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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE

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P R O C E E D I N G S

DR. MONSEES: Good morning. I am Barbara Monsees, and this is the NMQAAC meeting. We are going to start the morning with a Conflict of Interest Statement which Dr. Finder will read, and then we will move to Committee business, first with some intros, because we have a couple of new Committee members.

Dr. Finder, are you ready?

DR. FINDER: Yes.

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

To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests reported by the Committee participants. The conflict of interest statutes prohibit special Government employees from participating in matters that could affect their or their employers' financial interests.

However, the agency has determined that participation of certain members and consultants, the need for whose services outweighs the potential conflict of interest involved, is in the best interest of the Government.

Out of an abundance of caution, we have limited

Dr. Sickles, Dr. Dowlat, Dr. Nishikawa, and Mr. Pizzutiello's participation in equipment standards because of their involvement with mammography devices. They are allowed to discuss mammography technologies including digital devices as well as talk about their observations and experiences with these products; however, they will refrain from voting on specific equipment standards.

Full waivers are in effect for 15 out of 17 participants because of their financial involvement with facilities that will be subject to FDA's regulations on mammography quality standards with accrediting, certifying, or inspecting bodies, with manufacturers of mammography equipment, or with their professional affiliations, since these organizations could be affected by the Committee's deliberations.

The participants include: Dr. Barbara Monsees, Dr. Peter Dempsey, Dr. Laura Moore-Farrell [ph], Ms. Patricia Hawkins, Dr. Ellen Mendelson, Mr. Michael Mobley [ph], Mr. Robert Pizzutiello, Dr. Edward Sickles, Ms. Patricia Wilson, Ms. Kendra McCarthy, Dr. Kambiz Dowlat, Dr. Robert Nishikawa, Mr. Roland Fletcher, Dr. David Winchester, and Dr. Amy Lee.

Copies of these waivers may be obtained from the agency's Freedom of Information Office, Room 15A-15 of the Parklawn Building.

Also, several of our members and consultants reported that they received compensation for lectures they have given or will give on mammography-related topics. However, they have affirmed that these lectures were offered because of their expertise in the subject matter and not because of their membership on the Committee.

We would like to note for the record that if any discussion of State certifying bodies was to take place in any meeting of the Committee, it would be a general discussion only; no vote would be taken and no consensus sought.

In the interest of getting as many viewpoints as possible, all special Government employees, including State employees, would be allowed to participate in the general discussion so that all viewpoints could be heard. In the event the discussions involve any other matters not already on the agenda in which an FDA participant has a financial interest, the participant should excuse him or herself from such involvement, and the exclusion will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous involvement with accreditation bodies, States doing mammography inspections under contract to FDA, certifying

bodies, mobile units, breast imaging, breast implant imaging, consumer complaints, and mammography equipment.

DR. MONSEES: Thank you.

We are going to proceed now with introductions.

Would you like to introduce the two new members of the panel, and then I would like each panel member to, in just one sentence, say who you are and what your constituency is or where you come from.

DR. FINDER: Yes. Today we have two members who have not been at previous meetings, and I would like them to introduce themselves, beginning with Dr. Amy Lee.

DR. LEE: Good morning. My name is Dr. Amy Lee. I am an Assistant Professor of Community Medicine at the Northeastern Ohio University's College of Medicine. My previous background actually is as an ob-gyn, but I am not practicing clinical medicine anymore; I am actually putting together a master of public health program.

I am mainly here probably because of my affiliation with breast health programs. I help administer the local Breast and Cervical Cancer Program, and I am also on several advisory committees dealing with good breast health, including the American Cancer Society's Special Touch Program as well as the programs through the Asian American Pacific Health Organizations.

DR. FINDER: Thank you.

And the second new member is Ms. Ivis Febus-Sampayo.

MS. FEBUS-SAMPAYO: Good morning. My name is Ivis Febus-Sampayo, and I am here from SHARE, Self-Help for Women with Breast/Ovarian Cancer. I am director of the Latino program, and I am also a survivor of breast cancer for 5-1/2 years, and obviously, that is why I am here.

DR. MONSEES: Thank you.

Why don't we start at this end of the room and just say for the new members who we are.

MS. HAWKINS: Patricia Hawkins, Consumer Representative, affiliated with the Oklahoma State Department of Health.

DR. DOWLAT: I am Kambiz Dowlat. I am a surgeon at Saint Luke's Hospital in Chicago.

DR. SICKLES: Ed Sickles, radiologist, UCSF Medical Center, San Francisco.

DR. MENDELSON: Ellen Mendelson, radiologist at the Western Pennsylvania Hospital in Pittsburgh.

DR. FINDER: Charles Finder. I am a radiologist working for the Food and Drug Administration and the Executive Secretary of the NMQAAC.

DR. MONSEES: Barbara Monsees. I am a radiologist at Washington University School of Medicine in St. Louis, and I chair this Committee.

DR. DEMPSEY: Pete Dempsey. I am a radiologist at University of Alabama Medical Center in Birmingham.

MS. MCCARTHY: Kendra McCarthy. I am the director of the Women's Cancer Advocacy Network, and I am an 11-year survivor.

DR. NISHIKAWA: I am Bob Nishikawa. I am a medical physicist at the University of Chicago.

MR. PIZZUTIELLO: I am Bob Pizzutiello, a medical physicist in private practice.

MS. WILSON: Patricia Wilson, a radiologic technologist from Asheville, North Carolina.

DR. MONSEES: Thank you.

At this point, Dr. Finder wants to move on to the next item on the agenda, Alternative Standards Requests, and he will discuss this.

DR. FINDER: Since the November meeting, the Division has evaluated several requests for approval of alternative standards. Two of those requests have been approved. The first involved a facility that was performing mammography during some but not all weeks of the month. They requested that they be allowed to perform the required phantom test only on those weeks when they were actually performing mammography. Their request was evaluated, and an alternative standard was granted. The standard reads: "Facilities with film-screen systems shall perform an image

quality evaluation test using an FDA-approved phantom in each week the clinical mammography examinations are performed prior to the performance of such examinations."

The second request involved a facility requesting that they be exempted from the requirement that their mammographic unit continuously display the override status of the automatic decompression device. Their unit is used solely in screening mode, is always in the automatic release mode, and is never used for interventional procedures. their request was evaluated and an alternative standard granted with the stipulation that the unit be labeled as follows: "Unit always to be used in the Auto Release mode, and if the Auto Release is overridden, the status will not be displayed."

That's it.

DR. MONSEES: Thank you.

Are there any comments from the panel on that?

[No response.]

DR. MONSEES: Okay.

The next item on the agenda is the Open Public Hearing. There were no speaker requests to the FDA as part of that public forum, and therefore, we will move on.

The break is the next item on the agenda, but we will obviously not be breaking at this point.

[Laughter.]

DR. MONSEES: We will now move on to some information from Dr. Finder on Good Guidance Practices and directions for the discussion that we are going to have today regarding the guidance documents.

So our attention again to Dr. Finder, please.

DR. FINDER: For those of you who were here in the November meeting, I am going to be repeating myself again. This is some background and some of the material that we are going to be discussing today.

Before we begin our discussion of the proposed Draft Final Regulation Guidance, I would like to briefly explain the procedure that FDA is following as it develops new guidance.

In response to public comment regarding the use of guidance documents, FDA held an Open Public Meeting on April 26, 1996 and on February 27, 1997 and published a Federal Register Notice outlining the steps the agency needed to take prior to issuing guidance. In brief, it stated the following:

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

2) While statutes and their associated regulations

were binding and enforceable, guidance was to represent a way or ways of meeting the regulations, but other ways would be acceptable as long as they met the requirements of the regulations or statutes.

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

The documents that we will be discussing today contain a mixture of regulations and guidance. When you see words like "shall require" or "must," they refer to the underlying regulation, whereas the words "should," "may" or "recommend" refers to guidance. For example, in the question, "How does the facility demonstrate a satisfactory performance for mobile units after they are moved to a new location?" the answer could state that each unit must be tested prior to use on patients, which would be regulation, and then it could go on to recommend examples of tests that could fulfill the requirements, which would be guidance.

In the draft compliance guidance documents, you will notice that there are some modifications to the regulations as they were published on October 28, 1997.

These represent technical amendments which correct mistakes or omissions that occurred mainly during the printing process.

The Committee will be reviewing documents, some of which have already been released to the public and others that will soon be released for public comment. So anything that is discussed here will be available to the public for comment before it becomes final; we are still in an early draft stage in that sense.

DR. MONSEES: Okay. We can move on to the discussion now.

Does anybody have any questions regarding the rules or what we need to keep in mind from Dr. Finder before we move on to the actual discussion?

DR. FINDER: One question I would have for people--I just want to check with people on the Committee--do they all have the materials that we sent out to them, or are they missing anything, before we begin? If they have everything, I have some extra copies I can put out front for the people in the general public. But I just want to make sure everybody has all the documents.

Okay. I'll keep a couple extra just in case.

DR. MONSEES: Thank you.

For people on the panel and those of you who have copies, and some will be released for you to follow along,

there is a Document Number 3--we have been through Documents 1 and 2; this is Document Number 3--and the FDA also sent us another group of questions. The material that was sent to us had five items in it. Dr. Finder tells me that we have a few more items on his list today, and he will be good enough to try to interject those questions as we discuss them, moving through the guidance document.

So what we will focus on is going basically from beginning to end of Document Number 3, and where appropriate, he will add these other questions, and we will discuss those. Those that we do not work in or that we have neglected to discuss, we will discuss at the end after we have completed.

Are there any questions about that?

[No response.]

DR. MONSEES: Okay.

Let's start with page 1. This is what I suggest we do, rather than read it verbatim--are there enough copies in the audience for people to follow along, or should we make some reference? If they don't have a copy of it, we need to tell them what we are discussing, so we could do that if we think there aren't enough.

DR. FINDER: Actually, I think I would start not on page 1, which is just boilerplate kind of stuff.

DR. MONSEES: Dr. Dempsey made a request to start

on page 1.

DR. FINDER: Oh.

DR. MONSEES: So for those of you in the audience who do not have copies, we will make sure that some of this is discussed so you will know what we are talking about.

Dr. Dempsey, do you want to talk about page 1?

DR. DEMPSEY: Yes.

I would like to ask Dr. Finder, at page 1, line 3, are facilities of the Department of Veterans Affairs still exempt, and if so, why?

DR. FINDER: They are still exempt. It would require a change in the law to include them within MQSA. They have, however, developed their own program similar to MQSA. In fact we are now inspecting those VA facilities using FDA inspectors, so they are meeting the same standards, but they are not working under MQSA, they are working under their own requirements.

Does that answer the question?

DR. DEMPSEY: Yes.

DR. MONSEES: Are there any other comments from the panel on that?

[No response.]

DR. MONSEES: Okay. I believe the next page is also boilerplate. Does anybody have any comments on that? If not, we'll move to page 3.

[No response.]

DR. MONSEES: "Inspections - General."

The first question is: "Our facility has several patient waiting areas. Can I photocopy our facility certificate and place copies in each area?"

You see the answer.

The next question pertains to interventional. So, how about the first one, waiting areas and photocopies. Do you think the answer is okay, or do we need any amendments to that?

[No response.]

DR. MONSEES: I didn't see anything with that, either. Okay.

The next question: "We have a mammography unit that is used solely for interventional mammographic procedures. The unit is not MQSA certified. During the course of these interventional procedures, we take mammographic images. Because our unit is not MQSA certified, what restrictions exist on the mammographic images we may perform during such procedures?"

The answer says that these units must not be used to perform conventional mammography, but they can be used for interventional procedure. Then it goes on to say that they cannot charge for it if they use it to cancel a procedure.

I have a bit of a question with this one and an issue that disturbs me, and then I'll ask other people what they think about it as well.

In number 3, it says: "If the mammographic images obtained as part of the interventional procedure result in the cancellation of the procedure (the lesion is no longer present, e.g., calcifications are determined to be in the skin) the facility must not report nor bill the attempted procedure as a mammogram, but rather as a cancelled procedure."

I have an issue with--and I'll ask the other breast imagers here--taking a unit that is not MQSA certified, which may--presumably it may not--but presumably may have--lesser ability to see very small particles of calcium or whatever, and then tell a woman it is okay and obviate the need for biopsy. I have seen lesser units where that happened, so I have a problem with that, and I don't know exactly how to handle that, but I don't think we should let people think it is a good idea to cancel a procedure and tell somebody that it is finished when we only used a unit that is not MQSA approved, certified, and tell the woman she is fine.

Do I have any comments from other people here?

DR. SICKLES: Yes, Barbara. I flagged the same item, and I have you same concern, and I have a solution.

DR. MONSEES: Okay, good. We can always count on Dr. Sickles for solutions.

DR. SICKLES: Basically, if a procedure were to be cancelled on the basis of images that were obtained from this unit, the unit would be used for standard mammography, not for interventional procedure, because the decision to do or not do the procedure is the standard mammographic function, not an interventional function.

Therefore, this has to be changed to state something to the effect that if a procedure is about to be cancelled, the patient has to be transferred to a unit which is MQSA certified, and the decision made on the basis of images only from a certified unit. That would be simple, and it does not require additional regulation.

DR. MONSEES: Yes?

MR. PIZZUTIELLO: Bob Pizzutiello. I agree completely, and I have had experience with facilities where they have retained all the units which could not meet the current MQSA standards and used those exclusively for biopsy, and they have asked me to evaluate them just as part of the routine physics survey, and I found that the image quality on those machines was so inferior that I was concerned about exactly the case that you have brought up. So I think that from an image quality perspective, it makes abundant sense to ensure that if the case is cancelled

because you can't see something, you at least put your glasses on and make sure you are looking at the right image.

DR. MONSEES: Thank you.

Yes?

DR. DEMPSEY: Pete Dempsey. I would like to underscore what everybody else has said and take it to an even more fundamental level. If an instrument is not MQSA certified, it is entirely possible that what you are trying to localize, if it is a faint cluster of calcifications, you may not even be able to see it to localize it on this particular unit.

DR. MONSEES: This has been discussed before in this Committee, and I think the Committee felt that at least there was concern that all units, to guide interventional procedures, needle localizations, should be certified. That has not happened yet, as we all know, because interventional procedures were exempted. We thought that although stereotactic was a bigger jump and more work to be able to regulate that federally, that it was a smaller leap to have the equipment for interventional procedures required to be certified. That obviously has not happened. But I believe it was the consensus of the panel that we felt that that might be helpful.

Charlie, do you want to go around the table and hear again, or should we drop this here?

DR. FINDER: No. I think we have heard, and I think we can come up with some modifications to address some of the concerns.

DR. MONSEES: Okay. Yes, Dr. Dowlat?

DR. DOWLAT: Dr. Dowlat. Let me understand this quite clearly. A patient has come for localization of a calcification, and I am doing it on stereotactic, and I have discovered that it is only in the skin; the procedure is cancelled, and I send the patient back to mammography to reconfirm that this is in the skin.

Am I understanding you right?

DR. MONSEES: I believe so, yes.

DR. DOWLAT: Thank you.

DR. MONSEES: Okay. Are there any other issues pertaining to this same question and the answers?

Is there some other clarification, Dr. Sickles, that we need to make?

DR. SICKLES: No. I was just mentioning that I am not as concerned about an issue of calcifications being in the skin as being not visible and therefore perhaps limited by the equipment.

DR. MONSEES: Right. That was really an issue. I mean, in the skin is a pretty slam-dunk-easy answer, but where we might say they are not perceptible, and therefore maybe they don't exist--maybe they were an artifact or

something like that--that is disturbing.

DR. MENDELSON: Ellen Mendelson. Maybe the example should be changed so that it is clearer for those who are reading the guidance later.

DR. MONSEES: That's a good idea.

DR. FINDER: In terms of changing the guidance, to that point, we have to be all-inclusive, and it is difficult to start picking out individual examples that will follow these guidance statements and those that won't. If you want to have a separate procedure for skin calcifications versus calcifications that don't show up versus all those things, we would have to do that; otherwise, we have to come up with some general guidance that will fit all the situations.

DR. MONSEES: Right. I don't think we should have a separate procedure. I think it should be the same procedure, that they always need to go and get additional images at a certified unit.

I think she was just saying that this doesn't illustrate the point nearly as well as calcifications that are not perceptible; so maybe just use a different example so that people will understand that.

DR. FINDER: All right.

DR. MONSEES: Next question: "Our facility is undergoing accreditation. We meet all MQSA regulation requirements. However, our accreditation body recommends

certain actions that are more stringent than those in the regulations. If we follow MQSA regulations (but do not meet all those recommended by the accreditation body) can our facility be denied accreditation?"

The answer is "No," and then it goes into an explanation.

Does anybody have any comments on that?

Yes, Dr. Sickles?

DR. SICKLES: Only that the last sentence might be slightly misleading, unless maybe I didn't understand the answer completely. What I wouldn't want people to think in reading this is that they didn't have to worry to a great degree--I don't mean a lesser degree, but to a great degree--about the force of any State regulations that were beyond what MQSA requires. I mean, you have this qualifier at the end that "Facilities are reminded that States have the authority to require more stringent standards".

I would ask that you consider adding a clause at the end of that sentence that states "to the point of prohibiting MQSA accredited facilities from operating in the State," because they do have that power if they choose to exercise it. That way, if you like the language, at least it would be clear that, yes, you can be accredited, but you had better worried about State regs, anyway.

DR. MONSEES: Well, what confuses it is that they

are talking about accrediting bodies up above in the question, "our accreditation body recommends"--well, sometimes, it is the State that is the accrediting body--but what they are saying is that the State, even if it is not an accrediting body, can create rules that you must abide by in your State.

It is clear to me, but obviously, this panel knows more about it in general than the average. Do we think it is pretty clear?

DR. SICKLES: Ed Sickles. I think Charlie can think about it and decide whether or not he wants to put it in. It is just a potential source of confusion.

DR. FINDER: I feel like I have so much power here to think about it and put it in if I want to. It will have to go back to the entire group, and we'll look at it.

DR. MONSEES: Okay. Next page, page 4, "Definitions," direct supervision and what it means. I am not going to read all of this.

Does anybody have any questions? Yes, sir?

DR. PIZZUTIELLO: Bob Pizzutiello. I'm not sure I understood the intent of the last sentence in the question, "Must Physician B also include documentation showing that he/she is a qualified interpreting physician?"

Who is the "he/she"?

DR. MONSEES: Physician B.

DR. FINDER: In effect the one that is providing the direct supervision. It's a question of how much documentation we have for the inspector. We are saying that Physician A obviously has to show their qualifications, but how far do we take this down the line, and how much material does a facility have to have in terms of documenting all the people. Taken to the extreme, we could be talking about getting documentation for your college professor that he actually met the requirements. So we put the line at the point of saying the physician that is supplying the direct supervision doesn't necessarily have to supply the materials that show that he or she is qualified in certain positions.

DR. SICKLES: Ed Sickles. I think that's very reasonable, because interpreting physicians don't get a certificate or something simple that they could just photocopy. They would have to submit all sorts of documentation and it would get really unwieldy.

DR. MONSEES: Okay. So there are three situations that are almost the same. There is the physician, the technologist and the physicist. Then we move to the question of--yes?

DR. PIZZUTIELLO: I think there is a typo or a miswording in the section on physicists. In the second line, the question on physicists, it says, "Physicist B provides a letter documenting the number of examinations for

which he/she provided direct supervision." I believe that that should say "surveys".

DR. MONSEES: Yes. That's the danger of cut-and-paste.

Okay, the last question on that page: "Can direct supervision of an interpreting physician be provided exclusively through the use of telemammography?" The answer is "No," and they are going to entertain the idea later with digital.

Are there any questions on that one, or additions?

[No response.]

DR. MONSEES: Okay.

On the next page, physical science and its definition. "Is a degree in nuclear physics considered a physical science degree?" and the answer is yes.

Let's move on to personnel, if there are no further questions there.

The first one reads: "The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities."

Then, there are a variety of different questions here. Are there any items here that we want to discuss? The first one is: "At the time of inspection, the sole

interpreting physician, radiologic technologist, and/or medical physicist at a facility is found not to meet one of their requirements." I don't know if that language is right there. It is "not to" but should be "to not meet one of their requirements." "Must the person and the facility immediately stop practicing mammography?"

Then there is a long explanation. Does anybody have any comments on these answers or on this guidance?

Yes?

MS. HAWKINS: Patricia Hawkins. I wanted to just basically maybe get some explanation on the second paragraph where it says "continue to use the personnel for a limited time." Specifically what do you mean by "a limited time"?

DR. MONSEES: Would you like to answer that, Dr. Finder?

DR. FINDER: Let me give you a little background in terms of what we are talking about here, or what this is supposed to be addressing. Dealing with the situation of an inspector goes into a facility and finds that a person--and this is what we are encountering a fair amount--does not meet one of the continuing requirements. Most of the things we have encountered have been issues of continuing education, where they have some credits but not the full 15 that are required. The question comes up should they stop performing your services at that moment, or can they be

given some time in which to make up those credits and continue to practice.

The problem that we have encountered is that in some of these facilities, these are the only people who are there, and if they stop performing mammography at that time, you basically have a situation where they will have patients there who will have to be sent home.

We are trying to come up with a mechanism to allow these people some amount of time, and we are usually thinking about 30 days or so, in order to get these continuing requirements met so that we don't shut down these facilities.

That is where we are coming from and what we are talking about. It is to prevent a situation which we feel in a lot of cases would be worse than the alternative, which is to close down a facility based on a continuing requirement.

The other thing that we have encountered is that in some cases, somebody has been cited for one of these requirements, and when they respond, as they do within 30 days, it is a Level 2, so they have to come back to FDA with their response, and we find out that the citation was inappropriate, and we hated to have the idea of a facility actually being shut down and then finding out a week or two later that they were shut down for no reason, that it was a

paperwork kind of thing. So that is what we are trying to deal with here when we are talking about that kind of time span.

MS. HAWKINS: So this assessment would be done on an individual basis.

DR. FINDER: Right.

MS. HAWKINS: Perhaps that statement could be added, because it may very well be that further into this process, you begin to see problems that are more serious than just continuing education requirements.

DR. FINDER: Right.

DR. SICKLES: Ed Sickles. I think there might be a situation--I don't know if it has ever happened--where an inspector comes in and finds that somebody is completely unqualified. Under those circumstances, I am sure that calling the Help Desk would get an answer that they had better stop operating because the person is totally unqualified.

DR. FINDER: Right. But we are talking basically, again, about the continuing requirements here.

DR. MONSEES: Yes?

DR. MENDELSON: Ellen Mendelson. What exactly is the Help Desk? Who operates it, and what is the authority for making a decision? What are the appeals processes by which facilities can request review of their inspections?

What are those sorts of things rather than having things in the passive voice be helped by? Who is performing the help for facilities?

DR. FINDER: The Help Desk that we are talking about here is not a facility--information service. It is for the inspectors to call into FDA, and it reaches our division, so they speak to somebody in our division, and when questions like this come up, they are brought to my attention, to the division director's attention, and we usually try to evaluate the situation at that time. They will send or fax us materials, and if we can make a decision at that point, we give them some preliminary answer, and we go from there. But it comes directly into FDA. It is not a contractor that deals with them. It is our division.

DR. MONSEES: So it is during the inspection process itself, so they can come up with the appropriate answer for that facility if they have any question.

DR. FINDER: Correct. At this point, what we are telling the inspectors to do when they run into these kinds of situations is to call us so we can discuss it with them.

As for appeals, the facility obviously does have the right to appeal a decision of FDA. There is a whole procedure that they can go through. What we are trying to do for the immediate time is make a preliminary decision, if necessary, talk with the inspector, and if necessary, the

facility. Again, it is one thing for the facility to have the ability to appeal. It is another thing after they have been shut down for a period of time and the patients have been sent home to deal with it. We would rather try to solve these problems at the moment and not cause the facility to shut down inappropriately.

DR. MONSEES: Would you think that it would be appropriate if the facility felt that the inspector was wrong on a particular issue, and there was discussion about it? Of course, inspectors are never wrong--right--but if they were, do you think it would be appropriate that a facility could ask that the Help Desk be called, or is that totally the call of the inspector?

DR. FINDER: I don't think it is inappropriate. We have had situations where the facilities have requested that the inspector check with somebody, so I don't think that that is unreasonable as another operation or as further information. So we can take a look at that.

DR. MONSEES: I think that might be nice.

Are there any other issues here?

[No response.]

DR. MONSEES: Okay. And then the question at the bottom of the page: "Can time spent directly supervising other personnel or being directly supervised count toward the continuing education requirement?"

Is there anything on that?

[No response.]

DR. MONSEES: No. Okay.

"Can an interpreting physician position patients or perform mammographic exams?"

The answer is only if they are a tech or qualified a one, or if they are under the supervision of a qualified radiologic technologist.

Does anybody have any comments? Yes?

DR. PIZZUTIELLO: I guess I interpreted that perhaps a little differently. I have one client where the radiologist does with some regularity position patients and do mammograms. So the way I read this, "As long as the interpreting physician meets the qualifications of a radiologic technologist," and I went back and looked, and the qualification says you may be licensed in your State to perform general radiographic procedures. Now, in our State, medical doctors under their physician licensure are permitted to perform radiographic procedures.

So it would seem to me, at least in New York, that if the physician wanted to do mammograms, he or she could as long as he or she were licensed and met the other technologist requirements. The only thing that is different from the physician would be to document that they were doing 100 cases a year.

Does that seem right? Is that what you mean by this?

DR. FINDER: Correct. It is not 100 cases a year; it is 200 every 2 years.

DR. PIZZUTIELLO: Two hundred every 2 years.

DR. FINDER: But you are correct. We did check, and your medical license does allow you to perform radiographic procedures, so in effect you are licensed in the State.

This came up under the interim regulations in which a physician was acting as a technologist. In addition, we did check on it at that point. It is certainly possible for an interpreting physician to meet the requirements of the technologist; with the final regulations, they do have to be aware, however, that they will be required to meet the continuing experience requirement.

MR. PIZZUTIELLO: The only reason I would highlight that is that it might be good to make it clear that if a physician intends to do any mammograms, they need to meet those three criteria. Maybe highlight that they would need to--if you are expecting that--keep track of their continuing experience.

DR. FINDER: Again, it would be only if they are doing it independently, and in most of these cases where

physicians are positioning, the technologist is there; it is just a question if they want a certain kind of view, but they are not independently doing it, so they wouldn't even have to meet it in this situation because they would be under the direct supervision of the technologist.

MR. PIZZUTIELLO: In the case I know of, it is a small office, and sometimes the technologist goes away on vacation, and the physician does the whole thing when the technologist isn't there.

DR. FINDER: In that case, the physician is acting as the radiologic technologist and would have to meet all the requirements.

DR. MONSEES: Yes?

MS. WILSON: Patricia Wilson. I'd like to see it plainly stated that if the radiologist is going to perform mammograms independently, he does have to meet the 200 every 2 years requirement.

DR. MONSEES: Okay. So those words, if it were "independent." Most radiologists do what Dr. Finder was talking about--the same as I might go in, and I want a different view or whatever, and I will be there with the technologist, so it would not be a problem. But somebody who is going to independently do them should meet those requirements.

How about the next--yes?

DR. DEMPSEY: Pete Dempsey. Just a question to Dr. Finder. The physician who is acting independently as a technologist--this is a small point, but again, it is a requirement--his or her initials should be on the flashcard, correct, because as part of labeling, it is required that the technologist's initials, or more than that, be identified on the i.d. label; correct?

DR. FINDER: Right. The technologist has to be identified.

DR. DEMPSEY: And therefore, if a physician is acting as an independent technologist, his or her initials must appear on the flashcard.

DR. FINDER: Correct.

DR. MONSEES: Or i.d., or whatever. It doesn't have to be on the flashcard. It has to be on the film.

DR. DEMPSEY: It has to be on the film.

DR. MONSEES: Right. Well, some people put it on the film another way.

Are there any other questions on that--otherwise, we'll move on.

[No response.]

DR. MONSEES: How about if you read it to yourself, because I don't want to be in a position of having to read all of these because it will take a long time. Are there any questions on the rest of those above "Interpreting

Physician" there, the general things?

Yes?

MS. HAWKINS: I have a question on the question if the person providing direct supervision is found to be unqualified. How would a case like that arise, especially when we have looked at, on page 4, when you say that Physician B who is providing direct supervision does not have to show documentation--what situation would result in something like this?

DR. FINDER: These are unusual situations in which we become aware of somebody through other means. There could be a situation where we find out that somebody who has been providing services or training is not qualified. A lot of this comes through people telling us. As you correctly stated, we are not asking that all this material be sent to the facilities that they keep on record.

If we become aware of it in some manner, then we would have to look at those situations and see, because it depends on what is meant by "unqualified" again; there are different degrees. And if it is a question of whether they are missing, let's say, a continuing requirement at that moment, it is one thing; if they were never qualified at all, it is a bigger issue. That is why we did not come up with the specific answer here. We are just saying that we are going to look at those situations, deal with them, and

take what we believe are appropriate steps and actions at that time. But there are just too many variables to try to put down in guidance here.

MS. HAWKINS: I am wondering if the questions on page 4, where we looked at direct supervision by Physician B and Technologist B and Physicist B, I am wondering if perhaps a final clause or phrase should not be added that says, "No, does not have to include documentation showing that he or she is qualified as an interpreting physician, but can be examined if need be."

DR. FINDER: The only thing I would bring up about that is that we are talking to the facility at that point, and if we say "if need be," how are they going to get that documentation? We would have to go back to the source. I'm not sure we want to put that responsibility on the facility. I think it is something that we would have to look at.

MS. HAWKINS: But would a facility contract or hire someone that they have not documented as qualified?

DR. FINDER: Again, it is very variable, and there are all these different situations. But let's say you went to a course, and you assumed that everybody met the qualifications they were putting on a course, and it turns out that later, you find out, or we find out, that somebody in that course is not qualified. It is kind of hard for a facility to try to get proof that all the people giving that

course meet all the qualifications. They have to actually in effect act as inspectors before they send anybody to these courses. I don't know if we want to go that far.

DR. SICKLES: Ed Sickles. The problem is--it is not really a problem--the situation is that when you are an interpreting physician, you don't get some kind of certificate from the FDA. The FDA approves facilities, not the people who work in the facilities, at least in terms of a piece of paper. So that as one teaches at a course, you don't have any documentation to provide to the audience that you are an appropriate person. They take this on faith. And I think it is reasonable, because when you go to an educational facility, it is reasonable to assume that the people who are working there are legitimate.

If the FDA find out for one reason or another that somebody isn't, I think it is also appropriate that they can act on a case-by-case basis, because if the problem is you are one hour short in your continuing education hours, I am sure they won't mind it that much, but if the person were totally unqualified, they would mind.

DR. MONSEES: And to suggest that somebody has to produce those documents if they were asked would mean that they could be cited for not having that documentation there. So the reason--I believe--that the FDA wants to cut it off is because they don't want people to have to produce all of

those documents, because when they tell you that you have to be able to document such-and-such, it has to be there at the time of the inspection or you are cited right there and then for not having the documentation--even if you meet the requirements, even if you can produce it--if you don't have the documentation alone, you can be cited.

So they have to cut off what documents you actually have to produce that day; isn't that right, Charlie?

DR. FINDER: Yes.

DR. MONSEES: Okay. I think that's the reason.

Yes, please, Dr. Dempsey.

DR. DEMPSEY: Pete Dempsey. On page 6, the last question that appears before "Interpreting Physician," under the answer, I would ask that the word "Yes" be included, because that's basically what that whole paragraph says.

DR. MONSEES: "If a facility fails to have proper documentation for a personnel requirement, will the facility always be cited for failure of the inspection question, 'Required documents available?'"

Dr. Dempsey wants "Yes" in there.

DR. DEMPSEY: Because that's the sum and substance of what that whole paragraph says.

DR. MONSEES: Right. It is consistent with the rest of the document to have "Yes" or "No" in there.

Yes?

Ms. HAWKINS: Patricia Hawkins. I also have a question related to the last question before "Interpreting Physician." You say here that, yes, they will be cited, and that it will be recorded as an "N" generating a level 3 finding.

Well, now, we are talking about failure to have proper documentation for personnel requirements, and one of the examples that are given here, for instance, is that you and I have documentation showing they meet any one of their respective personnel requirements. But by this "generating a level 3 finding," is my understanding that a level 3 finding does not require a written response and that the inspector would not look at this again until they go back a year later and so forth, and then a year later, it could continue to be that.

So as far as personnel requirements, levels 1 or 2, I am just wondering if this should not warrant a lower level, at least a level 2, where there has got to be some sort of response back to FDA that says, yes, I do have my degree, and yes, this is in place.

DR. FINDER: Good question. In effect, this is in a sense a double citation, because whatever they are missing in the personnel category will likely, say, generate a level 2, so they are going to have to respond to that citation.

This is just a citation to show that they did not have the materials at the time, and if they do it again next year, that will be bumped up also. So we wanted to put it at a level 3 because we did not believe it was as important as the actual standards. That is a separate citation that the facility would be facing. For example, let's say they don't have proof that the person met the continuing education requirement. They would be facing a double citation--one for not having the required documentation and two for not meeting the continuing requirement. So they would face a double citation there.

This basically comes into the fact that we have not had facilities where the inspector goes in, and the facility says, "This person is qualified--we just don't have the records here today, but we'll get them for you." In that case, what happens generally is that the facility is given some time to show those documents, proof that the person is qualified, in which case they won't get a citation for not meeting the continuing education requirement. However, they will still have a citation that they didn't have the documentation available at the time. This is to kind of nudge those facilities that in the past have been telling inspectors time after time, "We just don't have the documentation with us; we'll get it to you in a few days." This is to try to decrease the number of facilities that are

doing that. We didn't feel it was at the same level of a real quality requirement--it is more paperwork--but we still wanted to end the practice of facilities not having its materials available, so we figured we'd start out with a level 3, and if they do it the second year, it gets bumped up and requires more response from the facility. That's why we did it that way.

DR. MONSEES: Anything else before we move on?

[No response.]

DR. MONSEES: Okay. The interpreting questions that are here involve basically two issues. This is the continuing experience requirement that is the first question, basically asking can you use interventional procedures to count this continuing experience, and the answer is no. And then, if a physician owns the facility, can they document their own continuing experience, and the answer is "Yes."

They seem okay to me. Does anybody have any comments on these things?

[No response.]

DR. MONSEES: Okay. On the technologist, what about the date? Does the certificate have to be stamped with the date it was issued? The answer is "No."

Dr. Dempsey has a comment on that one.

DR. DEMPSEY: The answer is "No," but in spirit,

it is really yes. It is a bit of a confusing answer, because they say you don't have to have it stamped no it, but then the second sentence of the answer says, "However, since this date is necessary...the facility must have some form of documentation identifying this date." So as opposed to the format where you give a "Yes" or "No" answer, this is one where I'd probably leave out the "No," because the spirit of the answer is other than that unequivocal "No."

DR. MONSEES: Okay.

Yes?

MS. WILSON: Patricia Wilson. I think this is related to the fact that when the ARRT first started issuing the advance certificate in mammography, the date was not on the certificate. It currently is on the certificates, and in fact the ARRT can provide you a written document and a list of all of your technologists with their dates of certification.

DR. DEMPSEY: The reason I am so sensitive about it is because it happened to us with one of our technologists at the last inspection, and we had to get the ARRT and everybody else on the telephone and fax things and all of that, so it was a very real issue on inspection, and we were facing a citation if, by the time the inspector left, we didn't have that little piece of paper in his hand.

DR. MONSEES: This is reality.

Are there any other questions or comments on this?

[No response.]

DR. MONSEES: Okay, let's move on, then, to the radiologic technologist experience.

They are basically asking can simulated exams-- patients not radiated--that is, positioning and interventional mammography, count toward the experience.

The first answer is "No," that simulated examinations don't count because you don't get to look at the product. I think that that is something we might want to discuss but seems to me to be appropriate.

And then, what about the interventional mammography, again does that count. It is currently excluded.

Does anybody have any comments on those things? It seems appropriate to me.

[No response.]

DR. MONSEES: Dr. Sickles gives it the thumbs-up. Okay.

Moving on to the physicist, we'll turn to our physicists here. I am a little confused about one point where the master's degree and the bachelor's degree are answered in these two different questions, because there are two times this comes up.

We are talking about initial qualifications, and

then there is a later one for alternative initial qualifications for the physicist. Under the initial, it says you have to have a master's degree or higher in a physical science; but then, the answer--I'm sorry--on page 9, the question is: "Is a bachelor's or master's degree in Radiologic Technology sufficient to meet the degree requirement?"

DR. FINDER: Let me just answer. This is the "cut-and-paste" problem.

DR. MONSEES: Okay. It is a cut-and-paste problem.

DR. FINDER: What it should say is just the master's.

DR. MONSEES: Thank you.

DR. FINDER: And in the second part, it should just be the bachelor's.

DR. MONSEES: Okay. That's what I thought, but I wasn't sure.

DR. FINDER: Originally, the question was devised for the general situation, and then we put it in the two places, and "cut-and-paste" gets it.

DR. MONSEES: Okay. Are there any other issues here? Did you physicists read this carefully, and it looks okay to you? Okay.

So we have gone through the initial and the

alternative initial qualifications there. And you read the parts about the physical science, the non-U.S. institution, et cetera. Okay.

Moving on, the survey part, and continuing experience for physicists--the surveys--this would be on page 10. Does anybody here on the panel have any concerns with this wording, with the intent of it?

[No response.]

DR. MONSEES: Okay. It looks okay.

We'll move on to "Equipment."

"Prohibited equipment. Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography." We all know why that should happen. "This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes implied acceptance of such systems," and so on, and then, "All radiographic equipment used for mammography shall be specifically designed for mammography and should be certified," et cetera, et cetera.

Then the question comes up: "At the time of the inspection, a mammographic unit is found not to meet one of its equipment requirements. Must the unit immediately be taken out of service?"

The answer is "No. However, the unit must be

replaced, modified or repaired as soon as possible."

I have a problem with that in that you are talking up above here about equipment that may not be specifically designed for mammography, and you are saying that it doesn't have to be taken out of service immediately.

Does anybody else have any concerns about that?

DR. FINDER: That may be the wrong place for the question, but the significant part of the answer deals with the fact that it still has to meet all the quality assurance tests. So what we are basically talking about are some of the individual requirements in section 12(b), but it still has to meet all the requirements in 12(e). So we are still basically talking about a mammographic machine; what we are really trying to address here is if a machine does not meet one of the individual requirements. We have had this come up with situations--I am trying to remember which one--the one that comes to mind is about, I believe, one of the compression paddles--

MR. PIZZUTIELLO: The compression paddle. If the compression paddle was not straight within one centimeter, is it necessary to stop using the machine immediately--probably not.

DR. FINDER: Right. Those are the kind of things that we are trying to deal with here. Again, we didn't want to have a situation where a relatively minor equipment

problem would shut a facility down.

DR. SICKLES: Chuck, I had Barbara's same concern about this one. Perhaps you could expand the answer a little bit to describe in some more detail what your thought processes are here, and that decisions might be made on an individual basis depending on the degree of severity of the problem. You know, if a unit doesn't have a compression panel, then maybe it would not be used immediately, but if a unit has a compression paddle that is 1.1 cm motion, they will be given a reasonable amount of time to fix it.

DR. FINDER: I think maybe this might be a solution or at least an attempt at a solution is to expand on the answer a little bit but also to put it under "General Equipment" and not under this section.

DR. MONSEES: Absolutely.

DR. FINDER: Okay.

DR. MONSEES: Please don't put it under "Prohibited equipment" and "general purpose units." I think we don't want anybody to think that this is acceptable for even a short period of time. It should be a clear "No" that if the unit is not made for mammography, the answer is "No."

DR. FINDER: Okay.

DR. MONSEES: Are there any other comments on that?

[No response.]

DR. MONSEES: How about the compression issues, application of compression and tapping the foot pedal, which I think is spelled incorrectly. It should be "p-e-d-a-l," not "p-e-d-d-l-e."

Did you want to talk about this particular one, about the foot pedal?

DR. SICKLES: I would like to solicit the comments of the physicists here, but I know that in our department, we have three machines that under this proposed guideline would have to be taken out of service, and yet I don't think that the images that we have obtained on them have suffered or not met the standards simply because we didn't have a two-stage compression system.

DR. MONSEES: Yes?

MR. PIZZUTIELLO: Since our last discussion on this, I have paid closer attention to a couple of these older units that I surveyed, and the way I see the problem is that on those units, when you step on the foot pedal, it is a pneumatic compression system, and it takes a little time for the system to engage, and once it starts, it adds a certain amount of compression that you cannot control. So it is not like a continuously variable control of compression which I would say is preferred. So that is my concern about these particular units, that it is really not completely under the control of the operator, that even when

they are trying to make the finest adjustment in compression, there is a certain stepped amount of compression that is added and a time duration that occurs, and if it is too much compression, the technologist really cannot stop it in the middle or back it off. It will move that amount, and then she would have to back it off.

DR. MONSEES: So in the answer here, it says "FDA is soliciting additional public comment before making its decision on this requirement".

DR. FINDER: We are, and I would like more discussion.

DR. MONSEES: Right. Any other comment here on the panel would be worthwhile.

Yes?

DR. SICKLES: I have a question. How many of these units are still out?

DR. FINDER: I can't give you specific numbers, but I can tell you that it is a significant percentage of the base that's out there. We're talking about, I would say, on the order of thousands of machines, not hundreds.

DR. MONSEES: Do any manufacturers in the audience have any numbers on this that would be helpful for the panel to know?

DR. FINDER: And I don't want to single out any individual company. This is a problem or an issue with

several different manufacturers. We use an example here because in the question, it is a very common machine that is out there, but this is not just related to one manufacturer or one type of machine; this is an issue that affects a lot of machines out there. That is why we didn't want to make any decisions that could affect so many facilities without getting as much input as possible, and we do want to hear from the Committee at this point what their opinion is.

DR. MONSEES: Now, this doesn't become effective until 2002, so if you decide now, it would at least give facilities the opportunity to purchase new equipment by that time.

DR. FINDER: Right. We still have some leeway here, and that is why we want to try to get this settled as quickly as possible, because facilities are out there trying to make decisions on whether to get new equipment, whether to upgrade certain things; so the sooner, the better.

DR. MONSEES: Yes, Ms. Wilson?

MS. WILSON: Will the majority of these units that do not have the hand-fine-tuned compression also fail to meet other standards in 2002, such as the automated exposure control meeting the 15 percent standards?

DR. MONSEES: Yes?

MR. PIZZUTIELLO: Many of the units will--the oldest generation, the 500T in this particular example, will

in my experience not meet the plus-or-minus .15 requirement for the automatic exposure control. The next generation 600T, which has essentially the same compression system, a well-tuned 600T may very well meet that requirement. We haven't looked awfully closely at that, but I think it may.

So we are now splitting the population in half. Just to give you an idea, the 500T's--and perhaps the manufacturer's representative could be more specific--probably stopped production well in excess of 5 years ago, and the 600T's were produced until perhaps 3 years ago--a ball park figure. That's close.

DR. MONSEES: Does the manufacturer or does the ACR which tracks the units as part of the accreditation process know how many units we're talking about here, so people can know? Do you guys know?

[No response.]

DR. MONSEES: Nobody knows offhand.

Yes?

MS. McCARTHY: Kendra McCarthy. From a consumer perspective, one of the biggest factors that is involved in women not getting a mammogram is because they say it compresses too much. And if we do not have very strong controls on the compression factor, we need to figure out how to get them there, because it is keeping women away from the machines.

DR. MONSEES: So noted.

Yes?

DR. SICKLES: I just have a general question that this brings up. Does the FDA have a target date for which issues like this will be decided so that facilities will have a reasonable amount of time to react to it? In other words, by April 2002 or some set date, you will have decided on all these issues.

DR. FINDER: I don't have a specific date that I can tell you is the shooting point. We're trying to get it done as quickly as possible. We are trying to get information from this group here. If we can get enough input from the response to this document from the public and from this group, the next guidance document that comes out could actually have our proposed answer, and we would go from there.

DR. SICKLES: I would suggest putting issues like this in the "Mammography Matters," because I think people will read that more readily than they will read something on your web site.

DR. FINDER: Actually, I believe the issue was brought up--I can't be 100 percent sure--but I believe that it was at least touched upon that this is an issue that we were looking at. The question is we have to get comments in. Unfortunately, sometimes, we send out a request for

comments, and we don't hear anything, and then, after it is too late or after the regulation goes into effect, we hear from everybody. So we are trying to use as many different mechanisms as possible. The web site is going to be a mechanism to do that. This is the first. This actually hasn't even gone out yet to the public. As soon as it does, we can start talking about it to an even greater degree, but we are just trying to get information now.

DR. MONSEES: While we are on that point and the public, when will this be posted on the web site, this document?

DR. FINDER: Good question. Obviously, we're talking about it right now. Some of the changes that you are talking about will probably be incorporated into it. It has to go through internal clearance. I am hoping in a couple of weeks to be up on the web.

DR. MONSEES: Okay.

MS. FEBUS-SAMPAYO: Ivis Febus-Sampayo. I just wanted to add to what Ms. McCarthy said. We do outreach with our organization within the minority population, and the fact is that very many are turned off because of the compression, and they will not go. We have to really stress the importance and continually tell them, and I figure that if we could monitor this, that would definitely help a lot of women, and they would then turn around and say, "It

wasn't painful, so I will go."

DR. MONSEES: Dr. Dempsey, who has this equipment, could you comment on whether you think that women who are examined with this type of equipment have any more discomfort or need to have any more discomfort?

DR. DEMPSEY: Well, I would like to make a couple of general comments, and not to minimize the comments of Bob Pizzutiello or the other people commenting about women's concerns about compression.

I think Ms. Wilson can speak to the fact that for many of the women who have alleged that there is a problem with compression, it is how the compression was applied and not the overall degree of it. For instance, technologists who are not as experienced or trained in some of the newer methods--if you cross-compress the pectoralis, or if you come down across the clavicle, or if you don't understand the nuances of elevating the intramammary fold--all of this has a play in how the compression is applied. And again, not to minimize the fact that overall compression is a factor, but a really, really good and experienced technologist will take women who have heretofore had a terrible experience and do an exam, and they will say, "My goodness, why wasn't it done this way the first time?"

So I think there are many factors, and I would hate to have all of it leveled at a mechanical etiology when

that may not be the entire thing. It is how it is applied, and that is extremely important.

DR. MONSEES: Yes?

MS. WILSON: Patricia Wilson. I would just like to add that having worked with both types of equipment, I feel like I can achieve good compression with either, but with the hands-one, fine-tuned compression, it can be applied slower and more gently than the automatic pneumatic compression, and patients in my experience seem to tolerate it better.

DR. MONSEES: Thank you. I think that's an important point. Okay. Let's move on to the compression paddle--yes?

DR. FINDER: Let me just ask this. Then, are we still agreeing with the statement, "The agency has received differing opinions"? Is that a fair assessment to make?

[Laughter.]

DR. MONSEES: Yes.

DR. FINDER: And we have no consensus or leaning or--

DR. MONSEES: We can poll everybody on the panel if that would help you.

DR. FINDER: That might be--again, we don't vote here, but we do ask opinions just to get an idea if there is any consensus. And I would just raise one point that has

been mentioned here already about compression and patients not coming back because of that. I think it is a very important point. We have heard this before. The question is, is it because of this type of equipment or because of other types of equipment. So I think the two are may be different, and it may be due to this equipment but it may not be. In fact, we have heard reports of more problems with compression with some of the newer equipment because people are using more force now. So I don't know if it is the equipment or how it is being used.

DR. MONSEES: Yes?

MS. FEBUS-SAMPAYO: I was just wondering if we could have a survey over at the facilities for a limited amount of time to find out whether or not we are getting that problem with the women for certain machines or not.

DR. MONSEES: It would be hard to get a controlled study there. We may have to have them done on two different machines in the same place. It would be hard to ask them was it better or worse than last year, or whatever.

DR. DEMPSEY: I'd like to make a comment on that. We have a particular machine in our department, and I am not going to mention names, but it is the newest of the new, and we get more patient complaints about that one machine-- because of compression? No. Because of the way the grid is positioned and the sharpness of the edges and so on. And

that single machine gets more complaints than all the other machines in our department, and it has nothing to do with compression.

We mentioned it--we had a big roundtable meeting with that particular manufacturer, and it was overwhelming. We had nine techs in our department, and every tech said that that machine hurt patients worse than any other one. So it is not all compression.

DR. FINDER: If we're going to go around, I think we should limit ourselves to the Committee's opinion on whether tapping the foot pedal can achieve adequate compression and not worry so much about whether it may or may not affect the patient's sensation.

The first question, if we don't believe that you can achieve good compression with this mechanism, that answers the question, and you don't have to worry about anything else. If you do believe that it can achieve a good image, then we can look at some of the other issues. But let's first try to get that first part answered or at least dealt with here.

DR. MONSEES: Not everybody is going to know the answer to this, so we'll have people who have some information about this.

Carolyn, do you have any opinions about this?

MS. BROWN-DAVIS: Yes, I do. I am going to go

with Ms. Wilson given the fact that she has used both machines, and she is also a female and has had a mammogram and knows what it feels like. So I concur with her opinion.

DR. MONSEES: Okay. Now, Ms. Wilson, in terms of can you exert adequate compression is what Dr. Finder wants to know right now--keeping in mind that there are other issues involved, and he has heard them, and FDA has heard them--

MS. WILSON: Correct. As I said, I feel like I can, with either unit, amply compress the breast.

DR. MONSEES: Yes, but the finesse and the subtlety--

MS. WILSON: Is much easier with the hands-on--

DR. MONSEES: Okay. So that's what you're saying. Yes?

MR. PIZZUTIELLO: I' just like to clarify one thing. The question talks about "tapping," but the example goes to the 500T. And my issue is less with the tapping than with the pneumatic systems, which allows you to not make subtle control. There are other machines which do not use a pneumatic system where I can tap the pedal and very precisely control small motion of the compression paddle.

So I don't think it is the tapping that is the issue; I think it is the pneumatic control which is only adjustable by tapping. That's the problem in my experience.

DR. MONSEES: Okay. Do you have any experience with this, Dr. Nishikawa?

DR. NISHIKAWA: I have none, so I have no comment.

DR. MONSEES: Thank you.

MS. MCCARTHY: Kendra McCarthy. I think this does affect the image, because if you don't get the woman to the machine, you can't take the image.

DR. MONSEES: Dr. Dempsey?

DR. DEMPSEY: I agree with Ms. Wilson.

DR. MONSEES: Ellen?

DR. MENDELSON: I think that you are able to get-- and we have had in the past, a 500T and a 600T--I think you can obtain a good image using that type of compression, so I would agree with Ms. Wilson.

DR. SICKLES: Ed Sickles. We have also had machines that in the past have used these devices. The images that they produced with skilled technologists are excellent images, so I don't doubt the equipment can produce good images. It is harder and requires more effort for the technologist to work with an older machine that doesn't have the fine-tuning, but I don't think it limits one's ability to take an acceptable or even an excellent image. It just makes it a little bit more difficult for the technologist to do her job.

DR. MONSEES: Do you have any comments from this

side of the table on this?

DR. DOWLAT: Yes. I just want to echo and reinforce Pete Dempsey's summary of this. I think it was excellent. It is the operator or the technologist that we usually get the complaints about. Patients will come up to me, one or two out of ten particular technologists are not very careful or sensitive to the issue, and maybe they are not even skilled in how to do the mammogram, we have problems with. I don't know about the technical issues, but the operator is definitely the problem that one may face.

DR. MONSEES: Yes, Ms. Hawkins?

MS. HAWKINS: My concern would be to make certain that this is an issue of training, because it appears to me that this is where the problem may be, with more expertise there and also injecting into the training that you have issues of client satisfaction and client concern and that you are not just dealing with a piece of equipment, and that it will differ from woman to woman and so forth.

This year, with the current mammogram, I had a very pleasant experience--in fact, it was so pleasant that I was wondering if I had actually had a good mammogram. So I think that that possibility is there, but as I say, I think the overlying factor should be how important training is in this process.

DR. MONSEES: Yes?

DR. MENDELSON: I do think it is important to separate out some of these issues. One of the things that I think we are really concerned with is accessibility, and the other is high quality, and I think that built into this legislation is an expression of that. But accessibility may be effective if there are indeed thousands of units which have good life and can produce good image quality around the country and to take them out of service where they perhaps cannot be replaced because of budgetary considerations I think would be a disservice rather than a service.

So if the appropriate images can be obtained with those units, I think we really ought to think ahead in terms of timing and replacement and assess a time in the future when perhaps they may no longer have that usable life, but currently, if they do, I think we should consider it in that way.

DR. MONSEES: Yes?

MS. WILSON: I would just like to strongly state that simply because a mammogram hurts does not mean that you have an inexperienced or uncaring technologist. Technologists are faced with an exam where compression and positioning are very important. I have yet to have a patient who comes in and says, "Good morning, I am so glad to be here." They all dread this exam, and the easiest thing a technologist could do would be to position poorly

and to compress poorly. But this is not in the best interest of the patient, and what would they be faced with when they brought the films to their radiologist?

So this is an exam that sometimes does hurt. Women's breasts vary in their degree of sensitivity and their monthly cycle. So I want to emphasize that all the pain from a mammogram is not directly related to a poor technologist.

DR. MONSEES: Absolutely.

Yes?

MS. MCCARTHY: It is also not attributed necessarily to the design of the equipment, either, notwithstanding what I said previously. Perhaps one of the things that we can do here is put into the answer the other factors that may prohibit absolute control or mitigate the absolute control of the paddles by bringing the technologist's experience and education and positioning and so on into this answer, so that we don't limit the supply of the equipment, we don't create access issues, but that we do sensitize the folks that if you can't control the paddles and the compression very finely, then you need to make certain that you compensate for that in the other ways that it can be done through the technologist positioning and so on.

DR. MONSEES: So perhaps we could make the point

that, one, as long as there is adequate compression, you may be able to obtain good images and that it may take more finesse, more experience, more patience to acquire them without additional needed discomfort or something like that in the discussion.

All right--yes?

MR. PIZZUTIELLO: Just to take that half a step further and connect it to what Patricia Hawkins said earlier, could we suggest in the guidance that if your unit does have only a foot pedal, then there be training directed specifically toward making sure that your staff is able to control the compression with whatever capability your equipment has? That would be more of an outcome-based guidance direction.

DR. MONSEES: Okay. I think that sounds like a good suggestion.

Let's move on, and we'll see if we can cover one or two more and then go to a break.

The compression paddle. "Can the single paddle meet the requirement of being matched to all full-field image receptors provided for the system?"

The answer is "No." That's logical.

Does anybody have any comments on that?

[No response.]

DR. MONSEES: Again, more issues about the

compression paddle--flat, parallel, and so on.

Then, the chest wall edge--straight and parallel to the image receptor.

I'm sorry, I didn't see your hand.

DR. SICKLES: Ed Sickles. I have a comment on the first question on page 12, where the question really is addressed to what is acceptable documentation when you are working with a paddle that is not flat.

I am concerned that the language in the answer is kind of broad. Basically, what it says is that if you have some documentation from the manufacturer saying "We designed it not to be flat," that then it is acceptable. I think that that is perhaps a little too broad if a manufacturer were to all of a sudden design a balloon compression the way we used to use for [inaudible] radiography and somebody produced that document, that wouldn't make it acceptable.

So I think you might want to not make it quite as broad as it is--if the manufacturer says it is okay, it is okay--because I doubt that the FDA monitors these paddles. If the FDA were to certify the paddle somehow independently, then I think the manufacturer's documentation would be okay, but I don't think they do that.

DR. MONSEES: Knowing you, Dr. Sickles, you always have a suggestion--

DR. SICKLES: No, I don't have one on this.

[Laughter.]

DR. MONSEES: Are there any other comments on this?

MR. PIZZUTIELLO: No.

DR. MONSEES: Charlie, anything else?

DR. FINDER: No.

DR. MONSEES: Then, how about the chest wall edge, "straight and parallel to the edge of the image receptor"? Are there any questions or comments on that?

Yes?

MR. PIZZUTIELLO: I've got to say I read this a few times, and I still can't quite say that I know exactly what it means. Being slightly quantitative in nature, I would like to see something like "straight within plus-or-minus 5 millimeters or straight," or something like that. I see lots of opportunity for someone to say, "Well, this is pretty straight," and then an inspector to say, "Well, it really isn't pretty straight," and we could start dancing around whether something is "straight."

So I would prefer to see a specification that says this is what we consider straight within a certain tolerance.

DR. MONSEES: Dr. Finder?

DR. FINDER: I agree with you in terms of the dance that we can get into about this, and that's what we're

trying to avoid. I'm not sure that by putting in numbers, we're going to first pick the right numbers and still avoid the dance that you're talking about.

What we basically then have to come up with is not only numbers, but a procedure for testing these things.

Let me give you a little bit of history on it. Obviously, we wanted to avoid the curved paddles that have appeared in the past. We wanted to go with the straight ones, which are felt to provide better visualization of breast tissue. However, there are paddles out there that are generally straight but have a slight curve in order to-- some are designed to, as they claim, improve patient comfort by not having the straight edges at the end. They have a little bit of a curve there. Now, how much is a little bit of a curve where we get to the point where it is no longer straight, in which case the paddle isn't allowed.

So we are trying to say here, to finesse this issue, that it generally has to be straight. Most people know what "straight" means. But there can be a little bit of variation in there.

Now, if we can come up with some numbers that you think are going to solve this problem, we would certainly be interested in hearing about it, but we were not able to come up with a test or a number that we felt would solve this problem without creating other ones.

DR. MONSEES: Yes?

MR. PIZZUTIELLO: There are two types of curvature that I am familiar with. The one that is of more concern to me is where the paddle is curved in the center--

DR. FINDER: Right.

MR. PIZZUTIELLO: --which is right where you, in my opinion, do not want it to be curved. I think the edges are a whole different issue, and perhaps you might just say that. Some curvature at the edges would be permissible. Then you know we're not talking about the center, because the machines that were designed in the late eighties and early nineties by one particular manufacturer have a notable curvature in the center which is easily replaceable with a better paddle, and I do not think we should be writing something that's going to let this move through. It is not expensive, and it definitely is a factor in positioning.

DR. MONSEES: Have those manufacturers actually made an alternative paddle?

MR. PIZZUTIELLO: The manufacturers as well as third party manufacturers have made upgrades available.

DR. MONSEES: So it says here that "If a manufacturer offers a paddle with a curved chest wall edge in addition to their straight paddle, then the curved paddle would not meet the requirement." So it wouldn't be just the manufacturer. You could say "if it is replaceable with,"

even if it is a different manufacturer, that it should be used. Do you see that part?

DR. FINDER: That implies that it fits the machine.

MR. PIZZUTIELLO: We are talking about third party manufacturers who make replacement compression paddles for machines A, B, C, D of all different manufacturers.

DR. FINDER: I think we'd have to take a look at that to see the impact of a statement like that, whether it actually changes anything; but we certainly can look at it. The concept of maybe addressing just the center curvature as compared to the edge curvature again is something we can look at and see whether it solves the issue that is brought up, because I think we have the issue of where inspectors at facilities and medical physicists were going up against the paddle with a straight edge, and if they saw a little bit of space between the straight edge and the paddle, then it was not perfectly straight. Those are some of the issues.

DR. MONSEES: Right. But if you are saying that "a manufacturer offers a paddle," I think you need to stipulate is it the original manufacturer, or can it be any manufacturer, because it may be available, but not through the original manufacturer, so to "any manufacturer offers a paddle."

DR. FINDER: Okay. We'll have to look at that.

DR. MONSEES: It's 10:30 now, and we're going to go to a 15-minute break. I have 10:30, so we'll come back in 15 minutes to continue the discussion.

Thank you.

[Break.]

DR. MONSEES: We're going to resume now.

We're at the bottom of page 12, "Technique factor selection and display. Manual selection of mAs or at least one of its component parts, mA and/or time, shall be available." And then it talks about kV and so on.

I expect to hear from the physicists here more than anybody. Does anybody have any comments on this part?

Are you okay with this, Mr. Pizzutiello? Do you need some time?

MR. PIZZUTIELLO: I guess I thought I understood it the first time I read it, and then when I look at it again, I was less sure. The machines that I am familiar with that display a pre-set kVp, most of them do not tell you what the mA is or any kind of mAs prior to exposure. So maybe I'll go back to Pete's comments--why is the first word "Yes"?

DR. DEMPSEY: Exactly. That's right. It should be "No."

DR. MONSEES: I see. So it should be "No."

MR. PIZZUTIELLO: That's the way I would interpret

it.

DR. MONSEES: So maybe you should take out that "Yes" or "No" there and just start with "Any technique...."

MR. PIZZUTIELLO: The only mAs that is displayed-- on some units, they display the backup mAs, but not all do that.

DR. MONSEES: So it is okay, then if we take that part out, if we take the word "Yes" out and start with "Any technique factor...." Okay.

Let's move to the AEC at the middle of page 13. "Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations."

Then, "Do all possible positions of the AEC detector have to be indicated on the compression paddle?"

There is a long answer there. Does it look okay to you?

MS. McCARTHY: I would suggest that the last sentence be moved to the very beginning of that answer.

DR. MONSEES: "The key is that the operator know what areas they may be select and the size of the detector."

MS. McCARTHY: Yes.

DR. MONSEES: Fine. Are there any other points here?

[No response.]

DR. MONSEES: All right. Then, the question about whether "The position of the AEC detector is infinitely variable over the entire area of the image receptor," and then a follow-up question to that, "An indication of the range of coverage and the detector size," and so on. "Do paddles designed to be smaller than the full size of the image receptor have to have the AEC detector position identified?" I suppose that meant the spot compression paddles and the fenestrated compression paddles.

Those look okay to me. Do they look okay to everybody here?

[No response.]

DR. MONSEES: Okay, then, moving right along. "The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physician." And film masking devices. They ask specifically about those view scopes, and I think that looked okay to me.

Does anybody have any comments on that?

[No response.]

DR. MONSEES: All right. "Medical Records."

DR. FINDER: Before we go to "Medical Records," I just want to go over a list of some of the questions that we

have.

DR. MONSEES: Great.

DR. FINDER: This is a question that isn't listed there that came up afterward, after we sent out this list. When the regulations were originally written, the requirement was put in for two image receptor size for film-screen, the 18-by-24 and 24-by-30. The Committee--not this Committee, but the previous Committee--felt very strongly that facilities should have both of those image receptor sizes. Some issues have come up, and people have been questioning about this. I wanted to get a sense of the Committee and their feeling about the fact that should all equipment have these two image receptor sizes; is it still considered by this Committee to be an important issue? That can hopefully be a very quick answer.

DR. MONSEES: What is your answer?

DR. DEMPSEY: Yes.

MR. PIZZUTIELLO: Yes.

DR. NISHIKAWA: Yes.

MS. MCCARTHY: Yes.

DR. MENDELSON: Yes.

DR. FINDER: Is anybody saying no?

[No response.]

DR. FINDER: Good. Okay. I was just checking on that one.

DR. MONSEES: Ms. Hawkins, you have a puzzled look on your face. Do you know what we're talking about here-- large and small format size. If you just have the small format size, and you have a large-breasted woman, it is a very labor-intensive exam, and there are many more exposures, and there is duplication and so on.

DR. SICKLES: There is a lot of unnecessary exposure.

DR. MONSEES: Right; not good practice.

Are there any others you want to interject here from that other list?

DR. FINDER: No, not at this point.

DR. MONSEES: Okay. Then, we'll move on to "Medical Records."

"Contents and terminology." This is "a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information."

All right. "Our interpreting physicians send out reports and lay summaries under their own letterhead. Must the certified facility performing the examination be identified on the report and lay summary?"

The answer is "Yes." So the facility needs to be on there.

Is there any dispute with that?

[No response.]

DR. MONSEES: Then the question is: "Must the radiologic technologist performing the mammogram be identified in the report and the lay summary?"

The answer is "No." The film itself needs to have their initials or i.d. on it, but it does not need to be in the report or the lay summary.

Is there any issue with that?

[No response.]

DR. MONSEES: Okay. Next is the overall final assessment of findings--this is at the top of page 15-- "classified in one of the following categories: Negative, Benign, Probably Benign, Suspicious, or Highly Suggestive of Malignancy.

Then, the follow-up to that is that if there is no final assessment category due to incomplete work-up, use the words, "Incomplete: Need additional imagine evaluation."

These were probably derived from BI-RADS categories in an attempt to standardize radiographic reports.

Yes, ma'am?

DR. LEE: I have a question about this. Is there some kind of mechanism to make sure the facilities are actually using this classification? Do the inspectors, for example, look at the reports?

DR. FINDER: The answer to that question is yes. Part of the inspection is that they actually randomly select reports and check to make sure these assessment categories appear.

I do have a question about this that has come up, and my question is how much flexibility, if any, should be allowed in the wording of the final assessment categories. These are the words that appear in the regulations-- Negative, Benign, Probably Benign, and Suspicious. We have been encountering some situations, and I want to get the pulse of the Committee on people who are using slightly different words.

For example, we have come across people who, instead of "Benign" are saying "Benign Finding." That has raised some questions. Some facilities have been using "Suspicious" for malignancy, or "Suspicious of malignancy," things like that.

Does the Committee feel that these are the only words that can be used in the assessment, or can we accept some flexibility here? I would mention the fact that when you talked about that these were derived from the BI-RADS category, that is true, they were derived from it, but they are not exactly the same. BI-RADS does use the term "Benign Finding."

So I'd like some discussion about that.

DR. MONSEES: That is correct that BI-RADS does use "Benign Finding," and that is probably why people are using "Benign Finding."

DR. FINDER: Yes.

DR. MONSEES: But I don't think it is ambiguous. I think it is pretty clear-cut what that means. It is a category 2. You don't use the Categories 1, 2, 3, 4, 5, and some people may use those in their reports in addition although it is not mandated that they do so.

Dr. Sickles?

DR. SICKLES: There are actually three ways in which the language in the legislation differs from the BI-RADS terminology. "Benign finding" in the BI-RADS versus "Benign" in the legislation; "Probably Benign Finding" versus "Probably Benign" in the legislation; "Suspicious Abnormality" in BI-RADS versus "Suspicious" in the legislation.

Now, I have heard a--

DR. FINDER: As much as I hate to correct Dr. Sickles, there are actually four.

DR. SICKLES: And there is also an "Incomplete."

DR. FINDER: Yes, the "Incomplete."

DR. SICKLES: Yes, I was getting to that.

DR. FINDER: Okay.

DR. SICKLES: I was getting to that one, because

it is there, but it is not bolded.

DR. FINDER: Exactly.

DR. SICKLES: I had heard the answer--I don't remember if it was from Dr. Finder or from someone else at FDA--that since the BI-RADS terminology involved additional words, that the inspectors did not really mind if people put extra words in there as long as they didn't leave out the words that were in the legislation, which is certainly fine with me, and we're talking here about how many angels dance on the head of a pin. I mean, "Benign Finding" is the same as "Benign," and anybody who speaks English knows that that is the same thing. And whether you decide that it is acceptable to have "Benign Finding" simply because the word "Benign" is in there, or whether you decide that it is acceptable because it is the actual language in BI-RADS, it doesn't matter; it should be acceptable.

DR. MONSEES: I agree.

Are there any other comments? Yes?

DR. MENDELSON: I think that as long as there isn't a substantive change--actually, if we look at the wording here, "Benign," and "Also a negative assessment" as its definition really doesn't tell you in what circumstance you should use "Benign" and in what circumstance you should use "Negative." They are essentially synonymous in this listing, whereas BI-RADS does make a distinction.

I think that in light of the fact that we are dealing with Federal legislation and inspection and a variety of things where there may be literal applications of these regulations, perhaps for consistency, we should keep it as with BI-RADS, allowing for a nonsubstantive change, perhaps as Dr. Sickles said, an additional word but not one fewer, and to list here in the guidance--because it will provoke some kind of discussion--instead of A, B, C, D, or E, change it to 1, 2, 3, 4, and 5, as it is found in the BI-RADS listings.

I think that that would simplify things and minimize the problems that people have with interpretation.

DR. MONSEES: I think that the A, B, C, D, and E was not intended to be put in the report. That is just listing them. Maybe if it were just bullet points, so you don't have to have that additional--

DR. MENDELSON: I think so, but don't put it in, because people will notice, as we have seen, that it will be compared to BI-RADS, and someone will say, "Well, should we use A, B, C, D, or E, or 1, 2, 3, 4, and 5?" and maybe the bullet thing would help to clarify.

DR. MONSEES: But my suggestion would be that we don't put 1, 2, 3, 4, 5, because it could be misconstrued as meaning that you have to put the category in there.

DR. FINDER: Let me try to stop the entire

discussion about that. This section is part of a larger document, and the structure of that document is the way it is--it follows the Federal Register requirements. There is no way we can change the A, B, C, D, and E because it is part of a numbering structure system for this.

I have had other guidance in which we say that you don't have to use the numbers, that numbers alone are not sufficient, and you have to use the words.

The only other issue that I would bring up about this is that I think it is fairly clear that if it has the word and a few other words, and it doesn't change the meaning, that that is okay.

We do run into one other problem, and that is the "Incomplete," where in BI-RADS, that "Incomplete" is on a different line, and it is not bolded, and all they say is something like "Need additional imaging evaluation."

DR. SICKLES: They do; that's exactly what they say.

DR. FINDER: And the question then is now we don't have the exact words; we're missing one of the words--it's not an additional word--and is that still acceptable. I'm asking if you think that that's still okay.

DR. SICKLES: Well, I have a question for you before we address that, and it actually relates to the regulation, not to the guidance, and I know that we cannot

change regulation.

I noticed when I read this something that I hadn't noticed before. I don't want to read it all, but in 21 CFR 900.12(c)(1)(v), in addition to using "Incomplete: Need additional imaging evaluation," one is supposed to state the reasons why no assessment can be made.

DR. FINDER: Right.

DR. SICKLES: I have not been doing that. First of all, these assessments come up basically only in the screening setting, and the reason why you can't make an assessment is because you have just taken two pictures--the woman has come in for a checkup, and you have taken two pictures, and she is gone--and you have looked at the films after she is gone, and there is no way you can hallucinate the findings that you would like to make by getting additional pictures.

I have not been putting in our screening reports, "This is incomplete because it was scheduled and performed as a screening examination." I think it is pretty obvious why. I would hope that the FDA is not going to require us-- I do not see that they have--but I would hope that they don't require us to put a sentence in the report saying-- even though the legislation seems to state it--that we have to say it is Incomplete because it was a screening exam.

I don't think was part of the previous guidance,

but as far as the word "Incomplete," when it first came out, and we had not been using it--we had just been using the "Need additional imaging evaluation"--I had very negative feelings about having to put it in, but we put it in. I was afraid it would generate all sorts of comments from our clinicians, saying, "Why are you doing an incomplete exam?" We have had zero comments saying "Why are you doing such substandard work that it is incomplete?" I haven't had any complaints, so I am less concerned about it than I was initially when I thought it would generate them.

I would be interested in others' experience.

DR. MONSEES: Did you have a comment, Dr. Dempsey?

DR. DEMPSEY: Just to say that I think that that one category of "Incomplete" has generated more comments from people that I have talked to than having to use the actual BI-RADS classification. Most people have fallen into that without any problem. But the "Incomplete" has generated more comments than any of the other categories.

DR. MONSEES: I personally have big problems with the "Incomplete" category, and I don't know whether I should address these to the BI-RADS Committee of the ACR or to the FDA or to both.

There are different things that you can do. You can say "Incomplete: Need comparison with outside films." You can say "Incomplete: Recommend ultrasound." You can

say "Incomplete: Recommend additional views."

The reason why I think this "Incomplete" is a problem, the Category 0, is that when we calculate our callback rate, if we are comparing it with outside films, calling it "Incomplete," there are two problems. One, it is not really a callback, so it should not be considered part of our audit as a callback, and it should be separated out. This Category 0, "Compare with outside films," should be separate from a callback.

Secondly, I feel like an idiot when I sent a report out that says, "Incomplete: Need additional imaging evaluation. Recommend comparison with outside films," and I have the patient sign a release and am trying to get her outside films. The doctors have had enormous problems in our community adapting to this, because when they see "Need additional imaging evaluation," they send the patients in for additional imagine evaluation. And I have written in the report, "Recommend comparison with outside films" according to the way that BI-RADS tells me to do it, but they send the patient anyway, and it is very embarrassing, and it is an unneeded visit to the department.

Yes?

DR. SICKLES: We have--I don't know if "solved" is the right word for this problem--but we have overcome it by in that situation, where all we need is requiring prior

films, giving it a "Regular assessment" category and then stating at the bottom that we would like to compare with prior films--but not putting it in "Incomplete." We use "Incomplete" only when we need to take additional images, not when we need to see prior images. That's our solution to the problem which has overcome clinician concerns and ordering unnecessary exams and things like that.

Now, you may not be comfortable with the approach, but at least we have made it work in my hospital.

DR. MONSEES: Well, you may or may not be able to give an assessment without those prior films is the problem.

DR. SICKLES: You can always do it, because sometimes they are never available, and then you have to do it anyway.

DR. MONSEES: The vast majority when we request are available, because we have already checked out where their films are and so on. We already know before we are requesting whether those films are going to be available, because we have every patient fill out a release form, and we know the date of their prior and the institution. So if we are requesting it, we know they should be available.

So I have problems with this, and I think it needs to be worked out probably between the BI-RADS Committee and the FDA to allow us to be more flexible and not to inconvenience people. I just wanted to state that.

Yes?

MS. HAWKINS: I have a follow-up question to Dr. Lee's question as to during the inspection, if the reports are checked to see whether they list the assessment. Is that report also matched with the lay summary that goes to the patient?

DR. FINDER: No, because it's not part of the record.

MS. HAWKINS: In other words, once the inspector looks at what is reported back to the physician, does he also look at the lay summary that is reported to the client?

DR. FINDER: They do check the lay summary, but they don't check to match up the lay summary with the actual medical report. It is like two separate evaluations. In a lot of facilities, the lay summary will not be kept together with the medical report, so there is no easy way to check and compare the two to see if they are corresponding reports. But the lay summaries are checked as a different part of the inspection; they do check to make sure that the lay summaries are available and that they are being sent out. But there is no direct check to see that they correspond.

DR. SICKLES: I think I can help you with that answer. Every facility has to have a procedure documented in the procedure manual of how the lay summaries are

distributed--whether they are handed to the patient, mailed to the patient or whatever. And the mechanisms have to be described there. The inspector is going to look carefully at that.

In our facility, the lay summary that is sent out by mail, by the computer, is generated by the assessment category, so whatever the assessment category is, that governs what letter goes to the patient. The inspector is obviously going to be happy with that, because if the computer sends a "negative" to the doctor, it is going to send a "negative" to the patient.

But most facilities do not put the lay summary into the permanent medical record. That is just something that goes to the patient. But they would not have a convenient way for the inspector to look at the particular letter that went to the patient.

MS. HAWKINS: And the reason I am asking this is because you asked how much flexibility should be allowed, and since the lay summary does not have to have a final assessment category, we are dealing with more flexibility here that may go to the consumer.

DR. FINDER: Right. Let me answer that. Actually, that's one of the questions further down. A lay summary does not have to have an assessment category. It should be written in lay terms. I would not consider most

of these assessment categories lay terms in a lot of cases. So yes, the lay summaries have a lot more flexibility in trying to describe what should be done. The lay summaries do not have assessment categories, so there is no one-to-one correspondence, or in most cases, there wouldn't be a one-to-one correspondence.

MS. HAWKINS: My concern is that in reporting back to the consumers, those lay summaries that would address "Probably Benign"--those that are neither negative or positive but may be suggestive--and how that goes back to the consumer and what sort of a message it conveys to the consumer. For instance, if the physician does not call that person back in or say "We need to counsel about this" or talk about this, what is given to the consumer when there is some uncertainty?

DR. FINDER: Right. Those lay summaries are reviewed during the inspection to look at the general templates of what these lay summaries look like and what is included in there--whether they are in a sense adequate to get the message across. So those are checked. It is just not that there is a one-to-one check of this patient--the referring physician got this report, and then the inspector would look to see the exact lay summary that that person was given--but they can look at the general summaries that are handed out or sent out to all the patients, and they do look

at those.

DR. MONSEES: And comforting is that there is a template or are templates available for those lay summaries from the Agency for Health Care Policy and Research, and those have been placed on the FDA web site. In addition, the ACR has mailed to all facilities sample letters that can be used to correspond to these categories. So it is not as if each institution is making up its own out of the blue. They have something that they can adapt to their own environment and use, and I think it has probably helped tremendously, although we do not really know. It helps a lot when you provide people with this type of template so they can go from there.

MS. HAWKINS: Okay. As I said, my concern would be with the client getting something that says it has a high probability of being benign.

DR. MONSEES: Right. The lay letter that would go with that probably would not be worded like that. It would be worded to say what the finding is--that the exam is normal, or the exam shows a finding that probably isn't cancer. And then the other important thing in the lay letter is what the next step is. It is always important for the patient to know "You need to contact your physician. You need to be in touch with your physician." So if there is anything at all that is suspicious or that needs

additional evaluation, as long as the person is instructed that the mammogram is not normal, and they need to be in contact with their physician or to come back in for additional evaluation, that's what we are looking for here, so that people understand that there is a next step, and it is not next year.

MS. HAWKINS: Yes. Thank you.

DR. MONSEES: Yes, Dr. Lee.

DR. LEE: In the Breast and Cervical Cancer Program, it is very important as we receive reports to see reports using the BI-RADS type categories or something similar, and we see a number of differing kinds of mammogram reports.

If we see a provider who is not reporting using these kinds of categories, what can we do to either encourage providers to do this or what could one do?

DR. MONSEES: Dr. Finder, what do we do?

DR. SICKLES: By the time they get inspected, they are going to have to have changed.

DR. FINDER: Right. There are a couple of things that can be done. You can just call us. You can talk to the facility. If the facility doesn't realize that they have to meet the requirements, notifying them will help them, and as soon as their inspector shows up, they are going to be informed rather quickly that they have to make a

change.

But if you know the facility hasn't done it, I would suggest giving them a call, jogging their memory that they have got to do it, and if you still don't get a result, you can give us a call, and we can talk with the facility.

Somehow, it's amazing how quickly getting a call from the FDA sometimes works.

Getting back to this issue, though, I wasn't exactly 100 percent sure--were we saying that if they leave out the word "Incomplete" and just put down "Need additional imaging evaluation," that's okay, or should they be cited for that.

The other issue I want to bring up is that this comes up to some degree because at least a fair number of facilities out there have gone to computerized reporting systems where they don't have control or that much control over what it says, and these are put in by the manufacturer of that software. And I don't know if this is the case, but if they use just "Need additional imaging evaluation" rather than "Incomplete: Need additional imaging evaluation," should they have to change the software?

DR. MONSEES: I think it's fine. I don't think it's ambiguous at all.

DR. SICKLES: Charlie, when I made the comments that I did before about how "Incomplete" did not affect our

particular environment, we put it in there because it was in the regulation, and I want to be in compliance with it. But I don't think that taking it out or not absolutely requiring it would somehow damage the intent of the legislation.

I think "Need additional imaging evaluation" is pretty straightforward. It means what it says. It means that you haven't come to a final conclusion, and you need additional imaging evaluation, and I think the use of the word "Incomplete" is in some ways superfluous, but there are probably--Pam, maybe you could answer this question for me--but haven't some of the software vendors already changed to add the word "Incomplete"? I believe they have. I believe some of them have already changed, so then, telling them that they should change back--I wouldn't tell them that they should have it in or that they don't need to have it in. I would just say that if it isn't in there, it is not crucial, but if it is in there, it's fine.g

DR. MONSEES: Okay. Shall we move on to "Communication of mammography results to the patient" at the bottom of page 15.

"Does the lay summary have to be signed by the interpreting physician?"

The answer is "No."

"Does the lay summary have to have a final assessment category?"

The answer is "No." We just discussed that.

"Do we have to provide lay summaries translated into different languages for our patients who cannot read English?" Now we are getting into some of these communication issues.

"Facilities are required to provide lay summaries of their mammography reports to all of their patients. The content is left to the facility.... While facilities are not required under MQSA to provide summaries in different languages....," and so on.

Then, "How should a facility handle a lay summary that is returned 'undeliverable'?" This is basically saying that you have done your job if you have sent it, but that you probably should make extra effort in cases where it is "suspicious" or "highly suggestive of malignancy."

How about patients who cannot communicate--people who are illiterate, deaf, whatever--illiterate and deaf would be more difficult.

Are there any comments on any of these issues?

Yes?

MS. FEBUS-SAMPAYO: My question is how do we determine what is the number or percentage of clients that speak a certain language. Do we have any regulations stating that if you have 50 percent or more who speak only Spanish, or Chinese, that you do then have to have these

forms translated?

Secondly, could the FDA get a translator to come in for the various languages and standardize a translation?

And with respect to getting information to the patient, I suggestion I would have would be to recommend that when the patient comes in and signs her form, have a close relative or close friend as a contact name, include their telephone number and address, so that if this person is away or at the moment not reachable, there would be a contact person who would then get the same information and could follow through.

DR. MONSEES: Dr. Sickles?

DR. SICKLES: Barbara, we actually had this discussion at the meeting prior to this. The language in here is very close to but maybe not exactly what we discussed, and that's why I flagged it. I mentioned when we had this discussion before, using my own example in San Francisco, that our patient population being extremely diverse, we deal with 40 languages--40 languages--in our entire patient population, and obviously, we cannot have reports going out in 40 languages, because sometimes it is even difficult for the technologist who speaks English to know which is the appropriate language for a particular patient.

What I would like to see in this last sentence

where you talk about making reasonable efforts, I would say "reasonable efforts if practical." I would just put in the words "if practical" because sometimes it just is not practical. But if it is practical, I think it should be done. The FDA has decided in its wisdom not to require, because then, what number do you assign? Do you assign 50 percent or 256 percent--and then, how would you know? From the facility point of view, how do you know exactly what percent of your population doesn't speak English? It is not speaks another language, but it is doesn't speak English or doesn't understand English or read it well enough to be able to get the import.

I think the intent of all of this is that if you perceive in your community that the majority or a substantial percentage of your patients won't understand the letter, then it is to your advantage to communicate to your patients better by having a second letter in that other language. But if as a woman, let's say you spoke only Spanish, and you received a letter in English and you didn't understand it, but you had a relative who understood English. You would probably bring the letter to your relative and ask, "What does it say?"

MS. FEBUS-SAMPAYO: I agree, but in many cases, it is perceived that something may be wrong by their getting the letter, and they may be so frightened that they won't

follow through.

DR. SICKLES: I understand, I understand.

MS. FEBUS-SAMPAYO: This is why I am suggesting a contact person who in most cases--and it may be suggested on the back that the contact person at least speak English. Therefore, you would have someone who could go on ahead and bring the patient back in and explain what is really in the letter or at least translate the information.

DR. SICKLES: We also will, and I am sure most facilities have adjusted to this by explaining to the woman at the time that she is having her examination that she will get a letter in the mail if she is going to get one in the mail. Sometimes it is handed out, but most of the time, they get it in the mail, and it is explained that you will get a letter in the mail, and usually, a woman who doesn't speak English will come with somebody who does, and that will be imparted, and the letter is going to say it is normal or it isn't normal, but you are going to get a letter no matter what. So if you get a letter, and you don't understand it, show it to this person, and they will tell you what it says.

MS. FEBUS-SAMPAYO: The reason why I recommended this is because then, if it is suggested, I think it is not just your facility we're talking about, or the one that I attend, but all facilities that are under FDA regulation.

DR. SICKLES: Right. I hear you. It would be very difficult for most radiology information systems, because I don't think they are set up to do this, to add a name and address of a contact person who then automatically would get a letter. It is difficult enough, and many systems just get the letter to the patient, because many information systems don't even keep that.

MS. FEBUS-SAMPAYO: Let me clarify. What I mean is in the case where you cannot reach--let's say, for instance, you send a letter out, and you are expecting a follow-up call, and the person does not call. Then, the next step would be to extract that information and then follow through.

DR. SICKLES: Yes. Okay. I follow you.

DR. MONSEES: In addition to patients speaking different languages, we don't have an insignificant illiterate population in the United States, and we presume and we hope, even though it may not be clear to us when they come into the department for their mammogram, I think it might be when you hand them a questionnaire for them to fill out. Often, they have somebody else do that for them; one of the technologists will help them with it or whatever. And then, if they get a letter in the mail, they will find somebody who is literate to help them understand what it says.

Are there any other comments on this? Yes?

DR. LEE: I'm wondering if we could expand the answer a little bit and try to define a little bit of what "reasonable efforts" might be--say something like, for example, get a contact name or tell the person who is accompanying the woman that they will receive a letter--and there are some good suggestions here, and it might be good to expand a little bit on what "reasonable efforts" might be.

DR. MONSEES: Okay. Moving to the middle of the page, "Must the radiologic technologist performing the mammogram be identified in the mammography report and lay summary?"

I think we have answered that before.

DR. SICKLES: Yes. Charles, you know that this is the second time that this has appeared.

DR. FINDER: Yes.

DR. SICKLES: There are several of these that have appeared more than once.

DR. FINDER: Was it the same answer?

DR. SICKLES: Yes.

DR. FINDER: Then what are you complaining about?

[Laughter.]

DR. FINDER: I'm just kidding. The reason it appears several times in the document is that eventually,

this document is going to be broken up into what we call our search engine, our guidance search engine, and these will have to appear in these sections, and we're just putting them in there. Hopefully, the answers are the same in both--as long as they are, we're okay. But you will see that in several areas where the same question is asked multiple times.

DR. MONSEES: Now, this is an important one, the last question on page 16. "Must a lay summary and/or mammography report be provided if the images from an examination are re-read by a physician not associated with the facility where the examination was originally performed and interpreted"--for example, a second opinion.

The answer is "No, there is no requirement that a lay summary or mammography report be provided when reinterpretation of images are done at a facility different from the facility that made the original interpretation. However, FDA strongly recommends that the second facility inform the patient or health care provider requesting the second opinion of the results."

I agree with that. Do we have any dissent here?

DR. SICKLES: No. I agree.

DR. MONSEES: This is an important one, because it allows second opinion.s.

MS. McCARTHY: I have a question. What if the

second opinion differs from the first interpretation? The woman might have had a "Benign" response and might not follow up, and yet the second opinion doesn't share that "Benign" response. I have some concern about that, because she is potentially not going to get the follow-up that she needs.

DR. MONSEES: Right. That's what the second opinion is about, and that's why the FDA says "strongly recommends," and so on. I think everyone understands--I hope--what that means. The implications of a differing opinion are very significant for that patient.

MS. McCARTHY: I would add to that, though, "especially in the cases where the second opinion does not agree with the first."

DR. MONSEES: Right. Some of the problem is that we don't always know what the first opinion is. I get things sent to me where I don't necessarily have the prior report sent. I do everything in my power to make sure that happens. I tell surgeons, internists, et cetera, patients coming for a second opinion, to bring the prior reports, but I don't always get them, and then I've got a woman there with these films, and I don't know what they said at the other place, and I can't tell her, no, I'm not going to read this until I've got the prior films. I don't always know. Sometimes, we try and have them faxed to us urgently, and so

on. The answer is that you don't always get it.

Do other people have those problems as well?

DR. SICKLES: Yes. We occasionally have that problem. A woman or a physician who is requesting a second opinion already has heightened concern--otherwise, there wouldn't be the second opinion--they are not just done routinely; they are done in particular cases. Every time a second opinion changes management, there is not only a medical and an ethical directive to communicate; there is also a legal one--there is a medial/legal one--and radiologists increasingly are becoming aware of that, because if they don't follow up with especially a "Benign" that goes to a "Suspicious," then they are going to be held accountable in the court among other places.

Logistically, I think it would be very difficult for the FDA to require this sort of thing because second opinions simply don't go into the information system of the hospital, and there is no way to track them.

MS. MCCARTHY: So a second opinion would have to be requested; it wouldn't necessarily be a referral for quality assurance?

DR. SICKLES: Well, there could conceivably be practices where double reads are done as part of quality assurance, but that would be part of the facility's own system, and that is really an amended report, which we are

going to get to. That's different from a second opinion. That's just an amended report within the institution.

DR. MONSEES: Dr. Mendelson?

DR. MENDELSON: Just to add that if, in conjunction with the second opinion, additional films are obtained for that patient when the patient comes for the consultation, that would generate a communication.

DR. MONSEES: Absolutely, and the lay summary as well. Any additional imaging that is mammographic would mandate it. If it were an ultrasound, it would not.

Are you okay with that? All right. Let's move on, then, to the top of page 17 and "communication to health care providers. It's long, and I am not going to read it. Does anybody have any problem with that first question and answer?

[No response.]

DR. MONSEES: The second question and answer, again, are redundant; they are duplicates. But the first question regarding that is: "Our facility's mammography reports are accessible to our health care providers on computer. Because of this, we don't print out reports to send to the providers. Will providing mammography reports through the use of computers be acceptable under the final regulations?"

The answer is really yes, but it doesn't say