U.S. FOOD AND DRUG ADMINISTRATION

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

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FRIDAY,
SEPTEMBER 29, 2006

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The above-entitled matter convened in Remington 1&2 of the Atrium Court Hotel, 3 Research Court, Rockville, Maryland, at 8:00 a.m., Carolyn B. Hendriks, M.D., Chair, presiding.

PRESENT:

CAROLYN B. HENDRIKS, M.D. Chair
JEFFREY W. BYNG, Ph.D. Industry Representative
SCOTT FERGUSON, M.D.Member
JACQUELIN S. HOLLAND, R.N., C.R. Consumer Representative
PHILIP Z. ISRAEL, M.D. Member
DEBRA L. MONTICCIOLO, M.D. Member
CAROL J. MOUNT, R.T. (R)(M) Member
JOHN M. SANDRIK, Ph.D. Industry Representative
JANE B. SEGELKEN, B.S., M.A. Consumer Representative
JULIE E. TIMINS, M.D.Member
MARGARET S. VOLPE, M.B.A. Consumer Representative
MARK B. WILLIAMS, Ph.D. Member
NANCY WYNNEExecutive Secretary

FDA PARTICIPANTS:

CHARLES FINDER, M.D.

Kish Chakrabarti, Ph.D.
Office of Device Evaluation

MIKE DIVINE
Chief, Inspection and Compliance Branch

WALLY MOURAD, Ph.D.

PUBLIC SPEAKERS:

D. DAVID DERSHAW, M.D., FACR
American College of Radiology and
Society of Breast Imaging

PENNY BUTLER
American College of Radiology

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(8:05 a.m.)

DR. HENDRIKS: I'd like to welcome everyone to the second day of the National Mammography Quality Assurance Advisory Committee.

My name is Carolyn Hendriks. I'm chairing the committee meeting.

We're going to start out with a conflict of interest statement read by Nancy Wynne.

CONFLICT OF INTEREST STATEMENT

MS. WYNNE: Good morning.

FDA conflict of interest disclosure statement: Particular matters of general applicability. National Mammography Quality Assurance Advisory Committee, September 29th, 2006.

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 of 1972.

With the exception of the industry

representatives, all members of the committee are special government employees or regular federal employees from other agencies, and are subject to federal conflict of interest laws and regulations.

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

FDA has determined that members of this committee are in compliance with federal ethics and conflict of interest laws. Under 18 U.S.C. 208 Congress has authorized FDA to grant waivers to special government employees who have financial conflicts when it is determined that the Agency's need to a particularly individual's services outweighs his or her potential financial conflict of interest.

Members of this committee who are special government employees hvae been screened for potential financial conflict of interest on their own, as well as those imputed to them, as well as those of their employer, spouse or minor child, related to the

discussion of today's meeting.

These interests may include investments, consulting, expert witness testimony, contracts, grants, CREDAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves a review and discussion of the following general issues. One, amendments to the current MQSA regulations; and two, all guidance documents issued since the last meeeting.

The committee will also receive updates on recently approved alternative standards and the radiological health programs.

Based on the agenda for today's meeting and all financial interests reported by the members of the committee, conflict of interest waivers have been issued in accordance with 18 U.S.C. Section 208(b)(3) to Doctors Philip Israel, Julie Timins, Mark Williams, and Ms. Carol Mount.

The waivers allow these individuals to participate fully in today's deliberations.

Copies of these waivers may be obtained by visiting the Agency's website, or by submitting a

written request to the Agency's Freedom of Information Office, Room 630 of the Parklawn Building.

A copy of this statement is also available for review at the registration table during this meeting, and will be included as part of the official transcript.

Drs. Philip Sandrik and Jeffrey Byng are serving as the industry representatives, acting on behalf of all related industry, and are employed by GE Healthcare and Eastman Kodak Company respectively.

We would like to remind members that if the discussions any other matters, products or firms not already on the agenda, but for which an FDA participant has a personal or imputed financial interest, the participant needs to exclude themselves from such involvement, and their exclusion will be noted for the record.

FDA encourages all other participants to advise the committee of any financial relationships they may have with any firms at issue.

Thank you.

COMMITTEE BUSINESS

DR. HENDRIKS: We have two small items of committee business.

The first is to introduce the new panel member, Dr. Israel. Welcome.

Would you introduce yourself briefly, please.

DR. BARR: I am Dr. Israel. I am a breast cancer oncologic surgeon from Atlanta, Georgia.

I am director of the Breast Center there which I started approximately 20 years ago, and have been heavily involved in all aspects of diagnosis and treatment and breast imaging for breast cancer.

DR. HENDRIKS: Thank you and welcome.

The other item of business is just to notify mainly the audience that the committee did review several quality standards at the end of the day yesterday related to revocation, accreditation, and accreditation body approval. And at the end of the session today, or towards the end, we will also review those comments for the benefit of the members of the audience who were not here for that discussion.

So now we will proceed to the portion of

the meeting that is the open public hearing.

OPEN PUBLIC HEARING

DR. HENDRIKS: I'll begin by reading the FDA statement again, and then we will welcome comments from Dr. Dershaw from ACR.

Both the FDA 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 this advisory committee meeting, the FDA believes it is important to understand the context of an individual's presentation.

For this reason the FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise this committee of any financial relationship that you may have with a sponsor, its product, and if known, its direct competitors.

For example this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance

at this meeting.

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

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

Dr. Dershaw.

DR. DERSHAW: Thank you. I appreciate the opportunity to be here.

I am representing the American College of Radiology, and the Society of Breast Imaging. They paid my expenses, but otherwise, I have no conflict of interest to report to you.

On behalf of the college and the society, I am here to state that these organizations endorse the regulation of stereotactive breast biopsy under MQSA, and we would like to suggest to the advisory committee that the ACR program, voluntary program, for accreditation of stereotactic breast biopsies, which has been designed using the same format as that used by the FDA for mammography accreditation, would be an

appropriate program to use for that accreditation process.

I'd like to review with you in the next few minutes what the ACR accreditation program is; its design; and its current position in the stereotactic breast biopsy world, at least in the United States at the present time.

The program was first offered as a voluntary program in 1996, so it has a decade of experience now. As I said, it's modeled after what was originally the ACR mammography accreditation program and is now the basis for the design of the FDA regulatory program.

It involves an assessment of personnel, equipment, as well as clinical performance.

The ACR additionally in putting this program together, and in the actual implementation of the program, has worked in conjunction with the American College of Surgeons, and in fact assesses the applications of the ACS applicants for their program.

As I've said the accreditation program of a college is a three-tiered program in terms of

application for accreditation. The personnel qualifications involve looking at physicians involved in stereotactic biopsy; the technologists involved in stereotactic breast biopsy; and the physicists who assess the performance of requipment using stereotactic breast biopsy.

In addition to looking at personnel there is an assessment of the quality of performance of the biopsy in the clinical setting by looking at clnical images that are submitted.

In addition to that there is an assessment of the safety and quality of performance of the equipment used by looking at phantom images.

And finally there is a quality control program to maximize safety of equipment between examinations.

The goal in looking at personnel, and in establishing the qualifications for personnel, was to make certain that there was a minimum level of training for the physician or physicians involved, for the medical physicists, and for the technologists involved in the performance of these procedures.

The physician qualifications were worked out in meetings between the College of Radiology and the College of Surgeons, and they are designed so that whether radiologists, surgeons, or other physicians alone or in combination are performing these procedures, that a minimum level of training and experience will be part of that physician package.

The personnel qualifications for all three types of personnel involved in these procedures include initial qualifications of basic education, as well as actual hands-on experience in performing these procedures.

Second, continuing education.

And thirdly, continuing experience, the belief being there should be a basic level of training and experience before one independently participates in these procedures; and secondly, there should be continued education and experience to maintain if not improve the level of quality that physicians and the technologists and the physicists are bringing to the procedures.

The case material, the clinical material,

is evaluated to determine the ability to accurately perform the procedure as it is ongoing. So we ask facilities to submit to us images taken during the procedure that indicate to us that the relationship of the biopsy probe to the lesion that is undergoing biopsy is appropriate for that point in the procedure. We ask them to send us what they believe is their best level of work. We ask them to send us images based on the equipment that they are using, understanding that there are a variety of biopsy probes that are available, and that the relationship of the biopsy probe to the actual target lesion is determined at least partially by which probe is being selected.

So we don't mandate what equipment is being used. We allow the facility to decide what equipment they will be using.

The assessment of phantom images is similar to the assessment that goes on with the mammography program, looking at dose criteria, which must be less than 300 millirads, and an objective assessment of image quality with phantom imaging.

Finally, the college has produced a quality control manual which was published three years after the program began. And the accreditation program requires that facilities follow the quality control test that are outlined in the manual at the intervals outlined in the manual.

The reviewers of images and of phantoms for the program must be ABR qualified or certified, and must be ACR members.

There is a formal training program for the reviewers to optimize quality of review, in addition to a quality control program of reviewers where each reviewer is given an annual report on their performances and any deficiencies that may be present.

The reviewers are all in clinical or physics practice across the United States, and in order to try to address conflict of interest, reviewers are not permitted to review facilities from their own state.

Now this is a chart of the number of facilities in blue, and the number of units in red - not a great difference between those two lines - that

have undergone accreditation in this voluntary program from the college, and you can see there's a slight increase as of this month compared to where we were four years ago, with about 441 facilities I believe currently accredited.

This shows the pass rates with red showing passing on the initial application of a facility; purple - I think that's purple - showing the percentages of facilities for renewal that have passed; and the last column in green showing the total pass rate.

And I think if you look at this chart you can see that there has been over the last five years a gradual improvement in all of those. And I think this represents a real influence of that program in improving quality of stereotactic facilities that are participating in the program.

This chart shows the reasons for failure on the first application for accreditation. The big red piece of pie is failure due to suboptimal clinical imaging. And as you can see that accounts for about two-thirds of failures.

The reason I'm sharing this with you is that I think it's important to understand also that about one-third of failures are due to factors other than or as well as clinical imaging.

So that means that the safety of the equipment, the radiation exposure, the optimal functioning of the equipment, has been a reason for failure in one-third - has been the total reason or part of the reason for failure in one-third of facilities, and a program looking at those factors as well as clinical factors should be the kind of program that's used because of these issues.

This is from a paper that was published very recently by Levin et al. In the Journal of the American College of Radiology. And it's breast biopsy trends based on CMS, based on Medicare data.

This particular table shows from 1999 to 2004 the performance of breast biopsies, all breast biopsies, imagining guided and non-imaging guided breast biopsies procedures by all physicians, the top light blue line; the next line beneath that is radiologists, the dark blue; surgeons, the pink; and

others which make a very small contribution in yellow.

So you can see that there has been an increase in those procedures over the past half decade, and most of the increase in those procedures is due to an increase in radiologists performing breast biopsies of all types.

Of imaging guided breast biopsies, again, based on Medicare data, imaging guided breast biopsies, 72 percent, about three-quarters, are done by radiologists at the present time, and about one-quarter are done by surgeons.

And during the period that was shown on that graph, from 1999 to 2004, there was a slight increase in the contribution of surgeons to the importance of imaging guided biopsies - 16 percent. But the performance of those biopsies by radiologists increased by 79 percent. So almost doubling in radiologists' participation, I think explaining that considerable increase in the percentage of radiologists performed biopsies that you saw on the prior slide.

The total number of breast biopsies in the

last year available for data which was 2004 was almost 150,000. And the number of imaging-guided biopsies was 125,000, accounting for more than 85 percent of breast biopsies performed. So 85 percent of breast biopsies performed are done as imaging guided procedures, and those procedures are done by radiologists in almost three-quarters of cases.

It is difficult to tell from available data how many are stereotactic and how many are not. But it is estimated that slightly less than half of those procedures are stereotactic biopsies.

So we're talking here about an issue that involves about 50,000 procedures as of two years ago, paid for by Medicare in the population.

So how you can transpose that into the general population is up to your deciding, because we don't have that data. But we are talking about a large number of procedures. We are advising that the procedures again be regulated under MQSA. We are advising that the program again be based on the college's program looking at clnical performance, and as importantly, looking at the safety and the

equipment performance involved in the program.

Thank you very much for your time, and I'll be happy to answer any questions you might have.

DR. HENDRIKS: Any questions for Dr. Dershaw?

Thank you very much.

DR. BYNG: I had a question for Dr. Dershaw, sorry.

On another slide you showed the number of units accredited and the number of facilities accredited. Do you have any idea what the total number of units and facilities are that do biopsies?

DR. DERSHAW: No, it's almost impossible to get that information. We do not know what that is.

DR. BYNG: So we wouldn't know how many people would be affected by the proposal that you have?

DR. DERSHAW: That's correct.

The only numbers that we have available are the Medicare numbers. So we can only give you that portion of the population. But in terms of the rest of it, in order to generate numbers we would have

to - the way the Medicare numbers are generated are through the applications for reimbursement.

So if one used the same technique they would have to go to all the third party payers and look at the codes for submitted billing and generate the number for that.

So because of the diversification of the system in the United States, it's well nigh impossible to figure that out.

DR. ISRAEL: May I ask an additional question?

Dr. Dershaw, are you familiar with the National Approvals Program for Breast Centers at the American College of Surgeons, and the American College of Radiology are working on together.

Are you in support of that effort?

DR. DERSHAW: Well, I'm here this morning to address stereotactic biopsy issues, and it's my believe that if there were a program for accreditation of breast centers that part of the accreditation that involved stereotactic biopsies should be the program that we are suggesting here this morning, and that a

program that accredits breast centers should not compromise the quality and the standards of accreditation programs that are in place.

DR. HENDRIKS: Thank you very much.

There's just going to be a small change in the agenda. We're going to skip the break at this point and move into the open committee discussion. There will be a break later on in the morning.

Dr. Finder.

OPEN COMMITTEE DISCUSSION

DR. FINDER: Good morning.

I'm just going to go over again the directions for the discussion we're going to be going through for the rest of the morning. This is going to be a redo of what we went over yesterday.

The main purpose of this meeting is to discuss possible changes to the final regulations.

Prior to the meeting the committee members were given a copy of the regulations along with certain sections highlighted for possible revision, based on our experience implementing the regulations, as well as questions and comments we have received

over the years.

They were also instructed to make their own suggestions to any portions of the regulations.

We will be projecting the document on the screen as we proceed through the regulations, and have made the document available to the audience as a hard copy handout.

It's also available on our website. As you can see there is a lot of material to cover, so I'm going to suggest that we go through each item in turn and asking for a show of hands for either a yes or no opinion.

In cases where there is a significant disagreement among the committee, Dr. Hendriks will ask for brief comments from the committee, and then we'll ask for another show of hands.

We are not asking for detailed wordsmithing, but rather a consensus on whether or not to make a change and what direction to go.

After the meeting FDA will take the committee's ideas, develop detailed amendments to the regulations, and then issue them for public comment.

Does anybody have any questions? Okay,let's begin.

We will be starting in the definition section, which is 900.2. Those definitions can be found on pages two through nine, and consist of footnoted items one through 30.

Let's begin with the first footnote, where we ask, should there be a definition added for unit and facility accreditation and re-accreditation?

Show of hands, yes.

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

And it's consistent with a lot of our discussions yesterday to add clarification to the topic about accreditation.

Next is number two. Should a definition be added for audit interpreting physician? The audit interpreting physician is that physician that deals with the review of the medical audit. It's actually described in that section.

But the question here is, should there be just a plain definition for it in the definition section.

And again, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And that's a yes.

Next, number three, should a definition be added for automatic exposure control? Again, it's a clarification fo what we mean by that. It has been defined in other areas outside the document.

Should we include it in here?

Yes, show of hands?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Okay, that again is a yes.

DR. SANDRIK: Just a comment that it is already defined in the performance standards that the manufacturers have to meet, and it would be appreciated if the definitions were harmonized, being

the same.

DR. FINDER: Or as we said yesterday, we would pick between more stringent, less stringent, or substantially the same.

No, that's a good comment. And that would be the plan I think to use that same definition.

Next, should we add a definition for automatic exposure control mode?

This is one of the issues that we've tried to address in guidance in terms of what testing has to be done during the mammography equipment evaluation versus during a survey.

And again the hope here would be that we would write a definition that would clarify the differences.

So asking for a show of hands on, should we include a definition for mode.

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And that also looks like a

yes.

Number five, where we talk about category one training, and this would apply to interpreting physicians, should residency and fellowship training be specifically mentioned here?

Again, it's to clarify what types fo training are acceptable for either initial or continuing requirements.

Show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And again we have a yes overall.

Number six, where we have the definition of certificate, should this definition be expanded to describe the four different kinds of certificates?

And those are the full provisional temporary renewal and limited provisional.

Again, a show of hands for yes.

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And again the yes is preferred.

DR. BYNG: Dr. Finder, a quick question on that one. That's essentially the same definitions as appear at the beginning of 900 R11, so is it just moving those definitions forward?

DR. FINDER: Yes, the answer to that is not only the ones that currently appear there, but the ones that we will have to add because of the change in the statute which added two different types of certificates, so it would be added into that section in 900.11, and also here.

Number seven, should a definition be added for corrective action. And before I ask that, I want to kind of clarify what we mean here.

Basically we're talking about corrective actions taken for failed quality control tests. And the definition we'd probably be looking at is a description that includes what would be required as part of that corrective action.

We have encountered cases where, for

example, a QC test has been failed; somebody takes some type of action, but then never repeats the test to show that the test is now actually back within limits, normal limits or acceptable limits.

So the idea behind this would be to lay out the framework for what would be considered a satisfactory corrective action.

Show of hands for yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And again that's a yes.

Number eight is, should we add a definition for final interpretation?

DR. TIMINS: For final interpretation I would argue that the term is self explanatory.

DR. BYNG: But there may be a connection with the discussion about digital soft copy images in particular.

MS. VOLPE: I think you also have to consider in these definitions those of us who are consumer reviewers for the first time and others in

the public who may be reading the document who wouldn't understand.

DR. FINDER: Okay, let's take a quick show of hands. Should we include a definition for final interpretation?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: It's kind of split.

I would just want to add in terms of that, one of the driving forces behind this is the idea of what happens when you transfer images, especially with digital.

We had in the past, under our interim regs, when we went to the final regs, there was always the issue of, could you release copies of mammograms, or did you have to release the originals? That got clarified in the final regs where it's required that originals be transferred.

The issue now is what is the quote unquote original in a digital world. And we have been getting

reports of problems of images that are being sent for comparison of other facilities, where the quality of those hard copy images is not felt to be sufficient, and the idea here would be to try and address that in some manner through this term of what truly is the final interpretation quality of those images? What do they have to meet?

So that's part of the issue there.

Number nine is, should a definition be added for hard copy image?

Show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Again it's a yes.

DR. SANDRIK: Just to sort of comment, this is something that could be defined in terms of today's technology. I would suggest not doing it, if you try to identify what is the concept of it that you need to define, do that rather than saying it's something like a laser-printed image or other kind of printed image, a list of what's available now but doesn't really -

might not have longevity value.

DR. FINDER: We have actually tried doing this both for final interpretation and for hard copy in some of our guidance.

If you would look at that, and if you have any suggestions you could get back to us later about it if there is anything specific.

Okay, number 10, should we include definitions for lossy and lossless compression? Again, we're in the digital world here.

And just a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And yes seems to carry the day.

Number 11 deals with mammogram, the definition fo a mammogram.

We're asking here, should this definition be expanded to address digital mammography, digitization of screen film mammograms, and the algorithms used for manipulation and compression of

digital mammographic images?

DR. BYNG: Can you expand on the intent of what you had in mind with respect to this?

DR. FINDER: Well, in the screen film world it's pretty well standardized as to what a mammogram is. It becomes a little bit more confusing when you're talking about digital where you can manipulate these images at various stages.

And at what point do you start losing the concept of this being a mammogram? And in effect, it almost becomes a copy, or a degraded portion of a mammogram.

So the idea here would be to kind of deal with that issue.

The other is the concept of digitization of film screen mammograms. Under our current guidance we have allowed that practice for use for comparison, so that if somebody is, for example, comparing a current digital examination, and wants to look at the old images, we do allow those old images to be digitized so they can be placed on monitors rather than having to view those as hard copy on a view box.

We keep getting questions about, well, can I take those, digitize them, and then destroy the originals and use these digitized versions as retention, and keep those for 10 years?

It all comes down to whether these are mammograms or not under the regulations and the law. So these are issues that we are going to have to deal with.

DR. SANDRIK: One suggestion that you might consider is something like a primary mammogram and a secondary mammorgram, where the primary one can be linked back to the original data acquisition process, and a secondary one might be one that has gone through a second acquisition process, like a digitization process or a copying of any sort. But as long as you have access to the original data from the original acquisition you could call it the primary mammogram.

DR. FINDER: We have kind of addressed that in our current guidance. We have said that if you want to digitize a mammogram, that's fine; but you do have to keep the original.

We've been getting questions from people

who want to, as I said, digitize the old mammorgram and then destroy the original because of storage issues. And this kind of ties into that. If we allow the digitized image to be called a mammogram, the original mammogram, it opens the door for that type of thing. Of course there would have to be standards presumably written for that.

But one of the things about definitions here, they carry a lot of weight. Because once you define something it either includes it under MQSA, excludes it under MQSA. So sometimes these words have huge importance.

So again I'll ask for a show of hands. Should we try and include or expand the definition as stated her, or at least try to do that?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And again it looks like a yes.

Next is should we add a definition for mammographic examination?

This really comes up at various times, hasn't come up very recently. But it concerns the issue of counting images usually for either the initial experience or continuing experience requirement.

For example a patient gets a screening study and then a diagnostic study in the same day. Are those two exams? One exam? Patient gets a single view as part of an exam, one image. Does that count as much as four view?

And just to give you what we've been doing in the past in terms of guidance, we basically have allowed the situation where if they're getting a screening and a diagnostic, those can be counted as two exams. If they are getting even a single view on a day, a single image, that would count as the exam.

But it hasn't been formalized in regulation. It has been kind of dealt with through guidance. And as we keep being told through the lawyers, if you can put it into regulation, if you are sure it's something that you want to do, it's better to do that, then you can enforce those things, you

don't have to deal with questions about it, or at least not as many questions.

So the question is, should there be a definition added for the term, mammographic examination?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Take that as a yes.

Okay, now we're dealing with the term, mammographic modality. And the question is, should this definition be modified to include full field digital? Tomosynthesis? Or breast CT? And as a corollary to that, should we also take zero mammography out of this defintion at this point?

DR. TIMINS: I am concerned that tomosynthesis and breast CT are not routinely performed in a lot of institutions, and do not represent the current standard of care, so I would be hesitant to put them into the regulation.

DR. FINDER: Okay, this actually carries

over to another question, which we deal with a little bit later, and that is whether we should regulate these things at all under MQSA. So this question is tied to that question.

I guess we can discuss the whole issue of whether we should regulate these issues at that point.

This question really ties down to, if we make an assumption that these will be regulated, would we try and include them as a new mammographic modality? In effect what that says is that anybody who would use one of these modalities would have to get the eight hours of training before they could do it.

So you're right, it basically goes to the bigger question; we're talking about the smaller question. If we decided to regulate it, would we want to treat it just as we do FFDM with the same type of requirements, basically the eight hours of initial training?

DR. TIMINS: I am pretty familiar with the American College of Radiology guidelines and standards program. And I have reviewed guidelines for

diagnostic mammography and screening mammography.

To my knowledge there is no guideline for the performance and interpretation of tomosynthesis or breast CT. There is a guideline for breast MRI.

I think that I would be very hesitant - in fact, I would not recommend including in the regulation procedures for which there is not a standardized procedure, or a standard of care.

DR. SANDRIK: I think one thing that complicates this question is that we really don't have a definition of what a modality is. We have a list of examples, but why screen fill mammography is a different modality from zero mammography, or digital mammography is a different modality from the other two, or any of these others are different modalities is not at all clear.

And I think maybe the first requirement is to define what a modality really is. Then you can address the issues of whether they belong or don't belong as new modalities.

DR. FINDER: Good point.

Okay, let's have a show of hands, should

we include this in the definition?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Take that as a no.

DR. HENDRICKS: Just by way of additional discussion, can we modify that then to include just the digital and exclude the tomosynthesis and the breast CT, because that would definitely alter my answer to that question?

DR. FINDER: Sure.

DR. WILLIAMS: Yes, for example, we could replace zero mammography with small field of view digital, but omit the other two.

DR. FINDER: All right, let's rephrase then the question.

It comes down to now, should we delete zero mammography from this definition?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Should we include full field digital? Again, as an example, and then to look at the issue about coming up with a real definition.

Include full field digital, yes?

DR. BYNG: Are we taking into consideration John's comments about making sure that we get a proper definition fo modality?

DR. FINDER: Yes.

All right, so that's a yes to include full field digital.

Okay, number 14, which I'm sure will go very quickly. Should the definition for mammography, which currently excludes interventional, should that exclusion be deleted?

Let's ask for a show of hands just to see where we are in the beginning.

Should that exclusion be deleted in effect saying that we should regulate interventional mammography under MQSA?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: All right, consensus, while it's somewhat split, the majority is a no.

Yes?

DR. TIMINS: Now the issue of accreditation for stereotactic biopsy is a very specific issue. Interventional radiography, all biopsies, is a very general issue.

I would like to support regulation of stereotactic biopsy.

DR. FINDER: Okay, we'll ask that as a separate question then.

Okay, so we've got a not for the global -

DR. ISRAEL: Is it appropriate at this time to make some comments about the issues regarding regulation of stereotactic breast biopsy?

I was before this committee approximately 10 years ago testifying, not as a member of the committee, but regarding stereotactic breast biopsy and regulation.

And at that time there was pretty good consensus that it should not be regulated at that time, 10 years have passed, as Dr. Dershaw has pointed out.

I guess I have devoted the last 15 years of my life to incorporating stereotactic breast biopsy into standard medical practice, and it has not been easy. Because stereotactic breast biopsy did not fit well into either radiology or into surgery. It - I refer to it as a homeless technology.

It didn't fit into radiology because the radiologists had never done breast biopsies. It didn't fit well into surgery, because surgeons didn't have image interpretation training.

So it's been a real struggle. But I want to sit here and say that I am very proud of radiologists and surgeons for taking this technology to the point that it has been taken today. I think that everyone involved in that needs a round of applause and a lot of credit, because it has not been easy.

But what it has done is, it has kept women

out of the operating room. It has allowed us to make a diagnosis with minimum invasive surgery.

I have found - I have searched my mind for reasons to regulate the interventional part of this issue, and I cannot state any problems.

Now, sure, there are going to be individual cases where the technology has not been performed correctly, as with any type fo intervention. But I think overall it has been amazing, both radiology and surgery, how this technology has been integrated and how well it has performed.

So I do think there should be accreditation. There should be quality assurance. And there are organizations from the medical professional community, and I've got a list here now that have already endorsed an effort put on by the professional organizations, the College of Surgery, the College of Radiology, the National Cancer Institute, the National Consortium of Breast Centers, to accredit breast centers and to put in quality assurance measures for specifically for stereotactic breast biopsy.

I think that work is already being done, and I would leave it, I would be in favor of leaving that with the professional medical organizations rather than regulate it by the FDA.

MS. VOLPE: What about the wire-guided procedures? Should they be included?

DR. FINDER: Well, that's a very good question, and that's one of the differentiations I think that we were just getting to in terms of the difference between interventional mammography and stereotactic biopsy.

Interventional mammography would include not only stereotactic but needle localization and other procedures that are done under image guidance such as galactograms, which are not very frequently done, but they do exist.

I heard at the beginning of this we were talking about regulation interventional. The consensus seemed to be no for interventional, and that we would then look at stereotactic. If we say no to interventional, that basically excludes out the needle localization procedures from regulation.

As we heard earlier this morning, the ACR program focuses in on stereotactic breast biopsy. It does not look at needle localizations. They have not established an accreditation program for that.

And as far as I know no one has.

DR. WILLIAMS: But aren't some needle localizations done under stereotactic guidance?

DR. FINDER: That is true. There is a mixing of those technologies. But again, yes, that is true. Leave it at that.

DR. ISRAEL: Just one other brief comment, in terms of expansion fo this technology, just around the corner we are going to be ablating cancers using image guidance with different energy forms such as radiotherapy and cryo and laser, and I think all of these - this is going to be a very big umbrella that - and I don't know where we would begin to draw the line here.

DR. TIMINS: When you do a stereotactic needle biopsy, the end result is the tissue you get during the procedure. So the quality of the image, the approximation of the biopsy device to the tissue,

and the specimen radiographs are extremely important.

When you do a needle localization procedure, where you're putting a needle and a wire through a needle into an area of tissue to assist the surgeon, the ultimate result is the tissue the surgeon takes out, so that it's a different end point. If you miss it on a stereotactic biopsy, you have missed it. When you put in a localization device, a wire, to assist the surgeon, then the amount of tissue depends to some degree on the surgeon and you do indeed confirm whether or not you've got the lesion with X-rays subsequently. But there is more of the - more leeway in how - in the relationship of the needle and the lesion.

That's why the quality control in stereotactic biopsy is so critical. So I would argue that they are different; that the need for quality control on the imaging end is higher for the stereotactic biopsy.

DR. MONTICCIOLO: I agree with Dr. Timins. Also I don't think there is any need to regulate wire localization because the people doing it and the

equipment that is used is already fully regulated by the FDA.

We use standard mammographic units, no?

DR. FINDER: No, interventional mammography is excluded from MQSA regulations right now. While somebody who is using, let's say a mammographic unit for needle localizations, if they are also using it for regular mammograms, yes, that would be covered. However, if they are using it strictly for needle localizations that was a dedicated unit only to that, we do not regulate that type of unit.

DR. MONTICCIOLO: Okay, I understand what you are saying, but I can't image that that is a very common occurrence. Or do you know it to be a common occurrence? Because it's hard to maintain a unit for only that purpose, so almost everybody if you are going to buy a unit that expensive, you would use it for regular mammography as well I would think.

DR. FINDER: We don't have any data on how often that happens. We have anecdotal cases where we do know that it does happen where a unit is dedicated to a purpose, sent into a room, and it's only being

used for interventional. And part of the reason for that is, they don't want to get that accredited because of the cost, and the fact that they would have to do a fairly large number of patients to go through the accreditation process to get the films for that.

So there is a disincentive to try and get it both accredited under MQSA and to use it for interventinoal in some sense. So there are definitely units out there that are being used just dedicated to needle which are not regulated.

DR. TIMINS: I agree with Dr. Finder. I don't know of specific instances. But for a lesion that is obvious, that's conspicuous mammographically, you wouldn't need the same quality image necessarily. You might take an old unit that you don't have a technologist assigned to on a routine basis and do a localization procedure there very competently, and not slow down your diagnostic mammography unit.

I could see how that could happen and not adversely affect patient care.

DR. HENDRIKS: I have a comment related to the regulation of stereotactic, looking at the ACR

data. Because remember that is a voluntary program, and the pass rate is relatively low. And that's on best image, and that does raise my concern.

These facilities and units, where their best images for stereotactic placement were submitted, and the pass rate was 60 percent. I have to believe in my practice that that is going to have a clinical impact on the patients if the image quality is unacceptable in a third of the voluntary participants.

DR. FINDER: This exact issue was brought up at the last meeting too where we discussed some of this.

One of the questions that comes up - and we didn't have any data at that time; I don't believe we have any data at this time either - is what does it mean to fail those images during that clinical review? The question is, do they actually get the lesion? And was the biopsy confirmatory and satisfactory?

And unfortunately that information wasn't available at that time, and it still is not available from ACR. So the fact that a clinical image may have failed that review doesn't necessarily mean that the

diagnosis wasn't made.

And that's one of the other considerations, if we do go ahead with regulation of interventional or stereotactic should the focus be changed from equipment, some of these procedures, to an outcomes-based situation?

So you're dealing with a somewhat different situation than typical mammography where the result isn't known right away. In stereotactic you know whether you've gotten a lesion, whether you've gotten concordance. Should we focus, if we decide to do regulation, should we focus on that instead of some of these other issues?

DR. TIMINS: Part of a quality review program for breast biopsy should indeed conclude concordance of findings and concordance means that the pathology tissue results makes sense in the clinical context, so that if you see a lump, and your biopsy comes back, normal breast tissue, that is not concordance; that is disconcordance, just to help others who are not familiar with the term.

Whereas if the biopsy comes back,

fibroadenoma, which is a type of benign breast tumor, then that makes sense.

So I think that if it is indeed included in the regulation, that one of the criteria should be a determination of concordance of results.

DR. HENDRIKS: I just had a follow upon the ACR data. When the studies were looked at for quality review, we are still just talking technically about clip placements. I would imagine. Because - can Penny speak to that? Were the films assessed on the accuracy of clip placement in a targeted lesion?

MS. BUTLER: Penny Butler, ACR. The images were assessed with regards to the needle placement. So this is stereotactic, and they are looking at the prefire images, post-fire images, and where the needle is in relationship to the lesion that they're going after.

And the failures in most cases as you can see from the data has to do with the needle not really being close to where the lesion is, and the impression that this is at their best work.

DR. FERGUSON: I'd like to ask, he put up

the slide, and I don't know that I fully understood the failure rate on first attempt deficiencies. There was a 63 percent - what were those first attempt -

MS. BUTLER: The first attempt deficiencies, the first time that a facility applied for accreditation with that unit.

DR. FERGUSON: But 63 percent were in one category. What was that category?

MS. BUTLER: The failures are the total number of failures, and then the pie chart that is shown after that sort of breaks it out between clinical failure versus phantom failure, or a combination of failures. The 63 percent was the combination of both clinical failures and phantom failures. The gist of the slide was that roughly a third of the failures were on a technical basis, and about two-thirds involved clinical problems.

DR. FERGUSON: I was trying to get to the pre-fire - people really submit images with the needle in the wrong place?

MS. BUTLER: You'd be surprised.

Are you referring to this chart here?

DR. FERGUSON: I was just curious, if that many people failed on actually having the needle in the wrong place, and they submitted those images saying that this is our best work, and they were failed on that basis, did that happen? And was that a large number?

MS. BUTLER: By the way this is not 63 percent of everybody going through accreditation. This is 63 percent of all the failures.

And it's happening. Now, when they repeat the test, because we require them to submit additional images, and they do pass, they finally get the point.

DR. MONTICCIOLO: But what percent fail? Because this is 63 percent of the number who did fail on first attempt.

MS. BUTLER: Yes, if you look in 2005, out of all the facilities going through accreditation, it's about just short of 35 percent.

DR. HENDRIKS: So although these experts are not reviewed positions, I do believe that that is going to have clinical impact, that percentage of failure at best effort, if it took place - if the

lesion was not targeted, irrespective of the pathology of course.

DR. TIMINS: When you look to the quality of mammography prior to MQSA, and you look at the quality of mammography now, there have been many quantum leaps in the development of quality mammography.

I think if we do promote, including stereotactic biopsy in the regulation that you will see a similar improvement in the quality of the stereotactic biopsy performance.

DR. BYNG: Do we have any data about the scope of the quality problem, then, in any of these procedures?

DR. ISRAEL: Are you referring to what type of measurement of quality? I'm not quite sure what you're asking.

DR. BYNG: Exactly. I think the question really is, we're talking about providing a quality control program to regulate potential quality problems. And I'm trying to understand what the scope of the quality problem that is trying to be addressed

here.

DR. ISRAEL: My impression of the quality issues, one measurement that we have that is universal is litigation. And I have monitored litigation issues with mammography and stereotactic breast biopsy. And stereotactic breast biopsy, even though not perfect - there will be failures - I think has been carried out very well, and the litigation rate with stereotactic breast biopsy is exceedingly low compared to mammographic interpretation.

DR. FINDER: This is Dr. Finder. Just wanted to - I think you're getting at, in terms of the scope of the problem, maybe one way to address it is, how many of these lesions are missed at biopsy? And I don't have any hard data, but I believe that the data would support a miss rate of about two percent or so where there is nonconcordance between what is obtained on pathology versus what they were going after at the lesion.

So again that's more of an outcomes-based type of an issue, and it may be the one that is of most importance to the patient, did they get the

lesion that they were going after when they went after it, or does the patient have to be redone?

And I think the numbers - and maybe Dr. Israel can have some other information about this - but I think we're talking about a two percent, which is similar to the surgical rate of missed biopsy?

DR. ISRAEL: Yes, I think the figure of two percent is probably accurate. And that is really controlled by a concordance, as Dr. Timins mentioned, if we get a benign diagnosis, and the lesion looks suspicious on the mammogram, and we've missed it, if we recognized the discordance then we're going to do another biopsy.

And of course that happens in the operating room as well as in the stereotactic room.

DR. TIMINS: Also another function of stereotactic biopsy or needle biopsy in general is just to confirm a highly suspected malignancy so that more definitive treatment, surgery, can be performed in one fell swoop rather than on two occasions.

There was a question about the placement of the clip and how that might be considered a quality

procedure. Clip placement is not as crucial in the determining of quality because there are a number of things that affect clip placement. Clips can migrate. If there is bleeding, with the hematoma, the clip may not ultimately be as close to the biopsy site as intended.

So and then there are -- many circumstances where clips are not used.

DR. FINDER: Okay, so let me go back and again ask the questions, should the exclusion for interventional be deleted?

And again, to clarify, interventional now we're talking about the wide range which would include needle localization.

So should that exclusion be deleted? Should we regulate interventional as a wide area?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: I would say it's kind of split, with more toward no.

Now for this specific question about stereotatic biopsy, should that be regulated?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And it's kind of a little bit split, but basically yes.

We add a definition for what a mammography system component is. Let me give you some of the background on this.

Currently for film screen it's been fairly well established that a mammography equipment evaluation needs to be performed on a new piece of equipment, such as a new mammographic unit, and a new processor.

It is not as clearcut for FFDM, for full-field digital. And the question comese up, does a medical physicist have to go out and do testing on every printer, every monitor, the various components of an FFDM system?

Again, because of FFDM, the ability to

separate out the various functions in different pieces of equipment, it's much greater than in film screening.

So the idea behind these two questions, should we create a category of equipment that would not require the medical physicist to go out to the site, but to have the testing performed under what we call medical physicist oversight, where personnel at the facility who had adequate training could perform the testing, and then just have it reviewed by the medical physicist, rather than the physicist actually going on site.

Again, it becomes a much greater problem with full-field digital, with the idea of telling mammography where the facility may be in one state and the monitor where it's being read may be in a totally different state.

So that's kind of the background behind these two questions about modifying the definitions.

And I would ask if anybody has any questions about anything?

DR. SANDRIK: Yes, I guess you added a new

interpretation that I didn't see at first. I thought the main focus was to simply bring the definition of medical physicist oversight on guidance into the regulation.

And I believe that's a good idea. It seems to have worked well. The idea of then trying to subdivide the system into components, particularly if you are trying to do that in regulation, adds complexity that is probably not necessary.

And again you can go back to the guidance where you've provided some guidance on what are components, what level the physicist is needed there, and what medical physicist oversight is sufficient.

So I think the idea of bringing forth the definition into the rules I think is a good idea. I think trying to identify which component it applies to within the rules is probably adding needless complexity.

DR. FINDER: Actually, footnote 19 is specifically dealing with, should we add a definition for medical physicist oversight.

So all three questions are actually

related. I will say that the guidance that we've issued about medical physicist oversight can only go so far.

If you take a look at the guidance that we have, it deals with under what conditions is medical mammography equipment evaluation required? If it is required as the regs are currently written, the medical physicist has to go out and do an on site evaluation.

The guidance we've issued deals basically with what type of repair beyond which you are into that mammography equipment evaluation? Once you reach that level we don't have any leeway. And that's the idea behind putting in for medical physicist oversight.

And then, as pointed out, with FFDM, we have various components. Do you believe that if a new monitor is set up, does the medical physicist have to go out there? Does he have to go out for a new printer?

Right now if we - if somebody gets a new printer, they have to have a medical physicist go out

and review it. That's the idea behind trying to separate these things. And it will make it more complicated, but we've been hearing about questions from the field out there, questions from medical physicists saying, why am I traveling hours to go look at a printer that I'm going to run a test on that somebody else could have done and just sent me the results and I could have looked at it?

So it is going to make it more complex; there is no question about that.

MS. VOLPE: I'd be interested in Dr. Williams' take on that.

DR. WILLIAMS: Well, I think that the intention here is absolutely correct, which is that it is a complicated thing. And the problem is going to come when we try to specify exactly which things need onsite involvement of the physicist.

Because even if you specify a particular component, say the laser printer for example, if that is switched out, there may be pieces of the laser printer that are changed. And the ability to have someone remotely feed information back to say for

example the physicist who is not onsite may vary depending on what the particular nature of the problem is.

And so I think it's a well intentioned thing that is going to be very difficult to specify.

DR. SANDRIK: Is my recollection of the mammography equipment evaluation regulation, as it's written, all it says is major repair. And that is not specified in any detail in the rule either.

And then it goes back to guidance, and it says, this we've declared as a major repair, and this is not a major repair.

So I think, again, that provides some guidance to the physicist, if there is something different.

And some have wondered about, like your example of the laser printer, if that necessarily has to be a medical physicist's visit, if it's determined that it is not a major repair.

DR. FINDER: Correct. The guidance that we've issued addresses the issue about when a repair becomes a major repair and has to have an equipment

evaluation done.

However, the reg is pretty clear about the fact that when you get a new piece of equipment you don't have any option.

And we can address the issue about what a major change is, what a major repair is, in guidance, and we've done that with processors, and FFDM pieces of equipment already.

It's the issue about new pieces of equipment that the way the reg is written now it basically requires that the physicists go out and examine it.

And it's an issue that we've even got with screened film, a problem where there will be a remote processor maybe hours away from the main site, the medical physicist has to travel out there to do some tests that at least from what we hear back from some of the physicists could have been done by the technologist and then have oversight of the films that were generated from those tests.

And it's a significant change, it would be a significant change to the regulations.

DR. MOURAD: And again part of the issue is whether or not unambiguous data can be given to the physicist who is not there. For example if you need to go and evaluate whether or not a fairly subtle artifact still exists or not, that may be something that requires the physicist to be there, because he has to look at - he or she has to look at the monitor.

On the other hand if it's a case of not tracking properly, and it's a matter of putting a series of stacks of acrylic in and identifying what the contrast to noise ratio, that's something that is fairly unambiguous.

DR. FINDER: Right, and those are the issues we've been trying to deal with. Certainly a large number of the tests seem to be able to be performed remotely, and then the results reviewed. And that's what we're trying to get at here.

And it's going to be difficult.

DR. BYNG: It might have some association to exactly how medical physicist oversight is defined. But the test is actually being performed, and it's probably at the discretion of the medical physicist

whether the test should be performed under oversight or whether they should travel there.

And I think that it's more than a question of can we get the medical physicist to make a right assessment in advance, or to take the right action once they've seen the data.

DR. FINDER: Let me clarify. The idea of medical physicist oversight actually has been addressed in our guidance. And it does go along with the idea of allowing the option fo a medical physicist to go out there, certainly if he or she feels that it's necessary.

But the major part of it is that personnel who are trained to perform these procedures, other than the medical physicist, could do those, get the results to the medical physicist who reviews the test data, and makes a determination on whether those tests have been passed, or whether he has to go out and actually look at the equipment at that point. So it basically gives more flexibility to the situation.

DR. TIMINS: I would like to speak in favor of that modification to allow medical physicists

oversight for mammography system components, just as the physician is the head of the clinical effort and takes responsibility for the clinical aspects, the medical physicist is in charge of those components and is in a position to determine whether it's adequate for the technologist to perform certain of the testing and quality examinations, and I think that we could to some degree trust to the professional judgment of the physicist.

DR. FERGUSON: And I would agree with what she just said, and also realize that they are going to do these tests, they're qualified to do the tests, they are going to submit them to the physicists. The physicist may determine whether he needs to come out right then or not, but he's going to come out and see everything once a year anyway. So you will know, it's not like you put it in and it will never be looked at.

DR. MOURAD: Yes, I think one of the problems is that a lot of these things will not fall either clearly on the side of a major equipment replacement, a tube or something like that, versus something that is a software change or something like

that that really doesn't require, obviously, the physicist.

But within that gray area there will be a broad range, an obvious artifact that is a big stripe across something is either there or it's not, to a large degree. But something, the underlying cause of that artifact may not at all be a very clear thing. And so if the artifact disappears, then that's one thing. If the artifact just changes in its nature, or doesn't disappear, then that's a whole other thing, and it probably needs a visit.

So this is going along with the last two comments, which is, I think it needs to be a physicist's call to a certain degree based on the nature of the problem.

DR. FINDER: All right, so let's go through these related footnotes here.

First one is should the definition be modified to specifically allow for medical physicists oversight for mammography system components?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Take that as a yes.

Should a definition be added for mammography system components?

Again, a show of hands for yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Okay, that's a little bit split, but basically a yes.

Should a definition be added for medical physicists' oversight?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And that's a yes.

Okay, very good. I know, we're going back to 18. And the footnote actually is somewhat misleading, unfortunately. It's not, should a definition be added for mean optical density, but

should it be modified to deal with the specifics of mean optical density in terms of performing the AEC test, the AEC meaning automatic exposure control.

DR. SANDRIK: I'm still confused, because that seems to be basically what the definition relates to.

DR. FINDER: Let me work on that a little bit.

Talk amongst yourselves. Let's take a two-minute break.

(Whereupon at 9:31 a.m. the proceeding in the above-entitled matter went off the record to return on the record at 9:37 a.m.)

DR. HENDRIKS: We'd like all the members of the committee to take their seats so we can resume.

Okay we're going to resume by Dr. Finder resuming the quality standards - we're going to return to the definition of mean optical density.

DR. FINDER: Okay, I did find my note on there. And it's basically to clarify in the definition again that it's the mean optical density is measured during the AC performance test in a given

equipment configuration, to clarify that it's not over multiple different configurations.

So again it's more clarification. It's not an addition really.

So if we can have a show of hands, should we go ahead and clarify?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And that's a yes.

Moving to page seven for the definition of positive mammogram, should the definition be modified to add cases where a biopsy is recommended.

Right now positive mammogram is one that is read out of suspicious or highly suggestive maglinancy. Should that definition be changed to include, or where a biopsy is recommended?

And a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FERGUSON: I'd like some discussion on that. Have we had tell me - give me some for instances.

DR. FINDER: The issue comes down to, the way the current regs are written, reporting requirements are different if it's basically a positive mammogram. If it's suspicious or highly suggestive, the report has to go out under regulation as soon as possible.

If somebody for example read out a case as benign but still recommended a biopsy, or negative and still recommended a biopsy, that report right now could go out in 30 days if we modified this to make it a positive mammogram, that report would have to go out, quote unquote, as soon as possible.

Another issue is that report, that examination, which has to be included in the medical outcomes audit, because again, only positive cases under regulation have to be included. So that would entail a situation where if somebody had asked for a biopsy or suggested that it's a reasonable possibility, they would have to track that case.

Yes?

DR. TIMINS: Could I ask for some clarification on the BIRADS? I know that there`s BIRADS for ABC where 4A is more likely - less likely to be malignant.

Are there other categories of BIRADS 3? BIRADS 3 is just probably benign, recommend short interval follow up, generally six months.

DR. FERGUSON: So you're getting at where we give an assessment that is not highly suspicious, or suspicious but at the same time, we may say, the mammogram is negative but the biopsy is suggested. If there is a palpable mass that you don't see on the mammogram, then what we'll just do is track that as an auditable case.

DR. FINDER: It'll do two things basically. One, it'll make it a requirement that this be included in the medical outcomes audit. And two, the report would have to get out as soon as possible.

DR. HENDRIKS: But there is that caveat that a lot of the reports that I see say that the decision to biopsy be based on clinical grounds only.

And would that then encompass all of those mammograms?

DR. FINDER: It depends on how we word this. That's a good question. If there is some type of recommendation for a biopsy, the question is, does it kick it over into the positive category.

And I have seen some reports where they say, if you feel like you want a biopsy you can go ahead and biopsy, or not. It does raise some issues.

Yes.

DR. TIMINS: And your comment, Dr. Finder, is a very pertinent one, because there are a lot of reports that come out with that caveat of if clinical indicate biopsy should be considered, but the mammogram doesn't support that.

So I would be hesitant, now that you have brought that up, I would be hesitant to include BIRADS categories that are not either suspicious or highly suspicious, four or five.

DR. FINDER: Okay, so let's see a show of hands. Should we modify the current definition to include cases where biopsy is recommended?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: So we have a split but basically more no.

Next one is, we have a definition for what a qualified instructor is. Should the definition be modified to require additional instructor requirements in cases where corrective action is being done?

The current definition basically covers two different cases right now. It covers the routine average standard type of training that one would get in any type of course and we have established who might be a qualified instructor.

But the other issue that sometimes comes up is a case where we have a problem facility and they have to undergo some type of corrective action, usually asked for by the accreditation body, what should be the qualifications for those type of instructors who are teaching at a problem type facility?

Should there be added requirements to the qualifications of those personnel?

Yes?

DR. SANDRIK: Is there any indication that they are in a corrective action situation because of the inadequacy of the original instructors?

DR. FINDER: Well, that's a good question, but those original instructors might have been 10, 20 years before. We are never going to find those people.

The real kind of type issue comes up right now, qualified instructors could be, for example, for a mammography technologist, another qualified mammography technologist can give that type of instruction.

The situation could arise where let's say one facility is under some type of corrective action from the accreditation body, another one of their facilities is not under that type of situation, and they could call in one of their other techs from that facility to retrain the ones at the problematic facility, and under a qualified instructor right now

that certainly would be allowed, because once you are a tech you are qualified to do this type of training.

Don't ask me what kind of qualifications we would ask for at this point.

I think those are -

MS. MOUNT: Dr. Finder, who could train a tech's position if it wasn't a tech? I mean a physician can't train a tech position.

DR. FINDER: Correct, and the question really here is not that we would be asking the physicians to train the techs, it is, should we be requiring a tech who has additional type training in teaching these things to be training problem techs who have already gotten a facility into problems.

And I don't mean to pick on the techs. This would also apply to medical physicists, and apply to physicians in those types of cases.

Yes?

DR. TIMINS: I think this is fraught with difficulties. I would speak against it.

DR. FERGUSON: I would be concerned about the number of whatever standards you set being

available and being timely available. Because most of the time when you say you've got to go do another 40 mammograms, finding, if you've got two people in my state that do it, and coordinating times to do it, you may be down six months trying to get somebody there.

I think it's fraught with -

MS. MOUNT: Plus it would probably be added expense to bring someone in to do it.

DR. FINDER: Okay, so should we have a show of hands? Should we modify the definition to require additional requirements?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a no.

Should we add a definition for repeat rate and reject rate?

And this involves one of the quality control tests, the repeat analysis as currently written, there is some confusion about that, and I believe we'll get into the specifics of that when we

get to the QC section itself.

So maybe we should just wait on these definitions, because it may become clear once we actually get to the QC issue itself.

MS. VOLPE: Dr. Finder, I think you should add them just for the benefit of the consumers on the panel or anybody else from the public that might be reading the document.

DR. FINDER: Okay. So let's see a show of hands.

Should we make definitions for these? Yes?

(Show of hands)

DR. FINDER: And no?

(Show of hands)

DR. FINDER: Okay, so that will be a yes for both, number 22 and 23.

Next page, should there be a definition added for requalification? The issue that comes up, and has come up in the past, is although the requalification process is described in the pertinent personnel section, there tends to be a

misunderstanding, at least there has been in the past, what requalification really allows you to do, and what status it places you back in.

And it's somewhat unclear to people that requalification just means that it allows you to perform whatever either interpretation or exams or surveys without supervision but it doesn't negate the fact that you are still responsible for meeting continuing requirements.

A lot of people think that the clock restarts on your continuing requirement when you requalify, and it doesn't under the current regulations.

So the question there is, should we put in a definition there to clarify that aspect of the requalification process?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: So I'll take that as a yes.

Should a definition be added for small-

field digital mammography? We've already got a definition in guidance. It would be a question of putting it in the regulations to clarify that, and a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a somewhat split vote, but basically a yes.

Should a definition be added for soft copy image?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. BYNG: This goes back - sorry, Dr. Finder - this goes back to the discussion that we were having about hard copy image, obviously. So with that discussion was the potential consideration of what it might have you do in addition to making the definition.

So is this just the same discussion with

respect to trying to clarify the state of the related information that is needed with each format?

DR. FINDER: I think the - as has been pointed out, I think we understand kind of what these things mean right now. We would probably try and look for a broader definition so we wouldn't have to adjust things as new technologies come on.

Whether we can do that, I'm not sure. But I'm sure we'll hear about it as soon as you guys get the draft of whatever we come up with, and we'll have plenty of comments at that point.

DR. BYNG: Yes, I think that is the concern, is making sure it encompasses new technology.

DR. FINDER: It's all in the details. But I'll take that as a yes, qualified yes.

Next, should a definition be added for starting date? And here the purpose would be to define a simple term, which basically is kind of addressed in other portions of the personnel regulations, which basically means the date on which somebody meets all the initial qualifications. That is the date at which you're able to read

independently. Again, it's a type of clarification that we're asking for.

So should a definition be added for starting date? Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes. Number 28 refers to a survey, and this is a medical physicists' survey, should the definition be expanded to differentiate between unit surveys and facility surveys?

Again, going along with the clarification aspect of this.

DR. SANDRIK: Just the observation. I think the regulation on surveys only identifies facility surveys, so as yet there is no rule associated with unit surveys. I'm wondering if you really need the definition.

DR. FINDER: Yes, this actually goes back to a portion of yesterday's conversation about whether we should allow counting of these for continuing

requirements and also initial requirements, and it talks about the survey of a unit, number of units, ten units that must be done, six units that have to be done.

So even though there is actually no definition here it is referred to in the regulation. That's another reason to put a definition in, to clarify the other section.

So show of hands, should we do that, include that definition? Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Okay, that's a yes.

In number 29, should we add a definition for what we consider technique factors?

Show of hand for yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: I'll take that as a yes.

DR. SANDRIK: One comment, it already

exists in the federal performance standards. And if you could copy that it would be appreciated.

DR. FINDER: I'll put down, cut and paste.

Should a definition be added for the time frequencies for quality control testing? This basically deals with the situation of what does it truly mean to do a test weekly, monthly, quarterly, semiannually, those types of things.

And we've already addressed this actually in guidance to clarify what it means to do a test, for example, weekly. Does it mean you must always do it on Monday of that week? Can you do it any time within that week?

And again with the monthly and quarterly it's the same thing. Again it's already addressed in guidance. We're asking whether we should put that exact guidance into here for regulation.

Yes for that?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Okay, again that's a yes

overall.

Does anybody have any ones they want to add?

MS. VOLPE: I have some I'd like to add.

On page 15, suggest adding a definition of image receptor.

DR. FINDER: Page 15, or do you mean footnote 15?

MS. VOLPE: Page 15. That's where I found the item discussed.

DR. FINDER: Oh, okay, it's footnote number 37, yes.

MS. VOLPE: Okay, and also suggest adding craniocaudal and mediolateral oblique.

DR. FINDER: Oh, definitions for those things?

MS. VOLPE: Yes. Again, for the benefit of those of us who don't have experience in the field.

I would also add SID and collimators.

(Sound-System Failure)

DR. FINDER: Any others?

Okay, there was a question from the

audience about whether we should add a definition for computed radiography systems, CR systems, for example, the newly approved Fuji system.

And if we're going to do that, then the question comes up, should we have a definition for not only CR but also DR systems, which would be more your standard FFDM type unit.

What do people think about that?

DR. WILLIAMS: I think it's a good idea if for no other reason than the fact that CR and DR are sort of historical acronyms that people relate to, that they recognize. So I think it's a good idea to try to at least make the bridge between those and some explanation of what technologies they actually refer to. If they're used to it in the context of a different type of exam and this is new to mammography, then I think this is probably worth clarifying.

DR. BYNG: One additional comment. It may depend to some extent on how you choose to define modality, and some of the other definitions that you apply, whether you need one in this particular location for CR/DR and other types of radiographic

imaging.

DR. FINDER: Right now we've addressed the issue by basically saying that CR and DR systems are all part of the mammographic modality known as FFDM, full-field digital.

But it probably would be a good idea to define those or try and get a better definition for what CR and DR systems are.

So a show of hands? Should we go ahead with those types of definitions?

Yes?

(Show of hands)

DR. FINDER: And no?

(Show of hands)

DR. FINDER: Okay, that's a yes.

Okay, so we're done with that section. Want to take a break before we begin the last one?

DR. HENDRIKS: I think we can go ahead.

DR. FINDER: Okay.

The last section, last but not least, deals with quality standards for equipment and quality control, which is 900.12B and E, sections that we'll

be looking at begin on page 30, through 34, footnotes 74 through 83.

And then pages 38 to 46, which are 99 through 128.

Okay, we'll give you a chance to set that up on the screen. And in the section on equipment, which is the 900.12B we actually start on page 32 with footnote 74.

And there the question is, should we include a requirement that all digital components - and that goes again back to the idea of the component definition - be approved or cleared specifically for mammographic use?

And what we'd be talking about, at least as examples, would be the image receptors, monitors, printers, digitizers, PAC systems.

Yes?

DR. MOURAD: It seems like the answer to that would probably be yes and no. Some things, clearly, the image receptors and probably the monitors and printers, yes. But PACS, I'm not sure that that is practical to have those specified, the work

station, the display, yes, absolutely.

DR. SANDRIK: One concern is what that really entails, and what that assures or doesn't assure.

I think one thing it doesn't assure right now is that you in fact come up with a compatible system that will provide whatever quality you're expecting to meet mammography standards.

Another concern for example is that the current requirement on monitors involves the specification of having 5 megapixels available for the display.

It's essentially linked to current technology, but it doesn't necessarily mean that any imaging system should be limited by that.

As far as my own experience, it doesn't result in having a 2-C plan provided with these components, and although I've heard that FDA is changing that, I had a call earlier this week already from a physicist who got brand new displays with no QC plan and is asking what is he supposed to do.

So while I think it is a good step, it

doesn't necessarily assure meeting your quality requirements.

I think what you put in guidance already in the more recent editions including the past, the facility's accreditation by the phantom and clinical image review process is a step in the right direction.

Admittedly as you say in the guidance, there isn't the facility for doing soft copy in maybe not all of these, but the direction towards looking at what is the clinical problem you're trying to solve, and that the equipment addressing that problem is a more important direction to go.

DR. TIMINS: I think what I'm getting from the discussion is the operative word, all, is problematic. So it seems that to require that all digital components be approved or cleared for mammographic use might be a bad idea.

DR. MONTICCIOLO: I agree, and I think what Dr. Williams said is really important. It depends on the component. I mean most of us as mammographers have no control over the whole department's PAC system which is used department wide, and we have no control

over that at all.

DR. FINDER: Okay, so what I'm basically hearing is that maybe the term, all, has to be reconsidered. But am I also hearing that certain components need to be.

And let's just take a show of hands that there are certain components, depending on which ones we're talking about, I would presume we're basically talking at least about receptors which should be pretty obvious, monitors and printers. What about digitizers? If we are going to allow digitization to be a part of mammography.

And again that goes back to some of these definitions, whether they are included or not.

MS. MOUNT: I would say that to some degree it should be, at least the resolution that the films are digitized at. There is a huge variation out there.

DR. BYNG: But doesn't it also depend on what the intent of the digitization was?

DR. FINDER: That brings us back to that definition for final interpretation. See, everything

gets tied into these aspects.

Yes, you are exactly right. Right now if whatever process we're talking about isn't being used and doesn't impact on the patient, we really don't have much to say about it, and we really don't care that much.

It's when it becomes an issue where it actually impacts the interpretaiton or patient care that these things really become important.

So that's why the concept of the final interepretation is important, and once you've established that, you can tie certain other aspects, and certain other regulations and requirements, to those types of specific purposes.

So if I can just kind of get a sense from the committee on a show of hands. Should for example image receptors be required to be approved specifically for mammographic use?

A show of hands yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

What about monitors? Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And that's a yes. And again I'm talking about for final interpretation.

Yes.

DR. FERGUSON: To clarify when you say, must be approved, are we talking about a general elective, so and so monitor? Or are we talking about a minimum number of pixels to be considered?

You'd hate to have every little thing have to come for approval. You'd like to set a minimum standard.

DR. FINDER: I think the concept here would be, we're talking about FDA approval from the Office of Device Evaluation, at least as one of the possible approval mechanisms.

The other is possibly to set some type of standard that these machines or components would have to meet, and as has been stated, it has to be done

very carefully because there are certain kind of agreed upon standards right now, but I'm not sure that they have been proven to be as clnically relevant, for example, the 5 megapixel monitor is kind of the standard for reading mammographic studies, but could a four megapixel monitor be just as good?

And we certainly do want to be careful if we do go ahead with some type of definition here, or some type of requirement that we don't preclude the possibility of allowing different pieces of equipment that can be shown to deal with this, to solve the problem and be cheaper and more beneficial and reduce the burden and cost on facilities.

I will point out that we do have the alternative standard ability to issue an alternative standard, or ramp one. That's one of the ones we discussed yesterday.

And these requirements are under 900.12, so it would be possible for somebody theoretically to come in, provide evidence that their monitor, printer, et cetera, would be comparable and produce the same type of quality, and be granted an alternative, even

though it wouldn't meet let's say what is written in the regulation as a standard.

Yes?

DR. CHAKRABARTI: I think one of the problems here is that in the early days of FFDM the displays were a part of the package. And so they were all part of FDA, the process. And now the trend is to a certain degree away from that, and having third party displays to view the mammograms is becoming more and more common.

So with that in mind I think it's probably important that we make sure that the displays are under some sort of scrutiny.

DR. FINDER: Under the current regulations right now, there is no standard that's set for what type of monitors or printers that can be used. The only requirement that we have from a MQSA stand point is that they must satisfy the quality control standard set by the manufacturer, the image receptor manufacturer.

So theoretically somebody could go and view images on a laptop computer and read off of that

at the present time. This isd a real problem that we've got that we need to address in the regulations, because other than the quality control test, there are no other standards that are set for these components of full-field digital equipment.

So I would suggest that we take a show of hands to see if this is important enough to try to move ahead, even though we realize that we don't have all the answers, the final answers, as to what the minimmum rewquirements truly are, but at least to move ahead at that point.

And I do believe we have somebody from the Office of Device Evaluation. Do you want to speak about something?

DR. CHAKRABARTI: I think Mark is right. Kish Chakrabarti, I'm a physicist with the Office of Device Evaluation. Until and unless the full digital mammography system is declassified, we require that any component of that FFDM system, even though we have branched it out to monitor or printer for 5 or 10K, we still require that the specifications and performance should be the same as what came with the original

manufacturer's monitor or printer.

And we mention only monitor and printer, nothing else, not the work stations, not the image processing. The monitor, the specifications, and we have crafted some specifications and performance criteria by which myself and Office of Science and Electronics - the laboratories here - we review the monitors, and the monitors that are reviewed are all minimum pixels, but not only that there is some other specification and results that are necessary.

And if somebody wants to prove that there is a three megapixel, we might need clinical data. It's not decided. Anything less than five megapixel might at this point need technical data.

DR. FINDER: So if we could move ahead and just see a show of hands, should we include the requirements for the monitors?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

What about the printeres?

Yes?

DR. BYNG: Sorry, Dr. Finder, just an additional clarifiaction, this is to make it specific and different from what's already specified by the manufacturer associated with the image receptors?

DR. FINDER: The difference between what ODE approves, the Office of Device Evaluation, approves, and what can be used by an individual facility are different.

So a manufacturer has to go through the ODE process so that they can claim that their unit or component has been approved for mammographic use. But the way that our MQSA regulations are written, there is no requirement right now that only those components that have been approved for that use actually be used.

And as I say, right now somebody could if they wanted to use any kind of monitor they want, as long as it passed the QC test. It wouldn't necessarily have to be five megapixel; it wouldn't have to be three megapixel; wouldn't hvae to be any standard in terms of that.