Obviously the regulations in the statute require that the records be released but at what point does the delay become a failure to release. We are talking about a time frame. Should we include one? Show of hands, yes? No? Now, the big question. How much time is enough time?

DR. FERGUSON: You know, we need the records. We send out the records when we get a request. I don't know. Some of the bigger facilities, how long does it take you to find films and get them from the time you get a request?

MS. MOUNT: We usually have them sent out the same week.

DR. FERGUSON: The same week.

MS. MOUNT: Um-hum.

DR. FERGUSON: So I would say within 14 days. I would like it to be quicker.

DR. MONTICCIOLO: I would love that because we have to fight with that all the time waiting for old films but you are depending on the file room and big x-ray departments. You know how that is. Maybe it would make them respond better if

we gave them a time limit. Two weeks would be tight, though, for some facilities, I think.

DR. TIMINS: I agree but so many studies are kept off-site so you have to go to the storage facility and then depending on weekends and holidays and whatever, it can take a while. I would certainly love to have them myself from the other facility within a week and have more time to send them out.

DR. HENDRICKS: I do think when we have to keep the time frame short enough so that it doesn't prohibit the release of the more suspicious findings once the comparison is made.

DR. MONTICCIOLO: Since we want mammos to be read in 30 days, it would probably be like 15 to half that time. I'm only thinking about out-of-state facilities because it takes longer for them to get things together.

DR. FERGUSON: And would you be talking about from the time they received the request? Fifteen days from the time they received the request?

DR. BYNG: Do you have an impression of how long that takes now on average?

DR. TIMINS: It varies widely because sometimes you'll have a hospital that stops doing mammography and then everything is in their archives and it's a low priority for them so you have to deal through their fileroom. In terms of their receiving the request for records, that's all faxed.

DR. BYNG: But you could -- well, the problem with putting it in a regulation is that if you put in 30 days, for one it's too long, but then some facilities might just say, "I have 30 days." I think that is the thing you want to avoid.

DR. MONTICCIOLO: I agree but I don't think they are going to say, "Gee, I used to do it in three days but now I can do it in 15." It will just make all those people who aren't -- I mean, you know, it comes down to communication like Jackie mentioned. Like the local people we've talked to the hospitals.

They want our films as much as we want theirs so those we get in a few days but it is the facilities we don't know that are out of state or the patient doesn't quite have the name right of the facility and so we have to look at every facility in

Tucson, Arizona to figure out which one they came from.

I've had a single person spend a whole week getting someone's films because they called every single facility because we thought it was so important. That took a ton of time but there is no way we would get those fast. Like I said, we're taking maybe measures other people wouldn't take but I think a good place is to send them out as much as possible. This will tighten up the outliers that send them three months later.

DR. FINDER: Go ahead.

MS. SEGELKEN: I just had a question just for information. Do you ask patients, new patients who are coming to your practices, to bring and to get old films?

DR. MONTICCIOLO: We do that 100 percent of the time and patients amazingly do not comply that well with that. It's very difficult for us. We will often say we absolutely need the name of the facility.

They can't remember the city or they give us the wrong city. It's really a problem for us

getting films and they are so important. We have all of our staff trained to do that including our schedulers.

DR. FINDER: So I'll take it 15 days. Show of hands? Yes for 15 days. Next question, business days, calendar days. Just kidding. There's a holiday in there. Do we count those days? Okay. Just asking questions. It's getting late.

Should specific requirements and penalties be set with respect to record retention for closing facilities, especially about notifying patients where their films would be if they are closing?

DR. TIMINS: It's a good idea but when you talk of penalties I remember when HIP went bankrupt and closed their facilities. All the mammograms that they had stored were no longer accessible. It's kind of tough to assess a penalty against a bankrupt facility. On the other hand, it would be appropriate to have on hand a requirement that they make mammograms available to their patients.

DR. FINDER: The issue you bring up basically is two-fold. One is a bankrupt facility

which is certainly difficult to deal with. The other is just a closing facility that is not bankrupt that may have moved to another location, may have other sister facilities. It encompasses both those situations.

DR. SANDRIK: I wonder if this is something you could put in on the front end, say an accreditation that they would have to demonstrate that they would have a way for dealing with mammograms in case of closing or bankruptcy rather than trying to do it after the fact and finding a way to do this.

DR. FINDER: This is an issue that has been, as you might imagine, come before this committee before. One of the issues about trying to get some kind of guarantee or some type of bond, the thought was that you would discourage more facilities from entering the field if they had to put up up front some kind of insurance policy. The consensus in the past has been try to go after the people that actually caused the problem and not penalize the other facilities, but that is certainly something we can consider.

DR. SANDRIK: There are different levels of going after it but part of it might be to have them think about this ahead of time to the point of submitting a plan. Whether you go as far as requiring a bond, insurance, that might be a matter of how much of a problem this really is. In many cases they never think that they are going to go out of business so why should they even worry about a plan.

DR. FINDER: Sounds kind of like a prenuptial agreement. As you're getting married you signed the piece of paper saying how you are going to get divorced. These certainly are issues to deal with.

DR. FERGUSON: I've actually read for a facility that went out of business and closed and I can tell you when you start talking about penalties, we sent a letter to every patient's address that we had in their chart. We took out an advertisement in the local newspaper that their records would be stored at the hospital that was 15 miles away.

If they didn't pick them up within the 45-day period, that's where they'd be stored. I'm

telling you I had some irate patients call me and this was in another state. They called me, "I can't find my records. I don't know where they are," because their addresses had changed.

They hadn't seen the advertisement in the newspaper for whatever reason. You can't cover every base as hard as you try so when you start talking about penalties, I was pretty penalized when they called and cussed me out pretty good. I did tell them where their films were located. I was able to because my facility name was on the report and they knew where to contact me.

DR. FINDER: That will teach you to put your name on the report.

Okay. Do we think that there should be some addressing of this issue in the regulation? A show of hands for yes? No? The answer is yes.

DR. FERGUSON: I would say that it does need to be addressed that this is the way you handle it. When you start talking about penalties, it should be that there should be some allowance that the patient didn't get it for whatever reason.

DR. FINDER: Next is regarding mammographic image identification. Should there be clarification that supplies only the images for final interpretation? Also, what does it mean to be permanent when dealing with soft copy digital images? Should this identification of information on the image itself only apply to final interpretation images?

MS. MOUNT: What wouldn't be final interpretation?

DR. FINDER: For example, on a work station. We're talking about basically digital images. On a work station the identifying information might not display and would that be acceptable. Anybody have any problem with that?

DR. SANDRIK: To your point, you have the acquisition station that maybe the technologist looks at. Would you be looking for the same labeling, same location as it would appear on the review work station where the radiologist is operating?

DR. FINDER: So, again, the question is should it only be for a final interpretation images or

for any image?

DR. BYNG: So one of the distinctions here is on a screen film image if the image is on the screen film it only distinguishes out from potential copies, right, where you don't have this information on it?

DR. FINDER: Well, let's not get into copies because for a final interpretation or for film screen there is the image and that image has to have all this information. That is the way this was written. The issue now that we're talking about really only applies to digital images where you can toggle the information on and off, have it displayed on some of the images, not on all the images.

Certainly we would be talking -- when we talk about final interpretation, certainly that would mean that images that were sent out to another facility for review would necessarily have to have this information on that.

It is interesting that we are now encountering situations where the information sometimes isn't present because they forgot to put it

on there, or it is present and overlies three-quarters of the breast. These are issues we never have to deal with in film screen but they are becoming more important and more common with digital. We are trying to address that information. That's where we're going on this.

DR. BYNG: But I think when you get to some of the other requirements it's quite clear that they were written for analog and this one is clear when interpreted in an analog context, but in the digital context, you have to look at all of the instances of the image because there may be some situations beyond just final interpretation images where it is appropriate to have some of that information and a lot where it's not.

DR. FINDER: That's why we're asking. The answer is yes? I mean, we're starting off with final interpretation because we assume that under those circumstances it has to be there. Now, if there are other instances where you believe that information needs to be present, certainly let us know. Tell us.

DR. WILLIAMS: Or are there instances

where having that information there would be bad?

DR. SANDRIK: Yes. I mean, sometimes it's just annoying to have the lettering is white in many cases. It might be annoying to have that extra luminance from the monitor. You would want to turn it off just to kind of darken the whole area surrounding the mammogram. I think many times radiologists toggle it on and off just to get it out of their way.

MS. MOUNT: At our facility that's what they do. They prefer to read it without the information but they view the information to make sure they have the correct patient.

DR. WILLIAMS: So that is final interpretation there, right? We would agree that it should be togglable at final interpretation but are there other situations where people, say at the acquisition work station, where it would be a liability to have that information there?

DR. SANDRIK: I think there is some concern if you are doing it maybe outside of MQSA but an interventional kind of procedure. If you're depending, say, on the location of some of this

labeling to identify left, right, medial, lateral, the angle of the view and you are depending on knowing which part of the breast where the labeling shows up, it may be important to have it on other displays.

It's a matter, I think, perhaps of how much the user is depending on location of that labeling, in some cases, or even the labeling itself just to know what view was being presented. If the radiologist are present during the procedure, it may be clearly obvious.

If the radiologist is in another room and you are sending them remotely between acquisition station and another display station perhaps not having that labeling could be a liability.

DR. HENDRICKS: I have a practical question about what the facility is doing right now in terms of their image storage.

DR. SANDRIK: I guess I did not realize we were addressing image storage necessarily.

DR. HENDRICKS: You know, we start with record retention and how to produce and what images to store. I don't know how they are. I see the viewing

stations and things but I do not know how the imaging is being stored right now at the digital facilities. Do they go to disk at the end of the day? Do they go to disk in 30 days?

DR. SANDRIK: I'm just not sure. Oh, I guess a lot of them will go to disk, for example. Some might make hard copy. I think most store electronically where, again, the image can be brought back and then the labeling turned on and off again. In most cases when the hard copy image is made, the labeling is put in the appropriate place pretty much following MQSA type guidelines.

DR. WILLIAMS: And all this information will be stored in the DICOM header so for storage purposes it's going to be there and it's going to be retrievable. I guess the question is how much of it should be displayed at any given time.

DR. BYNG: And I think until some of the other IHE related issues become more mandatory, it's still not a requirement that all of that information be in the right locations in the images.

I think the key word here has to do with

permanent in the soft copy context because the only way to make it permanent is to put it on the image itself and then all kinds of requirements about size and location and whether you are covering tissue. It's going to become a very difficult thing to interpret for that situation.

DR. FINDER: I think the issue here is the regulation right now as written does not differentiate film screen from digital. All this information has to be there permanently. What we're trying to do now is modify this regulation to take into the reality of what digital is.

One of the things is this business about toggling the information on and off. If we don't consider that permanent, the ability to toggle on and off as permanent in the context of FFDM, then all FFDM images don't meet the requirement right now. Obviously we have to come up with something that addresses the current situation.

This may not be the final solution. There may be other issues that have to be dealt with but, again, if you take this literally one could make the

case that none of the images from FFDM systems are permanently identified this way.

Now, we're not going to do that because we recognize the reality of it and we want to include something that allows this ability to toggle. If there are other issues that come up, we are going to have to address them.

Yes.

DR. MONTICCIOLO: So if I understand you, then if we agree to this, you're saying it's going to be mandatory for the final images. It doesn't mean it can't be some place on all the other images but it allows that flexibility to toggle.

DR. FINDER: Yes.

DR. MONTICCIOLO: Okay.

DR. BYNG: But I don't see toggle in here. It just says permanent.

DR. MONTICCIOLO: This just is saying for the regulations that requirement is that the final images have to have it. The rest of the images you can toggle all you want. You can do whatever else you want with it. It gives that flexibility.

DR. BYNG: So when you toggle it on it's a final image and when you toggle it off it's not a final image?

DR. SANDRIK: I think the idea of permanent has to be addressed here as to what it means. On a screen film image in a way it was fixed by burning into the film. Permanent will have to be addressed in a different way than digital imaging.

DR. FINDER: Again, I think we are trying to get the concept, not the words, and whether it has to be addressed in this regulation or under the definition section as to what permanent means here but as long as we understand that we have a different system and we have to deal with it. Everybody want to raise their hand to yes we've got a different system and, yes, we've got to deal with it? I think I'll go with a yes on that and address it in that manner.

Next one is -- no, that's it for this section. Now let's go to page 46 and 47, footnote No. 129. Should combining medical audits from different facilities under the same ownership be allowed?

Right now I'll tell you the situation.

Each individual facility must have its own individual medical audit with one exception. We haven't approved an alternative standard that allows mobile facilities under the same ownership that go basically to the same places so they basically see the same patient populations to combine their medical audit. Should we allow that for any group of facilities owned by the same ownership? Show of hands yes?

DR. BYNG: But if you had a problem in a small portion, like it's possible to hide a problem in a portion of the facility then. If you are combining groups of facilities together into a single audit and you've got one that is underperforming, it would be lost.

DR. FINDER: Let me kind of address the history behind all this. The original reg was written based on individual facilities. Part of the rationale behind that was that if you start combining multiple different facilities, you can do exactly what you're talking about, kind of lose some of that information.

However, you can also gain information by having larger numbers and better statistics. Probably

the major concern that we had at the time were facilities that see significantly different patient populations and trying to combine those was problematic.

You could have the sister facilities be screening facilities and the central facility be the diagnostic center. The numbers there would be quite different even if you are dealing with the same physician's reading because of the patient populations.

What do you gain and what do you lose by combining those? One thought at one point would be change the audit to require only that you must break down those cases by screening and diagnostic to try and deal with that. The original regulations did not address that. It just said medical audit and didn't necessarily require that there be a differentiation for screening from diagnostic studies.

These are all types of things, but I guess the general question here is should we look at this issue? Should we try and come up with some kind of conditions in which we would allow facilities to

combine their audits or should we just keep it the way it is and have them do individual ones?

DR. BYNG: Dr. Finder, is the benefit from combining them together simplifying the audit procedure and the cost associated with it?

DR. FINDER: No, it's more that if you are in a small facility or multiple small facilities, the individual numbers are not going to give you significant cases to include in the audit, whereas if you can combine a larger number, your statistics are going to be better.

It really doesn't have -- there is certainly a factor for the individual facilities. If they could do it all at once it would save them some of the computations but that wasn't the thrust behind our original requirement that it be an individual facility-based situation.

The other issue is if one facility screws it up, all of the facilities will end up getting cited for that so they are running a risk presumably if they did that, too. That is something they would have to deal with.

DR. MONTICCIOLO: I would be in favor of combining just for the reasons you cited. It's better, I think, to get more numbers so if you have the same readers and they are reading for multiple facilities, the more numbers you get, the more you get a real overview of what that person is doing.

It's actually better for us to assess the physicians, this is a medical audit after all, if you can combine more than one facility if the same people are reading.

DR. BYNG: Just to explore that a little bit further, if you reported over all, you combined them, but you also looked at the individual one?

DR. MONTICCIOLO: The audit is done by individual physicians.

DR. BYNG: No, individual facility.

DR. MONTICCIOLO: Yes, but it's the physician doing the reading. It's the readings that are audited.

DR. FINDER: I just want to add under the current system we do allow facilities to combine multiple facilities and give one overall, but they

still have to break it down by individual facility.

At this point we do not allow, except for that alternative standard that we've approved, a situation where multiple facilities could have one audit for all five facilities but nothing for breakdown for the individual facilities, if that helps. Show of hands for yes, we should allow different facilities to combine, or no? Yes? And no? Okay.

No. 130, should certain metric be required of the medical audit? This was discussed at the last meeting, too, but we always want to bring it up again. Things like positive predictive value, cancer detection rate, things like that. Should that be required as part of the audit or not? We'll take a show of hands. Yes? And no? Any comments?

DR. MONTICCIOLO: Well, as we talked about at the last meeting, it is extremely cumbersome to add more numbers than we already look at. It also is very population dependent so if you are going to have to set benchmarks, there are different people reading and your numbers are going to be a different cancer

detection rate than mine being in an urban center.

I think that would just add more -- it's more onerous also to extend the audit. We talked about the resources already being expended on auditing and I think this is just stepping it up a level that is not going to benefit and it's going to cause an awful lot of facilities to have difficulty meeting the requirement.

DR. FERGUSON: That was exactly my thought. It's going to be very cumbersome for very limited gain and I think it's going to create heartburn for quite a few facilities to be able to come up with this in addition to everything else that we do. What are you going to do with the data?

DR. BYNG: Maybe that's the part I was confused about. It just asked about measuring those metrics, not that there would be standards associated with those metrics.

DR. MONTICCIOLO: But then those kind of measurements takes time, personnel, and resources. Already it's hard to get people to even go into mammography because they feel like all this is so

onerous and to add more without much gain I don't think is going to benefit the mammography community or the patients.

Right now we already do an audit. We look at our positive results. We look at our detection rates but this is positive predictive values and rates. It's more resources to do this kind of thing.

If you haven't done this kind of paperwork, I can tell you it takes a lot of resources and it is driving people out of the practice. I think ultimately it's going to hurt the practice of mammography to keep putting more on facilities to do this type of data collection.

DR. BYNG: But some of these metrics are just recalculations of the numbers that you already have.

DR. TIMINS: I'd like to change my vote.

DR. WILLIAMS: I was just going to make a comment that I think, if I'm not mistaken, this was one of the recommendations from the IOM and I think part of their logic was that they could get many of these additional pieces of information by essentially

a reanalysis.

The way we are doing the analysis now didn't really allow us to do that so it's really kind of a data, I would say, research but sort of a data analysis issue.

DR. SANDRIK: I think one of the questions is how much is this going to add to improvement of the outcome of the mammogram or mammography at the facility? If you admit that it's just recrunching a bunch of numbers you've already crunched once before, how is it really going to change the practice necessarily or improve or change things? This might be one of these 80/20 percent kind of things.

By just doing the audit you've got 80 percent of the benefit. By playing with the statistics maybe you get a few more percent. Is there really a gain to be anticipated by going to other metrics to express essentially your same data?

DR. FERGUSON: I would say let those people who want to do research on it recrunch the numbers.

DR. FINDER: Okay. Let's get another show

of hands. Yes, we want these metrics? Everybody changed their mind? Okay, no? You don't want any metrics? Wow, that was quite a switch. All right.

Next one dealing with clinical image quality. Should we add phantom image quality to this section? Is it necessary to do that? Show of hands yes?

DR. MONTICCIOLO: Could you explain the difference between what goes on now? I don't understand. We already have to do the phantom and it has to pass. We do it on all our machines every week. How is this different?

DR. FINDER: As I think I mentioned before, these are questions and issues that have been brought to us and they have been brought to you. I'm not sure exactly what is added in terms of this if we added phantom image quality because, as you point out, it is checked every week and there are requirements that the phantom image must pass certain standards. I will ask the question. Show of hands yes? No? Okay. That's a no.

We are now talking about additional

mammography review and patient notifications. Just for some background, additional mammography reviews are done when we believe that there is a significant possibility that the quality of the mammograms are such that they could place patients at risk.

The additional mammography review is done to determine whether that is the case. If it is the case, then that usually leads to patient notification where the facility is required to notify all patients and their referring physicians that there could be problems with the mammogram and they either have to be re-reviewed or repeated.

So starting off with this, should the state certification agencies be added into this requirement that they be involved in this? I will say again this is more for clarification since they do have their own process for doing these things. Show of hands yes? No? That's a yes.

Should a requirement that facilities have to reimburse the accreditation body for the cost of the additional mammography review be included? Yes or no? Yes? No? That's a yes. Okay.

Should a qualifier be included to limit the notifications to only those patients who are at risk? For example, those patients who have studies within certain time frames? Or, for example, who have already had their films reevaluated? Yes? No? Show of hands. Does everybody understand what I'm talking about?

DR. MONTICCIOLO: This is for facilities that have already been told they are losing their accreditation or they have failed in AMR?

DR. FINDER: Now we are talking about patient/physician notifications. These are ones that have already failed in AMR and have been determined not only that they failed the AMR but a determination has been made that the quality of the studies represents a risk to human health such that we believe the notification should be done.

Yes?

DR. FERGUSON: I've been involved in a couple of these. The way we handled it was that we brought in radiologists who were on the Clinical Image Review Committee and we all looked at the mammograms.

If they were not of quality, we notified the patient that it was not of quality and she needed to come back and have the exam repeated.

If there was an abnormal finding we notified the patient of that and got them back in for additional imaging. If you went and notified every patient that the facility had done, and we had this discussion, you just scare women to death.

If we say, "The facility that you had your mammogram done at is of inferior quality, although we find your mammogram to be okay," I would think the woman would say, "Well, if it was inferior quality, I want to have it repeated," even though the reviewers looked at it and the image was passable and the exam was negative. I don't think you should scare women to death.

MS. VOLPE: But next year when they go for their mammogram, aren't they going to find out that the facility was inferior or that the films were inferior?

DR. FERGUSON: I don't know where they will go have their next mammogram or if that facility

will reopen. One of the facilities we did corrected their errors and was back in business a year later. They went through the recertification process.

DR. MONTICCIOLO: You know, I think it depends on the severity. It takes a lot for a facility to flunk an AMR. You have to be really bad. I am concerned about this. I don't want patients necessarily to be concerned but if somebody produces that many bad films in a review, my guess is they are doing bad films regularly.

The question is the time limit. Were they doing terrible films three years ago or did they just all of a sudden lose all their good techs and they hired people that maybe weren't so good or maybe the radiologist changed and is willing to accept bad films. I think there has to be some time limit but I have to say in order to really fail an AMR you have to be pretty bad.

DR. FINDER: Let me give you a little bit more background on this. Again, at this point we are talking about a facility that has already failed. There is no question. We are talking about what we

consider a risk to human health situation. Patients have to be notified. Nobody is arguing about that or bringing that up. The question is how far back do you go and who is involved and who is truly at risk in these situations.

Just to give you a sense of what we do, because obviously these situations do arise. They have arisen over the course of the program and we have to make decisions. The facility could be in operation for decades. The concept of going back and notifying all those patients that there was a problem doesn't help anybody.

We basically have tried to focus in on an individual basis to determine what time frames really are involved. If there is, for example, a new machine or new tech and we can localize it to that, then we try and localize the patient notification to that. If we can't, we basically look at a two-year span. Assuming that with an annual mammogram being done in most places two years would catch most of the patients.

If after two years they haven't come up

with anything, changes are that they are not going to show anything on the old mammogram anyhow, those types of things. There are limits. So just a rule of thumb if we can't localize it any further, we basically figure on a two-year time span and go back and have those patients notified.

A lot of this has been worked out over time. It just isn't stated in the regulations and we would like to try and input some of that information here. Again, the details are important and we do try and individualize the situations as best we can if we can.

So do I get the general consensus from the committee yes, that we should do some type of limits on these notifications along the lines that I discussed? Show of hands yes? No? I'll take that as a yes.

Should the regulations be modified to specifically state that if the facility fails to complete the notification FDA or the state can perform notification through any means available and require reimbursement from the facility. Show of hands yes?

No? I'll take that as a yes.

I will say that this is a very, very infrequent occurrence but it has occurred and in those cases we have kind of been forced to go out with general public announcements because we didn't have more detailed information to do that.

We finished that section. Does anybody have any questions about any of the areas that we just covered? Anybody have any? Okay. We actually finished the activities that we were hoping to get through today. What I would ask the committee if it's okay that we continue on to some of tomorrow's activities, go through those. Because the agenda is out to allow time tomorrow to recap those so if anybody comes in later, they are aware and can bring up issues on those topics without losing that ability.

I also would suggest that we start off with actually the last topic for tomorrow rather than the first because I think those will be of more importance to the people who will be coming tomorrow. If we would start with revocation of accreditation body approval, 900.13 all the way to 900.18. Those are

pages 47 through 54, footnotes 136 through 147. Does that seem reasonable to everybody? Okay.

We are now on page 48 at the top of the page. We are just going to get this up so everybody can see. There we go. Should this section be rewritten to clarify the differences when all units versus only some units are denied accreditation? Should the differences between initial accreditation and reaccreditation scenarios be clarified?

This goes along with some of what we talked about earlier about clarifying what it means to be accredited, what it means to be certified, initial accreditation, reaccreditation, recertification, those types of issues. There is a distinction. The accreditation bodies deal basically with accreditation of units.

We deal with certification of facilities. If any unit in a facility is accredited, that facility can be certified. It isn't until they lose all accreditation of all units that their certification status falls into jeopardy.

For example, if a facility has two units

and one fails accreditation and the other one passes, the facility still stays accredited but it should only be using the one unit that passed but it doesn't lose its accreditation because one of its accreditation units has lost its accreditation.

Should we rewrite this to clarify that to what I basically just said but hopefully in fewer words? Show of hands yes? No? That's a yes.

About the differences between initial accreditation and reaccreditation. I think we've talked about that in the past. Again, show of hands yes? No? Yes to both.

Okay. Now we're talking about No. 137 which deals with the situation where FDA withdraws the approval of an accreditation body. The question here is should the statement be clarified that even expiring certificates be extended for up to a year when that occurs?

This is a situation, for example, accreditation body is withdrawn or runs into trouble with us and we revoke their status. What happens to those facilities that are up for accreditation or have

an expiring accreditation? Will their certificate end because we don't have a situation set up yet for an accreditation body to take over for them?

Can we extend or continue to maintain their certificates valid, or should we, until we can get an accreditation body in there to newly accredit those facilities? Show of hands yes? No? It's a yes.

I will add that we may not be able to do that because of what the statute says but we'll have to talk with our lawyers and see whether that is a possibility. Again, we're just trying to get the consensus of the committee on this.

Should the one-year period be extended if no viable accreditation alternatives exist?

DR. TIMINS: Has this happened?

DR. FINDER: As I said before, the only accreditation -- we only lost one accreditation body and at that point there was another accreditation body to take over. The situation was a state accreditation body that dropped out and the national DACR was able to -- I wouldn't say easily but was able to take up

the slack and in a period of time was able to get those facilities accredited. There could be situations where more facilities were involved where we wouldn't have that possibility. Who knows? It's a hypothetical. I hope it never happens.

DR. FERGUSON: I think there is probably a good chance that we will see it again if we have seen it before. How long would it take to get all of these facilities accredited by a new body? I'm sure that would depend on how many facilities you are talking about so I think there does need to be a period of time to allow for that.

DR. MONTICCIOLO: I'm actually interested in what the ACR has to say about it because this says if no viable alternatives. The ACR is a national program so they are there. Like you said, if it's a large number of facilities and if they have to do it all within a year, it would be a crunch. Can we get their input to see how they feel about that?

MS. BUTLER: Penny Butler, ACR. We did it with California which was at the time the largest state body and we did it within a year. We worked

very closely with the state and also the FDA but it was doable. Maybe the issue is if the FDA comes to ACR and says you can't be an accrediting body.

DR. BYNG: What would the situation be then according to the current interpretation if the situation happened that the change wasn't made?

DR. FINDER: Well, if we couldn't find an accreditation body, they are not accredited, they wouldn't be certified, they wouldn't be doing mammography. Next question? No. So yes or no on that? Again, I'm not sure we would be able to do it anyhow.

Okay, next page 139. Here we are talking about suspension or revocation of certificates. The question here is should failure to pay inspection fees be a listed cause for suspension? Show of hands yes? No? Any comments?

DR. FERGUSON: Part of me says yes, you need to pay your dues and move on but are you really going to help the public interest by closing somebody down that doesn't pay their inspection fee? If there are facilities out there that are struggling and, I

don't know, maybe can't pay them, do you give them a time payment option?

DR. FINDER: The installment plan.

DR. TIMINS: What is the certification fee usually?

DR. FINDER: There is no certification fee. It's the inspection fee.

DR. TIMINS: How much does an inspection fee usually cost?

DR. FINDER: It depends on the number of units but I would say for the average facility, which is more than one unit, I think it's 1.5 units, you're probably talking around $2,000 a year. It's a little over $1,700 for a single unit and a little over $200 for each additional unit.

DR. MONTICCIOLO: I just want to ask how often this happens because I just can't imagine this scenario. This is a good concern you brought up, Dr. Ferguson, about can they afford it because some places it's really expensive for them.

I'm thinking about my own administration cutting that check and having some goof ball like lose

the check and then get suspended because they can't count on the administration. I hate to say it but these kind of things happen.

DR. FINDER: Let's put this into perspective. We're not talking about the facility that has a late check or inadvertently forgot this. These are situations where they have gotten multiple notifications. They've got the collection agencies and other things. We're not even talking about missing one inspection payment. We're talking about usually multiple years.

DR. MONTICCIOLO: If that's clarified that's what you're talking about, then I think they should have to pay it.

DR. BARR: In fact, what we could do if we had the language is not renew the certificate at the time of renewal if they weren't current on inspection fees which means they hadn't paid for three years. That is sort of what we were thinking of in general. Wasn't it, Charlie?

DR. FINDER: That's certainly one of the aspects to it of getting them at the time of

reaccreditation. However, this is actually in the area of suspension. We do have some facilities out there that haven't paid for periods of time. It actually impacts on the facilities that do. This is one of the issues.

I agree with Dr. Ferguson that the last thing we want to do is lose facilities because of this because access is very important. The question comes up is how far do you let this go before you do something about it.

DR. FERGUSON: Can you have discretion? I mean, obviously if it's a mammography facility doing very well that just doesn't want to pay, I feel one way, but if it's in an impoverished area doing everything they can to make ends meet, I feel a little different.

DR. FINDER: Let me add some of the background. We do have a program of governmental entities that they don't pay at all. That includes facilities that provide more than 50 percent of their work, mammography work, for the CDC programs, for low-income groups and things like that.

The idea here is not to put facilities out of business. It's to encourage facilities who do have the ability to pay who just don't want to pay to come up with this. You are right, this has to be taken in context. First of all, there are not that many facilities that do this.

A vast majority of facilities pay on time and it's not an issue. The ones that don't kind of set a bad example and if they continue to keep doing this and face no repercussions, the facilities start to say to themselves, "Why am I paying?"

DR. TIMINS: I think it's impressive that there is a program for facilities that do a high percentage of CDC cases to have a reduced or fee forgiveness. It's obvious to me that I have to pay for my medical license in order to practice medicine, I have to pay my malpractice insurance in order to be insured, and I have to pay my mortgage payments if I want to have a house over my head.

DR. FINDER: Show of hands yes? No? Split. Okay. Should continued use of an unaccredited mammography unit be a cause for suspension? Okay.

Here, again, we could be talking about a spectrum of situations. We could be talking about facilities for the space of two or three days through paperwork error forgot to get their unit accredited.

Letters didn't go out in time. That's one thing. We're not talking about that situation. What I'm talking about here is the situation where a facility has been specifically notified not to use a unit because it's unaccredited and they continue to do that. That has occurred. Question here is under those types of situations should we proceed or specifically state to go for a suspension of their certificate?

DR. FERGUSON: I 100 percent agree that they should be suspended. I just ask that when this is written, again, I just got back from another panel and they emphasized how much when you put out guidelines they became rules and they are strictly interpreted in the field.

I would hope that you would put in there that it's not for the people that are two or three days because of paperwork. I hope that is very clear.

But they ought to be suspended under the scenario you stated.

DR. FINDER: Okay, show of hands for yes? No? That's a yes. Okay.

Should facility denial of suspension of revocation of accreditation be a cause for suspension of the certificate without a hearing? Most suspensions and other type of actions require a hearing before any action is actually taken. If the accreditation has been either denied, suspended, or revoked, should that be a cause for suspension without a hearing?

DR. SANDRIK: Is there an implication there that the accreditation bodies have some sort of hearing procedure they would have gone through before the accreditation was revoked or whatever?

DR. FINDER: They do have those appeals as part of their process. Actually, now that I look at this question, it has different significance than when I first thought it did when I wrote it. Things change. If a facility is denied accreditation, right now what happens depends on their current

certification status.

If they are a provisional facility, meaning they actually don't have accreditation, they are applying for accreditation, they are under that six-month certificate, in that situation if the accreditation body denies the accreditation, the certificate is basically null and void at that point because there is no underlying basis for accreditation backing the certificate. It disappears.

If, however, they are a fully accredited and certified facility, they've got a three-year certificate, if the accreditation body denies the future, the new accreditation, the reaccreditation, that certificate remains in effect until its expiration date. They don't have to shut down immediately.

The rationale behind that is that even in an AMR type situation where we've got all these terrible problems, we have to take a suspension action. We have to do an action and allow the facility the right to appeal here.

We have been told by our lawyers we cannot

tell a facility just because it failed to get a future accreditation that it's current certificate is declared null and void just on the basis of that denial.

This question actually should have been divided up and we should look at it as should denial of accreditation be a cause for suspension of the certificate or a dropping of that certificate without a hearing?

In that sense, we have already discussed this with our lawyers and they pretty much have told us that we can't automatically do it. We would have to go for suspension of some kind and that would have to be based on significant problems with the facility.

Let me take denial out of that question. Let's go with just suspension or revocation of accreditation. Should that be a cause for suspension of the certificate without a hearing? Yes.

MS. VOLPE: I think that if it's a significant health or safety issue, then it should be suspended until after a hearing is held.

DR. FINDER: That is where we are trying

to go with this type of a question. A denial of accreditation means that the facility hasn't produced images that pass the quality standards for reaccreditation.

It does not mean that the images that were submitted were evaluated and found to be a risk to human health. The situation that we are deal with the AMR where we take the patient notification and basically we do pull their certificate at that time because it's found to be that bad.

But in a denial of accreditation, all it is is that the images didn't pass the accreditation standard, the high standard. That is one of the reasons why that is not an issue in terms of suspending the certificate.

The other, though, is if the accreditation body has found reason to suspend or revoke the accreditation for whatever reason, that usually is because of a failed AMR so we are dealing with this risk to human health, should that be a cause for suspension without a hearing.

The situation that comes up here, and this

has happened, an accreditation body has revoked the accreditation because of a failed AMR, we then declare that the certificate is either no longer in effect or try to get it suspended and then the facility appeals, they ask for an appeal.

That kind of puts a damper on what we can do at that time. It kind of puts a stop to that. I'm not sure the lawyers would even allow us to do this but, again, I want to get the sense from the committee should we try and say that if those facilities have their accreditation suspended or revoked that we would place this into a category where we would suspend their certificate without a hearing. That would shut them down quickly.

DR. FERGUSON: And I would agree with her. If it's a risk to human health, we should immediately prevent them from doing mammography. It says they do have a right of appeal. I think there ought to be a period of time that you have to give them a hearing. I mean, you don't want to be hanging out there for a year.

DR. FINDER: They have an opportunity for

an information hearing within a certain time frame of 60 days. This would shut them down in the meantime. I'm just trying to get a sense from the committee would that be yes for that? Again, I'm not sure we can actually get that through but we can certainly try. Okay, that was a yes overall for that for 141.

Now, No. 142. Should a regulation consistent with the statute be included indicating that owners of the facility with a revoke certificate can't operate a mammography facility for two years. That type of language is actually in the statute. It would just be a question of clarifying inputting in the regulations here.

DR. FERGUSON: Would you give me an example of that? I'm not sure that I understand.

DR. FINDER: Okay. We haven't revoked anybody's certificate during the course of the program. However, this would be reserved for situations where, for example, I think one of the ones that we might go ahead and do something like this would be facility failed an AMR, we required the patient notification to be performed and the facility

refused.

We had to go ahead with a patient notification without the facility and we have to make a general announcement. In that type of situation I think we would try and go and revoke the certificate so that that person would not be able to own or operate another mammography facility for two years.

That situation pretty much did occur where the facility refused to notify and we had to go and notify the public on our own but we did not go ahead and revoke because this person was not going to ever operate another facility again so there wasn't really a need to stop them.

That would be the type of situation that we would be talking about. Again, that is allowed by the statute. It's only a question of adding the language into the reg. We have the authority to do it anyhow.

DR. FERGUSON: So if this owner, I think it says owner, if it was a hospital chain and you had a small hospital in a chain and there was an administrator or somebody that didn't want to play

ball with you and they messed up, then you are saying that whole hospital chain wouldn't be able to perform mammography anywhere for two years.

DR. FINDER: That's a good incentive, not to mess up.

DR. FERGUSON: I don't disagree.

DR. FINDER: I can tell you that it's not one individual who can do that. I mean, the notification is not just the one person that we would be dealing with. In a large organization like this you'd basically be dealing with the entire corporate structure and they would all have to basically make the assumption or the decision not to do what was required.

This certainly would be a deterrent to a large organization. I can't imagine that anybody would do it in that type of situation. I think more likely the situation is the single facility where the owner basically has abandoned the facility and wants to forget about this facility that they've got all these problems with but start up another one with a different name on it. The purpose of this is to

prevent them from trying to do that.

MR. DIVINE: My name is Mike Divine. I'm Chief of the Inspection and Compliance Branch. Basically the owner operator would probably boil down to the person who we could identify as being responsible for the violation.

For instance, if it was a hospital and it was the administrator of the hospital and that person is giving orders to people that weren't necessarily in agreement and that person was named as the person that couldn't own or operate for two years, chances are if they replaced that person, it wouldn't affect the rest of the people at the facility.

It really would boil down to individuals most likely would be named. If there was more than one person who was identified as connected with the violation it could extend to other people but not likely to everybody associated with the facility.

DR. FINDER: Okay. So show of hands yes for that one. Yes? No? I'll take that as a yes.

143 deals with appeals of adverse accreditation or reaccreditation decisions that

preclude certification or recertification. Should this section be rewritten to separate out appeals of adverse accreditation decisions from appeals of adverse certification decisions?

Again, we have a lot of confusion about accreditation certification. This is an attempt to try and clarify exactly what we're talking about when we're talking about it. A show of hands for yes. No? I'll take that as a yes. Okay.

On page 51, No. 144. Should we include a separate section dealing with causes for denials of certification? This would be kind of a listing of various reasons why we would deny certification. We have reasons in for suspension. We have reasons in for revocation. Should we have a separate section for denials of certification?

This would be a situation, for example, a facility was accredited. Went through the accreditation process, was given accreditation of some kind, or was applying for a provisional certificate and for various reasons we felt that there was a history with this facility that the problems had not

been corrected, problems with us that wouldn't necessarily be accreditation decisions.

Would we be in a situation such as that that we would deny the certificate? I'm trying to think of a case where that might happen. Could be a situation where, for example, the facility met all the quality standards but we were aware that they weren't issuing reports so that might not show up on your accreditation side of it but we were having problems with either the release of reports or storage of films or something like that.

Again, the facility was not able to correct those problems. In those types of situations we would want to deny the certificate even though they might have an accreditation approval. We would, again, put in a section here that would describe those types of situations. Yes, show of hands? No? No? Okay.

DR. FERGUSON: No, I wanted to comment.

DR. FINDER: Okay.

DR. FERGUSON: I know we want to move on but it almost seems to me the way you explained it

that, "We don't like you. We don't think the way you've been doing it. We're not going to give you a certificate. Doesn't matter what." Most of your judgment it seems to me would be based on a field inspector's report who may or may not get along with the people in that facility. Help me.

DR. FINDER: Well, I think the purpose of this would be, again, to establish under what scenarios or conditions we would deny a certificate. Right now there are no standards for that. I would say that before we take an action like this there's a lot of effort that goes into it, a lot of back and forth with the facility.

Facilities are given every chance to correct whatever problems are found. It's not the typical situation where the inspector goes in, finds a violation of some kind and we are going to deny certification on the basis of that. That is really not the type of situation we're talking about but, again, this would be clarified presumably in the wording here.

DR. FERGUSON: Will we have an opportunity

to see the wording before this goes further?

DR. FINDER: Right. Again, the plan for all this is to take your comments here, develop a detailed draft amendment to the regulations, and then we would publish it for comment. The hope would be that we would have another meeting during that open public comment period so we will be getting all your comments in at that point about this.

This is just, again, an idea of should we be changing certain areas and what direction should we be going. As has been pointed out many, many times, the details are extremely important because a word change here and there can mean a lot.

Once the draft is made available and after public comment, there is going to be a lot of going back and forth on some of these issues. That is important. Let's try again on this one. Yes? No? Looks like a yes.

145, alternatives standards. As I mentioned earlier in the beginning of the day, which seems like many years ago, as currently written we can approve alternative standards for Section 900.12 which

are the facility quality standards.

Should we extend this to include alternatives to the accreditation body and state certification agency regulations which would be Sections 900.4 and 900.22? Show of hands yes?

DR. BYNG: Can you help clarify some of the implications of making that change then?

DR. FINDER: Yes. For example, we did have a case where an accreditation body requested a change in one of the requirements in their standards. They actually asked for an alternative standard for it.

We were not able to even evaluate whether that seemed reasonable or not because it wasn't in the section of 900.12. It was in Section 900.4 and, as I say, is currently written alternative standards can only be applied to the 900.12 section, facility standards.

The question is should we have the same flexibility we have for facilities with the accreditation bodies and certification agencies? If they come across something that they feel is important

or can be done easier or better, should we have the ability to evaluate that and approve an alternative in that situation?

DR. BYNG: But you are specifically looking at 900.4 and 900.22?

DR. FINDER: Right, because right now the only thing that has an alternative standard to it is 900.12 which is the use section on facility standards.

DR. BYNG: So help me with what 900.4 is.

DR. FINDER: It's the accreditation body standards and 900.22 is the certification standards.

DR. BYNG: Okay.

DR. FINDER: State certification. Okay. Knowing that as background should we try and move ahead with that? Yes? No? Looks like a yes.

Okay. The next is on page 53, No. 146. This also deals with approved alternative standards and it basically states where we will put an approved alternative standard. It talks about the dockets management branch in the Federal Register.

With the increasing use of the internet and the fact that we put almost everything else up on

our webpage, the question here is should we try and change this to instead of putting it in those areas put them up on the web instead.

Again, I'm not sure we can actually do this legally. I'm going to have to talk with the lawyers but, again, I want to get the sense from the committee of would they think that placing it on the web is sufficient to make these notices available. Again, all the alternative standards end up on our website anyhow right now. They are included as part of the policy guidance help system.

MS. SEGELKEN: Is this instead of or in addition to?

DR. FINDER: What we are looking for right now is instead of.

MS. VOLPE: I think it would be fine just to do it in addition to.

DR. FINDER: That is pretty much what we are doing right now. The question is is that necessary. I don't know if that many people would actually get the Federal Register delivered home delivery. Again, we are just trying to get a sense

from the committee should we do that or not. Show of hands should we just say the web? Okay. Or not? No, we should include it in the Federal Register. Okay. Kind of split.

DR. SANDRIK: Just offer a comment there. I think you have this troublesome aspect of looking at today's technology and putting that into a regulation I don't think is a particularly good idea in general. I mean, if you wanted to say expand through publicly accessible communications means or something along that line I think makes more sense than identifying the web.

In fact, something more publicly accessible than the Federal Register can also be helpful but pinning on today's technology I don't think is a good idea to put in the regulation.

DR. FINDER: Okay. That's a good point.

Next one is should we modify the regulation to say should the basis for the approval rather than the application itself be made available to the public? Sometimes there's material written in the application that is of a confidential nature so we

are wondering if we can modify this just to say the basis for the approval. Yes? No? Take that as a yes.

DR. TIMINS: What kinds of things would be confidential?

DR. FINDER: For example, let's say a manufacturer was putting in a request for an alternative standard. They may be submitting information to us that was obtained on their units in a certain way under certain conditions that they might not necessarily want to be spread out on the web but they might not care about the Federal Register. I'm just kidding.

DR. SANDRIK: Yes, I would agree. I think when you read the requirements for the alternative standards several times, FDA is asking for data to support the standard and several that we have written does provide some data that we feel is proprietary data for our equipment that we don't want necessarily to be made public.

We agree that the data should be provided to support the argument so we would appreciate

maintaining that confidentiality of data that we identify as commercially proprietary.

DR. FINDER: Show of hands for yes? No? Okay. I'll take that as a yes.

We finished that section. Anybody have any additional comments they want to include on that? Okay.

DR. HENDRICKS: What do you propose in terms of the schedule?

DR. FINDER: I suggest we take a five-minute break so we can discuss what we should do with the rest of the schedule.

DR. HENDRICKS: Agreed. We'll take a break then.

(Whereupon, at 4:59 p.m. the above-entitled matter went off the record and resumed at 5:10 p.m.)

DR. HENDRICKS: After some discussion we've decided to adjourn for this evening and then reconvene tomorrow morning at 8:00.

(Whereupon, at 5:10 p.m. the meeting was adjourned.)