So that's what we're trying to address here.

Just to clarify what we're voting on now, are we voting basically on the original question that this be limited to approval or for mammography use basically the 510K process, or that FDA would address a broader aspect of writing specifications for how this should address mammography quality?

DR. FINDER: While the question itself was addressed, the approval process I think that probably if we were going to actually write something here, it would be more an either/or, either approve or meet some list of specifications.

But again that's in the details, and I guess we're pretty much trying to go just in the general direction.

DR. SANDRIK: I was just saying, it wasn't clear what the general direction was here, if it was going to be limited to ODE approval as the direction, or a broader direction?

DR. FINDER: I think we would probably try and go for both, either an ODE approval or some list

of specifications that would be allowed.

And again it's a difference between what ODE approves and what the manufacturer can claim in their advertising. They'd still have to go through that process. We wouldn't negate that. But it's again what the end user could use.

And we are quite aware of the other issue you brought up about even if they are approved, and are of the right specifications, the compatibility factors, and whether they are actually compatible with various systems is going to be another issue that is still problematic.

But again right now we have very little control over the situation, and we're trying to get a better handle on it.

So if I could again see a show of hands for printers, yes.

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And again, it's a yes.

How about digitizers, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: They're kind of split.

And for PACS, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And that's a no.

Okay, next one is, should a unit that is converted from one mammographic modality to another, and we give the example of screen film to computer radiography, be considered a new unit for mammography equipment evaluation and accreditation purposes?

And again this is something that has just come up with the recent approval of the CR system. We're basically talking about in many cases a unit that has been used and accredited as a film screen unit. Now all of a sudden through the addition of the CR system it now can do either film screen or digital mammography, and the question here is, if it's going to be used for digital, should it in effect be

considered a new unit for purposes of the equipment evaluation, and accreditation purposes.

DR. WILLIAMS: It seems like the aspects of the unit that pertain to the tube and so on, and the unit assembly itself, that would be sort of a redundant set of tests.

If there was an up-to-date physics inspection on those, I think it should still stand. But of course evaluation of the individual plates and the scanner and the reader and so on, absolutely.

So in that sense I don't think it's a new unit, by my understanding of the definition of a new unit.

DR. SANDRIK: You could explain the difference between the new unit, say, versus calling this a major repair that was based on an image receptor replacement.

DR. FINDER: Well, in terms of trying to get in to all the details, it becomes very problematic. For example the film screen unit could have had its AEC already tested as a film screening unit. But now all of a sudden you insert this CR

plate in there. Well, would you say that you don't have to retest it under the new conditions? Well, some people might.

And the idea of saying that this is a new unit for mammography equipment evaluation basically says at that point that a physicist has to go out and do testing, and has to go through the unit now.

You are correct that we don't have all the answers yet to exactly what components need to be tested and what don't, what you can actually use from the previous equipment evaluation.

The other issue here is again that the survey is not the same as an equipment evaluation. There are other tests that are done in the equipment evaluation that are not required in the survey.

So a survey that was done 10 years ago when the unit was first put into operation as a film screen, I'm not sure that we wouldn't want even those tests repeated again.

Those details I think would have to be worked out. I think here we're going for the broader picture of, should we be considering these, that it

must undergo a mammography equipment evaluation, and that it must in effect reapply or apply for accreditation and submit new images under the new CR system.

There are going to be plenty of details that need to be worked out, but again, the general concept is the one we're going for.

Yes?

MS. MOUNT: Theoretically, if you had a system that you were doing CR on, if you were working in a dual environment, you could still use home.

DR. FINDER: Yes.

MS. MOUNT: So would that unit be accredited as two different units then?

DR. FINDER: Yes. Under what we've been talking about, we would be talking about - if it's being used for film screen and for CR, it's going to be accredited, and as two separate units they'd have to submit films for film screen and for CR.

I will tell you that we suspect that with the trends that are going there, that situation won't last very long, and that facilities would tend to go

over to CR exclusively. That's the thought.

But again we would leave the possibility open that they could, if they wanted to do both. But again they'd have to have their unit accredited as both for that type of situation and inspected as boht under that situation.

DR. FERGUSON: If you add this, is this not - could it not just be considered a major repair type situation where you are going ot have all your evaluation done, and then you're not going to hit somebody for a couple of different fees for one machine?

DR. FINDER: Well, they are going to get the fees anyhow, because I think the general consensus is that a mammography equipment evaluation needs to be done. It's now a question of just how etensive that has to be. And that again gets more into the details of this.

I think in terms of accreditation you have to submit images, and that's the major part, and also a phantom, and those types of things.

There may be some components that wouldn't

necessarily havew to be repeated, but again that would be in the details of what is necessary or not.

DR. TIMINS: I seem to be hearing from the physicists and industry members that rather than this being a new unit that is an old unit with a new image receptor. I'm concerned about requiring reaccreditation under those - which is another cost, which kind of discourages people from updating the image receptor.

So I'm coming against this based on what I'm hearing.

DR. WILLIAMS: I can certainly appreciate what Dr. Timins said. On the other hand I think that probably reaccreditation in this instance is probably appropriate since the image receptor will determine a great deal of the overall image quality in this particular case where you are swapping out a screen composite and replacing it with a very different technology.

And so I think that probably, even though it is probably going to be an extra cost and so on, just like switching to digital from general is, it is

probably appropriate to have those images reviewed and reaccredited.

DR. FINDER: I would like a show of hands. Should we basically go along - should a unit that is converted from one mammographic modality to another be considered a new unit for equipment evaluation purposes, and for accreditation?

A show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: No. Two hands.

DR. WILLIAMS: I would say no to the first one, but yes to the second one.

DR. FINDER: Okay.

All right, next question, should a light be required on all mammography systems? The way the current regulation is written it says that if there is a light it must meet certain requirements, but it doesn't require that there be a light.

Any comment?

MS. MOUNT: I would like to comment.

A light is very important. Just seeing the shadow of the breast on the image receptor can determine whether or not you are missing tissue before you even shoot the exposure. So yes, definitely.

DR. BYNG: I think the only clarification we wanted here was whether you were literal about light, or whether you were talking about identification capability. In other words it didn't necessarily have to be a light.

DR. SANDRIK: Yes, I guess I appreciate Ms. Mount's comment here, because the other possibility could be, say, an LED or laser indicator of the boundaries, the detector, which might serve partly that purpose, but it wouldn't be a light field in the conventional sense that we have it right now. And then also then it would effect this requirement on the illumination requirement.

So if you just had a device that indicated the boundary that might serve the purpose yet not quite fit in this rule as it stands right now.

MS. MOUNT: I don't think the boundary would be as efficient in helping the technologists as

a whole field.

DR. FINDER: Okay, so can we have a show of hands? Light, yes?

(Show of hands)

DR. FINDER: Light no?

(Show of hands)

DR. FINDER: That's a yes.

Does anybody happen to know offhand how many units are going to be thrown out of operation because of this? If we go ahead with it?

DR. WILLIAMS: I don't think I've seen any.

DR. FINDER: Okay, but that would be one thing that we would obviously want to look at.

Next page under compression, number 77, should we delete the effective date here?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: It's a yes.

Under 78, should we clarify what is meant by technique factors? And again, that would go back

into the definition section too.

Yes?

(Show of hands)

DR. FINDER: No?

DR. SANDRIK: Just a comment. I mean right at the beginning oif the rule you state what the technique factors are. Say, the technique factors, two potential, two current, and all that. So it's already stated in the rule.

What is the need for putting it in twice in the same rule?

DR. FINDER: Okay. We'll look at that again.

MS. VOLPE: I'm concerned about somebody who may need to flip back and forth. Having a definition section would be worthwhile.

DR. FINDER: Okay.

All right, the next one is number 79 on page 34. Should configuration here be redefined to be contact, magnification and different sizes, and exclude target filter combinations.

First, do you want to comment?

DR. SANDRIK: Yes, I'd comment, I guess. Again, I think this represents one of these situations of trying to define by providing a list. And again I think that's where we run into trouble by including in that list things that really don't belong.

And in this particular case, target filter combinations is one of the things that doesn't belong in at least in the context of trying to do this AEC test.

So it might be something again to consider a definition of what really you mean by the configuration, and then try to decide what fits in there or not.

DR. WILLIAMS: That's right and I agree. But on the other hand I think that there are some manufacturers who have AEC for some target filter combinations and not for others.

So the question would be, should there be AEC for all target filter combinations that are possible on the unit? And I think there are arguments that would say yes to that.

MS. MOUNT: And I question should we stop

at six centimeters? Should we go to eight?

DR. FINDER: That was the next question.

Let's go with the first one. Should it be redefined? Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: No one cares. Very few people care. All right, we'll take that as a limited yes on that.

Now should the range be limited to just two to six centimeters, ir should it be expanded to eight?

DR. SANDRIK: Comment on that. I think part of the problem is that eight centimeters of acrylic does not represent an eight centimeter compressed breast. It is considerably more dense than the breast. Most of the studies that have done evaluations tracing the composition versus thickness indicate that an eight centimeter breast is probably close to 20 percent glandular, 80 percent fatty, even the average standard breast is somewhere closer to 30

- 35 percent glandular, not the 50 percent we talk about.

And eight centimeter acrylic phantom is probably more than a 99 percent percentile level of the patient population. A six centimeter is around a 90 to 95 percentile coverage of the population.

So really going out to eight centimeters kind of pushes the limit. It doesn't really indicate a particular value in what you can cover in your population.

DR. FINDER: So a show of hands - oh, sorry.

DR. WILLIAMS: I was just going to ask a question. I think that the ACR recommendations in the current MQSA regs are a little bit different in that the ACR I think recommends going up to eight centimeters.

I was just wondering if there were date that were or are available to get at what Dr. Sandrik is raising here, which is how important of a representation in the population is whatever would be simulated by eight centimeters of acrylic? And was

that the basis on which any of these decisions was made?

DR. SANDRIK: Publication Medical Physics, 2001, by Kruger and Schueler goes through that definition, percentile ranges, whatnot, what is represented by various breast equivalent types, acrylic, BR-12, and that sort of thing, and what is the average composition of the breast.

And theirs is not the paper that covers that area.

DR. WILLIAMS: And so about what percentile then are we talking about?

DR. SANDRIK: Yes, they say eight centimeters of the BR-12 corresponds to the 99.8 percentile; eight centimeters of acrylic corresponds to more than the 99.9 percentile. I'm not sure if I can find the one on six centimeters right off. I think it was somewhere around 90 to 95 at six centimeters. I can check that later.

In fact they say, a more realistic recommendation for AEC performance may be obtained by referring to the 10th and 90th percentile levels, in

Table 3; 90th was like 6.2 centimeters of BR-12 or 5.7 centimeters of acrylic would cover you out to the 90th percentile level of the breast population.

And this in fact is from the Mayo Clinic.

DR. BYNG: In this part of the regulation you are essentially covering what's ultimately referred to in 900.12E-5, ion automatic exposure control performance. So in this section, if it referred to meeting the requirements of that paragraph rather than the explicit definition, would that cover it?

I know you are not interested in wordsmithing now.

DR. FINDER: I think the difference between the section D and E is, again, the difference between a mammography equipment evaluation and a survey.

And under the equipment evaluation, which would be the one we're talking about right now, part B, you talk about doing the AEC component, or the AEC testing under the various different configurations. Whereas under the annual it's only done in one.

But yes, there are obviously correlates

between the way you would do the test for the cofiguration between what's done here and what would be done in section E.

I don't know if that's an answer to your question or not. Close enough?

Okay, so let's go with, should we limit the range to two to six centimeters?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Next one is, should kilovoltage peak reducibility be added here? Right now it appears in the annual testing. We'd be talking about moving it out of there into the mammography equipment evaluation so it wouldn't be done as an annual test. It would jsut be done when the equipment was first installed, or when there were major repairs.

MS. VOLPE: I'd like to see that added on 900.2 definitions as well.

DR. FINDER: Okay. So again, show of hands

-

DR. SANDRIK: Pardon me, so do I understand, again, when you say added here, and you are also saying delete it from the 2C test?

DR. FINDER: Correct.

Show of hands for yes.

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Okay. Next is number 81, where we talk about X-ray films. Should a similar requirement be added for film use for hard copy interpretations basically meaning that the film has been designed for that use.

Or is that necessary?

Show of hands, yes, should we include such a definition or an attempt at such a requirement? Yes?

DR. SANDRIK: I guess there is the issue of how this is in any way verified, or can any manufacturer just put a label on tehir film and say

this is good for mammographic use?

As I understand it there is no 510(k) or anything required for mammographic film. There is no validation of this statement. In a sense it's reasonable to say, yes, it should be suitable for mammography, but there is nothing that really validates it or really means anything.

DR. FINDER: I would only point out the fact that that wording is already in there for X-ray film, and has served its purposed presumably for the last several years.

DR. SANDRIK: Well, I think another aspect of that that was brought up was that a lot of issues regarding printers, and the compatibility between printers and film. So you may have a very bad result, film may be labeled suitable for mammography use, but perhaps not in any printer. And it may be more of an issue of compatibility between printers and media than there is just for the film being used for mammography.

DR. BYNG: And I would also add that I don't see a particular hardship associated with this, but I'm not sure what it would accomplish.

DR. FINDER: Well, from what I'm hearing, should we instead try and do something about compatibility? State that there is some requirement that there be compatibility between the printer and the film?

DR. SANDRIK: I think again it comes back to kind of looking at the system, the outcomes-based aspect of this, that the film that you use should provide some level fo quality that serves a mammographic quality purpose.

DR. FINDER: So let me have a show of hands. Should we add a similar requirement, basically saying that the film has been designated by the manufacturer of the film as apporopriate for mammography? Should we include one for hard copy films?

Yes?

(Show of hands)

DR. FINDER: Or no?

(Show of hands)

DR. FINDER: Looks like it's a no.

And then should we instead do something

about maybe coming about compatibility issues between the film and the printer.

Yes?

(Show of hands)

DR. FINDER: And no?

(Show of hands)

DR. FINDER: And that's a yes.

Number 82, should view box and room lighting conditions be specified?

We had not specified those for film screen. However this is becoming a larger issue with digital in terms of illuminance from the monitors and the ambient light conditions in the reading areas.

So the question is, should we attempt to do some specification on that.

Yes.

DR. BYNG: When the regulator person proposed, this was obviously left out at that time, so there is some history with this now.

Is there any additional information you can provide as background on this particular item?

DR. FINDER: Not really more than what I

just said. Again, for film screen it was not felt to be sufficient enough to require regulation, although there was a lot of debate at that time.

Now we're dealing with full-field digital systems, and again, the manufacturers have specified certain requirements in the QC manuals. The question is, do we follow along with that in terms of regulations.

MS. MOUNT: Doesn't the ACR have recommendations in place?

DR. FINDER: The American College of Radiology does have recommendations for view boxes, and I believe even for viewing conditions for - we'll have ACR address that.

MS. BUTLER: Penny Butler, ACR. There is a chapter in the QC manual in 1999 for view boxes and viewing conditions with 3,000 candelas per meter squared for the view box, and no greater than 50 lux for ambient viewing conditions.

We feel that the - know a whole lot more about ambient viewing right now, and in the table that was distributed as handouts, the committee is

proposing 10 lux for viewing conditions at this time.

DR. BYNG: Obviously great potential benefits from controlling the viewing conditions. But it's been operating this way for some time, and this would have potential significant ramifications throughout the facilities to implement it, and including which view boxes would be covered, and all of the different reading conditions, and it would probably need a definition of reading locations as well.

DR. WILLIAMS: Yes, and again I think there is the problem - like Penny quoted the ACR's QC manual of a couple of numbers. But what are those - somewhat like the five megapixel monitor, whether those are the most appropriate under all conditions is not necessarily clear.

I don't think there has been much literature discussing that situation. Some that does indicates that wide varieties in lumens and illuminants can be accommodated by the user.

So trying to specify the number could be problematic. And again, maybe some sort of

performance based requirement that you be able to detect certain objects under the conditions that you are using. If you can see those things then you are probably in the right conditions for it.

And again look at the whole system, the density of the film you use, its contrast, the ambient, the view boxes.

DR. FINDER: I think that although we might not have enough data right now to really specify exactly what these numbers should be, I think there is probably a significantly greater incentive for us to try to push in that direction now than there was in the past simply because of the prevalence of these mixed reading rooms where you have roloscopes (phonetic) and view boxes right alongside the monitors. And I think it kind of makes it a little bit different problem now.

So while I agree that if the data are not clear, if our intent here is to say, should we think about this, then I would vote yes.

And so let's see a show of hands. Should we try and specify conditions for view box and room

lighting?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And it's split, but it's mainly yes.

Should we require - next one is 83 - should we require masking devices wehre hard copy images are interpreted or compared?

Basically it's an issue of should we specify specifically that you have to have these types of masking devices avilable for hard copy.

Probably the bigger issue here for facilities that are mainly doing soft copy interpretation, and occasionlly are doing printed hard copy and are interpreting off that. Just to specify that.

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: It's kind of split, but it's overall yes.

Okay. So all right, so we finished that section. Now we're going to move to page 38. And here we're dealing with Section 900.12E, which is the quality assurance equipment testing.

And starting with real easy question, number 99, should a new section be established to set specific requirements for full-field digital mammography? And what tests should be included?

I'm sure that's a simple question, should be. Shouldn't take more than a minute or two to figure that one out.

DR. SANDRIK: I don't understand why you looked our way.

DR. FINDER: Let me give you a little bit of background on this. Under the current regulations the QC testing that is required for these F-50 MDM units is basically determined by the equipment manufacturer.

And for the last five years that's a system that's been in place, and it's worked fairly

well. So one of the options is to say, let's leave things the way they are, and not address this issue, leave it in the manufacturer's hands.

The problem with that is that as we get more experience, and as there are more units out there, and as the manuals keep changing, it becomes harder and harder for the accreditation bodies, the medical physicists, our inspectors, anybody who works on these units to know exactly what testing needs to be done and how to do it.

So the hope has been that at some point a unified universal type QC set of procedures could be published and implemented. I can tell you that there are a number of people who have been working on this for quite a long time, and at this point they have not been able to do a universal QC manual.

However, there are efforts, and Nina presented yesterday, that they have come up with guidelines for hard copy printers and monitors. Their kind of universal type QC testing, and other organizations have been working on them for equipment.

The question really now is, do we have

enough information to go ahead and start this process, maybe not to work out all the details, but at least as we've done for film screen, to establish certain tests, certain frequencies, and in the cases where known, at least some action limits for various types of technologies.

I will point out that screen film was around for about 20 - 25 years before a unified QC manual came out. Here we've only got about five years of work with FFDM, and a major difference between film screen and FFDM is that with FFDM there are different technologies, four or five different technologies, that are involved. So the QC testing for one type of apparatus may not be appropriate for another.

So I guess the real question is, do we feel that there is at least enough information to attempt to include in the regulations a type of universal QC set of procedures?

And I would ask for a show of hands, yes?

(Show of hands)

DR. FINDER: Or no?

(Show of hands)

DR. FINDER: And again we're split, but basically it's a yes.

DR. HENDRIKS: I just wanted to comment. My vote was influenced by the ACR recommendations that were distributed. Do we feel that these would be similar to the type of testing that would be proposed? In other words, these current guidelines seem to encompass most of the technologies that you are referring to?

DR. FINDER: At this point we have not had a chance to review what ACR has developed. They are not the only one out there who is working on this. I would think that this would involve a process of reviewing all the available information, all the proposals that have been out there to try and wean out what's reasonable to put into regulation and what would have to wait for further additional information.

DR. TIMINS: I'd like to ask Dr. Williams, how many different types of digital mammography systems you're working with?

DR. WILLIAMS: There are right now I believe either four or five different technologies

that have FDA approval as digital mammography systems. And each of those has some fairly sizeable distinctions in the way that they operate.

But there are some fairly universal performance tests, and metrics, that can be applied to all of those systems and produce meaningful information.

I think that what the ACR has done to this point in time is to, number one, recognize the fact that a digital mammography quality control program probably ultimately will involve some tests that we don't do with screen film, and they may be in fact tests that can only be done with - or only practically done with software.

And right now we're in a little bit of a transition state in which the software to do those tests doesn't exist on the current systems, and it makes it impossible therefore to do those tests on the acquisition workstation.

And it's very difficult for the physicist to get the images off to do those evaluations.

So the ACR has taken a sort of phased

approach to this in which partially based on DMIST, DMIST was the very large research study that compared screen film and digital and incorporated most of the current technologies.

Based on those data, the ACR has generated a table, and that's the one that everybody has now, that has criteria, performance criteria, in cases where it seemed to be clear, either based on screen film or based on DMIST.

But in most cases there weren't specific criteria, because the data really don't exist yet. However there are recommendations in terms of what tests should be performed and how often.

DR. TIMINS: Dr. Finder, does the FDA and the Center for Devices and Radiological Health have any problems with writing QC regs on new evolving equipment under these circumstances?

DR. FINDER: I think the process that would be involved would have to be well thought out in terms of writing things that could stand for at least some significant period of time without having to be rewritten.

It's a balancing act between leaving it the way it is right now, or at least starting a process of setting certain requirements to kind of stabilize the field out there. Because right now it is very, very confusing to a lot of people with all these PC manuals written by all these different manufacturers where they change fairly quickly.

And again we can't get down into all the details, because a lot of these action limits and the testing procedures haven't been developed. But if we can even establish a framework for just making it clear that everybody should name the same test the same thing, and then giving a frequency of when it should (Sound-System Failure) and that would help.

So I think there may be a benefit to considering it as a new section.

(Sound-System Failure)

(Sound-System Failure) should we try and attempt this process and start working on it? Or should we just say we're not at that level yet (Sound-System Failure) -- ask again.

Show of hands, should we at least attempt

this process?

(Show of hands)

DR. FINDER: And again -

(Sound-System Failure)

DR. BYNG: Dr. Finder I wanted to show (Sound-System Failure) couple of things sort of mixed in here, including (Sound-System Failure) should this be done as a new section (Sound-System Failure).

And I think we all look forward to the point where there is some universal set of requirements. But I think the major concern would be that - for lack of specific information. And that was some test that get written down aren't really necessary.

And we had to work around to the regulations, in spite of those innovations and creation of new technologies and modes of developing that system.

DR. FINDER: The only thing I can say about that, it certainly is a concern (Sound-System Failure) any time you put something into regulation and lock it into place. The one saving grace in this is that we

do have that alternative capability. So it's not as bad as some regulations where you can't do anything with it once it's in there again once it's recommended into evidence.

The alternative is either we leave it the way it is or we try and do something. And again we ask that question twice we've gotten yes.

Next one is number 100, should we approve alternative standard for (Sound-System Failure) isn't available to be added here.

Basically what we're talking about is an alternative standard that was approved many years ago. And again the concept of the alternative standard is that when you get a chance you do include it in the regulation.

So yes, we should go ahead with it?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Number 101, should criteria for establishing new process or operating levels be added?

We have guidance that addresses this, but should we kind of formalize that guidance into regulations? Part of the issue here is that we have encountered some facilities that for no, quote unquote, good reason they reestablished their levels, instead of trying to find out what the problem was, they had the levels shifting to begin with.

So the idea here is, and it has been stated in guidance, basically you are not to use the establishment of new operating levels as a mechanism to basically not address the issue of why those levels are changing.

So the question here is, do we leave it in guidance, or do we put it into regulation?

Yes, for regulation, show of hands?

(Show of hands)

DR. FINDER: Okay, no?

(Show of hands)

DR. FINDER: Okay, and the general consensus is no, and I presume it's to leave it in guidance.

All right, next, on page 39, should we

require a phantom image to be obtained for each unit and process or combination?

This is the situation where you've got multiple units, multiple processors. Should you be running phantom images so you at least get a combination through each one of them.

DR. MONTICCIOLO: I just have a question. I mean the processors, the QC on the processor is run everyday, so if all the processors are within limits, I guess my question is, maybe to Dr. Williams and to Carol, I mean that's a lot of work for those technologists to do all those phantom images. Is there any gain here?

DR. WILLIAMS: Well, the phantom of course is sort of a bottom line test that looks at the entire chain right to the final product. And one thing that you might argue you could do in order to prevent doing all permutations would be to make the argument that each unit would have to pass with at least one processor, which meant that the unit was okay, and then each processor would have to pass with at least one unit, which means that the processor is okay.

DR. FINDER: This is one of those areas where we've actually issued guidance and dealt with this. And part of the issue is that while each processor may be within its own limits, right now there is no requirement that those limits be close to each other, either.

So in our guidance we've talked about if the processes are matched, and there is some question about, I don't have the exact specifications of what it meant to be matched, then point oh five, if they were matched then you could just run phantom images through one processor, but at least a film has to be run through all the processors so as to cut down on the number of images that have to be run.

Again, the question is being asked, should it be required of each unit processor combination? Or should we go kind of more with what we've got in the guidance and put that into regulation, or leave it in guidance?

So there are actually three components to this one. One, is a show of hands, yes, should they be run for each combination?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a no.

Should we consider the guidance that we've issue and put that into regulation here to allow the combination or the ability to limit the number of films that are run through each processor if the processors are matched?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And again that's a no. I assume that means we should just leave it in guidance.

Number 103, should the minimum optical density of the phantom be raised? Right now it's set at 1.2. There's been a lot of discussion about raising that to 1.4.

So should it be raised? Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Let me just say that the consensus was more of yes. But go ahead.

DR. SANDRIK: From the no side. I think this is a problem again, chasing after technology. And that once upon a time, 1.2 seemed like a good number. Now maybe 1.4 seems like a good number. Maybe in another couple of years 1.6 will seem like a good number.

A lot of this could depend on your luminance, your view boxes, the illuminance of your viewing area as far as what is a good number. So I think perhaps changing it from 1.2 is reasonable, but probably more again a performance based result is what you should be looking for, not trying to specify an optical density based on today's technology that may not be valid later on.

DR. WILLIAMS: While I certainly agree with that philosophy, I just have observed in practice that films that are now 1.2 OD are generally not acceptable to the radiologists. And this has been a trend over the past few years. So if we're going to keep

something in, I think it ought to be higher.

DR. BYNG: But is 1.4 going to achieve something that 1.2 is not?

MS. MOUNT: I would say from a technologist's standpoint, because this is to test the technologists, sometime they take it literal, and 1.2 is where they want to be. But I think the bottom level should not be lower than 1.4, and I would even increase it higher.

DR. SANDRIK: Well, this might be tied again to exposing the phantom under normal clinical conditions; that you get the density that you'd expect to get for your normal, in the standard breast conditions. And whatever that density is where you operate. You don't necessarily set it to some particular density value, but the guidance says you have to operate in your automatic exposure control mode that you normally use for the standard breast, that gives you some density. And if that density allows you to pass the test, then your view boxes and your illuminance situation, that should suffice.

But saying where the number has to be I

think is micromanaging the situation.

DR. BYNG: And because this is part of that weekly quality control test, it's done at the standard imaging condition, so you're not imaging at 1.2 anyway. It just means that you wouldn't go below 1.2. And I'm just wondering, if you make a change to the regulation, it will percolate through the system. And yet it's not going to impact a lot of facilities that are already imaging well above this anyway.

Do you have people that are doing this test at 1.2?

DR. WILLIAMS: No, in our institution the background optical densities are more like 1.7, 1.8. And so I just think that 1.2 is just historically a little outdated.

DR. MONTICCIOLO: I think we should - I was taking into account what Carol said. She's right, though. There are technologists who feel that if you put a number there - I mean maybe there shouldn't be a number there. But if there is going to be a number, which there already is, it should be raised.

DR. FINDER: Okay, next one. Should the

position and composition of the added test object -

VOICE: I'm sorry, there's audience comment on that, from Penny, ACR?

MS. BUTLER: Penny Butler, ACR. I just wanted to point out that we accredit 95 percent of the facilities in the country, and we still do see accreditation of phantom images come through at very low densities, optical densities, and result in failure with us of course.

So it still is a problem out there.

DR. FINDER: Okay, 104 should the position and composition of the added test object be further defined, yes, no.

Yes?

DR. MONTICCIOLO: I don't understand this. Has this been an issue, or can it stay in guidance? I wasn't sure about - if you could give me some background on this so I can understand it.

DR. FINDER: I can't tell you how big a problem it is or isn't. But in fact the issue has always come up when you're trying to measure the density difference, it just says, with an added test

object. It doesn't say what that is. So you theoretically could put any type of test object to get the answer that you want.

The idea here was that you are supposed to put a standardized test object that would be similar around the country to get this type of difference, but the way it's kind of worded, the regulation doesn't address what that object is. You could put a quarter there. You could put a piece of cellophane. It could be anything.

And the idea here is to kind of standardize that so it's uniform throughout the country.

DR. BYNG: And one additional point is, rather than a potential fixed specification is whether it could be a range of specification, and the point that they should use the same one on an ongoing basis.

DR. FINDER: Okay, so do we have a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Next one is should criteria for establishing new phantom image and optical density operating levels be added?

Again this is similar to that for the processor. So let's go with a show of hands for I guess the two or three possibilities here.

Either we do include some criteria in the regulations, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: So it's kind of split.

Or do we just kind of try and leave it in guidance? The guidance that we've actually issued, which again people can obey or not obey as they fee.

Yes, leave it in guidance?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: It looks like a yes.

All right, number 106 deals with the

repeat analysis, and then brings us back to the definition we talked about earlier.

Should this test be limited to either the repeat or reject rates but not both?

Right now the way it's worded, it's a little bit unclear. It says if the total repeat or reject rate changes from the previous rate by more than two percent, you've got to take action.

The question is, what does that mean? Does that mean you have to do both those tests? Or you can pick one of them? It's been a matter of debate amongst facilities about what they are actually doing. And if we want to do both, we should basically say that specifically. If we want them to do just one we should say that. And if we have one that we want them to do and not the other one, we should say that too.

So that's the issue here, and again it really goes back to what the definition of the repeat rate is and what you're trying to accomplish here.

We have tried to issue guidance on this as best we can with the regulation written the way it is.

And I guess one of the things that we've been trying to do, or at least get the concept across, and we want to see if the committee agrees, that the idea of this repeat rate would be situations that added additional exposures to the agent more so than how many test films needed to be run, and how many had to be discarded.

But it would be those types of situations that resulted in a repeat view for technical reasons, thereby resulting in additional exposure to the patient. So we can have I guess a little bit of discussion about this.

MS. MOUNT: I guess I would say that it isn't really any extra burden to do them both. Because you still have to have your total number of films, the total you threw away, and you're just sorting them out between repeats and rejects. So to me it would make sense to do them both.

DR. WILLIAMS: Which leads to the question, is the reject rate of value? Or is repeat sufficient in that it gets at what we are trying to determine, the spirit of why we are doing the test?

DR. BYNG: Well, and is there a concern over reject rate, because it's factoring in a lot of different uses for film. The quality would be assured by the repeat rate.

DR. FINDER: Those are exactly the issues that we want to raise and bring up.

For those who aren't familiar, there are different - there is no formal definition in a regulation for what a repeat or reject rate is. The ACR does have as part of its QC manual procedures for performing both these tests. One of the problems that we saw with the reject rate is that in the ACR manual they include films that for example might be involved in a biopsy as part of their reject rate. And again that's outside our authorization area.

It also includes QC films that might have been thrown away.

So again, the question is, where do we want to be, and do we want to clarify this?

DR. BYNG: Is there a definition you had in mind for total as well? Because it says total included in the analysis, but you haven't indicated

how total is defined?

DR. FINDER: Right. Again, we're getting into the details here. This would have to be, again, depending on what you're talking about. A reject total would be different necessarily than a repeat total. Because again, with the repeat you are going more toward the clinically exposed films; with the reject you would be including other films. So you could be talking about the total number of films that have been processed.

And there are procedures that have been put in place to try and determine these things, but it's still not totally clear. And facilities are doing them in different ways. Some facilities will keep every single film that's taken on a patient in the film jacket; will not throw any of those films away. Your reject rate in that case will be significantly different than a facility that will throw away films that they feel are not optimal.

So again we are trying to get into this issue.

DR. SANDRIK: Both the FDA guidance and the

ACR QC manual agrees from the language of repeat involving extra dose. I think that should really be more the focus of MQSA. The reject probably has value to the facility. More of a financial impact perhaps than the efficiency of the use of film. I don't think that should be part of MQSA.

DR. FINDER: Let's have a show of hands about should we keep repeat rate and define that.

Yes?

(Show of hands)

DR. FINDER: Okay, should we reject the reject rate?

(Show of hands)

DR. FINDER: Yes. And therefore we wouldn't necessarily have to have a definition for the reject rate.

Now here is another question. What would constitute an acceptable corrective action in this situation? And the reason I raise this issue is because this test if it's failed is under one of those 30-day corrective action issues, but the test itself is a quarterly test done over 90 days, and it also

doesn't have a defined action limit other than the sense that if there is more than a two percent change there is a problem you have to look at.

So what is the effect of corrective action, and in what kind of time frame do you do this?

And I'd like to hear just experience out there?

MS. MOUNT: What we have done, because we have exceeded at times, we simply write, I as supervisor of the department, when the data has been shared with me, write a note, and we put it in the QC log, that we are going to repeat this weekly.

Now the volumes are high enough that we can do it weekly until we can establish the cause of the problem and reduce that repeat percent. That's how we do it.

DR. FINDER: Okay, obviously it's not a hard and fast rule here, and for smaller facilities it becomes an issue.

And again it takes us back to the issue of, if we define corrective action as failing the test, taking some type of action and repeating the

test until you get it right, it becomes somewhat confusing here because we are talking about a two percent change. And for example if you are looking at 90 days worth of films and you see a two percent change that's one thing. But then if you have to go and do it on a weekly basis, you may see that number bouncing around quite a bit.

And it's not only two percent one way; it's two percent in either direction. So it's interesting just to hear how people are dealing with this type of problem without guidance from us on this.

DR. WILLIAMS: And I think Carol's approach makes a lot of sense, because it differentiates between the time to correct, or at least try to correct, the underlying issue, and the amount of time it takes to evaluate whether or not that worked. Which may be for some facilities that don't have the volume that she has a very long time. It could be 90 days. It could be something more than 30 days.

And so maybe that is the thing to do is to differentiate between the times to take the correction, and make sure that it's separated from the

time it takes to evaluate whether that is the right correction.

DR. FINDER: Next is 107 -

DR. BYNG: Dr. Finder, one more question there. Because it's based on two percent change. And no absolute criteria.

DR. FINDER: Correct.

DR. BYNG: Has there been consideration in the past about an absolute criteria?

DR. FINDER: Yes, there was a lot of discussion early on about whether there should be a n absolute rate of like five percent or something like that.

The problem that we were dealing with at that point is, again, how people do these analyses, and how they collect the films. And there is certainly the situation out there where a facility could, as I said, keep all the films and have a zero repeat rate in that sense and keep that and maintain that.

One of the problems, the other was the issue of if you set a certain limit below which

everything is okay but you don't check the change in that limit, you could have a situation where you get different readers in there, and all of a sudden they're willing to accept bad films because they don't want to change this rate.

So the idea was that we needed to have some type of standard in here. Neither one of them totally dealt with the problem, but we felt that allowing the facility to set some type of baseline, and then trying to measure off that baseline, which would be consistent with many of the other quality control standards in the regulations where the facility sets its own baseline within certain types of limits, and if there is a deviation from that, then they're supposed to look at that. Because it indicates a change in what is going on in the facility.

It may be a good change; it may be a bad change. But the idea here was, as long as there is a change, the facility is supposed to look at it and try to figure out why the change existed.

DR. BYNG: But the difference between those

established operating levels is that they have a range, and this one just says you can go two percent each time you do this test; two percent on two percent on two percent.

DR. FINDER: Right. It's not firm science on this one.

Okay next one is 107 dealing with the dark room fog test. Should this requirement be expanded to mention all areas where films are stored, handled or processed?

Because some facilities do that in rooms other than the dark rooms.

So just a quick show of hands, yes -

DR. BYNG: But just a quick clarification, I'm sorry. Your definition of handled.

DR. FINDER: Right.

DR. BYNG: Do you have a definition for handled?

DR. FINDER: No, but we could work one up for you.

DR. BYNG: I guess I'm wondering about what you have in mind, because an automatic film handling

device that loads it into a machine, or where film is stored it says. So if I store it in a box in a warehouse versus in my dark room, do I have to go down and check where I stored it?

I just see some difficulty with trying to interpret how to deal with this.

DR. FINDER: Yes, in fact the issue of the daylight systems has already been addressed in a guidance. And obviously you can't go inside those machines and try and figure out what the light levels are in there.

The issue of where films might be stored, it's a good one. Usually we would be imagining that the films would be stored somewhere at the facility in a place where they could actually do this type of testing.

Again the idea would not be - you could carry this back and have measurements all the way from the manufacturer, the truck, whatever. I don't think we're talking about something like that. We're talking about where films I think would be stored at the facility level.

Any other comments?

DR. SANDRIK: Yes, we're also talking here about a semiannual test. I'm just wondering whether from Dr. Williams' experience if you did say a radiation safety survey, you decided, determined there was no radiation level of significance where you are storing the film, there is no radiation of significance where the film is being loaded, whatever, that sort of thing, there is no light levels in those areas that could sort of do it once and forever that these are safe areas that film can be stored, rather than having to repeat this every six months.

DR. WILLIAMS: So then the question is, is six months too often to do the test?

DR. SANDRIK: Yes, I mean if we're talking about including all the things - storage, handling, process, particularly storage. If you have already determined no radiation level where the film is stored. There is no light there for the film that's in the boxes that can be detected. Is it really necessary to go and repeat such a thing every six months?

DR. WILLIAMS: I don't really have a strong opinion, but it seems to me that six months is not unreasonable given the possibility that things change in the next room; you get a floor unit moved in there; or nuclear medicine moves in there, something like that. Things could change. It seems like once every six months is not an undue burden, I don't know. Maybe Carol has a comment on that.

MS. MOUNT: Well, are we talking just a fog test? Or are we talking some sort of radiation monitoring test?

DR. SANDRIK: Well, it's described under fog test. I guess in this case it could be - we're talking about storage for example, it could be more radiation leakage in their facility as opposed to light gets in the dark room.

DR. BYNG: But just a clarification, there isn't a radiation fog test.

DR. FINDER: If I could just kind of jump in here, I think we're basically talking about light fogging the films. And I will say that it's one of the - if I'm not mistaken, somebody correct me - it's

one of the more frequent citations found during the inspections.

The issue really comes up with, for example, a room where the seals on the door of the room over time either peel off or deteriorate, and all of a sudden you've got light coming in there. That was the basis for requiring that it be done every six months. I don't think anybody is really that worried about some type of radiation coming in from the outside, other than light. And again it's a fog test. It's really being used to determine this light leakage thing, and we're trying to get at the issue of where these films are being handled more so than if they're just plain in the boxes.

But with the advent of various different types of machines, and multiple places in the facility where for example the daylight systems might be loaded, there may not even be a quote unquote dark room. There may a bag where somebody does this inside the bag.

There are all issues about this. I guess the consensus that we're looking for is, should we

look at this issue about dark room fog? Should we at least consider expanding this to these types of areas if we can come up with something that's reasonable that kind of addresses these issues that we just talked about?

Yes.

DR. MONTICCIOLO: Could I just ask - you brought up something to remind me of something that used to happen during my fellowship. I mean what about people who handle films in a mobile unit and use a small area to take the films and work with them? I think it is going to add a lot of burden for them.

DR. FINDER: Well, it certainly could if we go to that level. I mean there are situations where you've got remote processing where they don't have a defined darkroom, where they are using a storage room or something else to load cassettes and things like that.

This also in terms of the burden that's imposed, right now every single dark room would have to be evaluated at some point. It is reasonable to do that.

Yes?

DR. TIMINS: I had to step out for a moment. Is film being evaluated for fog?

DR. FINDER: Yes.

DR. TIMINS: So then there you have it, I think this becomes redundant. If you have a problem with your film with fog, then you are going to pursue the problem. I think it's sufficient to just limit this to dark room.

DR. FERGUSON: I would agree. The dark room we don't open any film anywhere else. I can't imagine very many people do.

DR. FINDER: Okay, so a show of hands, yes, no.

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Okay, we'll take that as a no. Moving right along, screen film contact test. There's been a recommendation that this be made an annual test instead of a semi-annual test.

Yes for that move?

(Show of hands)

DR. FINDER: Yes, number 109, should the effective date be deleted here?

Yes?

(Show of hands)

DR. FINDER: Yes.

Number 110, this basically also deals with the issue of the date. Should sections A and B be combined? And specific reference be made to performing the test in the contact configuration with at least one image size using the appropriate technique factors.

And then should we clarify that all AEC detectors and AEC modes be tested?

So there are a couple of questions here. One is basically do we get rid of the date and combine those things.

Yes on that?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: And it's a yes.

Should we specify that it be done in the contact configuration as listed here? Again this is what we've pretty much gotten guidance already.

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: No one cares.

DR. WILLIAMS: A question. Could we just say of all the modes that are used clinically be evaluated? Would that cover this?

DR. FINDER: Well, that creates more testing than what we are requiring right now.

DR. WILLIAMS: In some cases it might, but in other cases, there are rooms that don't ever do mags. There are rooms that don't ever - that don't ever use anything except auto kV. And so you wouldn't test anything that was an auto time or anything like that.

DR. FINDER: Right. Again the purpose of this is to kind of bring the testing down, put the

majority of the testing at the mammography equipment evaluation stage when it's just done once, and limit the testing to just this one configuration, one set of systems, where they wouldn't have to go and do multiple configurations, or multiple additional testing. And again, this is guidance that we have kind of already published, put out there. It's an attempt to try and put this into regulation.

DR. MONTICCIOLO: The guidance in this case is to not do all these modes?

DR. FINDER: Right, correct, and save that basically for the mammography equipment evaluation when that has to be done.

DR. BYNG: So there is not currently an outstanding issue you are trying to address with this one?

DR. FINDER: What we are trying to do is, we've addressed it in guidance, but the regulation itself could be clarified to make that statement. So again if we are going to be rewriting the regulations, it helps to have this in many cases in the regulation itself rather than as an accessory in guidance.

DR. MOURAD: Wally Mourad. The feedback from physicists since we published this guidance has been very positive. They all like it, for whatever it's worth.

DR. FINDER: Okay, so in an attempt to move on, we'll go for a show of hands, yes on this?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Yes, to move the guidance, right.

We'll take that as a yes.

Now the other part of this is, should all AEC detectors and AEC modes be tested here?

Some units have multiple AEC detectors. Should they be tested on an annual basis?

Yes?

DR. SANDRIK: I think in many cases you can probably have a similar sort of reduced level of testing where you don't necessarily test every detector, say within the two, four, six centimeter range, but pick one thickness, you do say the most

commonly used detector over the full range, and then check the other ones at just one thickness; again offers a reduced set.

DR. FINDER: Sounds somewhat similar to some guidance I've seen.

Again, this is - again, we have guidance that basically says what Dr. Sandrik just said. And it's a question of, do we move it into regulation to make it clearer?

DR. WILLIAMS: And this is different than where Mark was pointing out about modes used clinically? It wouldn't apply to this section?

DR. FINDER: The AEC detectors, there are some units that have as I say multiple detectors. And if you just limit your testing to one, and the other one is broken, you may not pick that up during this type of - if you limit yourself to one detector, you won't pick that up. And yet any time that detector is selected during clinical exams you will run into that problem.

So the guidance that we issued was an attempt to reduce the amount of testing yet still

cover over all the detectors to make sure that they work in a manner that was consistent with the spirit of the regulation.

DR. BYNG: But to Mark's point about, if they don't use a particular detector in a particular room, do they need to test that?

DR. FINDER: Again, the guidance that we talked about deals with those items that are used clinically. So we've already excluded in guidance things like for example if the unit is never used in a certain manner, it certainly wouldn't have to be tested.

Now that does - every time we have those issues it always raises the question of, what does that truly mean, that somebody says, I'm never going to use it that way, and then behind somebody's back they do?

But we have gone with the general guidance that if the unit is going to be limited in some manner there is supposed to be a notification on the unit that it's not supposed to be used in X configuration, because it hasn't been tested in that configuration.

So those are the types of things.

So again, yes for this? Or should we limit it to, yes should we test all the detectors, or basically no, should we kind of put the guidance in there that allows for a reduced amount of testing.

We would test all the detectors, but have reduced testing. I'm getting a little tired up here.

So a yes on that or a no on that.

Yes? Does anybody know what I'm talking about anymore?

Okay, let's go with, all the detectors that are used clinically would be tested, but they would be reduced testing for more than one detector. So if you get three detectors there you would do one at the two-four-six configuration, and the others would be done at let's say the four centimeter level, and then you would compare across those.

DR. BYNG: And that's what's in your current guidance?

DR. FINDER: Yes.

DR. WILLIAMS: And that goes under the logic that the same lookup table would be used for

each one of the detectors, so therefore if you tested one over the range you don't need to test the others?

DR. FINDER: Right.

So show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: I take that as a yes.

Next is 111, should focal spot dimensions be deleted? We no longer have that in our regulations any more, because the dates have expired on it. So should we delete it?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: It's a yes.

For system resolution, should we specifically mention that this test is being performed in a contract configuration rather than in some other configuration?

Show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Take that as a yes.

Should resolution also be tested in the magnification configuration?

Go for a yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Kind of split here.

DR. HENDRIKS: I'm sorry, I would need more background on that to answer that.

What is the background on that issue?

DR. FINDER: I think Dr. Sandrik would be more than happy to.

DR. SANDRIK: If I could make a few comments on that.

Publication by Gary Barnes and Don Fry, screen film mammography, talks about the benefits of magnification mammography, the main benefit being signal to noise ration not limiting resolution.

A paper by Kuniodoi, advantages of magnification radiography, main benefit, signal to noise ratio; secondary benefit, improvement of contrast by the error gap. Improvement of MTF, or the observer's eye, because you made the object bigger. Some benefit because of limiting resolution, but it's not proportional that you get benefit measured by limiting resolution.

A very significant document by J. Law from the British Journal of Radiology, the influence of focal spot size on image resolution and test phantom scores in mammography, one thing looking at the statement in his abstract, these two phantoms and others were used to investigate the changes of perceptibility of realistic details, all of which depend on a combination of contrast, resolution and noise, with changes of focal spot size and magnification.

As expected, when judged in this way, that is based on image quality, the image quality for realistic objects improved as focal spot size decreased. With fine focus it also improved as

magnification inreased unlike changes in high contrast resolution which decreased for high magnification.

Thus conventional bar patterns are not always a good guide to detailed perceptibility in mammograms where the effects of noise may be as important as those of focal spot size.

He goes on to say further that limiting resolution can be misleading as far as identifying which quality value for magnification.

Taking his data, I redid his measurements on a GE 600T system fortunately enough for me. And if you look just at his data, he talks about resolution values up at like 16 lines pairs per millimeter at magnifications near two. But that was measured far out from the chest wall. If you actually convert that back to equivalent measurements of limiting resolution near the chest wall as done under MQSA, where he says that image quality is still improving, the limiting resolution is about six lines pairs per millimeter, well below the 11 and 13 requirement that we are trying to apply to systems.

So I think basically he's saying that for

aspects of clinical image quality, limiting resolution by bar patterns is misleading; our numbers in MQSA are way off from what's clinically relevant.

DR. MONTICCIOLO: I just have a question then. For these two questions, I guess it's 112 and 113, I guess I don't understand what we're recommending versus what's recommended now in QC manuals or what's being done now.

DR. SANDRIK: The problem with the current regulation is that it provides no limit on where the magnification value should be set for testing magnifications.

I think it says, let's see, somewhere it tells you to do the magnification, doesn't it?

DR. HENDRIKS: I'm sorry, I'm still confused. So you're not questioning the value of notification. I do agree, I don't understand the question that we are addressing about whether these tests should be performed in these configurations.

DR. TIMINS: Actually the question is whether to do resolution testing on magnification. After hearing those studies cited, I am against it.

DR. SANDRIK: Right. I think as far as - I guess I am not finding the magnification. The issue that comes about is that there is no issue applied to magnifications that will be used.

Now some physicists then have taken this as, let's look at the worst case situation. Let's go to the highest magnification and see if we still meet these requirements.

And the indications are that maybe you won't, but very likely it's irrelevant.

Now I'm not saying there is anything wrong with the magnification. I think all the papers basically say there is a lot of value in magnification mammography.

The fallacy is trying to evaluate that clinical value based on eliminating bar pattern resolution measurement.

That, as well as applying these 11 and 13 line pair numbers to apply to an area where it's not really a valid measurement either.

DR. HENDRIKS: So you're addressing a bigger question than is raised by this question?

DR. SANDRIK: Well, basically it's item 113, should resolution be tested in the magnification configuration?

I say no. It's directly addressing 113.

DR. BYNG: Is your point more about not to test it there? Or what's the performance limit if you did test it there?

DR. TIMINS: What he's basically said is that the value of magnification is not necessarily image resolution; that there are other things that make a lesion more conspicuous than just resolution, and that the value of magnification is not necessarily a fine resolution value.

DR. BYNG: That I agree with.

DR. MOURAD: I think nobody would argue that the advantage in mags lies more in better S&R than in resolution. But in a mag configuration, entirely new focal spots are brought to bear than are used in contact.

And I think it's probably worth - although I agree that the current way of doing it, or by default doing it since it's not well stipulated, may

not be appropriate, I think there should be some way to just head off the fact that the small focal spot may in fact be unacceptably large for doing magnification views.

Now there may be an argument for including some more global assessment of image quality that does take into account the impact of S&R. But I don't think that's what we're asking right now, is it?

DR. SANDRIK: Well, I think someone could address that. Yes, I would prefer seeing the test going that way, and testing based on what's relevant to the imaging.

As a fall back position we could consider at least what was in the proposed final regs that the magnification be limited to 1.5. The number is still irrelevant, but at least it does no harm.

DR. HENDRIKS: Audience comment from Penny.

MS. BUTLER: I'm Penny Butler, ACR. I'd just like to bring out that this is one of the items we evaluate when equipment evaluations come through, the accreditation body.

And during annual surveys, and I just

checked with my staff back there, and this is not something that fails very often at all. So it does appear that the facilities are currently meeting these standards for magnifications.

Now what we may not be seeing if there is work being done at the facility in order to get them to meet these requirements. But it's not a big reason why physicists are failing their reports.

DR. SANDRIK: If I can perhaps offer a comment to that, before the guidance was issued and a statement was made at a previous NUMQWC (phonetic) meeting by FDA that testing be limited to 1.5, I probably got several calls a month from physicists or facilities or field engineers saying that they failed this test because the physicist felt it had to be done at the maximum magnification available on the system.

Since the guidance went into effect the calls have essentially gone to zero. So as long as physicists agree to limit the magnification to 1.5, I agree with Benny that there is essentially no failures. And now the only calls that come out again are the ones where somebody says, well, I'm going to

clinically use 1.8 so it should pass this test at 1.8, and that is not a valid conclusion based on these rules.

DR. FINDER: Okay, I think we've heard the issues here.

Let's move on to 114, where we talk about focal spot dimensions. Should this be deleted? Again, we're now past the time when focal spot dimension is actually being used. It's now a resolution test.

So should we delete this?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: It looks like a yes.

Next one is X-ray field light imaging. Should these tests be performed for all combinations of collimators, image receptor sizes, targets and focal spots used for full field imaging and the contact configuration.

Anybody? Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. HENDRIKS: I think we have to have some background. These questions are a little bit technical for most of the non-physics members of the panel.

DR. FINDER: Not everybody has to answer the question here. But so far I've only seen two people who said yes to this.

Anybody have a problem with having this testing done for the various combinations? And I'll that that no, yes?

DR. MOURAD: Yes, targets, certainly.

DR. FINDER: Okay.

DR. BYNG: This is for all configurations, again, or all configurations used clinically?

DR. FINDER: Clinically.

Number 116, should medical physicist oversight be allowed for the performance of this test? And the one we're talking about here is uniformity of screen speed, from the physicists? Would you be happy

with medical physicist oversight?

Yes, a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

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

Should separate averages for different speed cassettes be allowed? I will tell you that we have guidance that allows this already. It's been used for many years, and seems to be quite useful.

So a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. SANDRIK: You say averages here. Is that averages or ranges that you were referring to?

DR. FINDER: Ranges, as written in the reg.

118, this deals with system artifact test. Since there is no specific standard, should the medical physicist have the final say as to whether this test passes or fails?

Yes?

DR. MONTICCIOLO: How does the radiologist enter into that?

DR. FINDER: Well, that is the exact question here. This is a test in which there is no objective action limit value. So somebody looks at this test and decides whether it's a pass or a fail.

The problem we have is, at the present time, who makes that decision? Is it an interpreting physician? Is it the medical physicist? Is it the owner of the facility?

So this has happened where because there is no firm basis of this somebody can say, well, it failed, and somebody else will say, no it passed.

So who gets the final say on this quality control test?

DR. BYNG: But currently by default doesn't the radiologist have oversight as the lead interpreting physician?

DR. FINDER: Right. That's why we're asking the question. Is that one the best person to address this specific test? Or is it the medical physicist? Just a yes or a no.

DR. WILLIAMS: I think it's going to be tough to get the radiologist in during the annual testing or whatever it is to evaluate particular artifacts. That may not be something that is so practical. Physicists may have to make their best judgment, and then if it's a situation where it seems to be ambiguous, get the radiologist in.

But I'm not sure that that needs to be done on a -

DR. MONTICCIOLO: That's a difficult one, Mark. Because I mean we work very closely with our physicists. And if my physicist told me I'm uncomfortable, this should fail, I would fail it.

But usually when something like that comese up, they come to us and ask what should we do, and we make the decision together.

DR. WILLIAMS: Right, so those are the tough ones, where you need to have the radiologist's eye.

DR. HENDRIKS: Audience remark on that, Penny Butler.

MS. BUTLER: Penny Butler, ACR. Currently

this artifact test is a medical physicist test. It's part of the report that they produce, and they are the ones who actually pass-fail this test.

However it might be helpful to note that the - in the quality control manual we have a statement that if the artifact is difficult or expensive to eliminate, and it's settled, not mimicking or obscuring clinical information, it may be tolerable. The medical physicists should consult with the interpreting physician as to whether the artifact is tolerable.

Tolerance for artifacts should be lower with new imaging equipment.

So it really encourages communicating with a radiologist on some of these things.

DR. FINDER: Okay, but now lets get back to the situation we've got. They disagree. And the question has come up where we've had the physicist say that it fails, and other people in the facility say it passes.

So in order to move things along, should the medical physicist have the final say, yes or no.

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: When the medical physicist says no, that he shouldn't have the final say.

(Laughter)

DR. FINDER: I'll take that as a split, maybe.

DR. MONTICCIOLO: Can we vote again? I want to change my vote.

DR. FINDER: Okay, then we'll do another vote here.

Show of hands, yes, medical physicists should have the final say?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: I guess that's a no now.

(Laughter)

DR. FINDER: Again, for the system artifact test, should medical physicist oversight be allowed

for this test at mobile facilities using remote processors?

This is one of the things that we have already addressed in alternative standard. We do allow it under medical physicist oversight. It's a question of putting it into the regulations.

Show of hands, yes?

DR. BYNG: Clarification on this. This allows them to do the system artifact test remotely under medical physicist oversight?

DR. FINDER: Correct.

DR. BYNG: And who has the final say in that case?

DR. FINDER: Not the medical physicist any more.

(Laughter)

DR. HENDRIKS: Is the concern then that there would be more - that there is a higher tendency or likelihood of artifacts using the mobile, and then some relaying of the images to evaluate artifacts?

DR. BYNG: I think as I looked at it the concern was that medical physicists might not see

them, because the technologist said there was no problem.

DR. FINDER: No, no. That's not what medical physicist oversight is. Medical physicist oversight is that the person does the test, and then sends the film to the medical physicist to review.

It's just that they don't have to be there on site.

DR. BYNG: I'm sorry, I didn't read the definition of medical physicist on site, which doesn't exist.

DR. FINDER: Exactly, which doesn't exist yet; that's exactly correct.

DR. SANDRIK: Dr. Finder, the aspect of sending these as films, that sounds like that's perhaps a process aspect the physicist works out with the technologist as part of the oversight.

Is there anything in guidance or something that says that the films must be sent and reviewed by the physicist?

DR. FINDER: The concept has always been that the test was not just done by somebody else. It

was that the medical physicist would evaluat the results of those tests. So - okay?

But again, that's the purpose of putting these things into regulation and defining them, to address these types of issues where there can be some confusion.

Next is on 120. Should the regulation be simplified - and this is on radiation output - to basically require 21 milligray within a 3-second period?

There's always this business about averaging over three seconds and things like that. And again this is pretty much what we've put in guidance to clarify this, because we got a whole number of questions about it.

So a show of hands, yes?

DR. BYNG: Just before we take a vote on this particular one, because I agree with the basic point but it begs the basic point about the overall intent of this particular measurement.

And it's one of those things that has worked into the regulations over time. But it's

really about a clinical problem of making sure that you can image in an adequate period of time.

DR. FINDER: Exactly. It's a question of units having enough output to image a large breast in a sufficiently short period of time to basically reduce motion artifacts on this, so that they are capable of doing this.

The way it is written right now, it talks about averaging over a certain amount over three seconds. Which in effect is the same as what we're kind of putting in here as the total.

DR. BYNG: Well, I'm okay with that part of it, with the interpretation of 21 over three seconds. It's just the relationship to what you're really trying to achieve here. Is this the right measurement to be making?

Maybe it comes in more when we talk about the non-molly molly configuration.

DR. FINDER: Well, that's the other issue. Well, first let's address the first one.

Show of hands, should we make the change?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Looks like a yes.

Now comes the question: Because the procedure is actually established using a molly molly system, what about other systems that might use different systems. And we have encountered those types of situations, where type of standard if any should those types of units do?

And they come back to us and say, we don't use molly molly. They're not using it clinically, so what should they do in that case?

And if you're using different targets and filters, the 21 milligray may not be the appropriate output to be considering.

DR. SANDRIK: And I think that's exactly the point here. Because what you are really measuring is an entrance exposure to the breast. And what you really want to know is the exposure rate that occurs at the detector. And really what you're after is the setting on exposure time limits.

So rather than setting entrance exposure limits for other track filter combinations, rather than generalize the rule that any use, clinical use of this system under certain conditions of breast thickness should give you an exposure of three seconds or less. I think those add directions, then you don't have to worry about parsing out different track filter combinations or other conditions.

The main thing that you're after is the exposure time.

DR. WILLIAMS: I think that makes a lot of sense, and I might just add as a passing comment, given the current criteria, most if not all mammo units greatly exceed the current standard. So just something to think about whether or not those need to be changed to make them useful.

DR. FINDER: Okay, just a question. If we tried to go with what Dr. Sandrik is suggesting, how would the fact of digital units affect that if we couldn't establish like an optical density or anything like that, it would have to be something else.

DR. SANDRIK: No, but still on exposure

time, do you acquire the useful image? If it's like say 4-1/2 centimeters, 5 centimeters, acrylic, image on the system, that it can complete its exposure under say its normal automatic operating procedure within that exposure time. Or say the manufacturer's recommendation is to get to a certain signal level on the detector or something, those kinds of things could be done.

So whatever would be the reference for a properly exposed image of that detector under some conditions, you'd have exposure time limit.

DR. FINDER: Okay, next -

DR. BYNG: But there is some value in making sure that you isolate the equipment component of that as well, in the screen film context.

DR. FINDER: Okay, number 121, decompression, should we rename that compression release? Because that's basically what this requirement deals with.

Show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Number 122, should we include an already-approved alternative standard which allows units which are always in the automatic mode to be added here?

Again it's a show of hands, yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

Moving right along, should the film screen contact test be added into the annual basically taken out of I believe it is the quarterly? Semi-annual, and move it into the annual test?

Yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

All right, when done for new cassettes, as they're placed into service, should this test be done under medical physicist oversight?

This is a situation, as facilities add cassettes throughout the year, and if we wouldn't allow this, and we have under guidance, if we were not to allow it, the physicist would have to come out each time a new cassette was added to the facility.

So again we dealt with this in guidance, but we're talking about including it in the regulations here.

So yes?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: That's a yes.

We've kind of addressed 125 before, should requirements for view box and room conditions be added? So we've already addressed that one.

Next one is should a 90-day period for repeat analysis for corrective action be allowed? And again that kind of takes us to our earlier discussion about what's a corrective action for a test that's done on a three-month basis. So does it make sense to allow a 90-day period here?

And again we did have some discussion about what it really means to be a corrective action anyhow, and what the standard is. So I don't think we need to address that again here. Let's move to the next.

Next one is next page, 127, kind of address some of the other issues we talked about before, components. Should this section be limited to units, and a new section be created to deal with components that can be evaluated under medical physicists oversight?

DR. SANDRIK: Clarification on that. The way unit is used in this, it refers to the mammography system. Are you saying something about the leading processor or having a separate section for processor then? Or where are you going?

DR. FINDER: Yes, I think what we're talking about is making the mammography radiographic unit separate from processors, from monitors, from all the other components, listing those in as components, and then allowing medical physicist oversight for the processor and all the other components that we would

talk about.

So do we have a show of hands, yes, for that?

(Show of hands)

DR. FINDER: No?

(Show of hands)

DR. FINDER: Then it looks like a yes.

And now we've come to the last question, which we have a few minutes so we can discuss. We've already discussed it.

So I'm actually not going to raise this question about should we write a quality control manual or test required for FFDM units. But I do have a question that has come up that I'd like to get some input from the committee on.

And it comes back to this issue about what is a final interpretation quality mammogram in the FFDM, in the digital era?

The following situation. A facility does digital studies, reads soft copy, does not produce hard copy unless the patient is requesting the transfer of those images to another facility.

Does - we have already stated that facilities have to have access to, and the use of, printers to be able to produce those images for patients when they want those films. Is it understood, or do people here believe that it's understood in the community out there that when those images are printed off that the quality control testing needs to be performed, needs to be up to date on those infrequently used printers?

If anybody has any experience with that type of situation, do you think when a patient comes in, asks for her films, and the file room prints off those images that that printer has undergone the quality control testing as prescribed by the image receptor manufacturer, the FFDM manufacturer, or not?

This is a question that has come up, and the real underlying question is, is a film that is produced off printers that haven't had the appropriate QC testing, should those be considered final interpretation quality images based on the fact that the printer may not have been - had the QC testing.

So some thoughts?

MS. MOUNT: At our facility we do it everyday. I mean we do it just like a processor. The printer is, however, in our department, and not in the records area.

I can see where there may be some issues if the printer were located in some other area that is not clinically used on a daily basis.

I think it probably needs to be addressed.

DR. FINDER: Any other comments?

DR. WILLIAMS: I think it would be clear that if the printer was not under QC that those would not be technically speaking viable for final interpretation. Now if the question is, how do we make sure that those machines undergo QC, because right now it's kind of - well, do whatever they said, do whatever they said kind of thing, then that's a little bit of a different question. And I would urge us to go towards a direction where the facility itself, if they're going to print films to give to the patients that could ultimately be used for final interpretation, that they take QC of those machines on as their responsibility.

DR. FINDER: I guess the question that we're asking here is, the sense of the committee, do most of the facilities out there realize what we just talked about, and are they doing it?

Because one of the questions we have is, should we start enforcing this? And if most facilities understand this aspect of it, that's one thing. If they don't, then we would go out with guidance of some kind to tell them that this is required, and they need to start doing this, and make sure that they're doing it.

The concern is, the facility as I said that reads soft copy, and only produces images for these transfer purposes fairly infrequently.

I will tell you, we have seen images in which all the identifying information has been portrayed on the image all over the breast, so you can't read the image. So it is a question of who is looking at these images, who is making these copies.

And in those types of situations, I have great concern that the QC may not have been done in these types of situations, considering the fact that

the image is uninterpretable with all the identifying data appearing on the film.

DR. HENDRIKS: So in that instance would that trigger another survey or some evaluation of the facility?

DR. FINDER: Well, no.

DR. MONTICCIOLO: Well, I mean, I assume that the interpretation - you're saying they gave their interpretation off the soft copy. They're giving the patient the films, and your concern then is that those images other people couldn't use. Is that correct?

DR. FINDER: That's exactly right.

DR. MONTICCIOLO: It's not like somebody read them with all that stuff on.

DR. FINDER: Correct. The final interpretation originally was not done, presumably, with all that information on them. However, they are being transferred to another facility. The patient has now gotten the study. And we are now getting the complaint from the second facility about the quality of the images that they are getting, that these are

uninterpretable.

So does anybody have any kind of feeling for how many facilities out there they think might not be doing quality control on these printers?

DR. BYNG: Dr. Finder, which quality control test do you think would find that problem of text written over top of images?

DR. FINDER: None. These are two separate issues. I'm just saying I would tend to imagine that if somebody is releasing films in that status, they are probably not doing QC also.

DR. TIMINS: I have not run into that problem myself when I've received copies of digital mammograms from other facilities, but I"m in a large urban area.

DR. FINDER: And again, we're not talking about the problem with identifying information over the film right now; that's quite clear, and that can be addressed.

It's the issue of, do you think that facilities out there know that they are supposed to be doing QC, even when they use the printers infrequently

for film transfers?

MS. MOUNT: I think, it's been my experience anyway, that when the vendor comes in and does applications, they pretty much tell you to do that as part of your QC.

We just have a page in our book.

DR. FINDER: Okay. All right.

Does anybody else have any other issues they want to bring up in this aspect, this section?

Yes?

DR. SANDRIK: On pages 42, 43 line 17 - it's the X-ray field, light field testing. One item that is absent I think in some of those is a reference plane for doing the actual measurements. Only in item B is an actual reference plane identified.

But reference plane for the extension - the light field X-ray field, and the chest wall extension is not identified in these rules. And I would ask that a plane be identified.

DR. FINDER: Okay, any other comments?

Okay.

MS. BUTLER: Penny Butler, ACR. And this

is not in reference to the comment that John just made. But in the definition section there was a discussion about Kvp reproducibility, and I thought I heard Dr. Finder mention that there was consideration to remove Kvp measurement from the annual tests, because that was in the GAO report, that was my understanding.

But I didn't hear it come up here.

DR. FINDER: In the sense of time, do you want to ask about the section we went over yesterday while we look at this?

DR. FERGUSON: Yes, I was going to mention, yesterday on page 36 we talked about release of medical records, and the timeliness of that, and doing it within 15 days. And one thing we didn't address that I thought was important was that if you contact a facility and say we want your previous studies for this patient, if you - many times you never hear back anything. And I thought it'd be important to put in there that within 15 days they'll send you the films or notify you that they are not available; they have been destroyed or whatever; where you're not

constantly calling back and back and looking for the film.

MS. SEGELKEN: I'd just like to make a comment about that. I think 15 days to be notified that they are not available is too long. So seven days maybe, something like that, five days to notify you that they're not available. Because then at least you can move on.

DR. FERGUSON: And I have no problem with that. I said 15 because 15 is what we came up with for sending them to you. But I'd like to know right away.

But I think there ought to be something addressed as to notifying you that the films are not available rather than just leaving you out there hanging.

DR. FINDER: But how much time would you like to be able to send the films to another institution?

DR. FERGUSON: You know, I'm good.

DR. MONTICCIOLO: I appreciate both of those comments, that we do have to give the facilities

time to look if they do have them in a storehouse and all that, because otherwise there will be the temptation for the facility to say, they are not available. So if we don't give them enough time to look, they won't look.

DR. FINDER: Well, the problem is, if they are not available that's a problem. Because they are supposed to be available for up to 10 years.

So if you get a response back, they're not available, you probably should let us know about that.

DR. MONTICCIOLO: From a practical standpoint, Dr. Finder, patients sign them out. Their clinicians sign them out. So we don't have control over a clinician not returning films or a patient not returning them to us. So there are lots of reasons they are not available.

DR. FINDER: I should have modified what I said. Obviously if the patient has signed out the films, that's a reason for the film not to be there. I was trying to go more toward the situation of, we don't know where the films are. We have no record. We can't find them. That's an issue.

But you're quite correct. Most of the time what it's going to be, is the patient signed them out and they are somebody else's office. And that is perfectly legit; that's not a problem.

Okay, any others?

MR. DIVINE: This is Mike Divine with the FDA. I apologize for not bringing this up when we were discussing it earlier, but I wanted to mention something about changing the operating levels for the processor and the phantom image testing.

Over the years we've had a problem where this is I guess the lowest subset of facilities that have problems where they have their processors fluctuating, or they're having phantom data go out of limits. And what they do is, rather than trying to fix the problem, they will change their operating levels frequently. And we don't consider that to be having their system be in control. Basically they keep trying to move their levels to accommodate the fact that they are not taking corrective action, either because they don't want to fool with it, or because they figure that they are going to have to

replace the equipment or have it repaired which will be expensive.

So I know that we don't want to get into the situation where we're trying to micromanage the decisions of the facility when they're appropriate decisions like they replace equipment, they change their film, they change their cassettes, when changing operating levels are a good idea.

But I think it would be worthwhile to have something in the regulations that they are only changing those when it's appropriate such as major changes in the processing system, or changes in the equipment such that it's necessary rather than trying to accommodate changes which are occurring in the equipment, rather than just changing their limits to avoid having to do anything about the problem.

DR. HENDRIKS: Are there any more comments from the committee members or the audience related to the quality standards?

If not, Nancy Wynne has a few comments about the past meeting and future meetings before we adjourn.

REVIEW OF SUMMARY MINUTES AND FUTURE MEETINGS

MS. WYNNE: I'd just like to tell everyone that I have copies up here of the summary minutes from the September, 2005 meeting.

They are also on the MQSA website if you need to see them.

Our future meeting is currently planned for the spring of 2007, so sometime in spring of 2007, or summer of 2007, we will be meeting again.

At this time I'd really like to thank Dr. Hendriks for being our chair for the past two years, and also for serving on the committee for several years before that.

Her contributions have added greatly to the quality of these meetings, and we really do appreciate it.

I'd also like to thank John Sandrik for being on our committee, representing industry this year. And it is his last year and Dr. Hendriks' last year for being on the committee.

And before Dr. Hendriks adjourns, I'd like to add my thanks to the committee for their

participation and their help in my first meeting as exec sec. And I'd also like to thank all of the attendees and public speakers for their contributions.

DR. HENDRIKS: And with that the meeting is adjourned.

(Whereupon at 12:11 p.m. the proceeding in the above-entitled matter was adjourned)