did we miss answering? What is confusing about this? What do we need to do further? When the violations start, then we can start looking at are we decreasing the need for additional mammography reviews? When we do get them, are more passing than failing? Are we seeing less as a serious risk to human health so that we have to have the facility doing notification? So we do have metrics that we can begin to measure, but that won't be for a little while.

The other thing that you brought up is the burden, and the facility is responsible for complying with the regs, and most of you, like Dr. Lee said, this isn't going to be a burden because you're already doing it. You do it every day. You probably have some sort of ongoing -- you certainly have ongoing daily feedback. You may have mechanisms in place for some sort of regular review of the facility as a whole. This is what facilities should be doing, and they shouldn't -- we hope that even though we're not generating violations to the facility, we still hope to collect that information and see where facilities stand, and I hope that it comes back that 95% of facilities pass. You know, they don't have any problems; all of this is already in place.

We're going to do the best we can to see that there's not violations that aren't necessary, and that's why this is also a stepwise process where there's a learning process. There's a process that even if you don't get it the first time, you can get it the second time. And even if you don't get it the second time, then what we're going to do is take a look and see if this is translating to image quality. So we hope that we have mechanisms in place that won't do that. And we're very cognizant, as all of you have brought up, of access and what that can do.

You know, I get asked all the time about the numbers that physicians have to read is so low compared to other countries. Well, you know why? Because of access. We have a

wide range of facilities across the country, and there's the school of thought that raise the numbers, and those low-volume facilities will be out. And the other is that we have to keep them going, so we have to set appropriate numbers that can include them also. So this is what we deal with every day. I hear you.

DR. PORTIS: Natalie Portis. I just -- oh, sorry.

DR. ROSENBERG: Yeah, Ms. Chauhan.

MS. CHAUHAN: Cynthia Chauhan.

In response to what Dr. French was saying and Dr. Newell, yes, it can be perceived as a burden. But the burden is not caused by the regulating agency. It is caused by the providers who do not meet the standards. And so I think it's very important, and I live in a state that has a lot of rural areas. That's important. But you cannot let that be a reason to lower quality. The fox in the henhouse, I agree. I see this as the farmer saying I'm going to check the fence and find out where you're getting in and bothering my hens, and then we'll figure out what we need to do. So again, coming from the patient perspective, I am perceiving this as a very positive step in protecting patients, making sure that patients get the best quality of care that is possible and available.

DR. BARR: Thank you for those comments. And it's interesting, the fox in the henhouse thing. We actually heard that early on in MQSA, and the first director of MQSA was not a radiologist because of the fox in the henhouse concept. So while that's not, you know, a valid concern, you also have to have people who have been there and done that to get the idea. Thank you.

DR. ROSENBERG: A quick clarification by Dr. Lee.

DR. LEE-FRENCH: This is Carol Lee again.

Just to clarify my comment, I didn't say that this would be perceived as a burden in terms of compliance. What I said was that it would be perceived -- it could be perceived as

a burden that does not address the deficiency, and that was my point. I mean clearly something needs to be done to address image quality for those facilities that produce suboptimal images, and whatever burden is necessary to correct that would be justified. But I'm just not sure that these additional inspection questions or addressing this through the inspection process is the way to optimally achieve that.

MS. CHAUHAN: Thank you. I appreciate that.

DR. BARR: And we aren't sure yet either.

DR. BARKE: Yes. Lora Barke, breast imager.

So I appreciate the fact that we're talking about image quality, and I think it's important that we're bringing awareness to image quality. But I also want to recognize that we've come a long way in 25 years, that we've decreased dose, we've improved image quality in so many ways; this human perspective that we're talking about is actually very small when you look at the overall scheme of things. So I want people to make sure that they're aware of this.

And as others have mentioned, these processes do exist, and it's the small minority of processes that are out there that may not get that feedback. It's about building those relationships with your technologists and having good communication that every case is being discussed in this fashion. I don't think it's going to be a big burden on the facilities that actually do this, to document the fact that it's already being done. So I think it's important for us to recognize that good quality is out there.

I just wondered if some of the data that we're talking about and that we're raising awareness about image quality as an issue is based on the fact that the inspectors may have some quotas that they're trying to reach when they're going out to facilities, because all the other image quality pieces are not being mentioned, that they're doing well in those aspects and that we're trying to find some deficiencies overall. And I'm just going to take that with

the fact that I do think that training for the inspectors is going to be a very important part of this, which I know you're addressing as well. So I just wanted to raise that question.

DR. BARR: Great comments. Having been out there, and my staff will tell you all the time and I tell the inspectors, the training and everything, most of your job is to provide patient care and take care of patients. It's not to deal with federal regulations. Congress hoped that it would help you do that, but that's not what you're there for, and we certainly don't want to do that. Inspectors have no quota. In fact, we're thrilled that inspections come back -- and what you said is absolutely true.

Is Tim there? What are the statistics, like over -- less than 1% or around 1% of facilities have the most serious violations.

So you're absolutely right. Most facilities do what they're supposed to do. So hopefully this will be transparent to them. This is just another mechanism to try to find facilities that aren't doing that earlier than every 3 years, where then we have many women exposed to poor quality for a long time. But your comments are straight on. The quality is mostly out there, and the human factors things, some of them may not even translate to image quality. That's why when, say, QC isn't done, sometimes when we looked at images, it's like they're okay, that particular QC problem was minor enough that it didn't translate into image quality. Should it be done? Absolutely. The people who put these into place know that that's how you get the best mammograms. You know, it isn't always a one-to-one correlation. So we're really cognizant of that, but great comments. Great.

DR. NEWELL: Yeah, Mary Newell again.

I just wanted to assure our patient advocates that the breast imaging community absolutely believes there should be a farmer, no doubt about it. We just want to find the best way to find the bad fox. That's what we're talking about. Yeah.

DR. ROSENBERG: Okay.

UNIDENTIFIED SPEAKER: I think Dr. Barke --

DR. ROSENBERG: One more. Thank you, Dr. Barke.

DR. BARKE: I just wanted to comment on the communication with the radiologists and technologists. So as we were mentioning, we do talk to the technologists about every case, and there's a live communication in, I would say, the majority of facilities, especially when we're doing diagnostic imaging. And the way to communicate on giving feedback for some of the screening studies, I think, is nicely outlaid in the new QC manual where there's a form to communicate those findings, and some of those findings aren't completely punitive. To be honest, it's allowing us to congratulate the technologists when they're doing excellent work, because I think that's just as important to provide that relationship with them in a positive sense so that they take that back to their patients and so patients can go through a positive experience.

But I also think that we need to work on a mechanism to communicate and to tag cases in an electronic sense. So we've come a long way from screen-film to digital, and there are PACS systems that allow us to comment on image quality. But some of those PACS systems really aren't dedicated to providing image quality comments with regards to mammography, and it's more generalized when it comes to all of imaging. And so I would just urge manufacturers to help us in flagging some of those cases for particular reasons, to allow us to get back to them and then to create reports that can be generated in those electronic modalities or in an electronic fashion to allow us to get that information back to us.

DR. BARR: Great, thank you. Important comments.

DR. BERNS: One quick comment. A lot of technologists, when they have MQSA inspection events, are pretty terrified of the inspectors. So I think if you're going to pull anything like this off, the paradigm of the tech and inspector relationship has to change

because there's not a lot of education when the tech is terrified of an inspection, and a lot of that inspection is based on the equipment and the things that don't fail.

DR. BARR: Um-hum.

DR. BERNS: So they can't even think about taking on a new endeavor if we're shifting away from checking the KBP to let's talk about clinical image quality. So if the inspectors still carry that big stick, it's going to be very difficult. If they just go in once to say here's our new EQUIP program, good luck, we'll see you in a year, if they're so scared about passing inspections -- so I think there has to be a major shift of the perception of MQSA inspector and how they approach those inspections, otherwise the techs -- because they're going to talk to the techs. They're not going to talk to the physicians unless they're lucky. And the physicists aren't usually involved. So it's that one moment of connection that has to shift, that will have to come through MQSA inspectors.

DR. BARR: I think that that's a really good point, and having practiced under MQSA, you know, I hear you. I remember the time I got a Level 2 because, back in the old days, because somebody had put the wrong light bulb in the darkroom. It's frightening. And clearly my talking to them doesn't get through. But you just gave me some ideas, and actually the Branch Chief, Preet Sudhaker, who's in charge of the program and will be talking about inspector training enhancements we've made, is here listening. And you just gave me a great idea. Maybe bring some local techs into inspector training and talk about how it feels to be on the other end. You've given me some good ideas, good points.

DR. ROSENBERG: I would like to echo what Dr. Berns said and that it might be useful if there's a feedback mechanism from the tech to the FDA, rather than going through the inspector, because I believe you might get different kinds of feedback on this particular question and even the inspection process in general.

Dr. Lee.

DR. LEE-FRENCH: This is Carol Lee again.

This is what I was alluding to earlier, and I didn't express it as eloquently as Dr. Berns, but in terms of inspector training. But what about facility training, and doing it during the inspection process I don't think is a realistic expectation because, as Dr. Berns says, the inspection process is incredibly stressful for the technologists, and it's not an -- I don't believe it's an appropriate setting to achieve the educational purpose. So giving a year, having the inspector come in and say you're not doing any of this and this is what you need to do, I don't know, is going to be effective.

DR. BARR: Thank you. And we'll certainly take your comments and thoughts into account, absolutely.

DR. BARKE: I just had an idea there, is that perhaps in the closeout interview of the inspection, that could be the time to introduce it to the facility so that the pressure has been relieved regarding that initial inspection and that it can then be talked about in a more relaxed fashion.

DR. BARR: Rather than going through it as one of the inspection questions and say if it happens next year, you're going to be in trouble. Yeah, I hear you. You're getting all of this, Preet?

(Laughter.)

DR. BARR: And Michelle Garza is here, our inspector training coordinator.

MS. CHAUHAN: Cynthia Chauhan.

I appreciate what you're saying. However, I believe that if you change the focus to what is best for the patient and you help the facilities to focus on what is best for the patient, and that is what we're there for or what you're there for, I think your IPs are huge in this. What do they say to their staff about your coming in? I've been in administrative positions where we had very strict inspections not announced, and my approach was they

are doing this for our clients and we are here for our clients, so we work together, not as adversaries. So I think that's a big part, that not seeing these as adversarial but as patient supportive could make a difference there.

DR. BARR: And we certainly, on our end, need to support our inspectors to not -- this isn't an adversarial situation. We're all in this together. And actually, more than most inspections, we feel we're there to help and educate rather than ding you with violations.

DR. TORRENTE: Jessica Torrente again.

I just want to make a comment that it seems, moving forward, that we may want to involve, in this particular part of the accreditation inspection process, like the LIPs a little bit more because I do think that, you know, more like the QC things is more on the technologist and the lead technologist end, but because this is such, I think, a difference right where -- and we've all echoed this, that there is a constant communication between the interpreting physician, the technologist, that relationship there constantly be improving perhaps. In this particular era, you know, moving forward, there could be a little bit more involvement, you know, with the lead interpreting physician as well. I just think it's a little separate than running like the QC tests and things like that. This is more of kind of raising awareness to the small percentage of facilities that maybe aren't doing as good a job as others, that this really should be relationship building between the LIP and the techs. And I just think it's a little nuanced.

DR. BARR: I agree with you, it is nuanced, and we're trying to -- and we'll take your comments into account because we agree, it is a nuance, and we don't want the LIP having to look at every QC test and all of that. But, overall, if the tech is not doing it, somebody is responsible for that. But I totally agree with you, it's nuanced, and we're going to do our best to bring that out. Thanks.

DR. ROSENBERG: All right. It's lunch, so we will now break. There's a room for the

panelists where we can eat. Panel members, please do not discuss the meeting topic during lunch amongst yourselves or with any members of the audience. We will reconvene at exactly 1:00 p.m. Again, I ask all Panel members, please return on time. Please take any personal belongings that you need during lunch with you. This room will be secured by FDA staff during the lunch break, and we will not be allowed back in until 1:00 p.m.

CDR ANDERSON: This is Commander Anderson.

I want to remind the public and the press that you are not permitted in the Panel area, which is this area beyond the speaker's podium. Also, I request that reporters please wait to speak to FDA officials until after the Panel meeting has concluded. Also, FDA staff, not allowed to do interviews until after the meeting. And a reminder for panelists and FDA staff not to discuss meeting context at breaks.

Thank you so much.

(Whereupon, at 12:17 p.m., a lunch recess was taken.)

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

(1:10 p.m.)

DR. ROSENBERG: Okay, I think we're ready to start. It's now, we'll call it 1:10, and I'd like to resume the Panel meeting.

We'll start out with some comments from Dr. Barr, and then we will proceed with the Open Public Hearing portion of the meeting. Public attendees are given an opportunity to address the Panel, to present data, information, or views relevant to the meeting agenda.

Commander Anderson will now read the Open Public Hearing disclosure process statement.

Should we wait for Helen first? Yeah, Helen, why don't you do that, and then we'll do the statement.

DR. BARR: Helen Barr, FDA.

I was just asked -- I mentioned something during the morning session. Maybe I should --

(Pause.)

DR. BARR: Helen Barr, FDA.

I mentioned something during my talk to the morning session, and it was thought that I should mention it for the afternoon session in case people didn't attend both sessions.

I had mentioned that we have written regulation amendments to the MQSA regulations, and they're working their way through the internal process. We hope to publish them for public comment, and they're expected to address issues related to breast density reporting. And that's really all I can say. So if people ask me when or any more details, I really can't say. That's as much as I'm allowed to say at this point. Sorry, I forgot

to thank my staffer Holly Simms, who was Captain -- Commander -- I elevated you to captain -- Commander Anderson's partner in crime from my end to pull off this meeting. Thank you, Holly.

CDR ANDERSON: Okay, good afternoon.

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 the 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 such financial relationships. If you choose not to address the issue of financial relationships at the beginning of the statement, it will not preclude you from speaking.

Thank you.

DR. ROSENBERG: For the record, we have received seven requests to speak for today's meeting. Each scheduled speaker will be given 5 minutes to address the Panel. We ask that you speak clearly to allow the transcriptionist to provide an accurate transcription of the proceedings of this meeting. The Panel appreciates that each speaker remains cognizant of their speaking time.

The first speaker is Miara Jeffress from National Center for Health Research.

(No response.)

DR. ROSENBERG: If she arrives later, we'll change the order of the speakers.

Next on the agenda is Nancy Cappello, Director and Founder of Are You Dense Advocacy, please. And 5 minutes. Thank you for being here.

DR. CAPPELLO: Thank you. Do you have the PowerPoint presentation up?

DR. ROSENBERG: Hold on, we're supposed to.

DR. CAPPELLO: Okay, thank you. I appreciate that. So how's everyone doing this afternoon? I didn't eat yet because I don't like to eat before I speak, so I'll be gorging in the lunchroom afterwards.

So thank you for having me. Will you let me know when -- I can see when it's up, correct? Yes. I can either put them -- I mean, my presentation is here, but yeah, you can pass them out. You're my passer-outer. I used to teach school, so thank you, Jeremy. Teacher's pet.

DR. ROSENBERG: Yeah, I think the Panel has a copy of that.

DR. CAPPELLO: Okay. Yeah, I just made 30 copies for the public.

DR. ROSENBERG: Yeah, please proceed.

DR. CAPPELLO: Okay, I'd like my PowerPoint presentation, though. It would be great to have it. Well, let me just tell you my name. And I'm going to put my button on when I see the PowerPoint. But my name is Nancy Cappello. I have a Ph.D. I'm from Woodbury, Connecticut, and I am Founder and Director of two nonprofit organizations concerning breast health, called Are You Dense and Are You Dense Advocacy Inc.

Got it?

DR. ROSENBERG: We'll just assume you're out of order and that's the issue.

DR. CAPPELLO: That's all right, no problem. So I'm assuming I hit the green button when I start.

(Off microphone comment.)

DR. CAPPELLO: Oh, it will. Okay. So I'll give you my disclosure statement. I have

two nonprofit organizations, and as a nonprofit, we do raise money to keep our organization alive. And so the disclosure statement, which is in my PowerPoint presentation, basically says that we are nonprofit organizations that receive sponsorship and grants from imaging manufacturers, facilities, hospitals, and healthcare businesses, in addition to the general public. Are You Dense Advocacy paid for my trip today, which is our nonprofit organization.

(Off microphone question.)

DR. CAPPELLO: I do. Sure. Let me find it in my bowling bag, so hold on.

(Pause.)

DR. ROSENBERG: All right. Dr. Cappello, thank you.

DR. CAPPELLO: Okay, thank you. We're good.

I already did that.

I already did that.

Okay. So here I am, November 4th, 2011. Guess where I was? The Holiday Inn here. And you're probably looking at that picture and saying, wow, she looks pretty young. You know why? I was. It was 5 years ago. I was in my 50s, can you imagine? And here I am 5 years later in my 60s, a senior for sure, talking about her senior breasts. I'm actually here today to talk about what has happened since November 4th, 2011, in the area of breast health and breast density.

When we were here in 2011, there were 13 speakers, clinicians, lay participants, breast cancer organizations, the majority in favor of disclosure. In fact, at the end of the day, Dr. Finder, I said to him, when the Committee came to consensus that we would report density in the lay letter, through the MQSA-proposed regulations, I said to Dr. Finder, so does that mean maybe by spring I could rescue a dog and learn Italian and take golf lessons? And he said probably a couple years. Well, he was wrong. We still do not have a

federal standard.

So in 2011 there were two states -- Connecticut was the first, that's my state. The state of Connecticut became the first state in the nation in 2009 to disclose density to the patient through the mammography report, based on my inspiration. After 11 normal mammograms, I ended up with Stage IIIC breast cancer, metastasized to 13 lymph nodes. The first time I ever heard I had dense breast tissue was after my late-stage diagnosis. And when I went to the literature in 2004 and found out that there were about six major studies about density as masking with over 38,000 women, I knew I needed to do something for other women. It was also a risk factor, as you know, for more than 30 years.

So here we are after 2011, and we have 28 state density reporting laws. So 26 other states have followed suit. And I think it's interesting to note that while the majority of these states have been led by patient advocates harmed by their density, ending up with late-stage breast cancers, there were three states, and I want you to understand that, that were led by physicians. Even Minnesota was led by actually Minnesota Radiology Society. Arizona was led by a radiologist, and Tennessee was led by a radiologist. So it's not just patients, but the majority of them are.

As you may see that Joan Lunden is here, and she'll be speaking later, but Joan Lunden was down in Washington, D.C., with me and the American Cancer Society and Komen actually about a year ago, working on a federal bill. We now have a bill that has been introduced in both the House and the Senate to standardize the communication of density to patients.

So here's the question: Does it really matter? So I'm just highlighting some research since 2011. And keep in mind that the majority of women that get breast cancer are at average risk. And again, the majority of women who go for their mammogram screening -- or all women go because of one reason. The only reason why we go for screening is in the

unlikely event we have cancer, it's found at its earliest stage. And the majority of women who end up with breast cancer, as we all know, 75 to 80% are of average risk. So when we look at the discussion about who gets added screening, it's not just about the causal risk. It's about the masking risk, that the tool that we're using currently, 2D, and we know -- and I'll talk further about 3D, which is a better mammogram, for sure -- it's still inherently limited in dense breasts.

So a study, a Dutch study actually, Saadatmand et al., looked at the stage at diagnosis, and does it still matter in light of treatment, recent treatments? And what they came out and concluded was, even treatments after 2006 to 2012, even with new treatments, new chemos, new AIs, new medication, the stage at tumor is still vital.

Tabár. We all know László Tabár. The randomized controlled trials show that the greatest benefit to reduce mortality is to reduce advanced diseases, and the number one predictor of the failure of mammogram to find cancer is dense breast tissue. And typically what happens, you have to have later-stage cancer until it's found. It has to be palpable until it's found.

And then the third study is the study, the ASTOUND trial out of Italy, a multi-site trial that looked at 2D, followed up with 3D and ultrasound, and their conclusion was that ultrasound still finds more cancers than even 3D.

Because I come from Connecticut, we also have a couple of radiologists that have been working actively and have been publishing their studies and see the difference in the invasive cancers found by adding adjunct screening.

These are 10 women that I've worked with. Each of these women found me through the website. Each of these women never missed an appointment. Each of these women had either a diagnosis of Stage III or Stage IV. Each of these women had dense breast tissue. Each of these women are dead.

Now, I don't know if their cancer was found early and if they had an opportunity for adjunct screening they'd still be alive. But I think every woman has to have an opportunity to find out and have equal access to screening. The only reason why we go for screening is to find cancer at its earliest stage.

This is my last slide.

DR. ROSENBERG: Okay, thank you.

DR. CAPPELLO: My last slide.

So take-home points. Are we talking about a possible requirement and we're going to wait another 5 years? Are we making the possible requirement turn into a reality? Women should have this information, and they should be empowered to have discussions with their docs. The only reason why the MQSA and this FDA Committee exists is because of the regulations that had to be done. Congress acted in 1992 because voluntary measures did not work. So I'm giving you a call to action. Let's standardize it. Let's not wait another 5 years; 200,000 women have died since the last time I was here, and many of those women never missed an appointment.

Thank you very much.

DR. ROSENBERG: Thank you. Thank you very much.

(Applause.)

DR. ROSENBERG: Next on the list is Mr. Julian Marshall. Thank you.

MR. MARSHALL: Good afternoon. My name is Julian Marshall, and I have slides. I don't have a microphone.

DR. ROSENBERG: We'll see that.

MR. MARSHALL: Oh. I work for Volpara Solutions -- oh, that's awfully little -- for Volpara Solutions, and they paid for my trip to lovely D.C.

Mammography systems, of course, acquire images at the hands of the technologist.

It's not going. There we go.

And the technologist looks at the image and makes a decision, is it acceptable, in which case the image is sent to PACS and workstations and other places. And if they deem it unacceptable, then they have to provide a reject reason to not keep that image, something like positioning, for instance, and then the image gets tossed in the bin. And typically gantries cannot send those images anywhere else; they're lost forever, which is a little bit different. Digital mammography has killed our ability to go back and reanalyze why images were rejected. So no one can actually go back and check, unless you happen to run to the gantry before it ages off the system. So were the rejection reasons legitimate, and is retraining really needed? We don't know for those images. So we have to change that.

We do a lot of training for our technologists, and we do a lot of monitoring of our systems, but we do it in a manner where we're really spot-checking. We look occasionally at things. And if the spot checks are really sufficient, then why do sites fail accreditation? So I would submit that maybe they aren't sufficient. And as we heard this morning -- this was an FDA publication from April. You know, 92% of first-attempt clinical image deficiencies were due to positioning, and I think the FDA very nicely set up that case this morning. So thank you, FDA.

And I want you to remember, those images that were submitted were the result of the facility selecting high-quality images specifically for accreditation through a sometimes painstaking process. So those were the best ones.

We've introduced a product recently called Volpara Enterprise, which looks at positioning on every mammogram that's acquired. It provides daily statistics to the chief technologist to drive additional training as needed, and it really forms the basis for newer, stronger quality programs.

This is an example. I'm afraid you can't see it very well on this tiny screen. The

different colors represent the system scoring the images acquired by each technologist. And so all I want you to see here are the general colors. The two left-hand colors, the lighter ones, represent what we call perfect and good images based on a UK standard that actually provides measurable things that talk about quality, as opposed to there's enough pectoralis muscle in the image. That's not really measurable. But if an image is scored moderate or inadequate, those images have limited diagnostic value. So we need to work on technologists or help them if they're doing that.

So I point out two specific people. One is the operator shown there; 51% of images are perfect or good. This one at the bottom, 18% are perfect or good, and that means that 82% maybe have limited diagnostic ability or facility. So this shows significant operator variability, and the point is, if you're not measuring it, you don't know.

So one of the other important things is to understand why an image, perhaps, is inadequate. And so our system allows you to then investigate and learn that, in this particular instance, the nipple was not in profile. Okay. But it will show you any image ever acquired, what was the problem with that image?

And that allows us to look at statistics and trends. It lets us retrain technologists on the exact issues that they struggle with. So if you have one tech who has problems with the LMLO positioning, perhaps because they have a sore shoulder or something like that, the data will show it. And so then you can give them help to try and figure out how to accommodate that issue.

We also look at the physics of every system on every image. And this is just an example, but what I will show you is a real -- this happened really in the field. The distribution of dose across different mammography systems was vastly different for one image or for one system, and when we investigated that, what we noticed is that on thick breasts, the dose was reported as being extremely high. So we investigated this a little bit

further, and we found that, in fact, the patient doses were actually normal, but the reported doses were very high, and that was the result of the half-value layer being incorrectly typed into the system during calibration. The point is you don't know and you wouldn't have discovered that until the 6-month physicist visit, ostensibly, unless somebody happened to just look at all the dose values on every study, which is reasonably unlikely.

So it's our belief every woman deserves a diagnostic quality mammogram. So why wait for the next spot check? If there are problems going on, let's find them and start to address them in real time. I think it's a better way to go.

Thank you very much.

(Applause.)

DR. ROSENBERG: Thank you, Mr. Marshall.

Next, we have JoAnn Pushkin, Executive Director of DenseBreast-info, Inc.

MS. PUSHKIN: Do I need to advance this?

Mr. Chairman and members of the Committee, I appreciate this opportunity to speak. I am Executive Director of DenseBreast-info, Inc. and a patient whose breast cancer was missed an estimated 5 years in a row, hidden behind dense tissue. I am Co-Founder of Density Education National Survivors Effort, acronym known as DENSE, and in that capacity in 2010 requested consideration of an MQSA reporting amendment to include breast density in the lay letter. The topic was added to the agenda of the 2011 meeting, where I was both invited to testify and organized advocacy support for the proposal. At that meeting, as you know, consensus was reached that the lay letter should include information about a woman's breast density, and we eagerly await commencement of the public comment period.

Since that time, to address the unmet educational needs of both patients and referring doctors after a density notification, I have co-developed, along with breast

imaging expert Dr. Wendie Berg and rad tech Cindy Henke, a medically sourced educational website, DenseBreast-info.org, which is vetted by a medical review team of breast imaging experts. While aware that there was no density reporting-related initiative at this meeting, I did want to reiterate why breast density is a topic important for women to be educated on and why a federal reporting standard is needed.

Some fast facts about breast density: Forty percent of women of mammography age have dense breasts. Dense breasts do increase the likelihood of developing breast cancer. In dense breasts, mammograms will miss a significant number of cancers present, and that has nothing to do with a woman's risk factor. And study after study indicates that the addition of supplemental screening tools does increase detection of early stage breast cancers.

So 27 states right now, encompassing nearly 70% of American women, now require some level of breast density reporting. In fact, only nine states have not endeavored to address density inform or education in some manner through legislation. However, the answer to the question is all density inform equal is a resounding no.

Though some state density inform laws are more similar than others, there is no consistent inform language utilized. In some states, all women get notified; in some states, only women with dense breasts. Sometimes the notification is required to be in the lay letter; sometimes it is not. Sometimes women are told if they have dense breasts, and sometimes they're just provided general information about breast density. Every state that drafts a bill adds a potential new variation into the mix. As a result, women living in neighboring states may be getting very different density notifications.

A good example of inconsistent notification laws and the reason we provide legally vetted legislative analysis by state is best exemplified in the New York-New Jersey-Connecticut tri-state area, where my fellow New Yorkers will tell you that it would not be

uncommon at all for a woman to live in New Jersey or Connecticut but work in Manhattan and get her mammogram on her lunch hour. As we see, she would receive very different levels of notification. In New York, women with heterogeneously or extremely dense breasts receive clear, unambiguous notification that their breast tissue is dense. In Connecticut, though here, too, heterogeneously and extremely dense-breasted women receive notification, that notification reads, "If your mammogram demonstrates that you have dense breasts," and goes on to provide general information about breast density without providing personal notification of breast density. And most astounding of all, in New Jersey, by law, all women are told, even fatty breasted women, that their mammogram may show that they have dense breast tissue.

Notifications, such as those in Connecticut and New Jersey, can be particularly misleading if the mammography center batch reads exams at the end of the day, which we know is true at the majority of imaging centers. In this case, the patient has left the facility, having had no interaction or conversation with the radiologist, and her only communication about breast density is contained within the lay letter.

As the aim of the MQSA was to ensure uniform high quality of mammography imaging and reporting, a federal standard is much needed.

Thank you.

And if I could just have one more second to address something: In an upcoming slide, Dr. Lerner has a fantastic presentation coming, but I did want to address one slide, which cites no increased mortality for dense-breasted women. That study was based on a 6.2-year follow-up, which was very short. There is a long-term follow-up study, a 25-year follow-up study out of Sweden, which showed an increased mortality risk for dense-breasted women 1.9 times that of non-dense breasted women, and that is attributed mainly to the incidence, the higher incidence of breast cancer.

I appreciate the important work of this Committee and the opportunity to speak.

Thank you.

(Applause.)

DR. ROSENBERG: Thank you very much.

Next is Louise Miller. I'll let you introduce yourself.

MS. MILLER: Good afternoon. I so appreciate this opportunity to address you all and the public who are attending today. This is a true honor for me. My name is Louise Miller. I own a company called Mammography Educators, who paid for my expenses here this weekend, or this week. I have spent 30 years as a passionate and enthusiastic mammography technologist, educator, and as an advocate for both patients and mammography techs. So it's for them that I am here today to speak about some of the issues that we've had regarding positioning.

So the FDA Panel certainly is familiar with this statement that was published in April of this year that said poor positioning, and we heard some very excellent presentations this morning that also pointed this out. Now, from my perspective, I felt I really needed to defend the technologists. So luckily, I have the honor of sitting on the SBI committee, newsletter committee, and so I was able to write an article that addressed the technologist's perspective of poor positioning, and I have that available on a handout for you today.

Also, I have been passionate about addressing the issues of image quality in terms of positioning, on many occasions in the same format, and written articles that hopefully are meant to be helpful in making a difference in positioning challenges.

As Dr. Berns said, I think, earlier, said that we've seen so many changes in equipment and so therefore the tests have changed, and I think the same is true for positioning. We've seen changes in equipment, and therefore positioning has to be modified to accomplish our

goals of producing excellent images. So I believe now is the time to make a collaborative effort to establish, improve, and maintain quality.

So we know almost all industries have established standardized methods for performance of tasks to establish and maintain quality, reduce errors, increase productivity, increase consumer satisfaction, increase profit, and reduce possibility of litigation. The interesting thing is that mammography or positioning mammography does not follow the same standards.

It's interesting also that with general radiology, technologists are taught to perform all exams under standardized techniques or using standardized techniques to perform all exams in the same sequence and that all training is competency based, and their skills will be evaluated for positioning techniques as well as clinical image evaluation.

But not for mammography. Actually, I did a survey of 200 technologists, and of all the participants who answered the question, "Do you think that each mammography technologist in your facility positions the patients the same way?" over 80% said no.

So what are the results? Most technologists know what they need to see on the images but have not been taught how to correct the positioning problems. Most technologists have not been taught a standardized method of positioning, and most technologists have not been trained by a qualified trainer.

So how did this happen? Well, in my mind, since the early '90s and mid-'90s when we were working very hard and diligently with the ACR to establish standardized positioning, that has seemed to decline obviously per our statistics over the last several years. So everybody is kind of doing their own thing. Also, there is no hands-on CEUs required for mammography technologists at all. They can get all their credits online. Also, the initial 25 mammograms required by MQSA have to be done, but under whose supervision? So we don't have any quality standard for that either.

So in my mind, how did this happen? Technologists are getting most of their CEUs online, with no actual hands-on education for positioning. Radiologists are passing inadequate images and/or can only give feedback regarding the positioning criteria and not how to fix it.

So I think that because we haven't had updated positioning trainings that are not provided by our employers until they're cited by ACR is a major contributing factor. Disagreement among radiologists as to what's acceptable in positioning standards and what's repeatable. There is no current published data available to establish parameters for positioning, and there's outdated materials with no updates for positioning for full-field digital mammography or DBT, whose equipment design requires a modification of positioning techniques used for film-screen.

As you can see here, another survey we took, we asked 200 technologists if they felt that the 1999 ACR quality manual, which featured positioning, was a useful, current, and relevant source of information, and 80% said no.

So how are we going to fix this? Well, I think that we first of all have to look at the results. We have more failures and deficiencies, more repeat/rejects, more callbacks, increased patient anxiety, unnecessary radiation exposure, and OJT injuries by using techniques that are not ergonomically sound. But also the biggest thing is are we missing breast cancers?

So in my mind, we need adequate methods for determining actual number of images taken, an accurate method for analyzing positioning standards, the ability to provide corrective action plans for improving the positioning errors, and current data, which the last data was published in 1993. We also need the establishment of standardized positioning techniques.

I also believe we need 40 hours of initial training for technologists, to include a

hands-on component, and possible certification of positioning trainers. Also, I would like to see a requirement that technologists have to complete a hands-on positioning class every 3 years as part of their 15 CEUs. And we also need to have competency-based evaluations rather than just discussions about what's wrong with the images.

So do standardized positioning techniques work? Certainly. We've seen it in Sweden, as we just heard, for over 40 years. It was taught by the ACR in the 1990s with no update.

DR. ROSENBERG: Be wrapping it up.

MS. MILLER: Okay, I'll wrap it up.

DR. ROSENBERG: Please.

MS. MILLER: Okay. So let me just go to my recommendations, and you can all read in the handout. So we know that these work. We know that we're doing better with standardized positioning all the time. I have some examples. And finally, who's minding the store? Well, in my mind, it's all of our responsibility to make sure that all women receive the highest-quality mammogram achievable.

Thank you.

(Applause.)

DR. ROSENBERG: Thank you very much.

Next is Joan Lunden, please.

MS. LUNDEN: For disclosure, I am a special correspondent for the Today Show, and they are following me here today, but I applied online to speak to you as a private citizen, and they're not paying me to be here.

Good afternoon, and thank you for allowing me to speak to you today. I am not here as a journalist but as a breast cancer survivor, to share with you the fact that the discovery of my cancer tumor almost didn't happen. For me, it began the day I was told that I had

Stage II triple negative breast cancer. That was in June of 2014. And I went for my mammogram like I had done every year for 15 years. I even got a 3D mammogram that day, and I even got a clean bill of health. You're fine. And that's that moment when a woman kind of exhales. But then I walked across the hall, thank goodness, and I had an ultrasound, and I heard those words that none of us ever want to hear: You have cancer.

Leading up to that cancer diagnosis, none of my doctors, including my referring gynecologist, had ever spoken to me about dense breasts or the fact that I actually had very dense breasts, information that had been ascertained in every single mammogram I had had for 15 years and had been passed on to that doctor but never passed on to me. But even armed with that information, there was still no conversation, and especially that there was no conversation that there was about a 50/50 chance the mammogram would ever see my cancer but that there were other tests that would be able to see it. And, of course, the radiology lab didn't give me any of this information, but of course, I imagine they felt that they were giving it on to my referring physician.

And I'm the one who scheduled the appointment. I'm the one who went for the mammogram. I'm the patient, and I am just amazed that there was no regulation in place that required that information to be passed on to me. If I had gone for a blood glucose level, they would've given me the information so that I could've taken steps in my life to lower my risk. It was absolute sheer luck that I went for that ultrasound that day.

Fortunately, I had been sent about 6 years previous to do an interview with a breast cancer expert about mammograms, and during a break, I mentioned to that expert that I went for my mammograms every year, and they were always nerve-wracking because they were always calling me back in for more pictures and more pictures and you freak out. You know, I would say did you see something bad? And they would say no, no, no. Don't worry, it's just because we can't see anything at all; you have really dense breasts.

Now, I didn't know that I should make anything of that comment because no one had ever had a discussion with me about what that meant. However, the breast cancer expert was quick to say to me, well, if you have dense breasts, then mammograms might not ever see cancer. You also need to have an ultrasound. Well, thank God I listened to that expert that day, and I went back and I asked my gynecologist to add an ultrasound to my yearly screening, and he very quickly signed off on it. But that still didn't spark any kind of conversation about what it all meant and why I should be concerned about it.

I've got to tell you, I can't help but think back to that day in June of 2014. If I had only had that mammogram, I would've walked out of there thinking that I was perfectly fine, when I really had a fast-growing, aggressive cancer back at my chest wall, which means that it never would've been palpable to me. It wasn't in a position where I would've been able to feel it. Had it not been for that interview, I don't know. I don't know whether I would've even been here today to give you this testimony. And I am so thankful that we were able to find my cancer at an early enough stage that I was able to be treated. And after 16 rounds of aggressive chemo and 6 weeks of radiation and surgery, I am now cancer free.

But we all need this information. Information empowers women to be able to stay in charge of their health and stay in front of these deadly diseases like cancer. Because of that chance encounter, I am here, and had I known earlier that this kind of lifesaving information wasn't being passed on to me and to other women, I would've been here knocking at your door a long time ago. I hope we can get these regulations in place, and I appreciate the opportunity to speak to you and the good work that you're doing.

Thank you.

(Applause.)

DR. ROSENBERG: Thank you.

We had asked about Miara Jeffress. Is she here?

(No response.)

DR. ROSENBERG: And now Wendy Marshall, please.

MS. MARSHALL: Thank you very much for the time that I have been allotted. I am very honored to be here. My name is Wendy Marshall, and I am Co-Founder of Mammography Quality Management. You'll notice on my slides that I have been a mammography technologist for 37 years, and I have been a technologist as a QA/QC technologist for 28 years, and I have been an instructor for the initial qualifications course for 17 years, in which I did teach image quality. I would like to address -- oh, I forgot to say -- oh, I did say Mammography Quality Management. I would like to address two standards of the MQSA: quality assurance and clinical image quality.

There are three components, critical components that affect image quality and accuracy. Factors that affect image quality are the performance and reliability of the equipment and the technologist, while accuracy is affected by the interpreting physician's performance, which is dependent on the performance of the equipment and the technologist. Two of the components influencing image quality and accuracy, the equipment and the radiologist, are consistently monitored while the technologist is not. It makes sense to monitor the technologist's performance. The question is why isn't it being done?

Image quality usually defines what is contained on the final image for interpretation. The truth is behaviors that impact image quality take place before, during, and after the image production. To ensure that the images sent on for interpretation are of high quality, the entire process must be evaluated to determine which behaviors the technologist and the facility are strong or weak in.

Because there are so many variables introduced into the mammography

examination, developing a method to provide meaningful feedback has been challenging. The practice up until now has been to do random evaluation of a technologist's work. In order to assess the technologist's performance, two conditions of evaluation must be better defined. The subject variables must be controlled, and the reviewer acceptance thresholds must be defined for technologists to be equitably evaluated.

A quality assurance method recently developed by MQM evaluates pre-exposure, acquisition, and post-exposure behaviors of the technologist that affect image quality. This continuous quality improvement method is implemented under the guidance and oversight of the lead interpreting physician.

Our program's foundation is based on the image criteria published by the ACR and observe specific behavior patterns that repetitively impact image quality.

In 2015 we conducted a clinical validation study consisting of pre- and post-education evaluation of technologists' behaviors that provided us with over 31,000 data points. For example, the July study demonstrates that this technologist decreased the substandard percentages for the MLO breast placement feature, while increasing her standards for "meet standards" in the assessment of that same feature. And for those of you who are not mammography technologists and not radiologists, what this tells us is how much tissue was included either superiorly or inferiorly on that image. So if a technologist is repetitively clipping to cutting off inferior or superior tissue, then her repetitive behavior would be identified and could be taken care of through corrective action.

Another example from our study addressed the customizing of the MLO angle. In May, the technologist used the same angle of obliquity on all of her patients, while in July she customized the angle for each patient. By doing this, she demonstrated improvement in this positioning feature, increasing the length of the pectoralis muscle by approximately 25%.

This QCI method parallels the physician's medical audit by demonstrating performance outcomes individually for each technologist as well as an aggregate for the entire group of technologists. The advantage of a method such as this that can measure and quantify the images for the technologists can be used across one facility. It can be used across organizations that have several facilities. And one of the benefits to this type of measurement system that can give that information back to the technologist is that the facilities themselves can use the strengths that they have within their organizations to loan out those technologists from one facility to another, to help the other technologists that are weak into becoming stronger technologists.

Our program uses three separate assessment categories rather than the five that are used for the accreditation process. This is not an accreditation process. It is used for a CQI system, which means we want the technologists to be very familiar with it and to understand it. Those definitions, then, need to be strictly understood by technologists.

Our system for substandard, it tells the technologist that this image was to be rejected. If it made its way to the interpreting physician's monitor, it shouldn't have. It was below standards. Acceptability is it's an acceptable image for interpretation. Meet standards. If a technologist would be given that, that would indicate to the technologist that the image quality was so high and so good that that particular feature in that image would be something that could be considered for accreditation.

Our program is -- and I'm not going to go into this.

DR. ROSENBERG: You'll start to wrap up, please.

MS. MARSHALL: Okay. It is married to the repeat/reject analysis, and it is also married to, believe it or not, the processor quality control. That's how detailed it is.

So what do we look for? We look to reduce the suboptimal image, and this should be done for -- the purpose is to be done for the obligation and dignity of the patient, the

accountability and dignity for the technologist, but it must include reasonable solutions.

Thank you very much.

(Applause.)

DR. ROSENBERG: Thank you very much.

Does anyone in the audience wish to address the Panel at this time? I know we have one person. Dr. Monticciolo, step forward to the podium. Please state your name, affiliation, and indicate your financial interest. And you'll be given 3 minutes. Thank you.

DR. MONTICCIOLO: Okay, thank you very much. I'm Debbie Monticciolo. I'm Chair of the American College of Radiology's Commission on Breast Imaging, so I'm representing the American College of Radiology. I have no financial disclosures. I am an unpaid volunteer with the college.

I want to say first that the American College of Radiology strongly supports any efforts to improve image quality. We've been champions of mammography image quality for a long time. In fact, the current MQSA is modeled on the original ACR accreditation program.

Having said that, we do have concerns about the EQUIP program that's being implemented. Many of them have been echoed already by the Panel members. The biggest is that it probably will not address the outliers. I know you're cognizant of that.

But first of all, positioning problems are an issue, but it is a minority of cases. We've heard these numbers of 90% or something. These are the failures, but the failure rate has decreased over time. When we started the program, 70% of sites passed, 30% failed on the first attempt. Now it's more than 90% pass on the first attempt. And the overall number of positioning failures, in absolute numbers, have remained essentially stable. So it's not an increase in positioning problems. It's just that, as you've said, other things have gone away. That doesn't mean it's not important. We really do want to address these outliers, but we

are concerned about someone who sends in a film or interprets a film, worse, that's terrible, is really sitting down and talking with the techs is probably not going to solve that. So we wanted to express that concern.

The other concern was kind of initiated by Dr. Berns. And we hope the FDA is very concerned about the implementation because technologists do fear the inspectors. Everyone does because there's a wide variability in how inspectors interpret even the current regs. And I can say that in my experience as a lead interpreting physician in four different states -- so I was at Emory University and the division head there; I was at Mass General in Boston; Upstate New York; and now I'm in Central Texas at a large academic center. And in 25 years of dealing with inspectors, I've only come across one who was actually both knowledgeable about the regs and consistent.

And the problem is we have no recourse. Everybody's afraid of being failed, and sometimes we just give them what they want, even though it's not in the regs, it's not appropriate. I mean, I can give you horror stories about outlandish requests. But the fact is we have no way, as facilities, to give actionable feedback to the FDA. So we would ask that the FDA, when you're implementing this, make sure that there is consistency and that facilities have a way to get back to the FDA and not depend on going through their inspector. And we really need a complaint mechanism. I mean, the facilities are required to have complaint mechanisms. I think it's reasonable to have complaint mechanisms for us, too, when we're subjected to these regulations.

Thank you.

(Applause.)

DR. ROSENBERG: Thank you.

Okay, any questions from the Panel for the speakers?

(No response.)

DR. ROSENBERG: Seeing none, okay, I now pronounce the Open Public Hearing to be closed. And I thank everyone who made the effort to come here and address us. Thank you very much.

We will now continue with presentations by the Food and Drug Administration. Dr. David Lerner will now present. His presentation will be followed by a Committee discussion. And as a reminder, though this portion is open to public observers, public attendees may not participate except at the specific request of the Panel Chair.

Dr. Lerner.

DR. LERNER: Good afternoon. My name is David Lerner. I am a breast imaging radiologist and a medical officer in the Division of Mammography Quality Standards at FDA. I'm going to speak about breast tissue density, breast cancer risk, and state density notification laws.

The major areas that I'll cover are determination of breast tissue density, density and the increased risk of breast cancer, density and the masking effect on breast cancer, state laws regarding patient notification, and mechanisms of education and outreach to patients and referring healthcare providers.

In other words, what is breast density, why is it important, and what can be done about it? And I'll just say that some of the slides may presume more or less background. I'm trying to address everybody on the Panel, so if they vary a little bit, I apologize.

Talking about determination of breast tissue density, density is an expression of how much of the breast is occupied by fibroglandular tissue. It's a radiographic assessment. Historically, it's an assessment on a mammogram. It may be expressed qualitatively as a description and/or quantitatively as a percentage of the volume of the breast.

Components that contribute to the breast density include those that are white or dense on a mammogram, radiopaque on a mammogram: glandular tissue, fibrous and

stromal tissue, and most breast masses. And areas that are black or dark gray on a mammogram, because they're radiolucent and considered not dense, predominantly are the fatty tissue.

Density is most often, and was historically most often, estimated from two-dimensional projections, the craniocaudal and the mediolateral oblique projections. Dr. Kopans, in an article, outlined a number of challenges affecting this determination. One of the significant ones is anatomy. Sometimes there is central fat within a cone or shell of glandular tissue, and when you see it from the side or from the top in two dimensions, it looks like that whole area is dense tissue.

Positioning is certainly an issue, and one of the reasons is that the posterior or other sort of extreme margins of the breast, if they're not included on the image, then the sense of what the total volume of the breast is may not be accurate. Compression is an issue because tissue can be spread out in different ways and appear more or less dense. And exposure technique similarly can affect the appearance.

There is some concern for subjectivity in density assessment, and in a very recent article in *Annals of Internal Medicine,* there was the following line, and this was based on actual review of cases and interpretations: "There is wide variation in density assessment across radiologists. The likelihood of a woman being told she has dense breasts varies substantially according to which radiologist interprets her mammogram." So, of course, subjectivity would be a concern in making any decisions based on that density that's been determined.

Some of the causes of increased density or high density:

- Younger age is not a definite correlation, but it's a general correlation;
- Pregnancy, breastfeeding;
- Fibrocystic changes;

- Hormonal influences, including normal hormonal influences during the course of the menstrual cycle;
- Hormone replacement therapy;
- Weight loss, which can decrease the relative proportion of fat compared to glandular tissue;
- Some antipsychotic medications; and
- Breast masses.

And density can normally vary over time. These are three craniocaudal views of the same breast in the same patient over time, and although it's not perhaps the best example, there is at least, as you see, some variation in the extent of fibroglandular tissue.

This may -- yeah. Okay, so this is playing through a series of images of the same patient over several years, and you can see that, again, there's normal variation. It depends on not only things like the mammography technique, but also when the menstrual cycle of the images were obtained. And so there are normal variations.

This is a more dramatic example of images before and after starting hormone therapy 1 year -- before hormone therapy and then 1 year into therapy, and it's the same patient, mediolateral oblique views, and you can see that there's significant increase in the fibroglandular density.

Now, in terms of nomenclature, most practices will use the standards of the ACR's BI-RADS atlas, the Breast Imaging Reporting and Data System, and there's been a change, a slight change, from the fourth edition in 2003 to the fifth edition in 2013 in terms of classifying the density.

These are some sample images, and these are the four current categories in terms of the descriptions of a density, and from your left to your right, you have the almost entirely fatty breast, the breast with scattered areas of fibroglandular density, heterogeneously

dense breasts, and extremely dense breasts.

And the two, I guess, major changes from the 2003 to the 2013 edition, the fourth to the fifth edition of BI-RADS, in the fourth edition there was both a description for each category and a quartile. So, for example, the almost entirely fatty breast was a breast that was less than 25% glandular, and the extremely dense, to take the opposite extreme, extremely dense breast was more than 75% glandular. So those quartiles have been removed in the current edition. One of the reasons, which actually was touched on a little bit in the 2011 Advisory Committee meeting, is that sometimes there's dense tissue in part of the breast, and if it isn't diffuse throughout the breast, there might be some dispute about what to call that and how to classify that. And so the percentage of volume of the breast has been removed from the BI-RADS classifications. Also, the categories were changed to letters rather than numbers because, as many of you know, numbers are used for the BI-RADS for a final assessment of a mammogram, and so to avoid confusion these were changed to letters.

Now, the breast density distribution among women, this comes from the U.S., but it's similar around the world. Approximately 10% of women will have breasts that are almost entirely fatty, approximately 40% will have scattered areas of fibroglandular density, approximately 40% heterogeneously dense, and 10% extremely dense. And the two latter categories are typically grouped together and called dense or called high density. And so the term "dense" covers approximately half of women. And this is relevant in any broad policy decisions that are made.

It's just a graphical way of looking at it, and again a full half of the circle is BI-RADS C and D, heterogeneously dense and extremely dense.

So as I said, there is some subjectivity in assessing density based on two-dimensional images. There's been some various attempts with various different techniques to try to

quantify the density. Various 2D and 3D techniques have been proposed, and these have included volumetric analysis of digital mammograms, dual-energy mammography, digital breast tomosynthesis, computed tomography, magnetic resonance imaging, and whole-breast ultrasound.

For the most part, these various techniques are either under research or in limited clinical use at this point. One study did point out that density measurements vary between different modalities, so it can make some of these not directly comparable to one another. Also importantly, quantitative density measurements tend to be lower than assessments made by visual estimation. And so, for example, those quartiles that have been removed in the current edition of BI-RADS for density, in the past, in the previous edition when extremely dense was a breast that was 75% or more glandular, in fact, on quantitative measurements, it's virtually unheard of for anyone to be a true 75%.

Now, why is density important? There are at least two reasons, and we've already heard a little bit about each: density and the increased risk of breast cancer, and density and the masking effect. Density is an independent risk factor for breast cancer. Greater density corresponds to greater risk, and at the extremes, the effect can be significant.

Now, these numbers, I'll just say, since I mentioned just now that the quantitative density assessments tend to be lower than the traditional visual estimation, these numbers are in the range of the traditional visual estimation. But if you're comparing a breast that's more than 50% dense to 10% dense, the risk is over three times as great. And for the 75% dense breast compared to the 10% dense breast, the risk is almost five times as great.

The reasons for this are not known definitively, but reasons have been proposed, including the fact that density may be sort of a marker of the level of hormone exposure, and the hormone exposure may be part of the reason for the risk, and that could be endogenous or exogenous hormones; also, that greater density could represent or does

represent just the presence of more glandular cells, and the more glandular cells are more sites that are potential sites for cancer development.

Now, in a study that I cited here, high mammographic breast density was not associated with risk of death from breast cancer. And I defer to the other study that Ms. Pushkin cited, which I'll have to take a look at.

Now, also in addition to the increased risk is the issue of the masking effect, which has also been mentioned. Again, the structures that can contribute to density include glandular tissue, fibrous and stromal tissue, and masses. But since they can all be dense, if they're all in the same portion of the breast at the same time, one can obscure the other.

It's called the masking effect. It's a known limitation of mammography. Some patients, especially if they have other high-risk factors, personal history, family history, genetic risk, may benefit from additional imaging such as breast tomosynthesis, ultrasound, or MRI. However, supplemental screening always carries with it the risk of false positives as well.

So what are some clinical approaches to dense breasts? Patient evaluation should include an individual risk assessment because it will help to stratify which patients may need something in addition. Monthly breast self-exam with a question mark because lately there's been a concern that that is too inconsistent, and it raises too many false positives. There should perhaps be a question mark on the next line as well, the clinical breast exam by a healthcare provider. Some feel that it also carries the risk of too many false positives.

For the next bullet, I apologize, and I'll say routine mammography instead of annual because I'm aware that there are different practice guidelines out there, and it's a subject of discussion which FDA does not take a position on; but routine mammography, in which some studies show that for dense breasts, digital mammography is more sensitive and more accurate than screen-film. And as you've heard, digital is now the vast majority of units

across the country, and also studies showing that DBT is better in a number of performance markers, like sensitivity and reduced recalls and positive predictive value compared to two-dimensional mammography for dense breasts.

So some clinical options if breasts are dense. And this really should say if breasts are dense and the mammogram is negative or benign. Women with average risk may not need further screening imaging. If it's warranted based on their individual risk, supplemental screening imaging of dense breasts may include various modalities, another mammographic modality. So, for example, a woman who only had a 2D mammogram might go on to have DBT; screening ultrasound and screening MRI are usually reserved if a women has high genetic risk or a personal history of cancer; and nuclear medicine exams such as positron emission tomography and breast-specific gamma imaging.

Now, again, you've heard a little bit about this as well. I'm going to talk about the state laws around the country regarding patient notification. There's been state legislation gradually around the country. It's been encouraged by patient advocacy. Twenty-seven states thus far now have laws mandating patient notification of density, and most of them -- almost all of them, I believe, require a prescribed text to be given to the patient, but as you've heard, texts vary significantly from state to state.

So this is an example of a state notification paragraph. At the time I put this together, Alabama, I think, was alphabetically first, so it's not favoritism. But this is the Alabama text: "Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue may make it harder to find cancer on a mammogram and may also be associated with an increased risk of breast cancer. This information about the result of your mammogram is given to you to raise your awareness. Use this information to talk to your doctor about your own risks for breast cancer. At that time, ask your doctor if more screening tests might be useful, based

on your risk. A report of your results was sent to your physician."

So I put this up because I want to kind of go through it and point out what is included and perhaps what isn't included. The contents typically -- well, some states will include a sentence such as "your breast tissue is dense."

A number of them will include some sort of reassuring disclaimer, like here, "Dense tissue is very common and is not abnormal." Some states will even include the fact that 40 or 50% of women have dense tissue.

This makes reference to the fact that -- to the masking effect: "Dense tissue may make it harder to find cancer on a mammogram."

And in this particular example from Alabama, it also says, "may also be associated with an increased risk of breast cancer." Some states do say that, and some states don't mention it.

The sort of general goal of this paragraph is often stated, which is to raise your awareness and encourage you to talk to your doctor or your provider and to ask your doctor if more screening tests might be useful.

So some of the variations among the texts, I just alluded to them, and you've also heard earlier today, some go to all patients. Some only go to dense patients. Some of them are conditional. If you have dense tissue, some of them are definite and say you have dense tissue. Some of them will include a mention of the fraction or the percentage of U.S. women who have dense tissue. And some will and some won't mention the risk factor, density as a risk factor for breast cancer.

And then some variations in the laws that implement these texts. Some appear to separate the notification of the patient's density from the explanatory paragraph, and some will have a combined paragraph. Some apply to different levels of density. They either say -- the law either says that it should go to patients who have heterogeneously dense or

extremely dense tissue, or extremely dense tissue in some states, or just dense tissue. And then that, I suppose, is open to a certain amount of interpretation. Also, some states differ on the party responsible for doing this notification, whether it's the interpreting physician or the mammography facility.

So moving from state to federal legislation, again, as you've heard, there are House and Senate bills to propose federal legislation to require notification. They've been referred to the Health Committee in the Senate and the Health Subcommittee in the House. If they are or were enacted, they propose to amend MQSA.

And they propose that patients be told information about breast density, the effect of density in masking cancer based on the patient's breast density, and that the patient should speak with her physician regarding any questions and whether she would benefit from additional tests.

Now, in terms of the existing state of affairs, MQSA requires specific certain communications between the interpreting physician and, respectively, the referring healthcare provider and the patient. The MQSA requirements from the Act are detailed and elaborated on in the implementing regulations.

Under the current implementing regulations, a written report of the mammogram results must be sent to the referring provider and a summary in lay language to the patient. The report to the referring provider does have certain requirements. It must include a final assessment, and it must include recommendations, certain specific items, but reporting of breast density is not currently required. And a summary of the report in lay language must be sent to the patient. And although I didn't quite fit this on the slide, there's no specific content requirement; it's a summary of the results. And, in fact, if a facility sends a lay summary that says your mammogram is normal, they've sent a lay summary.

In the previous meeting of the Advisory Committee in November of 2011, there was

general agreement among the members to require reporting of breast density in both the reports to the provider, your referring healthcare provider, and the lay summary to the patient.

And as you've heard, FDA intends to propose amendments to the regulations. Any proposed amendments will be published and will be open for public comment, and any proposed amendments are expected to address the issue of breast density notification.

I will give the disclaimer that I am not a lawyer and don't play one on TV, but the question may arise -- might arise in terms of federal versus state legislations and jurisdictions. There are a very small number of states with density legislation that specifically say that their law would be superseded if there was any future federal density legislation. For most states that have notification laws, the relationship to any future federal density legislation is unclear. And it's worth noting that MQSA does specifically allow states to have more stringent requirements than the federal standards. It's possible that that sentence would play a role.

Some of the many considerations in terms of notification. There is a general consensus, of course, that patients are entitled to know their medical information and risk factors, and density notification promotes informed and shared decision making between the patient and her provider. However, of course, we bear in mind that any further decisions, then, also depend on other individual risk factors. Some patients may benefit from supplemental screening, and some patients may not.

Supplemental screening does, of course, incur added costs both to the patient and to the healthcare system. And it's worth pointing out that only a few states mandate insurance coverage for supplemental screening.

Also, supplemental screening can find additional cancers but also carries all the risks associated with false positives, going through further workup, imaging, biopsy, anxiety, and

pain, and as I said above, potentially also costs.

So from the Advisory Community summary in 2011, the Committee members were in general agreement on requiring reporting breast tissue density in reports and lay summaries, with caveats. And I'll go through the caveats.

Several members did express concerns about what constitutes a dense breast. And this, again, we've kind of touched on both. Is it density category C plus D? Is it only D? Is it throughout the breast, or could it be concentrated dense tissue in one area?

And continuing on in the caveats, what recommendations might be made in advising physicians and patients on what to do with the information?

The Committee did not reach a consensus in the professional community on the magnitude of the risk that having dense breasts confers on patients, or the best way to further evaluate these patients through the use of alternative imaging modalities.

So I just would kind of respond anachronistically to the Committee then by saying that since then, there is somewhat greater scientific consensus on defining dense breasts as heterogeneously dense plus extremely dense or the BI-RADS categories C and D. There's greater consensus on the degree of risk of breast cancer conferred by density, and we've talked about some of that. There is now the availability of more different supplemental screening methods. And there is more information available on how to choose supplemental screening tools based on the patient's individual risks.

So because it is an individual discussion for every patient, this becomes something that everyone really needs to be educated about. And so I'll say a little bit about mechanisms of education and outreach to patients and to their healthcare providers.

There are education and outreach efforts to patients from various sources, from medical and scientific organizations, from the imaging industry, from interpreting physicians. And, you know, many of us have encountered examples like newsletters,

interviews in the lay press, other kinds of educational publications and handouts, public lectures and presentations. Sometimes a radiologist may have a public lecture, and just come and hear a little explanation of breast density and why it's important to you.

There's also been education and outreach to referring healthcare providers from various sources, from professional and medical organizations, from continuing medical education providers, medical journal articles, and clinical decision aids have been published.

And I'm just going to show an example, just as a representative example, again, I guess, not an endorsement but an example. When California was about to implement its state density legislation on density notification, a group of interpreting physicians put together a sort of flowchart algorithm for referring physicians, for the non-radiology clinicians to know how to help their patients through this process. And so these are actually two different slides, and I know they're small and you can't see them, but it's sort of an if-then.

You know, my patient comes to me and she got her mammogram report, and it says she's dense and she wants to know this and this, and it kind of walks the referring clinician through what they can tell the patient and what other tests might be appropriate and when and why.

So hopefully we've touched a little bit on breast tissue density determination, the increased cancer risk with dense breasts as well as the masking effect, various state laws regarding patient notification, and mechanisms of education and outreach to patients and providers.

Before I put up the topic for discussion for the Committee, I'll ask if there are any clarifying questions.

DR. LEE-FRENCH: Just one comment. When you said that the factors that contribute to breast density or are associated with increased breast density, I noticed that race was

not in there, in your list, and it has been shown that Asian populations, women of Asian descent do in general tend to have denser breast tissue. So it's also not true that the distribution of 50% of women across -- in other countries also have that distribution.

DR. LERNER: Okay, thank you for the comment. I appreciate it.

DR. PORTIS: Natalie Portis.

I guess I want to continue what some of our speakers said. I'm a real fan of truly fully informed consent of patients, and the variability that we see in the laws, I think, is really problematic. I was in the 2011 meeting when we first made those recommendations, and talking with lots of women all the time, I think many women, even in more urban areas who are informed about their healthcare, don't understand this issue and, if they get a letter, don't even understand really what that means, especially if we tend to downplay the fact that this is a risk and that they do need to be able to ask questions. And so I think that this is a tremendously important issue, and I'd like to see us have some uniformity across the states in how we help to educate women and, of course, practitioners about this.

DR. LERNER: Thank you.

So this ties into that comment. Really, we'd like input from the Committee on how facilities, referring healthcare providers, and patients are currently responding in states that currently have density notification requirements.

DR. ROSENBERG: Thank you.

Let's see, who are the radiologists from states with density notifications that would like to talk about it?

DR. LERNER: States and District, I think.

DR. ROSENBERG: States and the District. Thank you. They don't have representation. That's a different story.

Oh, did you want to talk about your experience?

DR. LEE-FRENCH: I live in Connecticut, and I practice in the state of New York, and when the law first went into effect in 2013, we notified patients specifically. We have two letters. One is for the non-dense breasts, and one is for women who we judge have dense breasts. And with that letter, when we determined that a woman had dense breasts, we also handed her the ACR brochure giving information about what dense breast tissue meant.

Surprisingly, we had very few questions from patients about this, and I just wonder whether women, now that it's been in effect for a couple of years, actually know this, actually read. It's sort of the fine print at the end of the letter. And I think density, in my judgment, is a very complex issue, and unfortunately, you can't put it neatly into a patient letter. There's a lot of study that goes on about density and risk and masking effect, and I think this is something that we as a medical community, we as a general public need to figure out the best way to get this information across and then figure out the best way of how to deal with this. It's really not -- the answers aren't out there. Yes, we can tell women you have dense breasts, and it may mean that you need to have something additional done. But unfortunately, we don't know who and what and how to deal with it.

DR. ROSENBERG: Please, Dr. Portis.

DR. PORTIS: Going to your points -- Natalie Portis -- I think there's no substitute for a conversation when we talk about informed consent, that we hand patients all the time piles of literature, and they're so used to tossing those things away and not reading them. And I think a lot of it does fall on the physicians, since most patients don't have the luxury of having a conversation with the radiologist after their mammograms, though I wish they could, that they have to really sit down and have somebody talk through it with them and have that conversation and see if they really understand what that means for them in particular and -- yeah. So I think that that's so important that it can't just be this written

thing, even though we can certainly improve that.

DR. TORRENTE: Jessica Torrente.

Yeah, I wanted to just echo Dr. Lee's comment that it is a complex issue, and I think that a lot of the variability and the confusing language, that it's a result of how complicated it is. So yeah, I think we struggle with how to best communicate that to patients in a way that is informative and not alarm bell ringing, you know? And I do think that ultimately you're right, that it's probably a discussion best had one-on-one for each patient with their physician. And certainly involving the referring physicians in some way or getting them more aware, you know, is important. And I'm sure other radiologists here who like give grand rounds or other things to referring physicians, even all these years later, it's surprising how many don't understand to the same degree some of the patients understand what some of the issues are.

DR. ROSENBERG: Yeah. And I think one of the other problems I see as a radiologist, in trying to think about things more broadly, even though all I do is breast imaging, is adding this burden to the primary care docs because there are a lot of other things they need to talk to patients about. Screening frequency is one on mammography, but there are so many other health issues. So I understand what you're saying, and I think it would be great if the clinicians were able to answer the question, if asked.

But I think it's variable whether or not that -- how that fits on the priorities for what primary care physicians should do and have time to deal with. But I think it's a difficult question, and we had breast density as a four-compartment decision, but we all know, reading the images, that it's far more complex, multifactorial in terms of amount and pattern that the four categories don't do justice to. So I think that's also part of the problem.

MS. CHAUHAN: Cynthia Chauhan.

I appreciate that the discussion is focused on those of you who have state laws. I'm worried about the people in the states that have nothing. Ignorance is never, ever an answer or an excuse. And so I really would favor moving toward a federal reg and looking -- I think we can look to the blood pressure community for ways to reach patients in an informative but not necessarily frightening way, through PSAs that say bring this up with your doc. It doesn't affect all women, but those whom it does need to be informed.

DR. LEE-FRENCH: This is Carol Lee again.

I absolutely agree. I think at least the breast radiologists that I deal with, which are all over the country, there are very few who would argue that it is not a good thing for women to be aware of their breast density. But as I said, it's a very complex issue. It's important to understand that it's not like your cholesterol number or your blood pressure number. It's very variable. And clearly it's a good idea for women to be notified. We are not against -- well, I am not personally against notification, and I think it would be a good idea, but it's very complicated.

MS. CHAUHAN: I agree that it's very complex, but I think what I'm talking about is when patients have knowledge, they can change how they meet with their physicians. And so if a patient comes in and says I understand breast density can be an issue, can we talk about whether it's an issue for me, that's a very basic level that involves the patient in the dialogue, in the decision making in a different way.

DR. BARKE: Lora Barke, breast imager from the state of Colorado.

The state of Colorado does not have legislation in place. It was attempted, and it's still on the table, but we'll see if it resurfaces this next coming year. Practicing in a state that does not have legislation, of course, there's a lot of conversation about it because it does exist elsewhere and people hear about it. The way we've decided to tackle this is, as we talk about risk and the potential risk, we don't want to ignore the other risks that may

be very important for that patient other than density. And so we've established a team of genetic counselors that end up talking to patients. And so we flag patients based on history, and they have a deeper conversation with the patients regarding their risk, which is encompassing all other factors, including those who may need genetic testing. So it does become a very complicated process, a long conversation, an important conversation, but it does require a lot of resources.

DR. ROSENBERG: Please.

DR. LEE-FRENCH: So with breast density, is there a genetic component? If my breast is dense, are my siblings likely to have dense breasts?

DR. BARKE: So there are risk assessment models that are being developed to include density that are not readily used at this time, but they're in the works. To answer your question, not necessarily. And so it is very difficult to identify. But because we're looking at the images as well as encompassing patient history into that, which is a pretty extensive history, we're then flagging the patients and then having conversations with them at a higher level with folks that have knowledge about risk.

DR. ROSENBERG: Yeah, Rob Rosenberg.

I think there was one article on a twin study of breast density, and there was a significant correlation with identical twins. So there is a genetic component. I think the other problem, as I see it, with the breast density notification is dividing between scattered fibroglandular and heterogeneously dense. And while we say it's a complicated measurement, we're splitting people for whether you're dense or not dense in kind of the middle of the curve of density. And so that's a lot of this arbitrariness in terms of how radiologists will read the cases and variability between for the patient one mammogram and the next one radiologist and the next. So the categorization we're using was not designed for the purpose that we're talking about using it for, and I think that's another

complexity to the problem.

DR. GOODSITT: This is Mitch Goodsitt. I am a medical physicist.

It seems it's the radiologist who should be talking to the patient more than the primary care physician because the radiologist can see the patterns, like you mentioned. They can see changes in density and all kinds of other things that the primary care physician isn't even familiar with. And they could also be the person who recommends ultrasound or MRI rather than the primary care physician, because they know more.

DR. LEE-FRENCH: I think that in the best of all worlds, it would be nice for the radiologist to be able to have a discussion, but any discussion that the radiologist has is usually limited by the fact that we don't always know all of the ins and outs of the risk. There's a recent paper based on Breast Cancer Surveillance Consortium data looking at several tens of thousands of mammograms, and what they found was that the risk of an interval cancer, cancer occurring between screens, was not necessarily higher among women just based on their density, but it was a combination of the density plus other risk factors.

And so risk assessment is a very -- I hate to keep saying it, but it is a very complex issue. There are different models that are appropriate for different women, and only one model, the BCSC model, incorporates density. None of the others so far do. I don't know. I mean, it's wonderful if the radiologist can have the opportunity to talk to women, but we don't -- we can't have -- you know, it really takes the formal risk assessment to do this correctly and do it properly and do it in the best interest of the patient and not to over-test, by the same token as under-testing.

MS. CHAUHAN: Dr. Goodsitt -- Cynthia Chauhan -- what you said echoes what patients want. But to get to talk to a radiologist, it's hugely difficult and in many settings impossible.

DR. ROSENBERG: Yeah, I would agree. I agree -- this is Rob Rosenberg.

I agree with that. And the other thing is all radiologists aren't great at talking to patients on these subjects as well, and that's another problem. We traditionally -- not this group here -- don't talk to patients that much.

DR. GOODSITT: Maybe it can be a team effort where you would talk more with the physician, you know, the primary care physician and as a team decide because they will know a lot more of their patient's history than you know. The problem is it's about 50% of women, so it's a lot of people.

DR. BARR: Yeah. This is Helen Barr.

That's what I was going to say. You're going to have tradeoffs too, because while your radiologist is talking to millions of women, you're going to wait longer to get your mammogram report, you're going to wait longer to get your mammogram. You know, there are tradeoffs for everything.

DR. ROSENBERG: All right, I think that completes this session. Dr. Lerner, thank you very much for your presentation.

And now we are at, let's see -- yeah, we now receive a presentation from Dr. Sudhaker.

Mr. Sudhaker, please.

MR. SUDHAKER: Hi, good afternoon. I'm Preet Sudhaker, the Chief of the Program Management Branch, also known as the heart and soul of the MQSA program or just the best branch at FDA.

(Laughter.)

MR. SUDHAKER: Thank you, thank you, thank you. I feel like I've been kind of built up a little bit with the comments of this meeting, intimidating inspectors. Now you know who to blame. You can say that's the guy, you know?

(Laughter.)

MR. SUDHAKER: But we hear your comments, and I'll address some of those issues in my presentation.

The MQSA training program is for new inspectors entering into the program, and the primary audience is our field inspectors in the district offices and regional offices and the states that contract with the MQSA program. So this training program is geared toward them.

The solicitation process, we work with the regional RRHRs, which are known as the Regional Radiological Health Representatives, and the Office of Regulatory Affairs' Office of Partnerships. These two offices are our field arm. We collaborate with them in all the training efforts.

The training callout goes out about 6 months prior to training, and so far, for the past several years, we have been holding the training sessions every April of every year. So it's become an annual process. Before, I believe we would do it twice a year. But now in the past 5, 6 years, they've gone to an annual session.

Once again, we work with the RRHRs in the field. These are the regional reps. We have five regions in the FDA and the district offices and the Office of Partnerships. The nominations first go to them, and they vet them because these field experts have a more personal relationship with the states. So they get the initial nominations, and they'll review them, and they make the recommendations to us, the Division of Mammography Quality Standards, and we make the final decisions.

The training itself has no cost to the states. The cost for the in-residence course, Course III, is given to the states via contract. So we give them money to travel, to cover their hotel costs, per diem costs.

The inspector ratio: The general ratio is one inspector for every 50 facilities in a

state. Initially, we tried to control the number of inspectors for a state because it costs money to maintain a state inspector. They get audited every year. We give them money. So we have some general guidelines of how many inspectors every state can have.

Sometimes we get some unique requests based on a state's unique circumstances, such as Wyoming or Montana, where the state offices are spread out, the field offices, like to be more efficient with travel time, and sometimes you ask for more than the ratio of one inspector for 50 facilities. What we do is we take it on a case-by-case basis and consult our district offices and our regional reps, and we do have some variations to that general policy. Sometimes we also encourage states to be proactive in planning retirements. As inspectors retire, we hope and we encourage the states to talk to us well in advance -- we prefer 1 year in advance -- so they can nominate a person and to give them training and they can mentor them to make the transition much better.

The MQSA training program is broken up into three basic courses. Course I is an online course, and that deals with the basic radiological physics. Course II is also online, and it gives them a basic overview of the program, and it's like about 18 to 20 modules that we have online that they can view; and they also must conduct or be part of three observational inspections. Course III is the nuts and bolts of the training program, and that's held in residence at the White Oak location, and that's about 2 weeks long; and after that course, the inspectors are required to do three mentored inspections.

So more of Course I: Course I is the introduction to radiological health physics. It is the Mosby's course. It's a very interactive course, it's online, and we usually open up in January of every year, and it provides students with the fundamental concepts of radiation physics.

Course II is -- once again, the main goal is to help the students gain a better understanding of the basics of breast cancer and a mammography exam, gain knowledge

about the equipment and the quality assurance programs, and have foundation of the inspection procedures. And we open this up after Course I is finished, usually February, and they have 2 months to finish this course. And it's self-paced.

Enhancements to Course II: Previously, this course was an in-residence course for about 2 weeks. In fact, all of these courses were in residence, so it was about a total of 6 weeks a student was required to come to Maryland to be trained as an MQSA inspector. But early in 2000 we transitioned this course into an online course, and how we did this was we evaluated topics that we taught in residence and said what topics or what material can we convert to an online format? And we also enhanced the observational inspections to increase their benefit. And I'll talk a little bit more about that.

Why switch to online resources for Course II and Course I? Many of our state partners have communicated to us that they have many state travel restrictions based on budgets. Many states have completely shut down travel for out-of-state travel, even if the FDA pays for it. You know, we have written letters saying, to the state contracts, that we'll pay for whole travel. But just to even leave the state, some have restrictions.

Many state inspectors also have very taxing workloads. In addition to MQSA, many of them work on other programs. So to be away from the office for about 6 weeks was also a challenge for many of our state inspectors. And also the personal schedules, you know, we heard much feedback that being away for 2 weeks, including the weekends, away from family and obligations was a big challenge for them, and that kind of deterred them for even signing up for the program.

We also have within our Center -- we had a Center-wide initiative also to save money, also for budget reasons, to utilize more online resources. When possible, we were encouraged to utilize online resources. And we have a state-of-the-art studio that helps us record and videotape presentations. So with that resource, it was very tempting to move to

online.

MQSA Course III: This, once again, is an in-residence course. It's to learn the specific protocol to be used by MQSA inspectors, both technical and procedural. This really gets into detail. This is more of a hands-on. We bring in, once again, all the RRHRs. Four out of five usually come. We bring in the field experts, and we work directly with students for about 2 weeks, teaching them how a proper inspection should be conducted. We also have a state-of-the-art software system to capture inspection data. So we also spend some time in educating them how to use that IT system and the software.

Enhancements to Course III: Every year we strive to prepare our students to really work on real-world scenarios. We use role-playing. We teach the concepts, and then we challenge our inspectors to role-play with our field experts in how to confirm understanding of the concepts. And we really highlight communication throughout the inspection process, and this goes back to some of the feedback we heard earlier. We heard there was intimidating and -- so that is completely opposite of what we try to portray, you know, because communication -- we stress the fact that this inspection is educational, inspectional, and we try to hit multiple purposes. Does it always happen? Probably not, based on your feedback. But we really stress communication. And in that role-playing environment, we teach them how to ask for what's required and what not to ask for, how not to go far, because we created boundaries and different requirements of the program.

Now, some of the things that I'm thinking about right off the bat is feedback. Based on the feedback I'm getting is some of these inspectors have multiple roles. They do other commodities that FDA regulates. MQSA is very different. You know, we announce our visits, and we work with the facilities to get the documents. So there could be some different hats they're wearing, so maybe we'll bring forth what hat to wear during an MQSA inspection. So we definitely heard your feedback, and we'll stress that third bullet point

highlighting communication and the ease that we need to put people in.

MQSA training pass/fail criteria: Course I, which is online, is 70%, and it's an ongoing course. After each session, they are given questions to test their knowledge, and at the end of the course, they're required to get at least 70%. Course II is 75% and three observational inspections. And we have worked with the ASRT to provide our inspectors, our trainees to get 15 credits, MEU credits for that. And Course III is the in-residence course. Once again, successful role-playing evaluations, there are five of them that we work on. And on the written test, it's 70%. An example of what role-playing is we have to spend almost a whole day on the closeout and how to communicate to the facility the results and what's required. So we do spend some time on that. And once again, it's 35 MEU credits.

MQSA inspectors are also required to have a continuing experience requirement, and what this means is they must provide -- they must perform 24 inspections in a 24-month time period. If an inspector leaves the program -- some inspectors we have, the supervisors go to other programs and come back later on when there's a need or someone retires. We do have mechanisms in getting them back into being in certified status, and we have -- by making them review material or having some mentor inspections by one of our field inspectors, FDA inspectors.

We also have MQSA continuing education requirements for our inspectors. Each inspector is required to have 15 mammography continuing education units (MEUs) and contact hours every 36 months, and this is confirmed by the inspectors. And our division supports these inspectors by providing educational funds via state contracts. In the state contracts, we add money for every inspector; we add $1,500 for every 3 years to help them get these credits.

Course II was also -- we also worked with the ASRT in trying to get Course II as a way to achieve this requirement of a continuing education requirement. Once again, the main

reason is that we heard feedback from states that they are having trouble meeting this requirement based on travel restrictions based on budget constraints within the state. It's available to be taken every 3 years, and they will get 15 MEU credits to satisfy that requirement.

Over the years, we continue to evaluate our students. Every inspector is audited once a year by an FDA inspector, and we continue to see what factors are involved in making a student successful in our training program. And a couple of key factors we found is adequate time given to online courses. We know that state inspectors are stretched; they're working hard. But right from the beginning, from Course I, we encourage and work with the state program managers and directors to make sure each state inspector is given adequate time to start the program right. We give them 1 month, but we have some students the last 1 week cram everything to meet that deadline. So the more time they're given for the online courses, the more successful they are.

We also encourage our state directors to assign the best and the right mentor for each student for the observational and mentored inspections. And what this usually means is more of a seasoned inspector, one who can communicate well, one who encourages questions, one who puts the person at ease to learn. We want these observational and mentored inspections to be as best as possible, especially the observational inspections. The observational inspections are done prior to coming to Course III, and we have found that inspectors that have had effective observational inspections succeeded at a much higher rate in Course III because they're already aware of the concepts, they know terms, they know the procedures somewhat. So that helps.

And interest in the program: We never want an FDA student to come because the manager told them they had to go. We have examples where they'll come in that situation, and the lack of interest and other workload pressures definitely had a negative impact in

how successful they are in that program.

And utilization of resources: We have many resources for them, and any student who can utilize the resources, I believe, has the tools to succeed.

Prior to coming to the MQSA program, I worked in different programs at the FDA, including the food, feed, and different milk and drug programs. We take a lot of pride in the MQSA program, our training program, because we own the training program in the division. Other centers outsource that training program to a centralized office, but MQSA is one of the handful of programs that owns their training program, and we dedicate resources. It's a division-wide effort in making the program a success.

And I just want to recognize a couple of people who are key in that success. It's Michelle Garza, Rachel Evans, Marisa Baima, Dr. Kish Chakrabarti, and all the office division-wide.

Thank you. And I'll take some clarifying questions if you have any.

DR. ROSENBERG: Yeah. Any questions for Dr. Sudhaker?

Carol.

DR. LEE-FRENCH: This is Carol Lee.

You may have already said this, so I'm sorry if you did and I missed it. What are the minimum requirements before somebody -- to be an inspector?

MR. SUDHAKER: We have a couple of requirements. They have to be an RT and a bachelor's degree and certified by ARRT with 2-year experience and 30 hours assigned with a B.A. or --

MS. CHAUHAN: I don't know if you were here -- oh, Cynthia Chauhan -- if you were here earlier when we were talking about the terrified, terrorized technicians, and one of the points brought up was they don't feel they have recourse if they have a complaint about the situation. You mentioned in your thing that you teach them to be courteous and respectful.

Do they give the technician any kind of card saying if you have a problem with this, this is the person you can contact? Do they give them your card?

MR. SUDHAKER: No, not my card. Not my card.

(Laughter.)

MR. SUDHAKER: I might get some angry hate mail, but no.

MS. CHAUHAN: But to give them a direct --

MR. SUDHAKER: Yes.

MS. CHAUHAN: -- channel that does not have to go through any kinds of vetting, where they can say this was bothersome to me in this way.

MR. SUDHAKER: Yes, thank you for the question. The MQSA hotline is -- it's a national hotline that we have for inspectors, facilities. I think most facilities are aware of it. It is a third party that we contract out. It is completely independent. You can call the hotline directly, and each call we monitor. Each call is recorded. And we have received complaints, you know, but far and between. That's why I'm joking about it, but I think they talk about the issues, and a few problems can seem like a big issue. But overall, we have an amazing group of inspectors that do amazing work, but we do have a few situations where it can get -- that might need our mediation. So the MQSA hotline is probably the best resource, you have a facility, to call and report that. I can understand a facility being hesitant to call the state program for any recourse. They might be blacklisted or something. But yeah, MQSA hotline is the best source.

MS. CHAUHAN: Does the inspector make the technician aware of this at the visit and give them that information?

MR. SUDHAKER: If you're asking a direct question, that if you have any complaints, to call this hotline, probably not. We do leave a document behind at every inspection, and it has the MQSA hotline for any questions, to contact the inspector or the hotline for any

questions. So that resource is clearly listed.

DR. BARR: This is Helen Barr.

It also has the inspector's supervisor's name and contact information on there. But we will take a look at it and see if there's any additional information, because I was surprised to hear the comments about no resources because we have, you know, a really well-manned hotline that takes all sorts of calls, and we have gotten calls that say, hey, I don't think I should get this violation, and we look into that and work it out. So I guess we need somehow to raise the awareness better, so we'll take a look at those resources.

Thank you.

DR. TORRENTE: Jessica Torrente.

Are you planning any additional -- or any changes to the curriculum for training prior to rolling out the EQUIP program?

MR. SUDHAKER: Yes, yes. Our initial rollout will be direct to facilities, and it will also include -- we actually taped Dr. Barr's presentation today, and hopefully it came out well and we can post that also online as a webinar. And also each regional rep is going to meet with the states in each region, with the states they cover, and train inspectors directly with that. And then we'll also get feedback. I've heard so much from Dr. Barr, so I wanted to say earlier that the first year is going to be a great learning year for us, for facilities and us, and as we get feedback, we will make adjustments.

DR. ROSENBERG: I would reiterate the knowledge of the MQSA hotline because I was unaware that that was appropriate for at the inspector level, and I don't think it's well known. Maybe, then, that should be the lead when the inspector arrives at a facility. I think that leaves a good message both ways.

MR. SUDHAKER: Yeah. I mean, as Dr. Barr said, the MQSA hotline is used for literally everything. I don't think they even have any -- anything anyone has, you can call up. But

we'll reinforce that. Thank you.

MS. URIELL: Diane Uriell.

The first two modules of the training is online, and then the third one is in residence. When you have the third portion of the training, do you do a recap or kind of touching base to what they learned online, to then integrate it to the full learning in the practice sessions?

MR. SUDHAKER: Yes. The first day we give them a test on the first two modules just to make sure. You know, we kind of review. The first day we spend time reviewing and kind of assessing what they have learned, and based on the results of that first day quick assessment, we kind of spend time with what needs to be reinforced. And all the first two modules, the first one is more of a theory, the fundamentals of physics, but the second course kind of leads into Course III.

DR. BARR: This is Helen Barr.

Also remember that between Course II and Course III, there's those observational inspections where they go out with a seasoned inspector and actually see what it's like. So that helps to reinforce also.

MR. SUDHAKER: And the quality of those inspections is key because, once again, it reinforces the concepts.

DR. LEE-FRENCH: This is Carol Lee.

Do you think there would be any value in setting up a routine post-inspection evaluation online, perhaps by the facility, of the inspection process? I think many people would be very pleased with the way the inspection went and others would have some issues. And this way they wouldn't have to pick up and call a hotline and -- because I know I would be very hesitant, unless something was really egregious. But this way you would have more feedback on how your inspectors are doing, and it wouldn't -- if you just did it online and sort of routinely, it could be voluntary, for example. I think that would be a nice

resource.

MR. SUDHAKER: And I think that's a great idea. And for the past 1 year in the Center for Devices, we had to put a customer survey and an e-mail signature. We do really value the feedback, so we'll definitely look into that. Thank you.

DR. BARR: This is Helen Barr, FDA.

Yeah, I think all of that are really good ideas, and a lot of stuff is going through our heads based on the great suggestions, like the timing of when we're going to go over the EQUIP questions and stuff. Just realize -- and I have to investigate this more, but we have a lot of constraints on what we do and what's considered a survey, what input we can take, but the concept, we're hearing and we're looking to do what we can.

DR. ROSENBERG: Okay. Okay, thank you very much for your presentation.

And it is now time for a 15-minute break. Panel members, please do not discuss the meeting topic during the break amongst yourselves or with any member of the audience. And we will resume at 3:20? Yeah, 3:20.

Thank you.

(Off the record at 3:06 p.m.)

(On the record at 3:20 p.m.)

DR. ROSENBERG: Okay, I guess it's now about 3:15, 3:20. We now have a discussion led by Dr. Helen Barr, Director, Division of Mammography Quality Standards at Food and Drug Administration, titled Committee Discussion: What are the Future Challenges for MQSA?

Dr. Barr.

DR. BARR: I'm going to sit up at the table since this is a discussion, but first I have to take my Advil. You all give me a headache.

DR. ROSENBERG: Is that a one Advil or a two Advil?

(Pause.)

DR. BARR: Helen Barr, FDA.

Because I notice we're losing some expertise, so I always heard about people doing back-of-the-envelope, because I actually did back-of-the-envelope to see if it works or not. So what I wanted to talk about is some things that are coming to our minds at FDA about this brave new world that we've entered with certain pieces of equipment and different things like that. So some things I thought of that are challenges are coming up are the role of synthesized images, and I have some thoughts on that, and some information about accreditation. How do we accredit DBT units?

Of course, the issues related to breast density. Should we be looking at things like volume in terms of what physicians read, what technologists do? Should we look at phantom image score once screen-film goes away, could it be raised? Just different things like that, and I don't think we can touch on all of them today, and really, I'd rather hear your thoughts than my thoughts about what out there might be useful for us to look at. But I think I'll start with synthesized images just because I know Dr. Berns has to leave, so we can get some input.

So what happened -- so there are three DBT vendors approved for marketing, and they have various different indications for use. Some of them have indications for use that involve the use of synthesized images that can be used in place of acquired images. One of them has an indication for an all-DBT screening, so there are no 2D images. And the problem is that at the current time, accreditation for DBT doesn't exist, so what we at FDA had to do is come up with a mechanism that this technology could be used until there's an accreditation program, so we based that on the 2D accreditation, the 2D unit.

A portion of the unit has to be accredited, and the personnel requirements, you know, the personnel have to be people in a certified facility and meet all the requirements.

And we recently reached out with accreditation bodies and with the help of manufacturers to say, accreditation bodies, we really think that you're going to need to accept synthesized images because otherwise facilities are going to be having to acquire 2D images to submit for accreditation whose sole purpose is to submit for accreditation. So you may give extra radiation to a patient that's not needed, you may acquire views that clinically aren't needed solely because accreditation right now is based on 2D images.

So working with the manufacturers, the ABs are willing to do that; they're working through the technical aspects of how that could happen. So that's sort of the first step in that, and I'd like to know your thoughts on that, but beyond that, then the next step is how do we get a DBT accreditation program instead of the sort of ad hoc system that we have now, and can we, could we accredit DBT using 2D images, be that acquired or synthesized? We heard today that a great bulk of accreditation failures, although accreditation failures are a small percent, when they fail it's based on positioning, which, of course, doesn't change between the -- could change slightly if you acquire the DBT and the 2D images in separate compression sessions.

But for the most part, the positioning isn't going to change; it's going to be captured on synthesized images, so based on the fact that we know that's our biggest problem, is there a way to do that, or do we have to wait, which could be a long time, until accreditation bodies are capable of looking at a full DBT exam for accreditation? So that's where I think I could use your input the most right now; then if we have time, we can go into some other things.

DR. LEE-FRENCH: This is Carol Lee.

It seems to me that the synthesized or the 2D images could be acceptable for accreditation of tomo units in that it's -- the major factor is the positioning. I have concerns about the synthesized image, but that's a separate issue, and that's outside of the purview

of MQSA, but in terms of -- you know, the vast majority of the failures are for positioning, and that, as you pointed out, Dr. Barr, is the same no matter whether it's 2D, directly acquired, or synthesized.

DR. BARR: With your experience, and I'd like to hear from others, too, if they have experience, do you feel if a facility failed on something other than positioning, then there would have to be another mechanism of evaluation in the rare event that it wasn't a positioning failure? We're going to look at the numbers. I'm not sure how many people have solely a failure for something else that doesn't also include positioning, but I'd be interested in hearing your thoughts.

DR. NEWELL: So Mary Newell.

You're saying that the 2D would be the surrogate for -- it would be the way we would judge the whole unit would be based on the 2D. So we do tomo, and I would say I've never seen a case that was technically inadequate based on the 3D portion of the exam solely, so it's never like I saw a great 2D portion of the exam, and then the 3D was unacceptable. So in my experience, it would be an appropriate surrogate.

DR. TORRENTE: Jessica Torrente.

I would agree with that. I think just the way that those images are generated, if there was a problem, it would manifest first on the tomo portion and then necessarily be translated to the synthetic image, so I think it would be an adequate surrogate.

DR. BARKE: I agree with others in that. I would also have to add that there is some post-processing that can be done, however, to the tomo image, for example, to reduce metallic artifact that, you know, may be present on the tomo images. That may not be a problem on the 2D images, and I think that's the only situation I see that there could be a potential difference.

DR. ROSENBERG: Yeah, my experience reviewing is that the positioning is not a

problem for the synthesized images. My -- yeah. If you see, yeah, motion, you ought to see -- my problem, I think, with synthesized images is that if you are going with tomo and synthesized images, then there's no phantom image of what you're actually seeing, and that kind of bothers you with -- in other words, if you're -- the phantom is of the 2D image only, and so there is no routine phantom image being done of the studies that are being done for clinical purposes, so I think it's a separate issue; I've talked with Dr. Berns about that. But for the review process, you can evaluate -- I mean, you cannot evaluate the contrast or noise really on the synthesized image, I think it's -- that's not an issue, but that doesn't seem to be a common problem for failure, and that can be evaluated elsewhere.

DR. BARKE: Lora Barke again.

I would agree, though, that if a facility is using the synthesized images, they should be evaluated based on those images and not 2D acquired images that they're not using for clinical use.

DR. GOODSITT: This is Mitch Goodsitt, a medical physicist.

You can generate a synthesized image of a phantom, but I think there's been studies, like there's one by the Duke group, and it was published in *Medical Physics* that shows that the image quality is considerably worse than a 2D mammogram, essentially one less fibril, one less speck group, and one less mass almost, because the resolution is poor and the noise is very different also, and that has, in effect, unseen subtle microcalcifications in the ACR phantom, so I think that has to be considered also.

DR. BARR: Yeah, that's a good point. I was concentrating on the clinical images for synthesized, but you raised the question of the synthesized phantom image, and I think that's a really good point.

DR. ROSENBERG: Because, again, the resolution of the synthesized image or the tomo image is different than the standard 2D, I believe, for all the vendors.

DR. GOODSITT: Not really. For the Hologic, they do bin pixels, so it becomes 140 µ instead of 70 µ. They take 4 pixels and put them together, but then they reconstruct at, I think they say 95 µ, but it's still interesting to see what people have found, so -- and then the GE, as far as I know, it's all 100 µ pixels, and I'm not sure, I think the Siemens is 85 µ.

DR. LEE-FRENCH: But you can't do that with the phantom?

DR. GOODSITT: You can. We do. You can reconstruct -- oh, you mean what does Hologic do or --

DR. LEE-FRENCH: No, no.

DR. GOODSITT: You can synthesize an image of the ACR phantom with -- by taking DBT. It doesn't look -- no.

DR. LEE-FRENCH: So why is -- the synthesized mammogram is good.

DR. GOODSITT: That's something that you and every other radiologist is going to have to talk about. I mean, there is enhancement of certain microcalcifications of a certain size, but subtle ones are lost, and when you do many, many people like Skaane, I think it is, I'm not sure how you pronounce his name, he's done a huge study, and he showed no difference, but a lot of radiologists looking at many, many images, and you might not notice some subtle differences, so it's got to be side-by-side comparisons.

DR. BARR: This is Helen Barr, FDA.

So am I hearing that it might work for the clinical images, but it might not work or be more problematic for the phantom image without a true 3D phantom?

DR. GOODSITT: Well, tomosynthesis is quasi-3D, and it does require -- to really do it right, you need a phantom that actually has more anatomical noise, structural noise above and below the plane that you're interested in, so the ACR phantom is uniform with a nice plane that has all the targets in it, so you're right, you'd have to have different requirements, you'd have to set different levels, and I think the manufacturers do that. So

Hologic will, say if you do a C-View of, you know, of an ACR phantom, this is what you should see, and it's not the same as an FFDM image.

DR. BERNS: Eric Berns, physicist.

So Dr. Barr, is the question about the process of accreditation and what images, whether it's a 2D tomo or synthesized should be submitted and evaluated, is that sort of what you're trying to sort out?

DR. BARR: Helen Barr, FDA.

What I'm trying to sort out is what Dr. Newell said. So I'm trying to sort out two things: One is we don't want patients to have images acquired solely for the purpose of accreditation, so that's the first thing is, is can we -- you know, if I do all DBT and it comes to accreditation time or it comes time that I need an additional mammography review, can I synthesize the images and send them in? Then the second thing is can we, instead of the certificate extension program, which we have now for DBT, can we establish, can the ABs establish real DBT accreditation programs using 2D images, acquired or synthesized, as a surrogate for accrediting DBT, or do we have to wait until such time as accreditation bodies can get facilities to send, upload, and view DBT? So it sounds like I'm hearing, which I didn't really think about a lot, is that it might work for clinical images, but the phantom end might be a different animal.

DR. NEWELL: So it seems as though, for the phantom, a center, if it's going to do only DBT, its phantom has to -- you have to live with that with the phantom, right? So you can't send a beautiful 2D image as your phantom; you have to live by the results of your 3D phantom image would be what I think, you need to be held to that standard.

DR. BARR: Yeah, this is Helen Barr, FDA.

Yes, even though the phantom is designed for 2D, at least at this point.

DR. ROSENBERG: I assume that current -- I mean, currently we review C-View, and

I've seen the GE synthesized images for clinical, and at the same time, it is a 2D image phantom that's being submitted for the physics evaluation.

DR. BARR: This is Dr. Barr.

But that's for -- that's under this, you know, quasi non-accreditation program that -- you're correct -- reviews. Because what's happening is, is FDA is sort of becoming the accrediting body only in the sense that it is using an already existing certificate, and we're looking at the 2D portion of the unit as far as images and phantom. We're looking at the personnel and their modality training in DBT, but we're not looking, obviously, at any DBT images or DBT-designed phantom.

DR. ROSENBERG: Okay, next challenge.

DR. BARR: Well, I'd really like to hear from you. Do you see things out there that you think are going to be kind of the next thing we're going to have to tackle? You know, should we be looking at things like volume, even though that was a big contentious thing at the beginning of MQSA, and how to keep that across the country? We all know other countries are using much higher volume. Are other issues out there that you think need to be incorporated into MQSA or might be hard to incorporate into MQSA? I think this synthesized image and how to get DBT accredited is a big -- so I'm glad we talked about that. Anything else that people see out there?

DR. BARKE: Lora Barke.

So when it comes to volume, I only know the volumes that we in our facilities read, so I know that we're way above the requirements. And we talked about clinical image issues in places that have very low volume. So I guess I would want to know what sort of volumes are we seeing out there? Is it hard for people to get the volumes in those rural areas, or is this an issue to get to the minimum numbers that are currently established, and kind of what's the range of numbers?

DR. BARR: Helen Barr, FDA.

We do see that some people struggle to get the volume, and looking at volume is a bit difficult, and thank you for bringing it up because I meant to say this when Rachel Evans gave some volume in her talk. The volume that MQSA collects is from the facilities; whatever the facility reports to its accreditation body on the forms when it applies for accreditation is what we use. Now, some facilities probably calculate and put their exact volume, some facilities probably guesstimate, so when we say 35 million mammograms are performed in the U.S., well, first of all, it's only in every 3 years that we get that data. That's really, you know, not a hard and fast number.

So volume is hard, and even if we look at it, it's going to be a little difficult, but there are facilities that do struggle with volume. What we can try to do is see, you know, try to tease out what proportion and how many people would be affected by a change in volume, but you made me think of something else, too, that went out of my head, but --

DR. ROSENBERG: Facility volume or radiologist volume?

DR. BARR: I was sort of talking about radiologist volume because we were working on an IOM workshop where there were, you know, radiologists from Germany and the Netherlands and places where, you know, they look at us like how can that be volume, you know, you need to read at least this many. So I was really talking about physician volume, but you know, there's obviously technologist volume and physicist volume and things like that.

DR. LEE-FRENCH: This is Carol Lee.

The presentation about the failures talked about -- it was volume related, but my understanding is that was the facility, number of mammograms performed by the facility, and there are no minimum numbers of that; is that correct?

DR. BARR: You are correct. That is volume of the facility. We saw -- but, of course,

volume of facility is going to -- not always, because people may read at more than one place, but facility volume could translate to technologists and interpreting physician volume if they don't work at multiple places. But you're right, that was facility volume.

DR. BARKE: Lora Barke again.

I guess the question is how much would it impact access if we changed the numbers? That really is the bottom line, right? The radiologist numbers. And if --

(Off microphone comment.)

DR. BARKE: It is being looked at, okay.

DR. ROSENBERG: Yeah. And I would say one of the issues is audit, is my -- is one thing I work on a lot is with the low volume, then the audit is of little value for the radiologist, and so if we're talking about improving quality at that level, that is another consideration.

DR. BARR: This is Helen Barr, FDA.

I also had an interesting comment to me during the break, wondering if there could be different volume requirements, you know. Does a person who works at a university center who does huge amounts of mammograms need the same volume requirement as somebody who works in a rural setting; does it have to be equal across the board? Oh, and I know what I wanted to say about radiologist volume at least. So I serve on the review committees that review mammographic and ultrasound devices to come to market, and one thing that I look for and ask for in the reader studies that come in is that we have a spectrum of radiologists that represent, you know, radiologists who read low volume versus those who read high volume because we do have that spectrum out there clinically.

DR. ROSENBERG: I mean, it's an interesting question of having different levels depending on the -- I guess the population volume of the area or access. That wouldn't, I don't think that would affect as many. I don't know how the Committee would view that,

having different volumes depending on where the radiologist is practicing, where the facility is located.

DR. BARR: This is Helen Barr, FDA.

I don't know how the federal government would view that, but it was a thought-provoking question. And are we convinced, as a community, that volume improves interpretation? I mean, certainly the Europeans have us convinced of that; we're pretty convinced as a community that that's the case.

DR. NEWELL: With the new American Board of Radiology testing paradigm, do you anticipate any changes in the number of exams that need to be read in what period, over what time, during training?

DR. BARR: Dr. Lerner is much more astute at that. I don't think we -- do we, David, anticipate? Stand up, I can't see you.

DR. LERNER: I don't have all the numbers in front of me, but essentially, that just affected the timing during which the -- you're talking about people in training, I think, if I understand correctly? So the timing during which they have to complete their supervised examinations as part of their initial experience. Essentially, we extended -- there was sort of a leniency for those who passed the board exam at the immediate earliest possible time. Since the timing of the offering of the board exam was changed by the American Board of Radiology, we essentially just extended that time concession to all trainees. So if I remember correctly, it's within a 6-month period in the last 2 years of training. And, in fact, in practical terms, people tend to become qualified interpreting physicians without the boards because if they've done a certain number of months of training and they've done a certain number of supervised exams, they tend to complete that at the end of residency or fellowship but before they've taken their final boards.

DR. NEWELL: Out of curiosity, what is -- I never understood the within 6-month

period time frame. Why is that important, that 240 cases need to be read within a certain given time period?

DR. LERNER: Well, it dates from before I worked with MQSA, but my understanding is just in terms of the sort of intensity of the experience, the learning experience of, you know, reviewing the supervised cases with a mentor, that's -- it's sort of absorbed better if you're doing that in a concentrated period of time. And Dr. Barr may have other thoughts on that.

DR. BARR: Helen Barr, FDA.

No, I think that that -- before my time, too, but I think the original reasoning was okay, I do that, and then I wait 2 or 3 years to practice and --

(Pause.)

DR. ROSENBERG: Next?

DR. BARR: Well, again, I'd like to hear from you. Do you have any other thoughts on any issues that you think, coming down the pike, might be a challenge?

DR. ROSENBERG: I can raise one about image transfer with digital, with tomosynthesis, which can be a problem when patients change facilities depending on software that everybody has.

DR. BARR: Helen Barr, FDA.

Yeah, we certainly -- I mean, we get facilities calling and yelling at us that, you know, another facility wants to transfer them images, and they can't accept it and how horrible they are, and why can't they just, you know, do hard copies and send them over. So yeah, I hear you. But that made me think of another thing about lossy versus lossless compression, so --

DR. LEE-FRENCH: This is Carol Lee.

Where I practice, we have a very active second opinion service, so every day we get

multiple tomosynthesis exams that we are unable to view, and occasionally the finding is only on the tomo, so we're unable to comment on it, and it really is an issue, and I see it as only increasing as the availability of tomo increases.

DR. BARR: Helen Barr, FDA.

Let me ask you: Is that between manufacturers, of the same manufacturer, both?

DR. LEE-FRENCH: No, it's the same. My understanding is it's the same manufacturer in the vast majority of cases, because we were encountering this problem commonly when there was just one FDA-approved vendor. So I'm sure it's the way the facility transfers -- puts it on a CD. Sometimes it was loadable and sometimes it was not, and it continues that way.

DR. BARR: I think we have -- Helen Barr, FDA.

And maybe Diane can comment a little. We had, I think, even those kinds of issues with accreditation bodies looking at images or -- I don't know, you know, the ins and outs. Maybe you might help me.

MS. URIELL: Yeah, it's Diane Uriell.

Yeah, we do frequently get feedback from customers of the difficulty with the images, of transferring them or trying to upload them. It doesn't seem to be from the manufacturers' standpoint. It's really how they're loaded in the correct format so that it can be received, so that's primarily the concern we hear.

DR. BARR: Helen Barr, FDA.

Is there anything that could make this better from a manufacturing, the manufacturer's end or an outreach end? I mean, how do we -- because we're hearing the same thing, so how do we facilitate different facilities looking at different images? I mean, are there instructions on how to load your images or --

MS. URIELL: Yeah, I think that, you know, manufacturers prepare tip sheets or

guidances on how to load the images and, you know, trying to share that with the clinical specialists that are out in the field, but then they're transferring that knowledge and understanding of how to upload with the physicians and the radiologists. So there are methods. It's kind of the IT aspects of -- not the medical device itself, but you know, the IT part.

DR. ROSENBERG: Yeah, I mean my experience, in part, is that the facility never reads the exported images of that facility, so it's always when the images get transferred to somebody else that there's a problem noted, so there's no good feedback or -- you know, that it's -- or it's a difficult feedback, if there's a problem.

DR. LEE-FRENCH: This is Carol Lee again.

One problem that we actually run into very commonly, as well, is that the images get loaded onto our PACS system, we view it on a separate tomosynthesis viewer, but when they get loaded onto our PACS system, sometimes they -- every time you try to open that patient's exam, even to look at the 2D images, it crashes the system, and you have to restart your PACS system over and over, and occasionally there's a case that we cannot view at all because it just keeps crashing the system, so it's some sort of IT problem. I'm not sure exactly what it is.

DR. TORRENTE: Jessica Torrente.

I was going to say it seems to be like an IT problem, but surely it must be overcome-able because I just remember even during my residency, you know, it was more commonly a problem. You couldn't open outside CTs, for example, and then, you know, over time that problem seemed to kind of go away. So I don't know if we could look to how that was solved within our IT departments, or I'm not sure, but clearly I think it's a similar problem, you know, perhaps because it's a larger volume exam, maybe that has something to do with it as well, but I think it seems to be something on the IT end of things.

DR. ROSENBERG: QA on export.

DR. BARR: Yeah, this is Helen Barr.

Maybe instead of a universal QC manual, we need a universal transfer manual.

DR. PORTIS: Natalie Portis.

On kind of a different end of this, I think from the patient perspective, there is so much confusion and concern amongst consumers right now about mammography because there have been so much press in the variation of the recommendations, and I think our conversation about density kind of elucidates that. I just see that a lot of people are very confused and concerned, and even some people are shying away from mammography, and I applaud our efforts to have standardized training and standardized quality.

And I think this other issue we really have to deal with as well, and the IT problems, just bring that up again, that one center can't talk to another, and so to really give quality care to patients, I think we have to deal with this challenge too. I mean I have, you know, patients that run the spectrum from low income, underserved people who don't have access, but also more educated people now who are saying I'm not going to get a mammogram anymore, and that doesn't help the issue of volume, but -- so I hope that we will continue to have conversations about that and try to give a clearer message to patients about what mammography can and cannot do and help them really, you know, again, really be more fully informed about these issues.

DR. LEE-FRENCH: This is Carol Lee again.

I think, Ms. Portis, you bring up a very good point, and it's outside of the purview of MQSA or the FDA or really all of us, but we, as breast imagers, are faced with a very schizophrenic kind of situation where we're being told that we're screening too much and there's too much false -- there are too many false positives and too much over-diagnosis, but by the same token, we're being told that we should be telling women that they need

additional screening which is associated with even more false positives perhaps with the so-called over-diagnosis.

So it's really a struggle for us to know exactly how to counsel patients even though the mathematical models all show that the most lives saved are by screening every year starting at age 40, we're getting these recommendations against it, and it's very frustrating for us, as breast imagers, to have to deal with that and by the same token being accused sometimes of withholding important -- we're not -- that is not our intent. We're striving to decrease breast cancer deaths in this country.

DR. PORTIS: And I totally trust that intent, and I think, though, people are just confused, deeply.

MS. CHAUHAN: And I share your frustration and I -- oh, Cynthia Chauhan.

I, again, am concerned about the women who walked out without a good knowledgebase, either because of misinformation or because cost interferes with their ability, and so they're told you don't really need this, and they're thinking, well, then, I don't have to spend this money, and they get mis-served based on that, so I think you both bring up a really, really important issue.

DR. GOODSITT: This is Mitch Goodsitt.

I just want to bring back to the IT issue -- just mentioning the others. I think it will be solved when the PACS systems can all read the DICOM images that are in the special format for a DBT image. Right now a lot of them can't; I think that's part of the issue. Once that's done, then it will be just like a CT, and it should solve a problem that shouldn't be there.

DR. LEE-FRENCH: But does it have to be on the level of a PACS system, or can it be at the level of the acquisition of the --

DR. GOODSITT: Well, if you transfer the image to your PACS system, then take the

image from the PACS system to your workstation, if it's all in the DICOM format for DBT, it should all be easy. It shouldn't have any issues. Right now people store them in many different formats; I think that's the problem.

DR. BARR: Helen Barr, FDA.

Speaking of storage, if anybody has any thoughts on, you know, lossy versus lossless compression, I'd be interested in hearing them also.

DR. BERNS: Eric Berns, physicist.

This might be a reach and may be impossible, but maybe -- units and modality shouldn't be approved until they meet the DICOM standard so that the images can be shared. Maybe that should be a requirement that images can be transferable before they're approved, because this happened when we go, you know, at the beginning of 2D, digital images couldn't share and then this -- at these meetings, it was the biggest topic; it's like, well, how do we share images. Anyway, maybe we will bypass that but -- with your approval process.

DR. BARR: This is Helen Barr.

Well, I'll certainly, you know, bring it up to my colleagues who, you know, are in charge of approving medical devices. It's certainly an interesting thought.

DR. ROSENBERG: Yeah, given that I was at some of those meetings, I don't think it was -- it was not a consideration.

(Pause.)

DR. BARR: I wanted to give anybody who -- Helen Barr, FDA -- who needs to leave just a last chance to, if you want to say something before you have to leave, and then we're going to just, I guess, Dr. Rosenberg, go around and see if anybody has any final thoughts for me.

DR. ROSENBERG: I guess my only other thought was whether there needs to be

updates to the required audit, if the group has any thoughts on that, the medical audit.

DR. BARR: Helen Barr, FDA.

Just let me also say, in the same constraints I have about talking about breast density reporting, that we also expect the proposed reg amendments, if they ever get published for notice and comment, to also address the medical audit.

(Pause.)

DR. BARR: Helen Barr, FDA.

But if you have ideas, I'm certainly willing to hear them.

DR. BARKE: Lora Barke.

I would add that the medical audit is critical, and when we talk about numbers, that it's not just about numbers, it's about auditing and knowing your outcomes for improved performance.

DR. BARR: Helen Barr, FDA.

Right. No matter what your numbers are, certainly that has got to be a component, yeah. Thank you.

DR. LEE-FRENCH: I have a question. This is Carol Lee.

Dr. Barr, can you just summarize what the steps going forward in terms of MQSA and density notification are?

DR. BARR: Helen Barr, FDA.

I wish I could say more. I'm really under a lot of constraints. All I can tell you is we heard you in 2011. There were also concerns which, again, were raised here today, and all the same issues that were raised here today are issues that the Office of Management and Budget looks at and different things like that, so it's just a very slow process. As I said before, slow is frustrating on one hand, but on the other hand, you're taking on a huge task of imposing a federal requirement on, you know, millions of people, so it's taken very

seriously. And all I can tell you is that we have written reg amendments that are going through the process, and I probably said the same thing a few years ago, and I know it's frustrating to hear that, but I can't say anything about timing or give you any more detail other than some of the areas that we expect to be addressed and, of course, will be open for public comment if and when they do publish them.

MS. CHAUHAN: Cynthia Chauhan.

Through my time as a patient representative, I have come to deeply appreciate the quandary that you are in and that you have a very difficult job in setting regulations, and I would only suggest that you always set them with the best interest of the patient in mind, and then that follows that even if they're tough, if they're to protect the well-being of the citizens of this country or the residents of this country, whatever you want to call it, then go forth. I think it's a challenge. I appreciate your energy, your ethics, your commitment, and I'm speaking as a patient who benefits from that.

DR. BARR: Helen Barr, FDA.

Thank you for recognizing that. You know, some people think I can just make a stroke of a pen and pass a law. There's just so many considerations, but I agree, certainly if public health is the benefit, then challenges are worth it.

DR. ROSENBERG: Further comments to Dr. Barr, questions?

(No response.)

DR. ROSENBERG: Okay, so --

DR. GOODSITT: I do have one, I have one.

DR. ROSENBERG: Oh, please. Please.

DR. GOODSITT: It seems that the systems today are very reliable and much better image quality and there are very few failures, but mostly what we're seeing is positioning is the big issue; that was one that was brought up. So it seems maybe that we should -- I

don't know if the FDA could do it, but training on standardized positioning with models or with hands-on at the facilities in addition to the inspection might be more beneficial than the inspection itself in many cases. I was just wondering if it's possible to do something like that. I know it's very expensive, but it seems to be the missing link in the problem now that we have.

DR. BARR: Helen Barr, FDA.

I think we can reach out to groups who can do that. I myself was quite amazed that an RT can get an (M) and not have certain amounts of positioning training, so I think there are ways we can help facilitate that and organizations that can help us facilitate that, and you know, clearly, that's an effort in addition to raising all aspects of image quality. And luckily -- and I do want to reiterate on what Dr. Barke said: Most facilities do what they're supposed to do. We have a very compliant industry. It's the ones, the ones that don't and the patients that they affect we're trying to get to, and unfortunately, under the federal system, then everybody's captured in it, but those are good suggestions that I think we can outreach to groups that can help with that.

(Pause.)

DR. ROSENBERG: Okay. Thank you, Dr. Barr.

It's wrap-up time, so we can use the next 30 minutes to wrap up as well as hear recommendations from the Panel. Let's see, we have three presentations that were informative only, so the subject matter --

(Pause.)

DR. ROSENBERG: Okay, cool. So I think the subjects are --

(Pause.)

DR. BARR: This is Helen Barr, FDA.

Would you like me to reiterate the --

DR. ROSENBERG: Please.

DR. BARR: -- three subjects? So one was the presentation that I gave on the future, the next 25 years of MQSA and the EQUIP program. I think we had a pretty lively discussion on that, if anybody has any final thoughts on that. The other one is Rachel Evans's presentation on the compliance trends and the discussion we had around that about the piece of the pie versus actual numbers. I will try to provide the Committee with a slide or something showing real numbers. Any final thoughts on that? And then the third presentation was Dr. Lerner's on breast density.

DR. ROSENBERG: So I guess we can go with those one at a time. Further thoughts on the enhanced inspector information?

(No response.)

DR. ROSENBERG: Further thoughts on compliance trends?

(No response.)

DR. ROSENBERG: And now for the interesting one, further thoughts on breast density?

(No response.)

DR. ROSENBERG: Dr. Barr, you're a member of the Panel. Do you have any thoughts on any of those?

(Laughter.)

DR. BARR: Well, I think we had some really great discussion surrounding those issues; you've given us a lot of great thoughts and ideas to think about. I, you know, would in no way promise that all of them are going to happen, but what I can promise you is that we captured all of them, and we will seriously look at all of them with the best intent of using your ideas and really you -- the headache is going away because it got my brain thinking about a lot of different things, and we already have some ideas. You gave us some

excellent feedback, and I really appreciate it. Thank you.

DR. ROSENBERG: All right, thank you very much.

So I guess before we adjourn, I'd like to ask our Consumer Representatives, Dr. Natalie Portis, Cynthia Chauhan, Dr. Sandra Davis, and Ms. Uriell, our Industry Representative, if they have any additional comments.

DR. DAVIS: Going back to Dr. Barr's challenges and your comment, I do think that a big challenge for the FDA is more public communication; that seems to be a missing piece. We've talked a lot about trying to encourage discussions between patients and their doctors, but that assumes that patients are getting to the doctor in the first place.

MS. CHAUHAN: Cynthia Chauhan.

I think I've commented a lot.

(Laughter.)

MS. CHAUHAN: I appreciate the opportunity. And I don't know if it's possible, but can the FDA call a study on breast density? Or has called a study on breast density since it's a very complex area that affects different populations differently but basically affects women significantly?

DR. BARR: I can certainly look into that, you know. There may be mechanisms for that. And Dr. Davis, thank you for your comment. Mammography facilities are a regulated industry, but they in turn serve the patients, so I think your comment is something that we don't always keep in mind. We tend to focus on communicating with our regulated industry, and maybe there's more patient outreach which we could do that would help the communication issues. Thank you.

DR. PORTIS: Natalie Portis.

I think I've also said a lot, and I appreciate the other -- the comments from the whole Panel, it's been a great discussion, and I think that patient communication piece is really key

in this, and I appreciate that FDA is thoughtful about that.

MS. URIELL: Diane Uriell.

Thank you for the opportunity to be part of the discussions and representing the industry. I think we're all in agreement that, you know, we're here to make improvements, so there is more awareness for patients and they have the knowledge, but also from the MQSA program, that we have the proper controls in place as well. And I think, from the industry standpoint, it's also finding that balance of requirements and also, I guess, just really the requirements and the balance between the activities that need to take place.

DR. ROSENBERG: Thank you, all.

I guess at this point I would like to thank the Panel, the American College of Radiology, the Food and Drug Administration and their staff -- they've done a fabulous job of preparing us for this meeting -- and especially the public speakers. I think it's very important for their contributions to today's Panel meeting.

Dr. Barr, any final comments?

DR. BARR: Helen Barr, FDA.

Yes, I thank the public speakers, too. I learned some new things today. And again, just thank you for your service; it's really, really vital to what we do and greatly appreciated.

DR. ROSENBERG: Yeah. And I think part of the thanks to the FDA was convening this Panel. I think it's a lot -- I mean, the Panel, thank you very much for your time. But it was a great panel, and I appreciate my role. So I guess now I pronounce the September 15th, 2016 meeting of the National Mammography Quality Assurance Advisory Committee adjourned.

Thank you all very much.

(Whereupon, at 4:14 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

September 15, 2016

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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