1 the complaint has been lodged. The consumer should be
2 told how to go about doing that.
3 DR. FINDER: Okay.
4 DR. HENDRICKS: Any other comments from
5 panel members before we move into the next section for
6 discussion?
7 DR. FINDER: Okay. The next section we're
8 going to be talking about is basically the facility
9 quality standards. They are 900.12, Sections a, c, f,
10 g, h, i, and j. They are covered under pages 25
11 through 31, 34 through 38, and 46 through 47.
12 The footnotes that we would looking at are
13 54 to 73, 84 to 98, and 129 to 135. As soon as we get
14 up there -- yeah, there they are. Okay. The first
15 section that we're talking about, 900.12(a), deals
16 with personnel requirements.
17 The first question we have is should a
18 statement be added that facilities are responsible for
19 verifying that all personnel meet all applicable
20 requirements prior to allowing someone to provide
21 mammography services?
22 DR. SANDRIK: The question there is what

1 is your intent here and what do you mean by verifying?
2 Are you looking for some level of surveillance, a
3 greater level than is currently used now, an
4 enforcement requirement added to the facility of
5 checking out people's credentials, that sort of thing?
6 And, I guess, also has it been an issue of people
7 being part of a mammography facility who aren't
8 properly qualified.
9 DR. FINDER: The answer to your last
10 question is while it's infrequent, it has occurred
11 where personnel at the time of the inspection were
12 found not to have documented their initial
13 qualifications at the time they started working there.
14 In other words, there were a few facilities that
15 allowed personnel to begin practicing mammography
16 without ever documenting that they met the
17 requirements.
18 Obviously the issue comes up with the fact
19 that by the time we get to the facility it may be as
20 much as a year before the inspector can look at those
21 personnel requirements. The issue is should the
22 facility bear some responsibility, specifically in the

1 regulations, because ultimately they do get cited for
2 this. They are held responsible. It is a question of
3 whether we put this into the regulations telling them,
4 by the way, this is their responsibility specifically
5 in the regulations.
6 DR. SANDRIK: Just to follow-up a bit on
7 that, I mean, I think it has been reported at some of
8 the previous meetings that a lot of those
9 documentation problems have been mainly a matter of
10 not providing the documentation and not necessarily
11 that the person is not qualified. Is that largely
12 what you're talking about?
13 DR. FINDER: Well, some of that is true.
14 Certainly medical licensure. People have been cited
15 for that because a facility didn't bother to get the
16 license or didn't have a current one. Those have not
17 turned out to be real in most cases.
18 In fact, in all that I can think of, but
19 there are other issues of documentation, some of the
20 other initial requirements where there was no
21 documentation submitted at the time that the person
22 started there.

1 The facility allowed them to work and it
2 wasn't until the inspector came in and said, "Where is
3 this documentation?" Then people start scrambling
4 around to get it. In some of those cases it turns out
5 that those people did not meet those initial
6 qualifications.
7 DR. MONTICCIOLO: How would it differ from
8 what occurs now if we make this change? Right now the
9 facilities are cited so they end up responsible
10 anyway, don't they? I don't understand how it will
11 affect them.
12 DR. FINDER: I think what it basically
13 will help us do is provide us with a mechanism to say,
14 "Yes, it is your responsibility to do this so we don't
15 have the problems when the inspector comes in."
16 As the regulations are currently written,
17 everything is measured off when that inspection
18 occurs. True, the facility is cited for these things
19 at that time. However, a lot of them don't understand
20 the fact that they are responsible, they should be
21 responsible for ensuring that their personnel meet the
22 requirements before they let them practice.

1 It is both a mechanism to inform them and
2 also to try and reinforce that it's not just the
3 inspector who is there to check these things. They
4 are supposed to be checking them, too. At least that
5 is our belief, or my belief I should say.
6 DR. TIMINS: From time to time one comes
7 across a situation where a technologist's license has
8 expired and the technologist forgot to renew or
9 renewal was lost in the mail. This is almost an apple
10 pie and motherhood kind of statement. To me it is
11 kind of obvious that the facility should be
12 responsible for verifying documents.
13 DR. FERGUSON: I agree the facility should
14 be responsible. Is there a way for the FDA or
15 accrediting body or someone to say this technologist
16 or this radiologist is a certified reader and here is
17 a number. And again, I read for multiple facilities so
18 it is a matter of getting paper to them every time you
19 get an inspector. "Here is my number. I'm
20 qualified."
21 DR. FINDER: That is an issue that
22 continually comes up about shouldn't we, the FDA, be

1 keeping personnel databases on all these personnel and
2 certifying whether they meet the qualifications or
3 not. There are a number of problems with that. How
4 do we get the information sent to us? How do we
5 distribute that to the parties?
6 It's not only the inspectors that need it.
7 It would be the facilities. We have looked at this
8 issue many times. Our general belief is that the best
9 way to do this is to place the onus on the legally
10 responsible entity which is the facility to have these
11 records available to show that all their personnel do
12 meet these qualifications. At this point we haven't
13 been able to come up with a better system to verify
14 that.
15 DR. FERGUSON: I would go back to our
16 discussion last year about the guy in the field. It
17 would be simple and I would rather the onus be on one
18 central party than ever how many facilities we've got
19 in the state or country to say, "Here is a website.
20 Here is a secure way for you to access it and see the
21 credentials of the people at this facility."
22 Let the field guy print it out before he

1 ever goes where he's not spending a lot of time
2 looking through documents and seeing if they are all
3 there and then he can spend more time looking at
4 things that are really important that haven't given us
5 a problem.
6 DR. FINDER: Right. I would add a couple
7 of things. One is that currently these inspectors do
8 not review initial qualifications that don't expire.
9 We'll get into some of those issues in a minute.
10 Those come downloaded to the inspector already so they
11 are not looking at that. Basically they are looking
12 at the continuing requirements.
13 Some of the questions in the continuing
14 requirement section are designed to lessen the
15 problems that we've been talking about when we get to
16 those and that may help reduce the problem but it
17 won't eliminate it.
18 We don't have a system at this point, nor
19 do we think at this point that it is the way to go to
20 develop a national database, personnel database, on
21 everybody who is performing mammography and keep the
22 records for all these people. There are a number of

1 problems associated with that.
2 Dr. Barr wants to say a few things.
3 DR. BARR: Helen Barr, FDA. One thing you
4 have to keep in mind, and I think we've talked about
5 this before during meetings but if we haven't, when
6 the Government keeps information on individual people
7 it falls into a whole different realm that is covered
8 by the privacy act.
9 Currently our database system is not
10 covered under the privacy act. That would require
11 substantially more funds and people to establish a
12 privacy act system. Also when the Government keeps
13 information, there is all the issues of
14 discoverability of that information.
15 While in theory it would be nice to have
16 one central location, you might not want the
17 Government to be it and certainly at this point in
18 time we would not be capable of being that entity.
19 DR. FINDER: Okay.
20 DR. BYNG: An additional clarification,
21 Dr. Finder. With all those questions I wasn't sure
22 whether there was another question that deals with

1 maintaining the requirements because this is an
2 initial qualification and allowing the requirements so
3 by extension will this ultimately cover the facility's
4 responsibility associated with maintaining the
5 requirements?
6 DR. FINDER: Yes. Okay. So let's go back
7 to 54. Do we have a show of hands for yes or no?
8 Yes, we should? No? Okay. It's basically a yes.
9 No. 55. Should the format for all three
10 personnel categories be standardized? Yes? No?
11 Okay.
12 DR. TIMINS: I would just like to say
13 whereas it is reasonable to do that, I don't think
14 it's mandatory.
15 DR. FINDER: Okay. I'll take that as a
16 yes, though. No. 56 is how should we deal with the
17 fact that newly issued board certificates -- and right
18 now we're talking about for physicians -- expire?
19 Yes.
20 DR. TIMINS: I think that when somebody
21 meets the initial qualifications that they are
22 qualified, I am not in favor of requiring board

1 recertification to qualify as a mammography
2 interpreter.
3 DR. MONTICCIOLO: I agree with that. That
4 is something we addressed last time and currently we
5 allow people to either be board certified or meet
6 educational requirements so it would seem a backward
7 step to say you have to recertify when people can
8 recertify without being certified initially. I think
9 that if you pass your initial boards, that should be
10 enough.
11 DR. FINDER: Okay. Let's see a show of
12 hands about whether there is agreement with that
13 concept about allowing board certification to be
14 considered -- about board certification for physicians
15 to be a permanent initial requirement. Yes? No?
16 DR. FERGUSON: You're talking -- you
17 didn't state it the way they said it, I don't believe.
18 You said a board certification is an initial
19 requirement and we're talking about certificates that
20 are being reissued are good forever.
21 DR. FINDER: Right. What I'm trying to
22 say is once you've been issued a board certificate,

1 that would be good for life whether it expires or not.
2 DR. FERGUSON: But you still have the
3 other ability to have the educational requirements.
4 DR. FINDER: Oh, sure. This is just one
5 aspect of it. Yes? No? I'll take that as a yes.
6 Okay. Next one is No. 57. In the three months of
7 training that deals with mammography, we say that some
8 of it has to be in radiation physics and the
9 subspecial areas in there. Should we limit the amount
10 of the physics that can be included in that three
11 months?
12 I will say that under guidance since the
13 program has started, we have put a limit on that of 90
14 hours, that no more than 90 hours of the three months
15 could be specifically in physics. This is just a
16 question of whether we incorporate that into
17 regulation here but that has been a policy that has
18 been around for a long time.
19 DR. TIMINS: By no more than 90 hours,
20 what you are actually saying is the rest of the hours
21 should be spent on other training.
22 DR. FINDER: In mammography. In other

1 words, we wouldn't allow all three months.
2 DR. TIMINS: I mean, you're just defining
3 it the wrong way.
4 DR. FINDER: Oh, okay.
5 DR. TIMINS: It's not there should be a
6 limit on the amount of physics. It's that there
7 should be a minimum on the amount of other training.
8 DR. FINDER: Okay.
9 DR. TIMINS: One could never have enough
10 physics. The physicists know that.
11 DR. FINDER: I think the concept here is
12 we didn't want somebody to come in with three months
13 of physics training and claim that they met the three-
14 month requirement.
15 Yes.
16 DR. MONTICCIOLO: Just as a side, I can't
17 imagine anybody having to much physics. Just so that
18 other people know that are not familiar with residency
19 training, I wish we could get a couple of hours of
20 physics and mammography. It's usually the physics and
21 mammography training in residency programs is very
22 minimal so I don't know if this is -- it's probably a

1 good thing to say they can't have it all be physics
2 but I can't imagine they would have what I would
3 consider an acceptable amount.
4 DR. TIMINS: Clean it up. It's not stated
5 the right way.
6 DR. FINDER: Okay. Show of hands. Do we
7 agree with the concept if not the wording? Yes?
8 MS. SEGELKEN: If you say that there is no
9 more than three months, is there a minimum? In other
10 words, does there have to be at least a month or
11 whatever it would be?
12 DR. FINDER: What we're talking about here
13 is three months of mammography training. Your
14 predecessors on the previous committee when we wrote
15 this wanted to have included as part of that three
16 months some physics training. The problem is there
17 was no specification of either a minimum amount or a
18 maximum amount.
19 We have encountered situations in the past
20 where people were short on being able to document
21 mammography training and they were trying to make up
22 the difference in large amounts of physics training

1 that they might have had. In order to avoid that we
2 through guidance said that we would accept up to 90
3 hours but no more.
4 If they had more than 90 hours, that's
5 great. We love for people to have more education but
6 they couldn't then use that to say, "Well, I don't
7 have to have more mammography training." That is the
8 idea behind this just to put it into regulation. I
9 would go with a yes on that.
10 No. 58. We've had this question come up
11 where somebody has had fellowship training in
12 mammography or breast imaging. The question comes up
13 occasionally, "Well, should we accept that as part of
14 the three months?"
15 Of course, we say yes but, here again,
16 it's an issue of trying to clarify in the regulation
17 that fellowship training and mammography would be
18 acceptable toward meeting the three months of
19 training. Yes on that? Any nos? Okay. We'll take
20 that as a yes.
21 MS. VOLPE: Charlie, I have a question.
22 The last line, line 37, on that page mentions a three-

1 year time period. I was wondering if that should be
2 decreased so that the training is more recent prior to
3 the qualifications.
4 DR. FINDER: Anybody else have any
5 comments about changing that?
6 DR. MONTICCIOLO: Let me understand. You
7 are thinking that this is an initial qualification so
8 the training of residents?
9 MS. VOLPE: Yes.
10 DR. MONTICCIOLO: The reason I think for
11 the three years is most of the residency requirements
12 are three months training in mammography and I prefer
13 it so that they come once in the second year, once in
14 the third year, once in the fourth year so they are
15 continually exposed to mammography over three years.
16 it all at the end, they won't give a wit about it and
17 they will run through it while they are trying to
18 study for the boards. I hate to interject that piece
19 of reality but when they are studying for the boards,
20 they need to kind of be up on almost everything by
21 that time and the mammography will get short-shrift if
22 we do it that way, I think.

1 pushing to spread the mammography training out so they
2 are continually exposed to it. I think that is the
3 meaning of that three years. I think that's where it
4 comes from.
5 DR. FINDER: Okay. On the next page, No.
6 59. This deals with continuing education and
7 experience requirements and the question is: Should
8 the continuing requirement be measured from a set date
9 rather than from the date of the inspection? This was
10 an issue that has been brought up several times at
11 various committees in the past. Let's just take a
12 show of hands first. The agreement on that, yes? Let
13 me see a show of hands. No? Does somebody have some
14 comments?
15 DR. MONTICCIOLO: I just wanted to come
16 out strongly in favor of this because, as those of you
17 know that have like 15 physicians at your facility and
18 they all have different dates when they qualify and
19 did all these different -- they don't know when the
20 inspection is and they can't -- it would just be so
21 much easier if we just said, "In the calendar year you
22 need this many credits," and everybody could

1 understand that. Right now that is a terrible point
2 of confusion during an inspection.
3 DR. FINDER: I have a couple of issues or
4 questions. Does everybody like December 31st? April
5 1st?
6 DR. FERGUSON: My hours are in November
7 but I think the first of the year is a good time for
8 everybody to remember.
9 DR. FINDER: Now, I do want to raise some
10 issues and we can discuss it now or in another
11 section. The reason that we do it right now from the
12 date of the inspection is because that is when the
13 inspector is there. That is when the citation can be
14 done.
15 You have to understand that if this does
16 occur, if we make this change, then facilities will be
17 cited if on that date they are not able to document
18 that the person met the continuing requirement,
19 irrespective of the fact that they may have in the
20 meantime by the time the inspector gets there have met
21 that requirement.
22 By the time the inspector shows up and now

1 they are able to show that they have met the
2 requirement, for example, that they've got 15 CMEs,
3 it's now March, they have their 15 CMEs, but December
4 31st they did not have their 15 CMEs, they are going
5 to get cited.
6 Yes.
7 DR. TIMINS: So many radiologists and
8 technologists have problems with this, but more the
9 radiologists because they are reading from multiple
10 facilities. This is a big concern. Once we put in a
11 grace period for coming up-to-date on the CME like 30
12 days or whatever it turns out to be, then I think
13 there will be very little problem meeting this
14 requirement. The initial phase-in may be a little
15 problematic but that will be over within three years.
16 DR. FINDER: Okay. So, again, we
17 basically have a yes vote on that one. Okay. No. 60.
18 Should mammographic modality specific CME be deleted?
19 This is again a question that has been dealt with in
20 previous meetings. Show of hands for yes?
21 DR. BYNG: What was the outcome from the
22 previous meeting?

1 DR. FINDER: Yes. There was a
2 recommendation that this requirement be deleted.
3 DR. BYNG: So what would the alternative
4 be then?
5 DR. FINDER: The alternative basically is
6 that the rest of the requirement stays in place.
7 Personnel are required to have 15 CME of mammography
8 but we would no longer be requiring if this change
9 went into place that six of those 15 be in each
10 specific modality that was being used by that
11 physician.
12 DR. BYNG: So just for clarification there
13 could be a situation where you have a radiologist that
14 would read ultrasound that didn't have modality
15 specific?
16 DR. FINDER: This is mammographic modality
17 specific so we're not talking about other modalities
18 that are not covered under the statute. All we're
19 talking about here are the different mammographic
20 modalities of which we are basically talking about
21 screen film or FFDM. Those are the two, full-field
22 digital.

1 DR. BARR: So this is just continuing.
2 DR. FINDER: Yes, this is just a
3 continuing requirement.
4 DR. BARR: You would still have to have
5 the initial training in that modality.
6 DR. FINDER: Right. As Dr. Barr said,
7 this is a continuing requirement. There is another
8 requirement for initial training of eight hours in
9 each mammographic modality prior to use. That is not
10 being touched in this. That is not being changed.
11 This is a question of for the continuing requirements
12 do you have to have CME in each mammographic modality
13 used.
14 DR. MONTICCIOLO: If I could just make a
15 comment because it might be addressing a concern that
16 I think you are raising, Jeff. This says we still
17 have to have our mammo CMEs but they are not going to
18 restrict this, you have so many of this, this, and
19 this.
20 I think this is important for physicians
21 because we have physicians who are very, very good at
22 film screen and ultrasound but they say they just want

1 more on stereotactic or something. The way it's
2 written now it limits them because they have to still
3 get this much ultrasound. Instead they could go to a
4 digital conference and get a whole bunch of digital
5 credits.
6 Maybe they want to get themselves more
7 acquainted with that and want more CMEs in one area
8 than another and this gives the physician more
9 flexibility to meet their own educational requirement.
10 That's how I see it. I would be in favor of deleting
11 that and just say get -- I still want them to get the
12 mammo education but get the mammo education that they
13 need.
14 DR. TIMINS: This was also a
15 recommendation of the Institute of Medicine Report
16 where they suggested deleting the modality specific
17 CME requirement so that other educational requirements
18 could be pursued such as development of interpretive
19 skills.
20 DR. FINDER: If we could just have again a
21 quick show of hands for deleting this. And no? Okay.
22 That would be a yes for that.

1 Next one on the next page. This is for
2 reestablishing qualifications. This addresses one of
3 the issues that was brought up earlier. Should -- and
4 we are putting in quotes here -- before resuming
5 independent interpretation that mammograms be deleted
6 and replaced with a grace period.
7 In other words, if you fail to meet one of
8 these continuing requirements, should we institute a
9 grace period to allow you to continue to practice
10 while you make up for whatever it is, either the
11 continuing experience or continuing education deficit.
12 Yes? No? Okay. So it's a yes basically.
13 Should we include a statement about
14 requalification for a lapsed state license in here?
15 Yes? No?
16 DR. TIMINS: What would the statement be?
17 DR. FINDER: Basically as envisioned it
18 would be a statement that you have to get your
19 license. That is what it would basically say. It is
20 very similar to the fact that how we address some of
21 these other requirements. Basically you have to meet
22 the requirement. The initial requirement is that you

1 be licensed by a state to practice medicine. The
2 requalification would be to do exactly that.
3 DR. FERGUSON: I would say in our state we
4 did have a problem with statements from the State
5 Medical Board going out to licensees. There were a
6 number of people who were tardy in paying their state
7 license and, therefore, didn't have a current license
8 for two or three months. I just want to make sure you
9 didn't have to go through the whole ball of wax again
10 on a technical aspect. If you lose your license, we
11 need to nix you.
12 DR. FINDER: Actually, the situation you
13 have described has occurred several times in various
14 jurisdictions in the local area. In those cases what
15 we have basically done is we recognize the fact that
16 people can't get licenses because the licensing board
17 hasn't issued them.
18 They've been late. We have not cited
19 those people. We are talking about a situation where
20 somebody has let their license lapse for some reason.
21 It is not an additional requirement from our
22 standpoint.

1 They would have to meet whatever the state
2 requires for them to get their license back. Once
3 they have it and can show they have a valid license,
4 all they have to do is show that documentation to the
5 facility and the inspector and that's all it would be.
6 DR. TIMINS: I wonder if this isn't
7 already being handled adequately by the states.
8 DR. FINDER: Again, this is more just a
9 clarification in the regulations for us to deal with
10 this. We have in here what you need to do to
11 requalify for all these other issues, all these other
12 continuing requirements, except this one which is a
13 continuing requirement because we do enforce that you
14 not only have to have a license to practice medicine
15 but it has to be a valid one. This is one of the ones
16 that we're not treating as an initial requirement.
17 When we go back to the other section we
18 want to clarify which ones are true initial
19 requirements that persist forever versus ones that
20 continue on and have to be renewed and this is one of
21 them. We are trying to clean up the regs to be
22 consistent about this type of thing.

1 DR. HENDRICKS: Public comment?
2 MS. WILCOX: Pam Wilcox, ACR. I would
3 just like to put a little caution on this. While I
4 think it's important for the regs to be clear, I'm a
5 little concerned because you said there have been
6 multiple jurisdictions where there had been a problem
7 with the State Licensing Board not issuing the
8 licenses in a timely fashion.
9 If this becomes a reg that doesn't give
10 that exception, the inspectors may be citing people
11 when it's not -- you have a good process now to handle
12 it so I just would caution.
13 DR. FINDER: Let me address that. What
14 we're talking about here is a requalification
15 regulation. The initial requirement is that you must
16 be licensed, have a medical license. We are not even
17 talking about that. Again, we handle those situations
18 as they come up but that is not the regulation we're
19 talking about modifying anyhow.
20 DR. FERGUSON: I'm getting more concerned
21 about it, to be honest with you. Of course, if the
22 doctor doesn't have a license to practice in the

1 state, they are going to be -- you know, he's not
2 going to practice medicine in that state, mammography
3 or otherwise.
4 I think we might be setting up a situation
5 where somebody on a technicality could be cited and I
6 would think this would be a major violation if you
7 have an interpreting physician that didn't have a
8 license. You could go down a path that really is not
9 necessary.
10 DR. FINDER: Let me try and clarify. We
11 are talking about right now a requalification
12 requirement adding one. The one that you're talking
13 about actually is two pages prior to this. It
14 basically says you must be licensed to practice
15 medicine in a state. We are not talking about
16 modifying that at this point.
17 The cases that we're talking about, as
18 I've said, in those situations where we know that the
19 state hasn't issued licenses for some reason we have
20 dealt with that and not cited the facilities. That
21 regulation hasn't changed. It still says you must be
22 licensed but we realize what is going on.

1 This is a situation where we are talking
2 about somebody who either has allowed their license to
3 lapse and they have to requalify, whatever the state
4 requalification is. This is not a new requirement,
5 additional requirement set down by FDA. It would just
6 be you must go get your license fixed. You know,
7 requalified, show it to us and then you're fine.
8 If you have an issue with the fact that we
9 require that you be licensed to practice medicine in a
10 state and put some qualifiers on that to say only if
11 the state is actually is issuing the licenses at the
12 time, we can look at that wording but I will tell you
13 that has not been a problem in the 12 years we have
14 been in the program.
15 DR. MONTICCIOLO: I think the issue is
16 that what if the state is delinquent in issuing
17 licenses for people who are renewing them or, as you
18 said, people are -- maybe they have missed the piece
19 of paper that comes to send their money in and
20 something happens like that. How do you get around
21 that with the inspector because the inspector will
22 feel they have to cite you for that.

1 DR. FINDER: If it's a fact that you do
2 not have a valid license at the time of the inspection
3 or, in this case, it would probably be the date of
4 December 31st or January 1st or whatever, if you don't
5 have a valid license, they can't cite you based on
6 that.
7 Now we have told them when it's a
8 situation that the state is at fault for not issuing
9 licenses, let's say, to everybody from A to K or
10 something like that, don't cite. But if it's a fact
11 that somebody has forgotten to send in their
12 application or anything like that, then it's a valid
13 citation. It's a valid citation.
14 Now, this has occurred occasionally and I
15 will tell you that none of these, as far as I am aware
16 of, have ever turned out to be real. Most of the time
17 it's the fact that they even have a valid license.
18 They just don't have the documentation at the time of
19 the inspection.
20 They just don't have it there. So we are
21 talking about a minor thing and our thought about this
22 was just to kind of clarify things and, again,

1 standardize the situation here. We're not trying to
2 create new requirements. If that needs further
3 clarification, we can look at it.
4 DR. FERGUSON: But right now you would say
5 we have not had a problem with this?
6 DR. FINDER: Correct. Okay. Let's take a
7 look again for the show of hands. Yes, should we
8 included it? No? Okay.
9 Next is No. 63. How should we be handling
10 renewing of certification? That is a repeat of the
11 question that we asked before except that this one
12 deals with the technologist instead of the physician.
13 DR. TIMINS: My understanding, and I could
14 be wrong, do all states require licensure for artiste?
15 DR. FINDER: No.
16 DR. TIMINS: Then how does one deal with
17 certification for mammography in a state that doesn't
18 license artiste?
19 DR. FINDER: We are talking about a
20 different thing here. This requirement is actually a
21 two-fold one. The page before it talks about be
22 licensed to perform radiographic procedures in a

1 state, or have general certification.
2 The general certification we're talking
3 about is from the AART. It's not given by the state.
4 The difference is when the program started the
5 radiologist board certificates were issued for life.
6 They do not renew. For the technologists those
7 certificates have always been renewing. They have to
8 renew those every few years.
9 My question basically here is if we are
10 changing the status of the board certificate to say
11 their certificates renew but we are going to accept
12 them as an initial requirement that never has to be
13 renewed again or up-to-date, should we handle the
14 technologist differently because we have in the past?
15 We have been requiring that they submit a valid up-
16 to-date certificate for this.
17 DR. MONTICCIOLO: I have a question about
18 that. What does it require to renew that certificate?
19 Is it simply like our license renewal where it is
20 just financial or are they retested?
21 MS. MOUNT: To renew you send in a few but
22 you also have to prove so many credits for

1 mammography.

2 DR. MONTICCIOLO: That's a bit different
3 than having to be reboarded, I think, with the
4 positions we were talking about being reboard
5 certified but this is just renewal.

6 MS. MOUNT: And I would highly be in favor
7 of keeping it the way it is.

8 DR. FINDER: So unless there are more
9 comments, I guess the question that's here is do we
10 keep the general certification for technologist the
11 same or do we modify it? For the same, yes? Modify
12 it, no? Okay.

13 MS. VOLPE: I have a question. What about
14 the technologist who moves from one state to another?
15 Does the certification travel with her or him?

16 DR. FINDER: Yes, the certification is not
17 state bound. State licensure is issued by each
18 individual -- well, not all the states issue licensure
19 but we would accept a license from any state actually,
20 but the state itself might not and that is, again, one
21 of those issues where you could be compliant with MQSA
22 requirements, and yet be in trouble with the state

1 where they would have a problem with you being
2 licensed out of state and not having one of their own
3 licenses. There are some states that require that you
4 be licensed within their state with their state
5 licensure.
6 DR. MONTICCIOLO: An RT moving from a
7 state that doesn't have the license but they have the
8 certification, they move to a state that has the
9 license requirement and they can't work until they get
10 the state license?
11 DR. FINDER: That would all depend on what
12 the state licensure requirements are within the state
13 but that is not an MQSA issue. That would be a state
14 issue. I'll give you an example that is more clear
15 cut, I think, medical license.
16 We would accept a valid medical license in
17 any state, but I can assure you that most states would
18 not accept a medical license from a different state
19 unless they have reciprocity or some agreement. You
20 could be totally compliant with MQSA and still end up
21 in big trouble with the state. That's the issue about
22 the more stringent requirements. One of the issues.

1 DR. BYNG: So just to clarify the previous
2 point, the discussion was to keep it the same as it is
3 now which is that certification must be current where
4 it's necessary.
5 DR. FINDER: Right. Okay. No. 64.
6 Should a minimum number of hours of training in each
7 of the areas specified in the requirement be given?
8 We are talking here about training in breast anatomy,
9 physiology, position and compression, quality
10 assurance, and one of the issues that was brought up a
11 few minutes ago, imaging patients with breast
12 implants. Let's start with a show of hands and then
13 we can have some comments. Should we include a
14 minimum number of hours, yes or no? Yes? No? Okay.
15 Let's have some comments.
16 DR. TIMINS: I sit on my state radiologic
17 technologist board of examiners. I think that it
18 would be burdensome and unnecessary for this language,
19 these specifications to be legislated. I think there
20 should be a certain amount of freedom in the
21 technologist training programs to deal with this.
22 DR. MONTICCIOLO: I have to agree with Dr.

1 Timins. I think we need to allow them flexibility to
2 train the technologists.
3 MS. MOUNT: I also agree. I know there
4 are a lot of training programs out there that
5 technologists are going to for their 40 hours and I
6 think they generally spread the training very
7 appropriately. I don't think it needs to be mandated.
8 DR. FINDER: Let's see another show of
9 hands. Yes, we include the minimum number of hours?
10 And no, we don't? Okay.
11 Should time spent be doing the 25 exams
12 count toward the 40 hours of training? If so, how
13 much? It's kind of a trick question. Through
14 guidance we have actually established what we thought
15 was reasonable here. We do allow the 25 exams
16 currently and about half hour per exam so it's 12.5
17 hours at maximum for those exams toward the 40.
18 DR. MONTICCIOLO: I would be interested in
19 what Carol has to say about it. My first impression
20 is that the 40 hours of education is 40 hours of
21 education and it should be just that and the exam
22 should be separate.

1 MS. MOUNT: Currently we usually use the
2 12.5 as part of the 40. A lot of the training
3 programs also will offer you a 40-hour training. If
4 you want hands on, that 40 hours is complete. If you
5 don't want hands on, they cut it off so that you get
6 your 12.5 at your facility doing the mammograms at
7 your facility. I think doing it that way is quite
8 appropriate. I do think it needs to be counted as a
9 training because it's one of the more important parts
10 of the training.
11 DR. FINDER: Right. Go ahead. I'm sorry.
12 DR. FERGUSON: I was going to say I think
13 that doing those examinations with supervision would
14 probably be the most valuable stuff they get in the
15 training. I think it ought to count.
16 DR. MONTICCIOLO: I wouldn't not do the
17 25. The question is should it take up part of that
18 educational requirement. If you feel they get it in
19 the other 37.5 -- okay, thanks, 27.5. So I can't
20 count. That's not part of the requirements, is it?
21 If you think that's enough for the technologist. I
22 would just be concerned they get enough classroom time

1 and other education to help them get started.
2 DR. TIMINS: I would also tend to support
3 whatever Ms. Mount specifies being a radiologic
4 technologist.
5 DR. FINDER: Okay. So let's see a show of
6 hands for allowing it to count for 12.5 hours. No? So
7 that's a yes.
8 Next is a similar question to what we had
9 for the interpreting physicians. It is for continuing
10 requirements for technologists. Again, what we would
11 be talking about here is should we establish a set
12 date for measuring back for these continuing
13 requirements. Show of hands for yes? No? That's a
14 yes.
15 The next one, No. 67 for requalification,
16 replacing may not resume performing unsupervised exams
17 with a grace period similar to what we discussed for
18 the interpreting physicians. Yes? No? Okay. That's
19 a yes.
20 Just as a matter of course, what kind of
21 time frame would you think as a grace period? 30
22 days? 60 days? 15 days?

1 DR. TIMINS: I have a question now. There
2 is a lot of physician education that is readily
3 available so it's very easy for a physician to get
4 educational credit in 30 days. Is the same true for
5 technologist education?
6 MS. MOUNT: I would say it's there but you
7 usually have to travel to it. There is not a lot
8 offered a lot of times locally. Our facility we are
9 lucky enough to offer it all in-house if we want. I
10 would say that in some of the rural communities it may
11 be difficult.
12 DR. TIMINS: So considering the potential
13 hardship maybe we should give 60 days instead of 30
14 days for the technologist?
15 DR. FINDER: Okay. So what I'm hearing is
16 60 days for the technologist, 30 days for the
17 interpreting physician, or should we do 60 for
18 everybody and make it even?
19 DR. MONTICCIOLO: Sixty for everybody.
20 MS. MOUNT: Sixty for everybody. I think
21 it should be uniform.
22 DR. FINDER: Sixty for everybody. Okay.

1 We'll see what we come up with on the physicist. Five
2 days for the physicist, right? Okay.
3 No. 68. Again, this is just again because
4 we have differences in the way the regulations are
5 laid out. The first one was for continuing education.
6 This one is continuing experience. I assume we would
7 be talking about the same issue about allowing the
8 grace period 60 days, or is that too much? Sixty
9 days? Everybody agrees? Show of hands? Okay. Nos?
10 Okay.
11 Okay. No. 69 deals with requalification.
12 It talks about that if a technologist fails to meet
13 the 200 that is required for continuing experience
14 that they must perform 25 exams under direct
15 supervision.
16 There are two questions actually here.
17 Should we place a time limit on this? How much time
18 do you have to do those 25 exams under direct
19 supervision? We do place a requirement on the
20 physicians when they are doing their 240 of six
21 months.
22 We don't want them to stretch it out

1 forever and do two a day or two a month and do this.
2 It hasn't been a real big issue but, again, for
3 consistency should we place some kind of time limit on
4 these number of exams. Yes?
5 MS. VOLPE: I have a comment to make. You
6 can put a time limit on someone who is doing it in an
7 urban area that is much shorter than someone who is in
8 a rural area. Then you also have to consider someone
9 who may be working part-time.
10 DR. MONTICCIOLO: I was just going to say
11 that I would be interested in what Carol has to say
12 about the time limit. I think it would be hard,
13 though, to enforce different time limits for different
14 -- I think maybe we could come up with something that
15 is reasonable and in the middle.
16 MS. MOUNT: I think six months is generous
17 but then at a high-volume institution you don't need
18 six months but it probably is reasonable. I think we
19 should set it the same as we did the physicians.
20 DR. FINDER: Okay, six months to do 25
21 exams?
22 DR. MONTICCIOLO: That's not very many

1 exams per week. The physicians have more mammograms
2 to read so maybe we could shorten a little bit for the
3 technologist because I don't think they get enough
4 experience if they only did -- even if they did one a
5 day would be less than six months.
6 MS. MOUNT: Right. I would like to say a
7 week but I didn't know if that was going to be too
8 short everybody.
9 DR. BYNG: A clarification on this. This
10 says they didn't do their 224 months so they are going
11 to have to do 25 under supervision so it's not just
12 doing 25 exams. It's doing 25 under supervision.
13 DR. FINDER: Correct.
14 MS. MOUNT: And they can't do any without
15 supervision until they have been requalified?
16 DR. BYNG: So there's already motivation
17 for them to try to do that quicker.
18 DR. MONTICCIOLO: Yes, there is a
19 motivation but I think they probably do need a time
20 requirement. Three months would be reasonable. Don't
21 you think? Because anybody doing mammography should
22 be able to get that in three months.

1 MS. MOUNT: But if they didn't do 200 in
2 two years, maybe there aren't very many mammograms in
3 that area to do.
4 DR. FINDER: Okay. I do want to bring up
5 one point which I think we need to address. If we
6 grant a grace period, what are we talking about here?
7 The person has been cited. We've just told them now
8 they've got X number of months. We've given them a
9 grace period.
10 Presumably those mammograms would not be
11 done under direct supervision because that is the
12 requalification process right now is they go directly
13 under direct supervision. We are talking about giving
14 them a grace period. What happens to those mammograms
15 that they do during that grace period? Wouldn't they
16 count toward these 25 and aren't we changing the
17 requirement here?
18 DR. MONTICCIOLO: I think I misunderstood
19 you then. I understood this to mean that if somebody
20 failed to meet it, they have to do 25 under
21 supervision and the question was only what's the time
22 limit for that. I thought we were trying to limit it.

1 DR. FINDER: That is correct in the small
2 narrow sense, but I'm now bringing us back to the
3 issue of the grace period that we talked about a few
4 minutes ago.
5 DR. BYNG: But the grace period was for
6 CME.
7 DR. FINDER: And for the continuing
8 experience requirement. Both of them we were talking
9 about the grace period. What does it mean to have a
10 grace period in this type of situation and how does
11 that deal with this requalification requirement?
12 DR. MONTICCIOLO: So I guess you're asking
13 that if we give them a grace period they can maybe get
14 up to their 200 in that time and then it counts?
15 DR. FINDER: I'm asking you what does it
16 mean to give a grace period.
17 MS. MOUNT: I agree. I wouldn't tell my
18 techs there's a grace period.
19 DR. FINDER: That's the problem with
20 writing a regulation. Everybody knows about it. What
21 does it mean to have a grace period under these
22 circumstances?

1 DR. SANDRIK: I guess one thing that
2 bothered me about the grace period is that what it
3 says is that for some length of time the regulations
4 aren't necessary. The longer the grace period is, the
5 more unnecessary the regulation is until you get to
6 the point saying why do you have the regulation in the
7 first place if you will allow practice without meeting
8 the requirements.
9 DR. FINDER: These are some of the exact
10 same discussions we had when the regs were originally
11 written. That argument was brought up exactly. It
12 also demonstrates how difficult it can be to write
13 regulations. You want to do something that sounds
14 reasonable and then it starts to impinge on another
15 area so let's kind of think what happens here and do
16 we want to revisit some of those grace periods that we
17 just said we think are so good.
18 MS. MOUNT: I'd just like to comment. In
19 our facility if a technologist file is found to not be
20 up-to-date when the inspector comes, they leave and go
21 home without pay until it is up-to-date because we
22 have a regulation for it. I wouldn't allow mine to

1 have a grace period so I think it is very dangerous to
2 put that in there.
3 DR. TIMINS: When I first saw grace period
4 for the continuing experience requirement, I put down
5 a 30-day grace period. There are times when people go
6 on vacation and they take medical leave. You have
7 staff reorganizations.
8 We just went through a 20 percent staff
9 cut throughout the hospital including radiologic
10 technologist. Then people who used to do a limited
11 amount of something all of a sudden they are doing a
12 lot more of it.
13 I can see where there are circumstances
14 where a short grace period, 30 days, is plenty of time
15 to do however many mammograms you should need to catch
16 up because you have to do a certain quantity to be
17 proficient. I could see having a grace period but a
18 relatively short one.
19 DR. FINDER: Let me try and take you
20 through the scenario and maybe this will help think
21 about it. We come into a situation where -- let's go
22 with what we have right now, not with the December

1 31st date because that creates its own problems
2 dealing with the situation. Or maybe we should look
3 at that example.
4 Have a situation whereas of December 31st
5 a technologist had 150 exams done. The inspector
6 comes in six months later and checks that person and
7 finds that they failed that requirement as of December
8 31st. In the ensuing six months that person has been
9 doing mammograms and now has instead of 200 exams done
10 has 400 exams done so now they meet the requirement.
11 happens? Does that person have to requalify? Were
12 those mammograms that were done when they were out of
13 regulation still count? Do they have to go under
14 direct supervision at some point? These are the types
15 of questions that got us to the issue of setting the
16 evaluation date the date of the inspection because of
17 some of these things.
18 DR. MONTICCIOLO: Yes, I'm just starting
19 to comprehend that even more. As you said, if you do
20 it by date, which everyone is in favor of because it's
21 just easier, you have to deal with the fact that some
22 people like physicians, for example, they graduate

1 from residency in June so they usually start their
2 real job in July and that is going to force them if
3 they have to have everything by December 31st you have
4 to account for the person who started their practice
5 only half the year into it. Is that going to be the
6 first full year of practice? How is that going to
7 work?

8 DR. FINDER: Normally what we've done is
9 the requirement doesn't kick in for two years anyhow.
10 We have said that under the current regulations that
11 the date of the inspection two years past the date
12 that they first met their initial qualification so it
13 would be after that. In effect, they might have a
14 little bit more time to get that reading up.

15 Again, the time period under which you're
16 looking at that they have the 960 exams, let's say, is
17 still two years. It doesn't expand out to 27 months
18 or 28 months. It's still 24 months. This issue of
19 what do you do with a person who hasn't met the
20 qualifications as of a certain date in the past
21 brought us to the point of selecting the date of the
22 inspection.

1 DR. TIMINS: You have to keep in mind what
2 the purpose of the regulation is and the purpose of
3 the regulation is to protect the public. If you have
4 somebody who is a little short at one point and then
5 exceeds it another point, you're not harming the
6 public by allowing the accreditation organization to
7 make this decision.
8 I think the first thing is you're assuring
9 quality. If somebody exceeds the requirement more
10 recently, I think that certainly is an important
11 factor. I don't know. I had some other thoughts.
12 Basically you have to look at the overall scheme and
13 average it out. Also you could have a physician who
14 reads 800 mammograms one year.
15 If you exceed in the first -- take a four-
16 year stint and you exceed numbers the first year and
17 then you are lower on the second and third year and
18 then you're up again on the fourth year, you could say
19 years two and three you are under numbers. But if you
20 take years one and two together and years three and
21 four together, you're fine and you haven't harmed
22 anyone.

1 DR. FINDER: This is one of the problems
2 and one of the hard things to deal with anytime you
3 set a standard based on numbers. I mean, you try and
4 get a reasonable estimate. The discussions about
5 averaging obviously have been important and that is
6 one of the reasons that we don't do an annual
7 requirement.
8 We do a two-year requirement allowing
9 people to average numbers and to deal with sabbaticals
10 to deal with health problems so that at the time they
11 have enough time to make up for problems that may
12 occur during the two years.
13 However, once you set a requirement, once
14 you set a number, a date or whatever, once somebody
15 misses that, they are in violation. They haven't met
16 the standard. Now, the question here is if we set a
17 certain date and allow a grace period, what does that
18 mean and what does that do to the concept of
19 requalification?
20 DR. SANDRIK: A comment. I think maybe
21 rather than a grace period what you need is a
22 transition period because if people can meet their

1 requirements each time the inspection comes up, they
2 can probably shift from the inspection date to a fixed
3 date of December 31st.
4 Maybe it will take two or three years for
5 them to make that transition but if you made the rule
6 effective as of a certain time and then it switches to
7 the December 31st date, people will have the time to
8 transition from one to the other and try to get the
9 education or whatever at the appropriate time frame to
10 meet the new requirement.
11 DR. FINDER: Okay. I don't want to get
12 too far into the details of this but I'm beginning to
13 hear maybe something that we should look at the issue
14 of saying you can meet the requirement either on
15 December 31st or the date of the inspection. If you
16 do on either one of those, you are okay.
17 DR. FERGUSON: I like that and it also
18 protects the public. I mean, that is the bottom line
19 of what we are trying to do and I think that
20 accomplishes that.
21 DR. TIMINS: The wisdom of Solomon.
22 DR. FINDER: We'll think about it and then

1 I'm sure when we get back in the office we'll find all
2 the problems why that won't work either but it's
3 something to think about and we'll look at that as an
4 option.
5 DR. BYNG: Dr. Finder, the issue about the
6 qualification and the convenience of the December 31st
7 date was already discussed and the benefits of that
8 understood, but if we go back to the particular
9 scenario you described, you rolled into that scenario
10 the assumption of moving to December 31st.
11 The question was really about the grace
12 period. I think the gap that you identified is that
13 the inspection occurs after the infraction has already
14 taken place. How do you deal with that on moving
15 forward situation?
16 I was wondering about your scenario if you
17 take that part of the December 31st inspection date
18 out and just look at it, what do we really want to
19 achieve for the people who have fallen short of the
20 regulation as they move forward?
21 DR. FINDER: That's a good question.
22 Unfortunately it's different for different facilities.

1 If you've got a facility where you have multiple
2 people who can take up the slack, it is a different
3 situation than if you are dealing with a single small
4 facility in which the technologist or radiologist is
5 the only person there and you are basically shutting
6 down the facility.
7 I will tell you that when we were working
8 under the interim regs we did have a grace period in
9 there for these types of situations. Under the final
10 regs we got rid of it. I would say that both systems
11 "worked." Each one had it own problems. You allow a
12 grace period. People don't take you seriously and
13 they will go into grace period and get rid of their
14 problems at that time.
15 If you enforce the requirement strictly,
16 you'll have facilities shutting down. You'll have the
17 situation where, for example, an inspector goes in and
18 finds a person doesn't qualify a continuing
19 requirement.
20 We're not talking about initial now,
21 continuing requirement. Do they tell all the patients
22 in that waiting room to go home at that point? Do

1 they finish up the day? Do they do their scheduled
2 patients?
3 These are all issues that are being dealt
4 with and there is no simple answer. Welcome to my
5 world. You have joined this world because I will
6 write down who said that we should put this in here.
7 When they call me up and start yelling, I'll mention
8 names.
9 DR. FERGUSON: Then I want to say we need
10 a 30-day grace period.
11 DR. HENDRICKS: Dr. Finder, when the
12 citations are made at the time of the inspection,
13 isn't there a mechanism whereby there could be a
14 citation that existed and then was corrected or
15 rectified and that could be included in the
16 inspection? I understand there are some of these
17 citations which occur and then if there's a gap and
18 then the citation has been corrected couldn't that be
19 indicated in the inspection?
20 DR. FINDER: We actually have a policy to
21 deal with that. Certain citations that have been
22 identified during the inspection but have already been

1 corrected we have a term called corrected before
2 inspection and they don't get cited for that.
3 However, we're not talking about that
4 situation here. Here we are talking about a true
5 situation where the person doesn't meet the
6 requirement. They haven't corrected it before the
7 inspection so do we issue a grace period or not? I
8 think I've heard enough. Let's go on because, as I
9 said, we don't want to do wordsmithing here.
10 Next -- let's see. Oh, now we're talking
11 about the physicist on page 30, No. 71. Wait, did I
12 miss one? 70, I'm sorry. We're talking about medical
13 physicists. The question here is same comments as
14 physicians and technologists. I will leave it at
15 that. We will work on whatever we come up with there
16 and try and standardize it for the medical physicist.
17 Next page, No. 71. Should complete
18 mammography equipment evaluations be added here and to
19 other sections of the regulations? Okay. The way the
20 current regulation is written deals with the
21 continuing experience.
22 It talks about doing surveys of units and

1 facilities. However, there is another component, a
2 very important one, that the medical physicist does
3 which is a mammography equipment evaluation which is
4 where they do specific tests on the equipment usually
5 either when it's first gotten initially or if there
6 has been a major repair or problem with the unit.
7 What we are saying here is should we
8 include that as something that can be counted as the
9 equivalent of a survey of a mammography unit.
10 Basically they are fairly the same. In fact, in a lot
11 of ways there's more testing done on a mammography
12 equipment evaluation than on a unit survey. Let me
13 ask the question should we include that. Yes?
14 DR. BYNG: If you don't include that, have
15 you created a situation where they may not have
16 conducted such a survey?
17 DR. FINDER: No. This is again, a
18 personnel requirement has nothing to do with when the
19 equipment evaluations need to be done. It's just the
20 mechanism so that we would allow them to count it
21 toward the continuing requirement.
22 DR. SANDRIK: But I think on the other

1 side of it a mammography equipment evaluation can be
2 far less than what might be included in a survey as
3 well. I can see on initial installation it may be far
4 more but if there was a one component change, it may
5 be far less. Being able to account either one as a
6 full survey I don't think is reasonable.
7 DR. FINDER: I agree with you and well
8 understood. That is why we used the term complete
9 mammography.
10 DR. SANDRIK: Was that intended as a verb
11 or an adjective?
12 DR. FINDER: I didn't do that well in
13 English. This is one of the terms that needs to be
14 put in the definition section as to what it means but
15 we are basically -- I would be talking about an
16 initial mammography equipment evaluation because you
17 are totally correct.
18 If you are talking about a unit that has
19 had, let's say, a problem, a specific problem, and you
20 do a mammography equipment evaluation after that, you
21 would be focusing in on just those aspects and not
22 necessarily on the entire unit and that was what is

1 meant by the idea of a complete MEE.
2 DR. SANDRIK: By complete you mean a
3 broad-based one more like acceptance testing might
4 involve.
5 DR. FINDER: Correct. With that would we
6 see a show of hands for yes?
7 DR. BYNG: I still need to check on one
8 thing here. You are talking about the initial
9 qualifications?
10 DR. FINDER: I'm sorry. You're correct.
11 Yes.
12 DR. BYNG: So if you put that item in, how
13 do you envision changing the wording here because I
14 think the important thing is they need to complete an
15 entire survey at some point. If you add this I just
16 want to make sure that you are not creating a
17 situation where they haven't conducted a complete and
18 entire survey.
19 DR. FINDER: Again, we don't want to get
20 into wordsmithing but I believe that the idea of the
21 survey of at least one mammography facility would stay
22 the same. It would be the issue of the 10 units and

1 we could probably change that to surveys and/or
2 complete MEEs of 10 units. Okay. So I'll take that
3 as a yes.
4 Next page, No. 72. Should the limitations
5 on which type of medical physicist can provide direct
6 supervision for continuing experience be eliminated?
7 Under the initial requirements there are two pathways
8 to becoming a qualified medical physicist.
9 In this requirement only certain of those
10 physicists are allowed to perform the direct
11 supervision. What we are asking for is if we can
12 eliminate that stipulation and just say any qualified
13 medical physicist can provide that direct supervision.
14 DR. WILLIAMS: And what are the -- just
15 remind us what the two types are.
16 DR. FINDER: One is going through the
17 Bachelor approach and the other is going through a
18 Master or higher approach. At the time that these
19 regs were written it was felt that only those who had
20 been Masters or better were prepared or capable of
21 providing the direct supervision.
22 The question now is 12 years later, 10

1 years later are those people who have been doing the
2 surveys for all those numbers of years, are they now
3 qualified to provide direct supervision for other
4 people.
5 DR. SANDRIK: Yes, I think the idea is --
6 I mean, here you at least identified that certain
7 qualifications have to be met. You would still have
8 to maybe write other qualifications for these other
9 supervising physicists. I don't think it should be
10 left that any physicist could be a supervisory one by
11 removing meeting these qualifications. We would have
12 to identify some qualifications.
13 DR. FINDER: Right. I think we could just
14 change it to a qualified medical physicist providing
15 direct supervision. The same way we do for the
16 physicians and for the techs. Again, that is
17 wordsmithing but if we could have a show of hands on
18 that whether this should be changed. Yes? No? I'll
19 take that as a yes.
20 Should we include a requirement that
21 facilities must release personnel records to the
22 individual if requested. Show of hands for yes?

1 DR. TIMINS: I have a question. Isn't
2 this dealt with by state law?
3 DR. FINDER: All I can tell you is we
4 probably maybe once a year get a frantic call from
5 some technologist, interpreting physician, not usually
6 the physicist, where the facility is holding their
7 records hostage and will not release their own
8 personal records to them so that they can go to
9 another facility.
10 Yes, it is a problem. It is an issue and
11 they come to us because without those records, they
12 can't get a job in another facility, or it's
13 difficult. Usually it is a problem of the facility is
14 not willing to document their continuing experience at
15 the facility. Some issue has come up and they are no
16 longer on speaking terms so we would want to at least
17 clarify this in the regs.
18 DR. BYNG: But if you do clarify it, what
19 kind of enforcement can you have for that?
20 DR. FINDER: That's a very good question.
21 I will tell you, however, that sometimes a call for
22 the FDA saying, "You are not following this

1 requirement," and we can point to it in regulation and
2 show it to them, it's amazing how that works without
3 having to go and talk to them about, "We might suspend
4 your certificate or do other things to you." They
5 would only be personal records referable to MQSA.
6 Okay. Show of hands yes? No? Looks like a yes.
7 Okay.
8 Let's just make sure. Okay. The next
9 section we are going to be dealing with starts on page
10 34 through 38 and footnotes 84 through 98. Does
11 anybody think we should take a break? Can I vote?
12 DR. HENDRICKS: Yes, what's your vote?
13 We'll take a 15-minute break.
14 (Whereupon, at 2:35 p.m. the above-
15 entitled matter went off the record and resumed at
16 2:51 p.m.)
17 DR. HENDRICKS: We're going to begin the
18 afternoon session by asking members of the Committee
19 again if they have additional comments about the
20 topics that have been covered this afternoon related
21 to personnel issues. Okay. Barring none we'll get
22 started again with Dr. Finder.

1 DR. FINDER: At this point we are
2 basically talking about the requirements under
3 900.12(c). It should be on page 34 starting with
4 footnote No. 84. It doesn't seem to make sense,
5 though. It actually ends up as page 35 but, again,
6 it's the section dealing with medical records and
7 mammography reports.
8 No. 84 deals with the written report and
9 what information is required within the written
10 report. One of the questions here is should the
11 facility name and location be added to the mammography
12 report.
13 DR. TIMINS: I would like to speak in
14 favor of that. It greatly facilitates getting
15 previous records.
16 MS. MOUNT: I have a question. Is that in
17 addition to what is like flashed on the films? You're
18 talking actually dictated in the report?
19 DR. FINDER: Yes, there is a requirement
20 that the facility name and address be on the film
21 itself but there is no requirement that it actually be
22 in the medical report so it wouldn't have to be

1 dictated. It could be part of the letterhead but it
2 would have to appear in the medical report. A show of
3 hands yes? No? Yes.
4 Should the name of the referring physician
5 be added? And a yes, let's see a show of hands? No?
6 DR. FERGUSON: You said referring
7 physician?
8 DR. FINDER: Correct.
9 DR. FERGUSON: What if they don't have a
10 referring physician and what if there are multiple? I
11 mean, on our reports we do but I can see sometimes
12 you've got somebody who comes in that says, "I want
13 these five doctors to get a copy of my report." Or
14 they are referred on their own.
15 DR. TIMINS: I feel it's important from a
16 medical malpractice and liability point of view if a
17 patient is self-referred, then that could be
18 documented on there but when you give a report,
19 especially if it's an abnormal report, someone has to
20 follow-up on it and this helps define the locust of
21 responsibility.
22 Of course, if there is a significant

1 abnormality, then you have to confirm -- you have to
2 document transmission of that information either to
3 the patient or the referring physician. I think it is
4 important to have the referring physician named on the
5 report.

6 DR. MONTICCIOLO: While I agree with that
7 in principle, I think that in practice, at least in
8 some situations, if it were federally regulated we
9 would create a difficulty. I'll just give you an
10 example.

11 In our practice we have a free clinic in
12 our area that serves women who can't afford to pay.
13 It is staffed rotating through our family practice and
14 internal medicine individuals.

15 The report goes to the free clinic and the
16 nurse practitioner there does the follow-up so we
17 wouldn't be able to if we had to separately have a
18 physician required by law, it would make treating the
19 women more difficult.

20 DR. TIMINS: I'm sorry. I should have
21 said healthcare provider because certainly there are
22 times we deal with clinics as well and I will document

1 transmission of a report to a nurse or a nurse
2 practitioner.
3 DR. MONTICCIOLO: In this case it's a
4 group so it's not an individual that we send it to.
5 That's why I'm not in favor of designating there has
6 to be a single individual it goes to.
7 DR. FERGUSON: I have a similar experience
8 with a sliding scale clinic. You don't know who is
9 going to be in there but we make certain. Certainly
10 if there is an abnormal mammogram, we might direct
11 contact both with the patient and with the facility.
12 We put the referring physician's name on the report
13 but I don't know as far as putting that in regulation
14 whether that's a good idea.
15 DR. FINDER: Well, let me ask a question.
16 For the clinic situation, what do you put on the
17 report? Who do you send the report to?
18 DR. MONTICCIOLO: In our case we put
19 Temple Free Clinic because it is a free clinic. We
20 know the individuals there and we have a contact
21 person and our nurse interacts with them. If we had a
22 federal regulation that said we had to have a doctor's

1 name, we would have a lot of difficulty with that.

2 DR. FINDER: I think the point of this
3 comment was not to classify it just as a physician,
4 healthcare provider. It was supposed to be more
5 expansive and I think we need to look at again the
6 wordsmithing on this. This problem that generated
7 this was that reports didn't have anybody listed so I
8 wasn't exactly sure how they knew where to send it in
9 the first place.

10 MS. HOLLAND: Couldn't you just use
11 something like referral source?

12 DR. FINDER: That sounds reasonable.
13 Again, we might have to define that somewhere.
14 Probably in the definition section.

15 DR. BYNG: Again, I want to clarify
16 something here because you are talking about sending a
17 report and I read this as just whether it's included
18 on the report.

19 DR. FINDER: That is correct. It would
20 just be included on the report. There is a separate
21 section dealing with provision of the reports and how
22 those get handled. Right now we are just talking

1 about the makeup of the report.
2 DR. BYNG: But not how it's handled. You
3 will discuss that separately?
4 DR. FINDER: Correct. Next one, No. 86.
5 This goes into the final assessment. Should we allow
6 reporting by individual breast or by individual
7 lesion? Let me give you a little bit of history on
8 this. The way the reg is currently written there has
9 to be one overall assessment finding for the entire
10 exam.
11 We have already approved an alternative
12 standard under certain conditions where we allow an
13 assessment category for each breast to be given. This
14 question kind of asks that same question again. Also
15 should we even allow an assessment category to given
16 for each lesion or item identified? Let's go with the
17 first one. A show of hands for by individual breast.
18 DR. BYNG: Sorry. Question here. Are you
19 talking about having both an overall assessment and an
20 individual assessment?
21 DR. FINDER: No. Before we approve the
22 alternative standard we did allow facilities to have

1 individual assessments for each breast as long as they
2 included an overall assessment. That was accepted.
3 When we approved the alternative standard it allowed a
4 facility to report on each breast separately given its
5 own assessment category. Now we are questioning
6 should we continue that process and put this into the
7 regulation.
8 DR. BYNG: Additional clarification
9 perhaps for the radiologist. How does that deal with
10 or impact or the labor part when you have findings for
11 breast and findings overall?
12 DR. MONTICCIOLO: I'm assuming you
13 wouldn't be required to have both. This is allowing
14 you to assess both. I think it's a good idea to allow
15 this because let's say you have a lesion that you want
16 to follow-up in six months in the right breast but you
17 want a biopsy on the left.
18 In the past you would have to just make it
19 a four or five and biopsy the left but the right
20 breast where you had the six-month follow-up if the
21 clinician didn't read in the report that there was
22 also something there, they would miss that six-month

1 follow-up.
2 DR. FINDER: That's part of it. Another
3 is the reporting requirements, the way the software
4 gets set up and also some facilities out there have
5 systems where they follow-up as you specify.
6 That, however, raises the next question of
7 should we allow it to be broken down by individual
8 lesion because you sometimes have two lesions in the
9 same breast and you want to have the same issues dealt
10 with there so do we want to go to that level also, or
11 at least the allowing of that.
12 Let's go with the right and left breast individual
13 assessment category. Yes? No? That's a yes.
14 Now for individual lesion. Yes? No?
15 That looks like a yes also. I will say we do have to
16 be very careful when we talk about changing assessment
17 categories and how we deal with them for the following
18 reasons.
19 One is it has taken a long time to get
20 people used to what we have already established and
21 accepted that. Two, a lot of software systems are out
22 there and they have been designed for the last 10

1 years to meet our requirements.
2 When we start changing these things,
3 sometimes we have unintended consequences so I just
4 wanted to state that up front that we have to look at
5 all these issues before we actually change anything.
6 DR. TIMINS: I personally have not -- I
7 have used individual assessments right versus left
8 breast but I haven't used individual assessments in
9 the BI-RADS statement for individual lesions of the
10 breast.
11 I will describe things that I think can be
12 followed and things that need biopsy and just to some
13 degree feel when it comes to dealing with a patient
14 with a little complexity that the referring physician
15 or practitioner can read. Have you ever issued a
16 report that says statements for different lesions in
17 one breast?
18 DR. MONTICCIOLO: No, and I'm going to
19 shoot myself the day that happens because it's already
20 complex enough. I don't mind allowing it. I think
21 the left and right is a good idea. When you get down
22 to individual lesions it's just going to get so

1 complicated, I think. If your patient is that
2 complicated, I would just directly interact with the
3 surgeon and take care of it. Probably we need that
4 leeway.
5 DR. FINDER: Right. Again, we've gotten
6 comments and it basically comes back from those
7 facilities that use computerized systems to monitor
8 the patients and follow up on them. At least they
9 have said this gives them more flexibility to be able
10 to biopsy or do a follow-up on one lesion and still
11 keep track of another lesion. I believe ACR wants to
12 make a comment about BI-RADS.
13 I do want to point out one thing. These
14 assessment categories are not the same as BI-RADS.
15 BI-RADS is a related system but when we talk about the
16 requirements here, they are not necessarily attached
17 to BI-RADS. We have the wording that we use. They
18 have numbers. There are differences and sometimes
19 they get confused.
20 MS. BUTLER: Penny Butler, ACR. I brought
21 some BI-RADS here as far as how they deal with these
22 different assessments. There is a statement in here

1 that reports will be -- information will be included
2 in the same report with separate paragraphs detailing
3 each finding and one integrated final assessment that
4 takes into consideration all breast imaging findings.
5 The guidance in BI-RADS said to give one
6 final assessment category but the content of the
7 report should detail the individual findings within
8 the breast. It goes on to say the overall final
9 assessment should, of course, be based on the most
10 worrisome finding present.
11 For example, if probably benign findings
12 are noted in one breast and suspicious abnormalities
13 in the opposite breast, the overall report should be
14 coded BI-RADS 4, suspicious abnormalities.
15 Similarly, if immediate additional
16 evaluation is still needed for one breast, as an
17 example, the patient could not wait for an ultrasound
18 exam at the time and the opposite breast had probably
19 benign findings, the overall code would be BI-RADS
20 Category 0. That's the BI-RADS guidance.
21 DR. FINDER: Okay. So let me try and
22 clarify. For the individual breast we had votes of

1 yes. For individual lesion let's just see another
2 show of hands yes, allowing it? No? It's kind of
3 split.
4 DR. FERGUSON: The key word, I think, is
5 allowing it, not requiring it.
6 DR. FINDER: Right.
7 DR. FERGUSON: You know, because things do
8 get transmitted to the people in the field and they
9 say, "This is the way it is," like we initially had
10 with the words. You couldn't say negative. You had
11 to say a specific word or they cited you and I would
12 hate to get back into that situation.
13 DR. FINDER: Right. Right now we are just
14 talking about allowing, not requiring. Of course,
15 that could change.
16 Next is --
17 DR. BYNG: Why would -- if you put allow
18 in it is it not allowed to do it today?
19 DR. FINDER: It's only allowed if you then
20 go on to give a final overall assessment. They can do
21 that right now but they would not be able to, let's
22 say, have a report that had three different assessment

1 categories on it.
2 DR. BYNG: Even if it has had the final
3 assessment of this one?
4 DR. FINDER: No. If they said there was a
5 final assessment of whatever, the final overall
6 assessment, that would be acceptable but they could
7 not do a report without that overall final assessment.
8 Next in terms of footnote 87 where we
9 talked about the benign final assessment category
10 asking whether this should be clarified to avoid
11 confusion with the negative assessment category. What
12 we would basically be talking about here is getting
13 rid of the words that also say "also a negative
14 assessment."
15 I cannot tell you now many times we have
16 had people point to that and say, "Well, it's okay for
17 me to say benign/negative, negative/benign. I think
18 part of it comes from the wording that we have here.
19 Negative is supposed to mean there is nothing
20 worthwhile commenting upon.
21 Benign is supposed to mean there is
22 something that looks benign and you want to describe

1 it. You should call it benign. It is not a major
2 issue whether it's negative or benign but you
3 shouldn't use both those things because one means one
4 thing and one means something else and we try and use
5 these systems to clarify and standardize the
6 reporting.
7 If you mean it's negative, you should use
8 that. If it's benign, it means there should be a
9 benign finding that you have described. I think our
10 goal here to kind of define what benign means and get
11 rid of this "also negative assessment" category. If
12 people want to give a show of hands on that. Yes?
13 No? I'll take that as a yes.
14 Okay. Next one is should the suspicious
15 category be subdivided into low, intermediate, and
16 moderate? Show of hands yes? Does anybody want to
17 comment?
18 MS. BUTLER: This is a recommendation out
19 of the BI-RADS committee in the 4th edition of the
20 atlas to have low, medium category 4, 4(a), 4(b), 4(c)
21 as subdivisions but also there would be a final
22 assessment category that would be an overall 4.

1 DR. MONTICCIOLO: Up to this point this
2 has been optional because some radiologist are
3 interested in separating out the things that they
4 categorized as 4, but I think it's an unnecessary
5 complication to require it. I think 4 should be good
6 enough.
7 DR. TIMINS: I agree with that. On a rare
8 occasion I'll use those designations, maybe 4(a). I
9 wouldn't bother with the 4(c) but I don't think it
10 should be required.
11 DR. FINDER: Well, I think the other issue
12 is one, should it be required and, the other, should
13 it be allowed.
14 DR. FERGUSON: If you say it would be
15 allowed, it would still be a category 4, right?
16 DR. FINDER: Well, again, we're not
17 talking about the numbers. That's part of the
18 problem. Right now we require that the word
19 suspicious be used and part of the issues that come up
20 people start putting qualifiers on it and they mean
21 different things. Some say it's mildly suspicious,
22 moderately suspicious, somewhat suspicious. Then they

1 start going into, "Well, it's somewhat highly
2 suggestive versus highly suspicious versus..."
3 They start using the words and you start
4 losing the distinction between the two categories.
5 That's why sometimes we get fairly dogmatic about
6 requiring that the wording be there. Again, it's a
7 question of can we allow people to use these terms
8 instead of just the overall suspicious category.
9 MS. HOLLAND: From a consumer standpoint
10 suspicious is suspicious and needs follow-up period.
11 I mean, as an advanced practice nurse I used to go
12 through that with Pap smears, you know, high, low,
13 this, that, and the other. The bottom line is it
14 needs to be followed up so I don't see any reason to
15 break it down.
16 DR. FINDER: I don't want to speak too
17 much for people who aren't in the room but I think
18 part of this goes back to the medical audit. They
19 want to be able to classify these lesions so that when
20 they do an audit they -- there are a lot of lesions
21 that they really don't think are highly suspicious but
22 they have to biopsy and they want to somehow make a

1 differentiation from those that they really thought
2 would turn out to be cancer so they fill better about
3 it.
4 But in terms of what the clinician has to
5 deal with and what they should do, I don't think --
6 well, I hope that the fact that somebody gets a low
7 suspicion doesn't necessarily mean that the referring
8 physician will not biopsy a lesion. That is one of
9 the concerns that we have about even allowing it
10 versus having an overall assessment of just plain
11 suspicious. Those are the issues again to think
12 about.
13 MS. SEGELKEN: I just want to say that
14 what Jackie said is true, suspicious is suspicious.
15 If the consumer gets the report that says low
16 suspicious, it could for somebody who is less informed
17 give a false sense of hope. I think just saying
18 suspicious is fine.
19 DR. MONTICCIOLO: I agree with that. I
20 also just wanted to add that I understand these audit
21 issues as a radiologist but I don't think our goal is
22 to make their audit numbers make them look better or

1 whatever. I think it's an unnecessary complication
2 that could have bad consequences for patients.
3 DR. FINDER: So a show of hands whether we
4 should allow this. Yes? No? No. Okay.
5 Next is should known biopsy proven
6 malignancy be added as one of the assessment
7 categories? Just to let you know, we have already
8 approved an alternative standard to allow this but you
9 certainly can give your opinion. Yes include? No?
10 That's a yes.
11 Should post-procedure mammogram for marker
12 placement be added? Again, I don't want to bias you
13 but yes, we did approve an alternative standard. Show
14 of hands yes? No? I'll take that as a yes.
15 Another change that has been suggested.
16 Should the word "incomplete" in the incomplete
17 assessment be changed to inconclusive or allowed to be
18 used as inconclusive? We've had a number of people
19 who have said that they are giving out the wrong
20 impression when they say it's incomplete.
21 The study is not incomplete. The study is
22 complete. It's just that other studies have to be

1 done or other work-up has to be done and they would
2 prefer the word "inconclusive." That has to be
3 weighed against the idea of changing the assessment
4 categories on all those issues it might bring.
5 DR. TIMINS: Inconclusive could be
6 referred to as a lot of mammograms. I don't like the
7 term. It seems to relate more to the interpretation
8 rather than the clinical condition. I would rather
9 say, "Incomplete. Need additional imaging
10 evaluation."
11 DR. FERGUSON: I would agree with that.
12 DR. FINDER: Should incomplete be changed
13 to inconclusive?
14 DR. FERGUSON: No.
15 DR. FINDER: Hands for yes? No? I'll
16 take that as a no.
17 Should a separate category for "need prior
18 mammograms for comparison" be added? Show of hands
19 yes for that? No? Kind of half-hearted.
20 DR. FERGUSON: I don't like a separate
21 category for it. I mean, I think there is a place for
22 "need prior mammograms" and we put that in our

1 impression or conclusion now. But to give a category
2 to that I think would be cumbersome.
3 DR. FINDER: Let me give you a little bit
4 more background on this. One of the thoughts behind
5 this by having a separate category is the fact that
6 right now there is no requirement that forces somebody
7 who gives an incomplete assessment category to go back
8 at some later date after either the films have been
9 obtained or something else has happened to issue
10 another report.
11 The idea behind this would be if you had
12 it as a separate category, you said, "Incomplete.
13 Need prior mammograms for comparison," the idea would
14 be that there would be another requirement that if you
15 used that assessment category, within some period of
16 time you would have to issue another report.
17 Either you got the old films and you were
18 able to make an assessment, or you didn't get the old
19 films and you have to make an assessment on what
20 you've got. Right now you can issue an incomplete so
21 you want to get the old films for comparison. Never
22 get the old films and never issue another report under

1 the regulations. This is an attempt to try and
2 address that issue.
3 DR. MONTICCIOLO: Right now if I
4 -- I know it's different than BI-RADS zero. If we
5 call a patient back for ultrasound or additional
6 views, what is the federal requirement? There is none
7 so there isn't for that so why would we need it for
8 this? It would be more important if I saw abnormal
9 calcifications and wanted magnification images to get
10 the patient back for that but we don't require --
11 DR. FINDER: The problem with this is
12 right now, as I said, you can issue a report. In the
13 other cases the patient is going for some type of
14 other study and we'll get another report based on that
15 examination, or should get one. Of course, it may be
16 outside of MQSA.
17 The problem here is that if you ask for
18 comparison films, the way the reg is written there is
19 no final assessment that ends up getting issued so if
20 the comparison films never become available, there is
21 no requirement that you re-review that case and give
22 an assessment based on what you have.

1 Yes.

2 DR. TIMINS: In my practice if we don't
3 get previous films within let's say 10 days, we will
4 issue a final report. We won't give it a BI-RADS
5 zero. However, I think it's important for the patient
6 to be involved in their care and I don't object to
7 others using the term BI-RADS zero when they feel they
8 need the prior films. I feel that there is a
9 responsibility with the patient to be part of the
10 process.

11 DR. FERGUSON: My practice doesn't work
12 like this. I guess maybe I'm doing it wrong but if I
13 get a mammogram, I read it. I say I need previous
14 mammograms and give it a BI-RADS and we follow it up
15 and get the mammograms. I could see nine out of 10
16 screening mammograms getting this category saying we
17 need previous mammograms. That would be a default.

18 DR. BYNG: Is it a possibility to include
19 that with the previous assessment where you are saying
20 it's incomplete? That one specifically is need
21 additional imaging evaluation but if you are waiting
22 for your prior images to complete your report.

1 DR. FERGUSON: Usually I use incomplete
2 when we are wanting to do additional studies and when
3 we are using -- need an ultrasound or we need
4 magnification views, not for previous mammograms.
5 DR. FINDER: However, that is one of the
6 uses for that category, so this is actually happening
7 right now. This is being used right now. this is an
8 attempt for those facilities that have been using the
9 incomplete as a means to not issue a report or
10 forgetting about it in some manner to force them at
11 some point in the process if they don't get the old
12 films to actually issue an assessment category.
13 That's the purpose of this. Okay. Let's see a show
14 of hands. Yes, we should do this, no we shouldn't.
15 Yes? No?
16 Next, this deals with the procedure --
17 yes, go ahead.
18 DR. FERGUSON: Before we leave that, could
19 you explain to me? I know we've got BI-RADS which is
20 a number thing and we've got assessments. Is there
21 not a way that we could combine those or is BI-RADS a
22 proprietary or private system? Is that the problem?

1 DR. FINDER: Yes. I mean, we don't care
2 if in the short-hand people refer to the numbers. I
3 think it's pretty well established that the
4 concordance between the words and the numbers. We try
5 and make the two systems as similar as possible to
6 avoid confusion but BI-RADS is a proprietary system.
7 It's not - In fact, you can get your BI-
8 RADS manual and I would suggest people consider that.
9 We have to have an open system and ours uses just the
10 words. We don't use numbers and we discussed that
11 before. We force people to write the words down. If
12 they want to add numbers also, that's fine but the
13 words are the important thing.
14 MS. WILCOX: Pam Wilcox, ACR. The ACR BI-
15 RADS may be proprietary and copyrighted but we share
16 it universally and we would have no objection to
17 changing the letters to numbers but the words are
18 important.
19 DR. FERGUSON: And I would agree 100
20 percent that the words are important and I wondered
21 while we are changing these words and things up could
22 we attached some numbers to them if that was

1 permissible.

2 DR. FINDER: I think we have a problem
3 with the numbers. right now, or at least in the
4 initial one, the higher the number the more suspicious
5 the lesion was so BI-RADS 5 obviously was a lot more
6 suspicious than a BI-RADS 1.

7 Now that we've started adding some of
8 these other categories that are not really related to
9 necessarily the change of malignancy, and the one I'm
10 thinking about is the post-procedure mammogram which
11 is not actually part of BI-RADS. It's one that we got
12 and we included separately from BI-RADS.

13 We don't give it a number. If you give it
14 a number, it would probably be No. 7 but that's not
15 more malignant than anything else. There is a problem
16 with the numbers. We had discussed this with other
17 committee members and their consensus was it is the
18 words that are more important than the number itself
19 and it carries better.

20 Certainly with the referring physicians by
21 now they should understand that this was more of a
22 problem when things first got started because they

1 weren't all used to receiving these things. It is
2 probably less of a problem now. However, if we start
3 adding new categories, that will engender even more
4 confusion. At least in the beginning we would have to
5 start off requiring, I think, the words in there.
6 DR. FERGUSON: I guess that was my point.
7 Could we put numbers to these words? I don't think
8 you can do away with the words but when you talk to
9 somebody, I'm sure you say it's a category 4. I mean,
10 that's common.
11 DR. FINDER: We certainly allow it. We do
12 not say that a facility can't put the numbers there
13 but we don't force them to do it either so it's their
14 choice.
15 Next deals with the process of
16 communicating these results to patients and their
17 referring physicians. It's page 36, No. 93. Should
18 time frames in this section be modified to take into
19 account the fact that there is no requirement as to
20 when the mammogram is interpreted or how to deal with
21 the situation where the facility is waiting for prior
22 films before issuing a report.

1 Again, this deals with the situation that
2 there is a requirement in here that says that the
3 reports have to go out within 30 days unless they are
4 felt to be suspicious. How do you know what is
5 suspicious until you have read the report -- excuse
6 me, until you've read the films? There is no time
7 frame for saying when you have to read the films.
8 There certainly is no time frame dealing
9 with the situation where somebody has looked at the
10 mammogram and decided he or she needs the old films
11 for comparison. They are waiting on a report before -
12 - they are waiting on that evaluation before issuing a
13 report.
14 We are questioning here this business
15 about are the times frame appropriate and how do we
16 take into account those time frames? Should we have a
17 time frame for when those films need to be read
18 initially interpreted? Do we get into all that kind
19 of detail and how do we do that? Not a simple
20 question.
21 DR. MONTICCIOLO: Well, I don't think it's
22 simple but we already have a 30-day limit in the regs

1 so I would leave it as is.
2 DR. FINDER: Okay. The 30-days is in
3 there for the average report. If it is suspicious or
4 highly suggestive, it's "as soon as possible." We've
5 had problems with that over -- we have issued guidance
6 what we think is "as soon as possible" is reasonable.
7 Even that takes into account the fact that
8 it is "as soon as possible" once presumably the
9 diagnosis, the assessment has been given to that film.
10 Should we leave it the way it is or should we start
11 changing it?
12 DR. BYNG: What is the guidance that you
13 clarified?
14 DR. FINDER: The guidance that we've
15 issued is "as soon as possible" means three days to
16 get the report out to the referring physician, five
17 days out to the patient to get the lay summary. That
18 is the guidance.
19 Again, that is assuming that we are
20 talking about from the date that an assessment has
21 been given to that report -- to that case, not when it
22 was done necessarily because you've got situations

1 there you've got mobile facilities that are out there
2 and the films don't come back for interpretation for a
3 couple of days.
4 Remote reading where it takes some days to
5 mail things out. Then you've got the situation where
6 somebody has seen the case, looked at it and says, "I
7 want to wait before I issue a report until I get the
8 old films to compare because it is either going to be
9 take me out lesion or it's been there for five years
10 and leave it alone. There can be a big difference
11 between the assessment that is given to that so we
12 have to be careful about how we deal with the
13 situation.
14 DR. TIMINS: You also have the situation
15 where the referring physician is not available, on
16 vacation for a week or two. I would leave it as is.
17 MS. VOLPE: From a patient perspective, 30
18 days is way too long to wait because we are anxious to
19 get the results. Every woman is scared to death when
20 she goes to get a mammogram and I would say that the
21 requirement should be set that the mammogram should be
22 read within 10 days and it's imperative to let the

1 patient know why there is a delay.
2 Fifteen days should be the maximum time
3 the patient should have to wait. They should require
4 a letter to the patient explaining why the delay if
5 the delay is over 15 days. The delay should be
6 allowed only when waiting on prior films from another
7 location.
8 Furthermore, the facility should ensure
9 that the results are communicated to the patient as
10 soon as the mammogram is read if it's suspicious or
11 abnormal. I recognize vacations are a problem and
12 everything but some sort of arrangement should be made
13 for that.
14 DR. BARR: Helen Barr, FDA. I think --
15 well, we are sort of mixing apples and oranges here.
16 The first situation we're dealing with is, for
17 example, there is a facility that has a number of
18 unread mammograms. The person left who is reading
19 them. They haven't got anybody else to read them.
20 Right now we don't know if they are
21 suspicious or they are benign. Once they get read,
22 whenever that is, then the clock starts ticking that

1 the patient has to be notified within a certain amount
2 of time.
3 Right now there is nothing we can do to
4 this facility because there is no up front clock from
5 when the mammogram was taken to when it gets
6 interpreted. I mean, right now it could sit around
7 for a year and there is nothing we can do. The clock
8 doesn't start ticking right now until the mammogram is
9 read.
10 DR. FINDER: I would just clarify that.
11 There is one clock and that's 30 days. It has to be
12 read and the report go out in 30 days if it's normal.
13 The thing is that --
14 PARTICIPANT: You don't know it's normal
15 until you read it.
16 DR. FINDER: Right. That is the issue.
17 There is no requirement on when you have to read it
18 and give an assessment. The "as soon as possible"
19 basically for the suspicious and highly suggestive
20 only kicks in once you've made that assessment because
21 if you've got a mammogram in front of you and you
22 haven't determined what it is yet, you can treat that

1 as a benign situation and you have 30 days to get
2 those reports out.
3 DR. BARR: If it's benign but you're only
4 assuming it. There really is no specific clock from
5 when the mammogram is taken.
6 DR. FINDER: Right.
7 DR. BARR: We are making up this clock
8 because we say you have to have results in 30 days and
9 a normal mammogram but you don't know if it's normal.
10 DR. FINDER: Yes.
11 MS. SEGELKEN: So are we looking at then
12 issuing a time that the mammogram has to be read by?
13 DR. FINDER: Well, that is one of the
14 considerations that we would be asking you to consider
15 here.
16 MS. SEGELKEN: I mean, under Dr. Barr's
17 scenario, if it takes a year to read a mammogram --
18 DR. FINDER: It can't take a year. All
19 mammograms have to be read and a report issued within
20 30 days.
21 MS. SEGELKEN: But even 30 days. If I
22 found out 30 days after I had my mammogram taken that

1 I had a malignant or anything. It doesn't even have
2 to be malignant but something that somebody wanted to
3 look at again, that is inexcusable.
4 DR. FINDER: Right.
5 DR. BARR: How does it read? It reads for
6 a normal mammogram.
7 DR. FINDER: No. All reports have to go
8 out within 30 days. If it's a suspicious or highly
9 suggestive malignancy, as soon as possible. That's
10 what we're talking about.
11 DR. BARR: That's what I've always
12 thought. You can say what you want but it all has to
13 be out in 30 days.
14 DR. FERGUSON: In my practice, and I don't
15 know how many of them around the country are like
16 this, but I'm the only radiologist. I go on vacation
17 for 10 days. I don't take long because the work piles
18 up. They do screening mammograms while I'm gone,
19 okay? They pile up.
20 Now, when I get back I read them as fast
21 as I can and we get the reports out as fast as we can
22 but it's not going to be within 10 days of the day the

1 exam was taken because I'm not going to be there for
2 10 days. I guess the alternative is I can hire
3 somebody to come in and read them if you could find
4 somebody who reads mammograms but I read the
5 mammograms for about a five-county area.
6 There's not anybody to read them. There
7 are technical difficulties. I think all of us that
8 are doing the business now are trying to communicate
9 the best we can with patients and get reports out as
10 timely as we can. I think that 30 days is a
11 reasonable period to make certain that everything is
12 out.
13 Certainly when there is an abnormal
14 mammogram we are all doing our best to talk to the
15 patient directly and say, "You know, you've got to get
16 care and we're tracking where you go and your biopsy
17 results and talking to your doctor and saying we had
18 this abnormal mammogram." I think we're all trying to
19 do the right thing. I don't know if there are
20 examples out there that people just don't do the work.
21 DR. BARR: Unfortunately we wouldn't have
22 jobs if everybody operated the way you all do. That's

1 why there is MQSA.

2 DR. MONTICCIOLO: I agree with Dr.

3 Ferguson. I mean, we are concerned about the

4 patients. In my practice we let everybody know we

5 read the mammograms right away. I'll give you a

6 scenario where the 30 days is helpful. We'll read a

7 mammogram and it will just be, I think what Dr. Finder

8 was talking about, we'll see a solid mass.

9 If it's been there five years, it's benign

10 but we don't know without the prior films. What we do

11 is we call the patient and we say, "We really need

12 these prior films because otherwise you are going to

13 get a biopsy recommendation and we don't want a biopsy

14 if it's not needed so it helps us avoid unnecessary

15 biopsy to wait.

16 The reason I would rather not be forced

17 into issuing a report is because there are all those

18 things that go with that; auditing, letters that have

19 to be sent that take manpower and time.

20 It is expensive for us to have a nurse

21 that makes all these phone calls actually which is why

22 some people don't do it and just wait for the films to

1 come and make a final decision. I see a fair number
2 of films with significant findings that would be
3 considered suspicious but they don't look like cancer.
4 If I could just get the prior films I can
5 help avoid unnecessary concern and unnecessary biopsy.
6 That 30-day window gives us flexibility to deal with
7 it. We are courteous to our patients and we call all
8 of them. I don't know if everybody has that ability,
9 those resources.
10 I am sure in your practice, Dr. Ferguson,
11 I'm sure your techs let them know you're not there and
12 it's going to be a week before you get a reading so
13 the patient has the option of coming back in two weeks
14 and having their mammogram done.
15 I think it is a reasonable time period.
16 It wouldn't change, I don't think, the treatment of
17 their disease should they have it. I think that is
18 why 30 days was chosen.
19 DR. BARR: Dr. Barr. Okay, just so we
20 realize then that "as soon as possible" is very
21 squishy because on day 30 you could be sending out a
22 report 30 days later that says there is a malignancy.

1 I think we are just looking at it from a different
2 aspect.
3 MS. SEGELKEN: I think there is a
4 difference between something that is a BI-RADS 5 and
5 is so highly suspicious of malignancy. We don't wait
6 at all on those. We just bring them in. There is
7 such an overlap between benign and malignant disease
8 and things that are very slow growing and there's lots
9 of benign findings.
10 There's just way more benign findings than
11 there are malignancies even though that's the thing
12 I'm sure is scariest for patients. We don't want to
13 biopsy everybody. We would just be generating all
14 kinds of paperwork for very little gain.
15 DR. BARR: Exactly. We get a lot of
16 consumer complaints that say, "Why didn't I know that
17 I had a suspicious lesion two days after my mammogram?
18 Why was it a month later when somebody told me?" The
19 problem is because you don't know until you read it.
20 MS. SEGELKEN: I think it comes down to
21 communication. I think what you all are talking about
22 is you have great practices and I wish where I lived

1 we had practices like yours where you communicate with
2 your patient.
3 You tell them, "The physician isn't here
4 but your film will be ready within two days." Or you
5 call up and say we are waiting for whatever it is.
6 That is not the case everywhere. I don't know how to
7 address it here but saying "as soon as possible" means
8 one thing for me and one thing for you and it's too
9 ambiguous. Somehow the communication issue has to be
10 addressed.
11 MS. HOLLAND: I agree. There is also
12 something that I think we should remember. In a
13 perfect world everybody would be practicing the way
14 the people are on this panel. I live in a huge city
15 and work for a major university and medical center and
16 I can tell you I work in the community seven days a
17 week and there are many people, especially poor and
18 under-served people, who are suffering because of the
19 lack of communication so it needs to be addressed.
20 DR. FINDER: Okay. So let's have a show
21 of hands. How many people think that the regulation
22 should stay as written. Yes? How many people think

1 that there should be some attempt at modification to
2 address some of the issues that we've heard? Okay.
3 Let's move on to the next one, 94. Right
4 now it says maintain a system for referring such
5 patients to a healthcare provider when clinically
6 indicated. There has been a suggestion to add "when
7 mammographically indicated." Either add it to
8 clinically or replace clinically with mammographically
9 indicated. What do we think about that? Show of
10 hands.
11 MS. VOLPE: Could it be read "when
12 clinically or mammographically indicated?"
13 DR. FINDER: Yes, it could. Let's go with
14 the vote on that one first. Show of hands. No? Yes
15 on that one.
16 DR. BYNG: But is there in terms of
17 standardized handling of that if there is no clinical
18 information available, then you can't obviously say
19 clinically.
20 DR. FINDER: That's why the "or."
21 DR. TIMINS: We take histories. Either
22 the technologist helps the patient fill out an

1 information form so there may be information like
2 bloody nipple discharge where you would say, "The
3 mammogram looks all right but this should be
4 correlated clinically."
5 DR. BYNG: But what if you just said
6 indicated instead of either clinically or
7 mammographically?
8 DR. TIMINS: If you see something on a
9 screening mammogram, then you are going to refer the
10 patient as well, especially if it's a self-referred
11 patient.
12 DR. FINDER: Again, I don't want to go
13 into wordsmithing but I think I get the general
14 consensus of where we should go on that.
15 Next one is basically the same as the
16 earlier question about time frames so let's not go
17 into that one again.
18 No. 96. Should there be a time frame for
19 release of records? This is an issue that comes up
20 not infrequently where somebody requests old mammogram
21 reports and they call us up because they haven't
22 gotten it and we have a question.