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AT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE

Monday, January 13, 1997

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P R O C E E D I N G S

Conflict of Interest Statement

MR. SHOWALTER: As usual, I will begin by reading the conflict of interest statement for the National Mammography Quality Assurance Committee Meeting, January 13 through 15, 1997.

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

To determine if any conflict existed, the Agency reviewed the submitted agenda and all financial interests reported by the Committee participants. The Conflict of Interest Statutes prohibit special government employees from participating in matters that could affect their or their employer's financial interests. However, the Agency has determined that participation of certain consultants and members, the need for whose services outweighs the potential conflict of interest involved, is in the best interest of the government.

Full waivers continue in effect for 18 out of 24

participants because of their financial involvement with facilities that will be subject to FDA's regulations on mammography quality standards, with accrediting, certifying or inspection bodies or with manufacturers of mammography equipment, since these organizations could be affected by the committee's deliberations.

The participants include: Dr. Elizabeth Patterson, Dr. Raquel Arias, Dr. Tamsen Bassford, Ms. Margaret Botsco, Ms. Priscilla Butler, Dr. Carl D'Orsi, Ms. Carol Garlinghouse, Ms. Rita Heinlein, Ms. Kathleen Kaufman, Ms. Amy Langer, Dr. Michael Linver, Ms. Ruth McBurney, Ms. Marsha Oakley, Ms. Maria Romero, Ms. Esther Sciammarella, Mr. Roland Fletcher, Dr. John Lumpkin and Dr. David Winchester.

Copies of these waivers may be obtained from the Agency's Freedom of Information Office, Room 12A-15 of the Parklawn Building.

A full waiver was granted to Dr. Ellen O'Mara, a radiologist, since she will be asked to provide advice on the qualifications needed by members of her profession to provide quality mammography services and to comment on

guidance documents directly related to this discipline.

A waiver is in effect for Dr. Joel Gray that limits his participation in discussions of mammography phantoms. He may discuss phantom technology in general but will not vote on standards for these devices.

Out of an abundance of caution, we have also limited Dr. Edward Hendrick's and Dr. Lawrence Bassett's participation in equipment standards because of their involvement with mammography devices. They are allowed to discuss mammography technologies, including digital devices, as well as to talk about their observations and experience with these products; however, they will refrain from voting on specific equipment standards.

Drs. Gray, Hendrick and Bassett also have waivers in effect because of their financial involvement with facilities that will be subject to FDA's regulations on mammography quality standards, with accrediting, certifying or inspecting bodies or with manufacturers of mammography equipment, since these organizations could be affected by the committee's deliberations.

Also, several of our members and consultants

reported that they received compensation for lectures they have given or will give on mammography-related topics. However, they have affirmed that these lectures were offered to them because of their expertise in the subject matter and not because of their membership on the committee.

In the event that the discussions involve any other matters not already on the agenda in which an FDA participant has a financial interest, the participants should exclude themselves from such involvement and their exclusions will be noted for the record.

We would like to acknowledge the following guests:

Dr. Daniel Kopans, from Massachusetts General Hospital, Boston, Massachusetts; Dr. Carole Chrvala, Colorado Department of Public Health and Environment, Boulder, Colorado; Dr. Gilda Cardenosa, the Susan G. Komen Breast Center, Peoria, Illinois; and Dr. Barbara Monsees, Mallinckrodt Institute, St. Louis, Missouri.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with accreditation bodies, states doing

mammography inspections under contract to FDA, certifying bodies, mobile units, breast-implant imaging, consumer complaints, the American Board of Certification in Radiology, and mammography equipment.

We have the great pleasure this morning to have with us Dr. Michael Friedman, who is Deputy Commissioner for Operations of the Food and Drug Administration, and we have asked Dr. Friedman to address the committee at the beginning of the program.

Dr. Friedman.

Michael A. Friedman, M.D.

DR. FRIEDMAN: Thank you. I appreciate the opportunity to address you this morning. I also apologize to everybody behind me. It is not the politest presentation, but it may be the most attractive all things considered.

I would like to take this opportunity to welcome this committee. My involvement with this activity is relatively brief, certainly much briefer than your involvement of the FDA staff's involvement, which is of a much more considerable nature, so my points today will

reflect my perspective coming into this as I do.

I want to apologize to you that although I think this is a very important and worthwhile topic, that my schedule precludes me from participating and observing as much as I would like to, and I hope you will excuse me when I have to leave a bit later in the morning.

In welcoming you to this latest meeting of the National Mammography Quality Assurance Advisory Committee, I would like to make a few points. I very much recognize, even though I have only been briefly involved in this activity, the serious dedication that you all have brought to this advisory effort.

We certainly anticipate receiving your advice on many important topics to be addressed over the next three days. I would hope to do two things this morning in my remarks to you: first, to emphasize the importance of this meeting to the process of completing the final standards, you are well aware of this; and second, to respond to your letter expressing concerns about the process from this point on, and to make some suggestions and I hope a proposal that I think will address your concerns. This certainly has been

our intention to try and do so.

On the first point, the discussion over the next three days will have a significant impact on the final standards as they -- I am so sorry, it's not my pacemaker doing that, it's something back here -- over the next three days will have a significant impact on the final standards as they are drafted after this meeting.

We have always valued the advice of this committee and appreciate the expertise and diversity of representation of the committee. Our actions in the past, particularly reflected in the proposed final regulations, indicate the weight that we have placed on previous committee advice.

This, I believe, is the 12th meeting of this Advisory Committee. It will be the 7th at which the primary topic of discussion will be the quality standards.

We have had to revise, as you know, our time schedule in order to comply with the congressional directive to publish final regulations in Fiscal Year '97. This is a mandate which goes beyond the Agency's control. The Agency, therefore, is committed to meeting its deadline of October 1st, 1997.

This is also the year that appropriations for implementation of MQSA must be reauthorized. This makes it particular important for us to meet this congressional deadline. There are many reasons that we should do so. These are merely two. As you may recall, Congress, in its amendment to MQSA, that allowed us to do the interim regulations, expressed its intent that we complete the final regulations by October 1st, 1995.

It has obviously taken longer than that to complete the process in a truly comprehensive way. At some point, however, we simply must finish, and I believe that it is now time to come to closure on this particular process in order to publish by October 1st, 1997, we must complete the drafting of the document within FDA and have that package of regulations moved on to the administration for the rather extensive clearance process, and the date for that will be June of this year.

That moves us to a discussion of this meeting. This, I believe, is a very important opportunity for you to give us your view on issues raised by the public comments, so that we can translate those most meritorious ones into

the final regulations.

The April of 1996 proposal was based in large part on Advisory Committee comments on previous meetings, as well as committee comments on numerous earlier draft standards. The April 1996 meeting was held to get committee comments on the proposal. It resulted in significant recommended changes in about 35 of some 500 published sections of the proposal, roughly 7 percent.

One way of interpreting this is to say that there was general agreement on 93 percent of the sections of the proposal as it was published. This, I think, reflects how seriously we have taken the committee's comments in the past, and similarly, many of the recommendations made at the April 1996 meeting will likely be incorporated into our further revised drafts.

Nevertheless, in order to meet the October 1st, 1997 deadline, there is insufficient time for another formal meeting of this committee at which you could consider what should be contained in the final standards.

I think that makes this meeting especially important. It is critical that we get your best advice,

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your best comments, and your best thoughts on the many issues raised by the public discussion and comments.

I have given real consideration to your letter expressing your desire to participate further in this regulatory cascade, and I would like to offer this proposal.

We would like to offer you a chance, probably in early April, but that date is still a little unsure, sooner if possible obviously, to review the penultimate draft that will at that time be in the process of being polished by the Agency.

If you would like this opportunity, I would ask, though, for a couple of things. I would ask that your comments on that information be submitted to us within a two-week period of time. I recognize that that is a very short period of time, I recognize that you all are terribly busy, and this puts a real strain upon your abilities; nonetheless, in order to meet the deadline, I would ask for that.

Late comments will not be able to be considered given the strict time constraints under which we are working. I have a further request, and I would ask that you

limit your substantive comments to major new items. If an issue has been raised, if it has been debated within the committee, if you have expressed your position, and if the draft does not reflect that view, I would ask you, please, not to reiterate it.

The reason for that is in order to allow the staff to be able to review information in the most efficient and most timely way, certainly, if you feel the need to list something and say I still believe X, that, of course, is your right, but I would ask you not to spend extensive amounts of time describing it and discussing it once again.

Obviously, if you have new data, if you have new information, that is always welcome. This is not an attempt to preclude the submission of new information, this is simply not an opportunity to restate what I am sure you will articulately and carefully state at this or previous meetings.

Please point out issues that are new, issues that you feel are significant.

I have also asked the staff to look into how best to extend the status through this period to those of you

whose official relationship with the committee as Special Government Employees is scheduled to end in January, and they assure me that they think there is a way in which that can continue to be done.

I believe this proposal balances your desire to contribute and provide your very best judgment and the need for these regulations to be published on time. Since it will not be possible to depend upon this final check to catch everything, I have to emphasize again how important this meeting is in bringing up all the issues that you feel are relevant and important to give us your clear advice obviously in the most concise and effective way that you can.

Let me turn just for a moment to this meeting. Notwithstanding what I understand to be your substantial endorsement of the proposed regulations as published at the April 1996 Advisory Committee meeting, we need to recognize that many, many comments reflected that fact that mammography facilities have been concerned that the standards that were published are simply too detailed, too costly, or unnecessary to assure quality mammography, so we

have to look at the final regulations as they would be implemented and to make sure that they are necessary, that they are feasible, and that they are cost effective.

You have been engaged in this activity, you take this very seriously, you bring very important perspectives to us. That is a very, very valuable function for you at this meeting. We need to keep asking ourselves the public health question: is this requirement essential to ensuring quality mammography? Issues that have been mentioned to you later in the morning, raised by GAO and others, are also important to the construction of the final regulations.

In summary, it is extremely important for us for you to consider a variety of issues at this meeting. Let me just list a few for you.

The first is how important are individual issues relative to all matters contained in the regulatory package, are they essential.

Second, what other options exist in accomplishing a particular goal.

Third, how important is flexibility in allowing facilities options in complying with the regulations.

Fourth, how will a particular requirement affect access and cost versus improving mammographic services and quality of course.

And, fifth, what are the costs and benefits of a particular potential requirement.

This is a very important meeting. I very much appreciate, not only your participation in this meeting, but the substantial amount of effort and time that you have invested in previous meetings.

We look forward to receiving the benefit of your advice on these issues that are desperately important to the American public.

I would like to conclude my remarks at this point, give you an opportunity that if you have questions, I will be happy to try to answer them for you.

Yes, ma'am.

DR. PATTERSON: Thank you, Dr. Friedman.

Are there any questions to be addressed to Dr. Friedman?

Dan. By the way, welcome.

DR. KOPANS: One of the concerns that I have had

through this whole process is that ultimately, after the committee has passed on the regulations, that FDA can make alterations, and what I would suggest is that any alterations that are made subsequent to the committee's approval be annotated and the individuals who made that decision should be accounted for, so that if there is question in the future, there will be accountability for changes in the regulations.

Is that doable?

DR. FRIEDMAN: I am not sure it is. I am thinking as you ask. Would you have the same accountability for differences amongst the committee members?

DR. KOPANS: I have no problem with accountability. I think that with regulations that are as important as these, any changes, I would love to even see, you know, people sign off on the regulations, so that it is known in the future who made the decisions and why they were made.

DR. FRIEDMAN: Well, I think in a sense you do, and in a sense it is the leadership that has to take -- and I have no trouble with accountability either -- I guess what

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I am saying is ultimately, it is the Commissioner or me or someone who will sign off on these, that person or these people will, in fact, be accountable. I think we should be held accountable, and I am perfectly comfortable with that.

I fully expect that there will be differences between -- and I don't have anything particular in mind, so I am not thinking of a particular issue -- but it seems impossible, with an enterprise of this scope, that there won't be some differences.

Now, my hope would be that they are relatively minor. There may, however, be substantial differences, and ultimately, I think it is me or the Commissioner who will be held accountable for that, and I accept that.

DR. KOPANS: The only difficulty I have with that is that if there is a discussion that ensues with a regulation that has been changed, that it would be very difficult for you or the Commissioner to be able to go back and dissect how that change came about, and I think that there must be someone -- I mean unless you know all there is about mammography, I think that there is someone in the FDA or several people in the FDA who will make that decision,

and I would like those names to be available.

DR. FRIEDMAN: I am not sure. I am listening. It seems much more important to me to have a debate on the science of the issue or the facts of the issue rather than the historical identification of who approved or who generated a certain issue.

We may disagree about that. I think that it is a spokesman's responsibility, be it me or somebody else, who says these are the agencies best fit of the regulations, and these are the reasons, and then there certainly should be debate and discussion about that when necessary.

As you clearly recognize, this is an ongoing process, and we fully expect there to be refinements both in our thinking and technical refinements. That is to be expected. So, I see these as an important closure to a certain legislative process, but not a closure to our ongoing thinking about how best to interpret mammograms.

DR. KOPANS: I appreciate that. I still would propose that and FDA will do what it wants.

DR. FRIEDMAN: And be held accountable for it.

DR. PATTERSON: Yes, Penny.

MS. BUTLER: I have two questions. First, it is my understanding that in the publication of final regulations, that in the early part of the publication, there is discussion of the public comments, which I hope would include the Advisory Committee comments and why comments were taken or not taken, is that correct, so some of the rationale --

DR. FRIEDMAN: As you know, the preamble to the regulations does usually have a place for that discussion. What I have just been assured is that there will be a discussion, there will be an opportunity to present Advisory Committee positions that weren't ultimately taken and a rationale, just as you would have a rationale, you can't address each of the public comments individually, those are sort of bundled, but I do think that for substantive issues, there will be an opportunity in that preamble for that discussion.

As you can imagine, that is a fairly extensive process, and given the public interest in this, given the professional interest in this, I think it is going to be a pretty formidable task to draft that properly.

MS. BUTLER: Good. Will that be contained within the package that we review in April?

DR. FRIEDMAN: That will not be ready, I am told. What my understanding of what will be available in April is the regulatory portion. If you think of the whole package as being two parts, there is this discussion at the beginning, and then there are the regs. It will be the regs that will be available hopefully in April.

MS. BUTLER: I guess my only point here was that may help answer some of Dan's questions that he had.

DR. FRIEDMAN: I think it will answer the subject questions. It won't answer the particular person question, which I think was an important part of what he was asking.

MS. BUTLER: My second question is, is there any possibility of including in this review a one-day meeting to discuss these comments, where we would submit our comments on the final rules in writing, but discuss them in an open forum?

DR. FRIEDMAN: I asked the same question, because clearly there were two options outlined in the letter that was sent to me. One was for a public meeting, and one was

to at least participate by mail.

Much as the staff would like, there simply isn't going to be time to be able to do that. I think that in trying to incorporate another opportunity for the Advisory Committee to give its thinking, I think that doing it by mail, we could do it by E-mail, as well. That would not be a hard thing to set up. But I think that is the option that looks the best.

MS. BUTLER: In view of the answer to my previous question, I would think that a public meeting would give the FDA the opportunity to provide some of the rationale for why they either accepted or rejected certain comments, and my personal feeling is it would be valuable, not only to the committee members, but also the FDA, to have this.

DR. FRIEDMAN: Thank you.

DR. PATTERSON: Yes, Joel.

DR. GRAY: Dr. Friedman, you mentioned in this penultimate draft, you asked us to limit our comments to -- and I am not sure whether you said major new issues or major new areas -- and I guess I was a bit surprised to hear the word "new."

DR. FRIEDMAN: Let me define that. Let me tell you what my intention was, and then you give me the best words for it, because I may not be describing it properly.

I haven't been at the 12 previous sessions of the committee, but my experience with advisory committees and all sorts of committees is that each time a committee meets, there is a mixture of re-discussing old issues and identifying new issues, and that sometimes you take an old issue, but you bring new facts to bear on it, or a new position or a new synthesis or some new insight into it, and what I would ask, please, is that if you have a new insight, new information, new data, a study that was just published, something that you just became aware of, that informs a decision about a topic that has been discussed before, please feel free to submit that, you know, I feel that we should do X, and I have made that statement before, that wasn't part of the final, but I have new data that I would like you to see, this is something that I have just received, and you could share that.

That is something new. It is not passionately restating what you have stated previously. I don't think

that would be valuable at the last draft. I don't know quite how to say this, and you can challenge me and say, well, how do you know something is new.

I accept that. I have to count on your perspective, on your judgment on that, but I really think you all can do that. That is what I mean is feel free to say, if you want to say I think that we should use a certain standard, and that has been discussed and not included, feel free to have a single sentence that says I still feel strongly you should use that standard.

You are welcome to say that, but please don't go on for pages and pages restating what you stated before. This strikes me as there will be lots of situations where there will be some real data on several sides of an issue, there is no clear one right answer. It will ultimately be a matter of judgment, and it is not that there is a preponderance of good data that show that everybody would agree leads to a certain direction. If there were, then, we would have easily resolved it.

I am just trying to make the staff's -- because I am really worried about whether we are going to be able to

meet this deadline even with the discipline that I am suggesting we have to impose, it is going to be a near run thing, and so I ask that in order for your comments to have the maximum impact, try and use your judgment in those ones.

DR. PATTERSON: Yes, Carl.

DR. D'ORSI: Dr. Friedman, can you restate the position of the members who are going off the committee vis-a-vis reception of the penultimate document and attendance at this proposed early April meeting?

DR. FRIEDMAN: I am sorry, there is not an early April meeting. If I implied that, then, I have made a mistake. Let me be really clear about that.

There is not an early April meeting. I hope -- you know, knock on formica -- I hope there will be an early April draft to share with you all, that you can read, give comments on, and return them within a two-week period.

I would like for those members of this advisory committee who were otherwise due to rotate off this month to be continued on to allow them to read and comment on the final information. It seems to me the case that was made that people have been invested in this for a long time, they

are very knowledgeable, they care deeply about it, they should have access to the completion of the work.

Those seem like reasonable arguments to me. I am sympathetic with that, and that is why we are going to try and accommodate it.

DR. PATTERSON: Yes, Dan.

DR. KOPANS: I guess as a corollary to what I asked earlier, and then hearing some of these other comments, I would like to propose that if FDA either changes or disagrees with the recommendations of the committee on specific portions of the regulation, that the rationale for that disagreement be included somewhere in a discussion along with I think the preamble that we heard about earlier, and I had mentioned at a previous meeting, the intent of these regulations should be very carefully described, so that future individuals don't reinterpret them without understanding the information that went into them.

So, I would like to see, to summarize the rationale for any decisions that take place after the committee is no longer involved in the drafting, if there are changes made, and also the intent of the various

regulations.

DR. FRIEDMAN: Let me deal with each of those.

With respect to the first, I cannot today promise you that every disagreement would have a rationale attached to it, and the reason I say that is there may be small things, there may be big things.

What I would commit to is that what are considered to be substantial differences would be clearly spelled out. I think that that is a valuable thing.

With respect to your other point, which is what the intent of the regulations is, I have the sense that that will be clearly defined in the preamble. Nonetheless, although my experience is brief, it is my experience that no matter how clearly you state that, there is no proof against reinterpretation at a later date, and so we can attempt to do it, but I think that is going to be an imperfect process, but we will try.

DR. PATTERSON: Yes, Bob.

DR. SMITH: I just want to say, first of all, that I really appreciate your coming down and talking with us about these issues and responding to the concerns that was

raised by the letter.

I guess I have a procedural question. I also want to reiterate the concern that Penny raised and hope that you can revisit this question about the possibility of a meeting one more time. I know it may appear that it shouldn't be that big a deal to set up a meeting, but I know a lot goes into it. I see your faces, some of you are groaning. I know a lot goes into these meetings.

DR. FRIEDMAN: What they are groaning about is they are afraid I am going to say yes.

DR. SMITH: You and I can agree it is not that big a deal, but I know it is a big deal.

But the thing is, is that when the committee members are asked to respond as individuals, and we have that opportunity, and that opportunity was raised in the letter, you really don't get -- and we have actually responded to issues in the past this way through the mail, and I think we all found it rather unsatisfying in a way because it was never entirely clear how the full committee was weighing in on an issue, in ways that oftentimes might not change with the unique expertise that one or two

individuals bring, but that the way they raised that issue, and the issue itself suddenly gains new meaning as it is aired.

So, the issue that Dr. Kopans was raising, and has been raised in the interests of perhaps seeing the preamble, is sometimes the logic of going in one direction as opposed to the other is never entirely clear, especially in instances when the committee feels that it ought to have been more persuasive.

So, you can see that there is an area here of where the committee would like to have some clear understanding even if it doesn't much go beyond that is just the way we want to do it. In that instance, the opportunity for a meeting provides an opportunity in a very abbreviated format to get the key issues out on the table.

I know what you are saying in terms of new issues as opposed to raising old issues, but in some instances, it would be good to just have some final closure on, yes, you have raised this issue repeatedly, and we have accepted this advice, we have completely accepted this advice, we are marginally accepting this advice, we are not accepting this

advice for the following reasons, and that is where the benefit of a get-together of the committee getting together actually transpires.

Otherwise, what you end up is that we are sort of reduced to individual comments much as the public comments are.

DR. FRIEDMAN: I do recognize what you are saying. When intelligent folks get together, ideas play off one another, and there is a dynamic when you get a committee together that is different than when each of those individuals, no matter how smart or experienced they are, gets a chance to comment individually.

I am not disagreeing with you at all, nor am I saying that if I had the leisure I wouldn't prefer to have a public meeting. I would. I see advantages just as you do. I think the reality, though, is that with the schedule, with the still very, very substantial efforts that the staff have to make in order to meet this deadline, I don't think it is going to be possible.

I understand that it is a less good resolution than a get-together, but I do think that it meets the major

requirement, which is if we can't have at least group closure, there will be an opportunity for individual closure as much as that can ever occur in something medical and biological. That is sort of artificial, but I fully appreciate what you are saying.

DR. SMITH: Just one additional thing. I know you said that the preamble would not be ready at the time that the rules were. Will there be an opportunity perhaps even if it were necessary to give us even less time and for the rules to look at the preamble before it goes out?

DR. FRIEDMAN: I don't know the answer to your question, and I don't mean to -- what I don't want to do is cloak this in some sort of bureaucratic garb and say oh, no, we can't do it --

DR. SMITH: We are not strictly privy to a lot of those rules, so even just what is possible and not possible.

DR. FRIEDMAN: Sure. Joe, please.

MR. LEVITT: Let me try and give my perspective on it. What we are trying to do in the next essentially four months is to do kind of this version of what it took food labeling, while it was a larger effort but something I was

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also very much a part of, essentially a full year.

The reason we are sending you the reg is that we have learned through our history is why write the preamble on the wrong thing. If you write the reg first and get an agreement on what is in the reg, and get closure on what is in the reg, the preamble follows.

If you start writing all the preamble, you get lost, you go back and forth, and back and forth. Now, what we have kind of committed to do amongst ourselves is to get a regulation done, as Dr. Friedman said, by early April, you know, we are going to get some internal feedback on that, we are going to get some feedback from you.

It is then going to be not until early May that we then have amongst ourselves what we feel is a final regulation text, so we can, you know, write preamble. I mean there will be some along the way.

At some point, there is no time left. You know, we feel as much, if you will, a victim of the schedule as you do. This was not of our making, but at some point we have to figure out how to reach closure.

I think of the sharing of the regulation as what I

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would call an eleventh hour check, an eleventh hour check that reflects the fact that you think you are pretty much there, and you are checking did I miss this, did I miss that as opposed to re-going through the whole thing again.

We have had very extensive discussions with the committee, you with each other. At some point, these issues are going to be winnowing down. We have three full days to devote, and I have every confidence that a lot of good is going to come out, and if I were in your shoes, I would want to say, yeah, but I want to know what is FDA going to do, and by sharing you with the reg, I mean you will have the same reg that we have, that we are sending and sharing with Dr. Friedman, and we will flag, we will at least flag any what we feel are significant departures from what we feel the committee said.

But at some point, we have our own process that we have to share and get our clearances on, and just like time for a meeting, we just don't feel we can do it, and I have to say from the outside world, they are looking at us and saying, FDA, why can't you finish this.

And we are in the year, as Dr. Friedman said, of

MQSA reauthorization. You know, we feel this is a deadline, and again, I can remember from previous issues, food labeling being the best example, when the Commissioner has said this meeting will be met, but all of a sudden we convert to, okay, let's figure how to get there as opposed to let's figure out how, you know, go on and on and on, because the FDA can go on and on and on with the best of them independent of any advisory committee.

I can assure you this is as hard on us as it is on all of you, and what we are trying to construct here is the most feasible way to get there given our experience on how to do these kind of projects, given our experience in working with you and experience on these issues for the last three years, given the letter that came in, which is my memory of it -- I don't remember by word -- did include the option of reviewing by mail as individuals if the meeting is not available, and this is what we feel is the way we can most try to bridge what I ultimately would anticipate would be very minor tweaking at that point. At least I would hope at that point we would view it as very minor tweaking.

But, you know, these people are going to be

working day and night, weekends, I assure you, through the months of May and June, and, you know, just the process of sending it out and getting it back, you know, we want to look at your comments, you know, and everybody is going to edit the preamble, and everybody is going to -- you know, we are not going to get there.

So, what is important ultimately is what is in the regulation, that is what the facilities are going to have, that is what is in the Code of Federal Regulations, that is what is going to be enforced, and that is what I would hope we can focus on.

DR. PATTERSON: I think what I am hearing the committee saying is that when we went through these proposed final regs in April, and you quoted the figure that there was like 7 percent of the things that we really discussed and were against, I think they would like in the preamble these items be addressed. I think that is what I am hearing pretty much, because the rest of them we have already had our say on. I am assuming, unless those are changed in the proposed final regs, that -- and they may be -- that they have had their say on those.

I think what they are saying is if you didn't go along with what we recommended on those 7 percent of things, can these be addressed in the preamble on your rationale for doing it. Is that what I am hearing?

DR. FRIEDMAN: Not just those 7 percent. I think the question also came up -- if there were things identified at this meeting that are new, that you propose, that aren't incorporated in the final, that you would like that recognized as well.

DR. PATTERSON: Right.

DR. FRIEDMAN: I don't want to commit to a 7 percent solution, but to say that for the important issues, and I think we can identify those, that you have made these suggestions in a serious way, that you would like them dealt with in a serious way whether they are accepted or not.

DR. PATTERSON: Yes.

DR. FRIEDMAN: I think that is what the staff has indicated they will do, because you are not unique in this, you are not the only ones who have thought of this. There are other people who would make a similar comment, and they deserve an explanation of those things as well.

DR. PATTERSON: Yes, Dan.

DR. KOPANS: I am sure you haven't lost sight of this, but the comment -- I am sorry, I don't know the gentleman who spoke earlier -- it is not just an issue I don't think that it is hard on the FDA or it is hard on the committee.

What I am concerned about is that these final regulations are going to impact on how we care for women who may have breast cancer or in whom we are looking for breast cancer, and just in hearing so the history of the whole committee relationship with the FDA in a very subjective way, as I have as an outside consultant, I am just concerned that regulations not be codified that are not supported by science and that I see the committee as the spokespersons for the community, and that I hope that again, if you do not take the committee's recommendations, that it be clearly explained why.

Again, I understand the committee members wanting to see this until the end, and my only reason for wanting them to see it to the end is they know what has taken place over the last three years, they know the discussions, and a

lot of time has been taken from my understanding is that a lot of the earlier recommendations were not accepted and then it was realized that maybe they should be, and so they have gone back and forth between the committee and the FDA.

Again, I don't want you to lose sight of the fact that we have to deal with these regulations once they are finalized.

DR. FRIEDMAN: I think that is a very reasonable point. I have specifically stayed away from going over past history, and I would like us to stay away from that, because I don't think it is really valuable in terms of the important task that is before the committee today, that the committee represents the individual's best thinking.

To some extent you are invested with authorities from bodies that you represent, but you really are individuals, and I think what this committee represents is very good thinking, and that is why the comment should be taken very, very seriously, but there are other members, other parts of the same constituencies from which there are members drawn here who have different opinions, and so what we have a special responsibility to you as the people who

have been the most devoted advisors in this, is to take your comments with especially serious weight, but we recognize that there are a lot of different views.

The goal is to get, as I think you said, the best mammograms interpreted in the best way, whether there is one best way to do that or three best ways, that is what we should be thinking about, clearly identify where we want to go and to figure out what are the ways that we can get there, that we are able to define today.

I don't want to take up too much time because in a way, you know, I am eating into the important discussions that you need to have, and I apologize for that, but these were very heartfelt concerns that you raised, and that is why we wanted to deal with them seriously and right at the beginning.

DR. PATTERSON: Don't be concerned about taking extra time. I have been known to keep the committee until late at night.

Yes, Ruth, you had a comment.

MS. MCBURNEY: As one whose job entails quite a bit of rulemaking, I can appreciate the horrendous job that

FDA has facing them in going through all the comments, and I appreciate the opportunity for the Advisory Committee to be able to look at that draft final rule, that that may be the best that you can do on that.

DR. FRIEDMAN: I appreciate your understanding.

DR. PATTERSON: Are there any other comments or questions for Dr. Friedman?

[No response.]

DR. FRIEDMAN: Thank you very much for giving me this time. I appreciate it.

DR. PATTERSON: Thank you for presenting to the committee.

Committee Business and Introductions

DR. PATTERSON: Now, I will get an opportunity to welcome everybody. I would like to welcome all the committee back. It looks like the West Coast had some problem getting in. I don't know whether weather is a problem, but I hope they will get here eventually.

I do want to officially welcome our guests this morning, our invited guests, Dan Kopans, who I am sure everybody knows, and Barbara Monsees and Carole Chrvala.

Welcome, all three of you.

I just want to say a couple things about the committee. The three subcommittee reports, two have been signed off, and on their way up through the ranks to get to Congress. The third one we will have -- when you say that, what are you referring to?

DR. SMITH: By the end of the committee meeting.

DR. PATTERSON: Okay. Thank you. That one, I need to do a cover letter to go with it also to go up to Congress.

Charles.

MR. SHOWALTER: I just wanted to add a couple things to what Dr. Friedman has said.

As most of you know, we had a GAO report on the initial implementation of MQSA. According to statute, the GAO is obligated to do a second report, that report focusing on the inspection process.

We have had the opportunity to do a confidential review of that draft of that report, which is due to be released perhaps in February of this year. There are some points that were raised that we did tell GAO we would bring

to the committee for discussion as a part of the discussion of the final regulations, and I just wanted to mention some of those points, and we will bring them up again as we get to the discussion of particular sections of standards.

The first one is an issue that I raised briefly at the October meeting, that I think needs to be discussed a little more fully here, and that is the issue of the large image receptor, and are there quality control parameters, tests associated with the large image receptor that need to be incorporated in or specified somehow made a part of the final regulations on quality control or somehow otherwise in the final regulations.

Then, there were a number of issues associated with the accreditation body standards that the GAO had some concerns about, and I think need to be discussed at this meeting.

One is the current procedure specified in the draft final regulations using the eight attributes and the two sets of films, is that an adequate procedure for assessing quality in a facility.

Secondly, as the proposed final regulations

specify, there was a 3 percent random sample during the accreditation period that was specified as sort of a quality check by the accreditation body on the accredited facilities, is that an adequate sample and is the procedure used an adequate procedure for assessing ongoing quality during the accreditation period.

The third issue associated with really accreditation bodies, but also FDA, I think, and that is how do we follow up on facilities where we think there may be a problem.

Now, currently, we have been working with the accreditation bodies to use the tool that is available, which typically is a directed -- initially at least -- a directed random clinical imagery group.

GAO raised the concern that while this is a tool that you have, and that you are using it, is this the appropriate tool to use for a facility that you think may be in trouble, and indeed may be image quality problems, should a new tool be designed that is more elaborate, more extensive, looks at more cases, gives one some indication of whether or not patient notification might be necessary if

indeed these quality problems and issues prove to be true, how broad should that be, how many cases should it include, what is the nature of those cases, what time frame, all of those things we would like to put on the table as we talk about this issue of additional clinical image review and patient notification, that section of the standards.

So, those are issues that have been raised. We would like those to be a part of the discussion over the next three days. We think it is important. Again, Charlie Finder and I will try to bring them up as we come to those various sections of the standards where they would be included.

DR. PATTERSON: Okay. First of all, I understand there are no alternative standards requests, is that correct?

ME. SHOWALTER: Right. Nothing is happening in terms of approving any alternative standards requests since the last meeting.

DR. PATTERSON: We will now move onward to the Medical Records and Mammography Records.

Penny, did you have a question first?

MS. BUTLER: Before we get started on discussing the individual parts of the proposed regulations, there is a general concept that has sort of been nagging at me about how the FDA intends on approaching the final rules, because I think it could color a lot of the comments that I have.

Reviewing the public comments and recalling back to when Dr. Kessler came out -- what was it, two years ago now -- to speak with the committee, listening to Dr. Friedman and some of the excellent points he brought up this morning, there appears to be a strong feeling that we need to make these rules very manageable and only hit on the very essential points, basically to try to streamline this huge document, which I cringe to try to think that, as a facility, I have got to comply with in this present form.

On the other hand, when I hear, for example, some of the GAO comments brought up, and some of the other discussion points that I know we will listen to this afternoon, they are very detail oriented and asking for very specific rulemaking on very specific points, which seems to deviate from the streamline approach that we have been hearing.

So, what is the FDA leaning towards the revision of these rules?

DR. PATTERSON: Charles, do you want to answer that first?

MR. SHOWALTER: I will take the first shot at it. I think that illustrates that we have many constituencies, many of whom want different things. I still remember the words of a former commissioner who said, well, I have got the consumers yelling at me on one side for not being strict enough, and I have got the manufacturers yelling at me on the other side for being too strict, I must be in about the right place.

That sort of illustrates the quandary we have here. I think our view generally is that we have to be reasonable with facilities, and we have to really try to focus on important issues relating to quality, but as I mentioned, there are other forces that want other things. They want more detail and they are not forces that can be ignored.

We will try to strike a balance. I mean that is the best I can say. I can't be any more specific than that

except that we will try to hear all of the concerns, and we will try to reach a midpoint that is not unreasonable for facilities, but yet, at the same time, meets what GAO wants, and I don't know exactly how we will do that.

DR. PATTERSON: Yes, Penny.

MS. BUTLER: Can you be specific enough to say that perhaps these detail-oriented questions can be and should be more appropriately addressed in guidance documentation?

MR. SHOWALTER: I certainly think that that is one approach to it, and I for one don't have any problem at all with that approach. I think that it can be somewhat unfortunate to put too much detail into a standard especially when you are not absolutely certain that that needs to be in the standard because it's not flexible, and if we can satisfy people's concerns by using guidance, I think that is the best way to do it.

DR. PATTERSON: Yes, Cass.

MS. KAUFMAN: I can say that many facilities that we deal with actually prefer very detailed regulations because it gives them a very clear idea of what they have to

do to be in compliance, and so I think there are positive points to both perspectives, and that there can be a very positive impact on specific regulations in terms of the clarity of what facilities are required to do.

DR. PATTERSON: Are there any other general questions regarding the process? Penny, did Charlie sort of answer your question?

MS. BUTLER: I am sure it was the best he could do.

DR. PATTERSON: Yes, Joel.

DR. GRAY: I guess I would like some clarification as to the procedure we are going to follow. The question in my mind is what is different about this discussion of the comments from the public today compared to the meeting that we had in October. To me, it seems like we are, for the most part, looking through the agenda, we are rehashing a lot of the same comments and a lot of the same issues.

DR. PATTERSON: The reason why we are starting off with rehashing the comments that we finished up with at the October meeting is because by the time that Ellen was giving her presentation, the committee was down to less than a

handful because people were leaving early, and so that is the reason why yes, that is a rehash.

DR. GRAY: No, but what I am getting at is, for example, Penny and I are scheduled to go over some sections that we went over in October, and I am not sure that anything has changed in the public comments in that period of time.

DR. FINDER: Well, first of all, we did get more public comments, and we did get those additional, and two, we wanted to go over the entire document this time to give everybody a chance, so if there are any unresolved issues, this is the time to bring them up, and that was the purpose behind listing everything, so it can't be said that we left out an area. Everything is going to be discussed here, and if you have any questions at all, this is the meeting to bring them up really.

MR. SHOWALTER: But I would add if there is little to be discussed, if that happens to run short, that is fine.

DR. FINDER: Yes, we don't have to fill up the time.

DR. GRAY: We may adjourn early?

DR. FINDER: No.

DR. PATTERSON: No, but I won't keep you until
midnight.

Yes, Dan.

DR. KOPANS: The invited guests received a series
of pages summarizing the comments. Will we be going through
these individually or should we pipe up when we think it is
appropriate? It is FDA discussion questions for the meeting
January 13th to 15th from Mr. Showalter.

MR. SHOWALTER: As we discuss each section, we
want to address the questions pertaining to that section.

DR. KOPANS: So we are going to go through these
systematically.

MR. SHOWALTER: Yes.

DR. KOPANS: Good.

DR. PATTERSON: Yes. Each of the different items
are listed there in the questions that they want us to
answer their advice on in addition to the public comments.
Okay? Any other process questions?

[No response.]

DR. PATTERSON: If not, Ellen. Can we have

somebody to handle the projector?

Medical Records and Mammography Reports

DR. O'MARA: Am I correct in assuming that you want me to run through what I did in October since most of the committee members had left?

DR. PATTERSON: Any way in which you want to address the public comments regarding the medical records and mammography reports.

DR. O'MARA: Well, I think probably because of having new committee members, as well as guests, and with the absence of several members previously, that the best way to go through the public comments would be to summarize them again as I did in October.

[Overhead.]

DR. O'MARA: I reviewed the Section 900.12(c), which had four subparts, contents and terminology, communication of mammo results to examinees and communication of mammography results to health care provider, as well as recordkeeping.

I was sent approximately 200 letters the first time plus since October, got some additional letters to

read. These came from consumers, physicians, radiologic technologists, states, and various organizations involved in breast cancer screening.

The summary of comments given to the members, at least what I got in October, includes the comments contained basically about 1,000 responses that were gleaned from those letters that were received.

I have read through the letters, and I have also read through that summary and basically can state that the summary is an accurate reflection and interpretation of the comments that were made in the letters that the FDA staff has summarized on this particular section.

Just as a note for those looking through these summaries, especially for the new members and guests, that they were all codified, given a number assigned, and that number may actually represent more than one commenter. Several organizations had several individuals sign the letters, so not just one number representing one individual comment.

[Overhead.]

DR. O'MARA: I guess we can address these. I

don't know if you want to make comments after the entire presentation or after each section, but for Section 1, Comments and Terminology, there were general comments with both positive support, but a few comments disagreeing with this section.

The general comments included suggestion to change the title of the section to include the word "time frames." One of the other comments was that a unique patient identifier was needed, that it was not enough to have a first and last name.

As I said, back then, working in an area where we have families, several families with the same last names and the same first names, that certainly makes a lot of sense.

There was a question proposed, who can sign the report for an unavailable interpreting physician, does it have to be another interpreting physician or can it just be somebody covering the practice, and also is an electronic signature acceptable, how will FDA determine compliance with clinical questions addressed in the report, in other words, if a patient is sent in from their referring physician with a clinical question, how is the FDA going to look at the

report to see if there is compliance in terms of the radiologist or interpreting physician addressing that problem.

With regards to the negative category in the report, can the interpreting physician address clinical findings or symptoms and attach symptom intake form. Apparently, one practice was doing this, and did not want to change that practice, did not want to include it in the actual report, but have a separate sheet of paper to address that.

There was a comment made that the included standardized assessment category should be used in the report that went to the patient and the lay report. They felt that this was very helpful in educating the patient.

Another comment stated that the category "Needs additional imaging evaluation" should be deleted and returned to the ACR's initial category. I think it was "Needs additional evaluation," dropping the word "imaging," because physical examination may be part of the evaluation, and by adding the word "imaging" precluded the ability to look at the whole picture.

Recommendations should not be subject to restricted classifications was a statement made in many of the comments, and another commenter basically said that they wished to have an additional category, and that was the indeterminate category.

They were concerned that without this category, that it would force radiologists or interpreting physicians to put reports into a suspicious category, which would automatically suggest that the lesion was malignant, and they did not want to do that.

Positive support for the section, basically, that there would be consistency in reports with standardized assessment categories, and that this was something that was started with HCFA, but was lost, and two benefits. Clearer reports to physicians and to the patient, and also the importance of these standardized categories in terms of evaluation for outcomes analysis.

[Overhead.]

DR. O'MARA: Basically, the negative comments on this section included that the referring docs were used to facilities' customary terminology in the reports, and this

was going to cause the doctors who use that facility to have to learn all new terminology in understanding the reports they were getting.

There was a statement made that it was inappropriate for government to put medical terms for classification into regulations, and a question proposed whether the message -- they felt that the message that was conveyed by the report was important, and not the exact wording.

A comment that this section caused a lack of flexibility in reporting, and also that a negative report or the negative category would be misleading to both patients and physicians, obviously because the negative category does not exclude the possibility of breast cancer, and that could be misinterpreted.

Another comment on that said that that probably could be handled by education of the physicians and patients to understand what was meant by that category.

Also, utilizing the standardized terminology, there was concern by one facility that it would be forced to ensure compliance with the use of the terminology. They

apparently used a lot of locums and felt that this would put an unnecessary burden on their facility to police their locum tenens radiologists, and that if it was used, that there should be a phase-in period over which this is brought into I guess being.

The FDA's question on this was in view of the public comments, which expressed concern over the appropriateness of mandating assessment categories, does the committee feel it has additional advice for the FDA, and this might be a good place to stop and discuss this one before we go on to the next one, which is probably much more difficult.

DR. PATTERSON: Yes, I agree this is a good stopping point to discuss this.

Do we have any comments regarding the question?
Yes, Esther.

MS. SCIAMMARELLA: I think we discuss with the customer terminology including language, that it was a comment. I mean it was defined by the people need to receive maybe in their native language the notification. I think we discussed that.

DR. O'MARA: Esther, I think we are going to get into that in a minute, the next section.

MS. SCIAMMARELLA: Okay. Thank you.

DR. O'MARA: This is the terminology that the radiologist should put the report out into the referring doctor.

DR. PATTERSON: Tammy?

DR. BASSFORD: Maybe I can address that a little bit in terms of referring docs. I think what this comment refers to -- and you can correct me if I am wrong, Ellen -- is that terminology that the physicians are used to reading in the reports that they get from the radiologists, I would just like to offer the observation in terms of that one point, aside of what the correct terminology is and what would be most appropriate -- that referring physicians generally have to accommodate themselves to a broad range of "customary terminology" because especially with increasing health maintenance organizations and PPOs and other forms of mandated requirements for where you send your patients, you don't get to pick one radiologic facility that uses language that you find particularly clear.

So, in that point, customary terminology and being used to it as a referring physician really requires you to be used to anything that comes across your desk, and I don't consider that a particularly valid comment from the response of a referring doctor, and individual facilities change their "customary terminology" all the time as new physicians come in.

So, I think the benefits to referring physicians of having a standardized terminology would be significant because we wouldn't constantly be adapting ourselves to how different radiologic facilities classify their results.

DR. PATTERSON: Yes, Bob.

DR. SMITH: Just to follow up on that point, Larry Bassett and I worked on a small research project, and presented results at the RSNA two years ago, showing there really was a wide variation in reporting styles, that with our very careful scrutiny, you know, to essentially apply a qualitative assessment to every aspect of that report frequently found information that was contradictory, uneven, where the meaning wasn't clear, and if you are reading a lot of these reports, you could very easily overlook something

very serious or overlook something that might qualify what would otherwise be interpreted as a serious interpretation.

So, insofar as the general trend is to try to make things easy for patients and referring providers, and even facilitate communication between radiologists, anything in this rule that strengthens that is a good thing.

Just on this other point, the idea of speaking to the issue of symptoms, if the report is negative, again, is just another aspect of communication. The referring provider and the patient needs to understand whether or not the radiologist truly was aware that the patient was symptomatic.

There is a tremendous emphasis right now in trying to explain to referring physicians that a negative mammogram in the presence of symptoms does not rule out breast cancer, and yet we too frequently hear stories that that is exactly the reassurance someone was looking for, and it was, you know, months and months and months later that a much larger mass was identified.

DR. PATTERSON: Tammy?

DR. BASSFORD: With regard to that, I agree that

is a significant educational issue in terms of educating the referring physicians, and that could conceivably be addressed by one of those standard comments at the end of the report, but your first point is also important.

If I send a patient with a particular symptom or mass, and I don't get something that I would expect sending a patient with a mass, an ultrasound of that mass, I don't know why it wasn't done unless I am sure that the facility knew that I was sending a patient, that I want attention to a particular area. So, noting the symptoms lets me know that what I expected to get out of the consultation with the mammographer is what, in fact, I got out.

So, it is kind of two different issues. One is an educational issue for referring physicians, but the other is whether the consult was adequate.

DR. O'MARA: Absolutely.

DR. PATTERSON: Larry.

DR. BASSETT: I think that the purpose of these regulations is to improve the quality of mammography specifically, and there certainly were problems in reporting. There are two reasons why these final

assessments are essential besides the fact that they are better in terms of informing the referring physician about exactly what the assessment is, but also they are essential to do a medical audit.

If you don't categorize with some kind of assessment at the end, that can easily be translated into a positive or negative report, then, you cannot do an adequate medical audit, which is something I think most of us feel is important whether it is in the law or not.

The other thing is that the final assessment categories expedite patient management or examinee management, because if they fit into certain categories, then, you know a certain recommendation is fitted to that, and without that, then, you are leaving that really up to the individual, you know, vocabulary of the person who is interpreting the report, which can lead to misinterpretation by the person reading the report.

So, at least for the final assessment category, I think there is good reason why they should be there, and I can tell you from experience that I don't know of any referring physician who resisted having these. They have

all welcomed them, because it has made their jobs easier.

DR. O'MARA: Larry, I would kind of personally like to second that comment, and having practiced in a group, gotten phone calls from referring physicians who wanted me to interpret a report of another referring physician. We probably all have had that when that was not the practice to use standardized assessment categories.

Carl.

DR. D'ORSI: I just want to underscore what Larry said. I think, reading these comments, that there is some confusion on the part of the people writing the negative comments. These comments, the assessments anyway, really also incorporate any recommendation you could possibly give, so your thinking process has to fall into one of these categories.

It is not like you are inventing new words and you are trying to force some terminology on people using these assessment categories. Anything you want to do, any conclusion you come to, fits into one of these categories, so I think there is a lot of misconception about what these assessments mean, and I think that is just an education

process, but I think this is probably one of the most important, in my view, additions to this entire MQSA document.

DR. O'MARA: Dr. Kopans.

MR. KOPANS: I just want to second that. I think there was a comment earlier that you had, saying that there had to be an indeterminate category. It wasn't clear to me what that actually means. It just means I can't make any decision about this particular finding. I think that is a mistake.

These final assessment categories have been thought over by multiple committees for years, and I don't think there is -- I haven't come across a situation where you couldn't categorize an imaging study using one of the five. So, I don't see any support for dropping them.

DR. CHRVALA: I just want to say that the customary terminology is critical and the indeterminate could be handled by the category saying that additional evaluation is required, and that is how I see it being used.

The other piece that is missing here potentially is the fact that between radiologists, they differ greatly

on what is a negative mammogram, and I think there is a need for training in use of the terminology.

I ran a mammography tracking system in Colorado and found that negative was used as infrequently as 5 percent of the time and as frequently as 40 percent of the time, so that is a tremendous range and I think that in addition to the customary terminology, there is going to have to be definitions of what each of the categories mean and possibly some training.

DR. PATTERSON: Did you get the feeling that some of the comments, they felt that the only thing that was allowed was the final assessment, and no narrative whatsoever, because I was reading through, and that was some of the things, I think it was misinterpretation of the regs by not thinking that they could say anything other than --

DR. O'MARA: I think some of the comments, yes, to answer your question, but I think we have actually come to some consensus on this one.

DR. KOPANS: Actually, I think that is an important point that you are bringing up, and that is that it might be valuable to explain in the rationale for this

particular part of the regulations, that there can be subcategories in this. For example, the category of suspicious, an individual group may have data to say this is suspicious with a 10 percent probability of malignancy, or a 30 percent probability of malignancy. It doesn't mean that you just have to use that suspicious category without any qualification, so it might be worthwhile building that into the discussion, that there is some flexibility as long as each report can fit into one of these five categories.

DR. O'MARA: Anybody else or we are going to close this section? Good. I think we can go on to the --

DR. KOPANS: There was something about unique identifiers, is that at this time?

DR. HOUN: Yes.

DR. KOPANS: There was a comment made that we should have unique identifiers, and it is not in the regulation, is that right?

DR. HOUN: It is not proposed.

DR. KOPANS: Was there a reason not to require unique identification?

DR. HOUN: Because I think there was a lot of

discussion on what is going to be acceptable for a patient identifier that wouldn't breach confidentiality, and there was not a consensus on what that should be.

DR. KOPANS: But there needs to be -- I mean you can't just have Barbara Smith. We have 500 Barbara Smiths.

DR. HOUN: It doesn't prohibit facilities from doing their other, in addition to having a name, they can use their chart number, their hospital --

DR. KOPANS: But shouldn't there be a regulation that says that some form of unique identification should be affixed to the image, and you maybe give some examples. Examples would be date of birth, Social Security number, and name and date of birth, Social Security number, hospital, unique hospital identifier, maybe not requiring the exact unique identifier, but some way of doing it?

DR. HOUN: So you are saying --

DR. KOPANS: Just a general statement, the name of the examinee and a unique identification code, number, whatever, should be affixed to the image.

DR. O'MARA: I agree totally with Dr. Kopans. I think I made a comment back in October, practicing up in

Lancaster, Pennsylvania, we have five Amish names, and while we don't always see these women for mammograms, we also have a limited number of mennonite names, and it is incredible the number of patients who have the same first and last name and even the same middle initial.

DR. HOUN: Do you think that is an appropriate regulation to have saying in addition to the name, date of examination, some other unique --

DR. O'MARA: Some other unique identifier.

DR. KOPANS: I think that is one of the good things to regulate.

DR. O'MARA: Yes, some other unique identifier, that they know will separate that patient from another patient, Social Security number.

MS. SCIAMMARELLA: [Off mike.]

DR. O'MARA: Even that is a problem from my experience.

DR. BASSETT: This is not the image we are talking about, I don't believe. We are talking about the report now, right? But, nonetheless, because clinical image will come up later, and there are definite requirements there for

information about identification, but this is the report, but still on the report, I agree with Dan, there should be some unique identification, however, we did hear before discussion about what that should be, and I think just leaving it general is probably better, because as Ed Sickles mentioned, particularly in the mobile type of practice, for example, your unique identification number may not mean anything to the referring physician in their office if it is not in the same hospital or whatever, so that something like a birth date or Social Security number or whatever their pros and cons are of these individual things could be considered, but I think just the fact that it is a unique identifier is the important thing.

DR. O'MARA: Is there anything else before we close that section? Elizabeth.

DR. PATTERSON: I would like I think to hear the committee's comment about the needs addition, the terminology in the proposed regs is imaging evaluation, and I guess the question is should the term "imaging" be deleted.

DR. HOUN: It is not the ACR lexicon saying -- as

I recall it said, there was the word "incomplete," and then there is an indentation that says "needs additional imaging evaluation."

DR. PATTERSON: I think it says "additional evaluation." I don't think the term "imaging" is part of that. Lexicon people, isn't that correct? Yes, it just says, "Needs further evaluation." It doesn't use the term "imaging."

DR. KOPANS: The only concern I would have with leaving the "imaging" out is that then every report could be "needs additional evaluation," meaning a clinical breast examination. This is for mammography. This is for imaging.

You may put, you know, at the end of your dictation the mammogram is negative, but don't forget you still need to do a clinical breast exam. That is "needs additional evaluation." But I think it is appropriate to leave "imaging" in, quite frankly, if that is what the radiology report is alluding to.

DR. HOUN: There is also a Recommendation section, so if you don't need "imaging," but you are recommending clinical exam, you can put that in Recommendations.

DR. O'MARA: Tammy.

DR. BASSFORD: I think that is important because I have gotten reports where it is not clear whether they are recommending additional clinical evaluation, in other words, they feel they have definitively gone as far as they can with imaging, or they really need the patient to come back for more imaging.

So, I think having an incomplete evaluation due to the need for more imaging studies is somewhat different than suggesting the patient go on for additional evaluation, which could be a broader range of clinical ways of finding out what is going on.

DR. O'MARA: So, basically, what you are saying is you would like a category needs additional evaluation with specification of exactly what that is?

DR. BASSFORD: Well, I think what I am hearing is that in terms of the assessment, if the assessment is indeterminate because additional imaging evaluation, that that is an appropriate place for imaging, and then under Recommendations, I think there is a category for suggesting further clinical evaluation, whatever that might need to be.

DR. O'MARA: Dr. Kopans.

DR. KOPANS: Just as example of how this might work, someone has asymmetric breast tissue where the mammogram is basically negative from an imaging perspective or benign finding, asymmetric breast tissue, the only caveat would be if there was something palpable in that area.

So, that would be classified as either Category I or II from the mammographic point of view even though you may want to recommend a comparison of the two sides as suggested clinically.

So, I would suggest that you leaving "imaging" in the regulations, and anything else would be what you would normally qualify as your clinical description with any report.

How about the issue of electronic signature, can I bring that up? Is that part of this now?

DR. O'MARA: Sure.

DR. PATTERSON: It is part of the section.

DR. KOPANS: It is my understanding that the issue of electronic signature was resolved years ago legally at least, if not -- I have got one big hospital with a whole

lot of patients who have been doing things illegally, and I don't understand why that isn't just -- why FDA has to even pronounce on that. That has been decided. Electronic signature is legally acceptable. Why should the regulations have to even discuss it?

DR. O'MARA: I don't think they do. I mean this is just the comments that people have sent in.

DR. KOPANS: So that is okay, then, electronic signature.

DR. O'MARA: Larry?

DR. BASSETT: At least in the guidelines, there is something. I would think we would need to have it stated that it is acceptable. The reason is we have had inspectors tell us that it wasn't when it was, so we want to make sure that is clear. Otherwise, you are going to run into problems at the time of the inspection.

DR. HOUN: In the preamble to this proposed regs, it is discussed as acceptable. What I think people got confused was -- when I was reading those comment letters -- was this business of authenticating using the electronic signature and having those documents released. This is some

kind of procedure HCFA requires in the JACHO audit versus the mammographic report.

So, we have not proposed anything on authenticating documents. That means after it is printed, you have looked at it, and then you electronically signed to release them to go into an envelope and be mailed or sent E-mail. That procedure we have not even discussed, but I think people wrote in confused with signatures for a mammography report versus authenticating and releasing it as a check.

DR. O'MARA: The next section.

[Overhead.]

DR. O'MARA: Part 2 of the section was Communication of Results to Examinees, and this was, by far and away, the largest number of comments were received on this section. The gamut of response ranged tremendously from support of written lay notification to all examinees plus minus the actual report to complete disagreement with this section.

There were many modifications suggested including substituting verbal for written notification to the

patients, and only giving written notification to self-referred patients.

Just comments of a general nature that I included here were that question basically could verbal communication substitute for written report to the patient when the facility was acting as a primary care provider. I think this facility was discussing the results of the mammogram with every patient before they left the facility.

There were other facilities that said they actually telephoned the patients to give them their reports, and questioned the need, then, for sending out another letter.

If immediate follow-up was needed, can a phone call suffice, or did they have to send a letter. If they did, did it have to be sent registered. There was a question to define "immediate" in terms of what was meant by that, communication for highly suggestive or suspicious lesions, one hour, one day, one week, could the FDA further define that for them.

Some stated that 30 days was an unreasonably long time to notify an examinee of the results. Others felt that

the notification should wait until imaging workup was completed, but basically, they felt 30 days was a reasonable amount of time unless there was delay in obtaining films, and in that case, they felt that notification should wait until comparison films were obtained or other imaging workup was done if that was the case, and the report was completed at that time.

Facilities should have a system for referring patients to provider if clinically indicated, referring to the self-referred patient, and I think that centers noting that -- a few centers indicated that they did not accept self-referred patients, that all their patients had referring docs, and they therefore didn't feel a need to have lay notification because they were dealing directly to the referring doc, and that those centers that chose to have self-referred patients should have a system in place to refer their patients if it was clinically needed.

One center suggested that appointments be given to self-referred patients, to have them come back to the facility to discuss the results, and that there should be documentation of this in the medical record.

Another facility indicated that the way they handled notification was to send monthly lists to referring physicians of names of patients who had positive mammograms at a facility to allow the referring docs to double-check, and this was what they preferred to do rather than trying to notify patients themselves. They felt this is how they would catch patients who had not gotten notification from their doctors by having the doctors check these lists.

From reading that letter, it sounded to me that they actually sent all names of all patients that they did to all the doctors, and that might be considered breach of confidentiality.

Another facility wrote in that they felt that they should have the provider of care enter into a written agreement with the mammography facility where the provider of care assumed the responsibility and the liability to inform the patients, and that the mammography facility could breach this contract only if they felt that the patient had not been informed correctly or had not been informed of their results, but they basically again did not want to be the one in charge of notifying the patient.

You can go to the next page.

[Overhead.]

DR. O'MARA: There were some positive comments. I think the last time Penny asked me a question, and I went back to the letters to try to look this up. I will go through these, but let me answer Penny's question first.

She wanted to know whether there were any letters that physicians wrote in, specifically, physicians wrote in giving positive support to communication of results to the examinee in lay language, and after looking back through, the majority of physicians who wrote in did not support this, the majority of them being radiologists, but there were a few.

There was a group of nine radiologists, each of whom signed an individual letter that was identical, from Canton, Ohio, that basically said they thought it was a good idea. They did raise some concern basically about the cost, and stated that they talked to their attorney who said that they needed to have a certified return receipt letter to ensure this for medical-legal reasons, so that they would then later not be held accountable.

They basically felt that if this were to be put into regulations, that it would require an increase in reimbursement for mammography because otherwise it would result in a decrease of accessibility. They estimated the cost to be about \$2 per mammographic study to do this.

Another individual radiologist said that he favored lay notification, but only if the results of the patient study were negative. He felt that in no instance should the patient receive lay notification if she had a positive study.

Another individual radiologist favored lay notification only for abnormal studies, but not for positive studies. As I said, they went from one end to the other. Basically, his concern was the cost of notifying everybody.

The hospital right around the corner from me favored lay notification. It was a letter written and drafted by the department of -- the head of the quality assurance, I guess -- and also many techs, but there was a radiologist's signature on that, and addressed multiple issues, and within that they did say they supported lay notification and that they felt that the FDA should even

take it one step further and eliminate the out for second-party notification that is currently in there.

Now, just to go on to the positive comments.

Written notification was supported by breast cancer survivors. There were several breast cancer survivors that wrote in to say that it saved their life and that it obviously resulted in people -- would help from having people slip through the cracks and also to empower the consumer, and obviously the positive medical-legal aspects of communicating results to the patient and that there is a public health need for this.

The examinee has the right to know the result, and the facility has the responsibility to communicate the result to the patient. One facility performing mammography said that their patients actually appreciated the letters, they had had a lot of feedback about this, and they did not find it a hardship for the facility, they are currently doing it.

Comments again. Women were entitled to timely and accurate information. There should be nationwide consistency in reporting to patients their results. Many

comments were made that patients' doctors may not wish the results to be discussed with their patients.

[Overhead.]

DR. O'MARA: The State of Massachusetts said that they have been doing this and that to date there has been no facility closure that they were aware of as a result of the requirement, and they felt that the letter should be drafted by the interpreting physician.

It was pointed out that lay notification may result in earlier treatment with the benefit of decreased cost and extension of lives. The positive comments that were received with some modification to the way it was currently written.

Again, notify the patient with a written letter only if the study is abnormal as it is under the interim regulations, only those without referring docs should get written notification. Give the patient the choice if they desire to receive written notification at the time they come for the study, have them answer this question on an intake questionnaire, and if they don't answer it, to send them a report; that the FDA should set requirements for

notification, but let the facility adapt its own system.

On the other hand, one letter also said that the FDA should not only set the requirement, but they should develop the standard notification form for facilities to use.

Next page.

[Overhead.]

DR. O'MARA: A continuation of these positive comments that contain modification of the existing proposed regulation, that other parties should not be allowed, other than the facilities, to distribute the written notification, as I already said, notification to the examinee should indicate the importance of the clinical breast exam by a qualified physician, monthly breast self-examination, as well as appropriate mammogram intervals.

There was a lot of concern in the letters that I read that there may be an opportunity for patients to bypass having any contact with their referring physician and having a clinical breast examination because of their ability to deal directly with the facility and get their report, and also the ability of the patient to really understand the

concept of total breast care, and not just having their mammogram.

Many of the consumer advocate groups wrote in basically saying that the notification to the lay person should also include a statement regarding the location of films and how to obtain them with the actual name of a person to contact.

Letters agreed with the lay notification, but felt that the referring doc should still be responsible for follow-up care.

The negative comments. Actual medical mammo report confuses the patient and generates more inquiries. There was concern that there would be a lot of phone calls to the department by patients to have their reports explained; that it is unrealistic to expect facilities to monitor that lay notifications were sent out and it would cause the facilities to have to act as police.

With regards to referring doctors, if referring doctors were given the option to handle this instead of the facility, that obviously, there were additional costs and that they were concerned that there were substantial

concerns of postage and labor costs to have this done, and that this would present hardships to the facility.

There was one estimate -- I think this is what is on the next page -- of what the costs would be with a hypothetical situation, and it was estimated that the overall additional costs for this proposal alone would be \$14 million, and that the average expense of approximately 1 to \$2 per written notification.

A facility with an average of 30,000 exams per year would need to employ approximately one and a half additional employees at a salary of approximately \$15,000 per year per employee, and 50 cents postage, if that was not sent out certified mail, then, that this would cost the facility an additional \$37,500 per year.

Other comments stated that the patient must owe some responsibility for communication with the physician, that the patient may bypass the referring doctor and never have a breast exam. Comments made said that MQSA did not allow for this provision and that these regs were going far beyond the intent of MQSA.

Obviously, paper waste, environment concerns, many

comments made that the referring doc was best able to convey the results to the patient, knowing the patient best, that this interfered with the referring physician-patient relationship, that there would be confusion if the patient was notified prior to the referring doctor, and there would be confusion if there was a difference in the lay notification and the physician report, and also confusion from the patient who does not understand or misinterprets the report, or who just simply lacks the education to read the report.

I think that was almost it. They felt that this proposal would increase litigation. There was a letter written that basically felt that the medical audit would assure that the patient would receive additional follow-up of an abnormal mammogram and take care of the concern that the patient would fall through the cracks, and therefore the letter not be necessary.

It was felt unrealistic to expect radiologists to determine the literacy level, the ethnic and cultural and social sensibilities, patient detail or the written notification.

Under HFCA, somebody writing in from Ohio stated that their patient notification system was unsuccessful, that it caused undue concern and anxiety. It was interesting that in Massachusetts, they felt it was successful, the person who responded from that state.

Somebody writing on behalf of small and rural facilities felt that this particular section caused tremendous difficulties and especially in the smaller hospitals, smaller facilities that did not have a computerized reporting system.

I think that is it on this section.

Are there any more blue sheets? I will open it up to the floor. Yes, Dr. Kopans.

DR. KOPANS: First of all, coming from Massachusetts, I did get a letter from a patient who was very upset that we had sent her a letter, but it is the only one I have ever seen. I think it is a good idea.

I am curious, though, did the GAO -- the issue of the cost of doing this, \$37,000 for 30,000 mammograms is probably not that unrealistic -- did the GAO look at that, and is that a reasonable cost for the requirements to

engender?

DR. HOUN: The GAO did not look at this, however, the Office of Budget and Management, which must approve regulations by the executive branch, does, and that is a concern for them, as well as also for Congress and the Agency in terms of making sure, if we are going to have regulations, they are cost effective, that they are essential, and they don't increase regulatory burden that has little impact.

DR. KOPANS: Given that I don't know if their 14 million number was correct in terms of the facilities across the country, but then how is it decided whether that would be cause for removing the regulation or for keeping it in? I mean cost-benefit, who decides that?

DR. HOUN: Well, I think we get advice in terms of it is easy to calculate a hypothetical cost, and if you say, oh, 14 million might be right, well, then, we hear discuss benefits for it, and benefits can outweigh costs.

DR. FINDER: One other thing. In terms of the cost analysis that you have all gotten in the past, there was an estimate for this regulation of a little over \$14

million, so that is where the number comes from, at least one of the places.

DR. BASSFORD: I have seven points. Okay? But I will get them all over with at once.

DR. O'MARA: Tammy, just remember I didn't write all these letters.

DR. BASSFORD: I know. Just referring to addressing some specific comments that came from organizations specifically, regarding the scope of the law, it seemed to me there was some confusion between the requirement and the MQSA as legislated for the actual mammography report to go to self-referred patients versus patient notification, which at least needs to be addressed in some fashion just under the general mandate of the law to ensure adequate quality assurance, and I don't think anyone could disagree that patient notification is a key aspect of quality assurance.

So, I don't think that addressing patient notification exceeds the mandate of MQSA. There was an additional specific mandate with regard to mammography reports, which is a separate issue.

I noticed, because I happened to get a lot of letters in my own section that also addressed the QA, that the pap analogy was used quite a bit, and I want to just point out that women do not self-refer for pap smears. They don't do their own pap smears and bring in the slide to the pathologist. It is very difficult for a woman, then, to present to a pathologist for a pap smear without having had some contact with a health care provider, a real contact, an actual face-to-face, shall we say, contact.

So, I think that is a pretty specious analogy. If we eliminate or if we restrict written notification to examinees to self-referred patients, it is going to be incumbent on facilities to have a reasonable definition of what self-referred is.

I speak from a market that is heavily saturated with HMOs. It is probably the most saturated section of the country in Arizona with managed care, and I need to point out how increasingly difficult that is going to become, and if we are looking at these regulations as something that we hope to be able to live with over the next even five years, I just would like to make the committee aware of a few

points about the difficulty of determining whether a patient is, in fact, self-referred or has a referring physician.

Most mammography facilities in my area not only accept self-referred patients, but most HMOs now, in the interests of accessibility and consumer satisfaction, allow women to present for mammography without a written referral from their physician.

They may, in fact, give a physician's name. They may not be registered in that physician's office. The physician may not have a telephone number or any way of tracking down the patient.

Doctors who terminate their contracts with a certain HMO will have a whole backload of patients that were seeing them through that HMO, and that HMO will send a routine notification out to all those patients saying your new doctor is Dr. so-and-so. Dr. so-and-so, the new doctor, may never even have had any contact with that patient.

Eventually, it is going to be more costly for facilities to determine who truly has a relationship with the referring physician, who is truly a referred patient, and who is truly a self-referred patient, because of all the

blurring. I think due to valid public health concerns and consumer satisfaction concerns that it has made it easier and easier for women to walk into mammography facilities without a true relationship with a referring physician or, in fact, any contact at all, even a telephone number or a way of tracking somebody down.

So, I think a simplistic and probably in the long run cheaper solution is to notify all women of their results. I would note that if the interference with referring physician patient comments have come mostly from radiologists, and not referring physicians, that that is not very useful. I think it is up to referring physicians to determine what kind of direct notification would be interfering of their relationship with the patient.

In terms of all the interferences with the doctor-patient relationship, I think this is probably one of the lesser interferences. I am not referring my patients to a technologist when I refer them for mammography, I am referring them to another physician, and I have very few consultants who don't at least give the patient I refer them to some idea of what is going on in addition to contacting

me.

I think the suggestion for the no news is good news or only notify patients for negatives is what led at least to some of the most vivid examples of misdiagnoses that we have heard presented to this committee from consumers.

I do think if we are going to be flexible in any area, that the form of notification, I know some facilities do an excellent job of informing the patient of mammographic results at the time of the mammogram.

Personally, I think that that works just as well, and in fact, those facilities, in their report to me, note that they have already informed the patient, so written versus oral, I think is an area where we might leave some additional flexibility, but I just want to, as a referring physician practicing in a market where physician-patient alliances are constantly shifting, really make a strong appeal for direct lay notification of all examinees.

DR. PATTERSON: Amy.

MS. LANGER: I read the rather extensive comments on this section carefully for two reasons. One is that it

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is of great interest to me as a consumer rep and to my organization, and also because I had originally volunteered to present on this section.

I think, unfortunately, what has happened is we have gotten ourselves a bit -- we have become overelaborate in our efforts to accomplish this goal, which is actually straightforward, and in looking at some of these comments, I wonder if we might step back and suggest another mechanism to accomplish this, which might go along the following lines - where at the time the woman is processed on her intake form, she is asked how she would like to receive her results.

Now, obviously, this is not always going to work, for example, in the mobile setting, but understanding that the vast majority of the time her results will be normal, it may be that a verbal communication of the results does suffice as long as we do have evidence through the examinee's initials or some other way that she has actually received her results.

So, perhaps there is kind of a multiple choice approach to this where the examinee could indicate how she

wants to receive her results, that when it is preferable for her to receive her results in writing. The only place the pap analogy is not specious is that they do it very effectively with a very small postcard, and it is not always just sent by itself with its own 32-cent stamp. It is included in a bill or something else.

So, there are many ways for the vast, vast majority say, instead of the 30,000 where you are worrying about your postage, et cetera, it could go way down in that you have no certified mail requirement for normal results perhaps, and then when the result is abnormal, which is what we are all worrying about here, there is another communication mechanism that takes place or supersedes it. I just think that we have gotten a little too elaborate and confused the medical public in responding to this because, you know, people said okay for screening and not okay for diagnostic, okay for self-referred and not okay for others, and they indicated their own confusion in how they were going to make this regulation operative, and I think that we should attempt to simplify it.

DR. PATTERSON: Marsha.

MS. OAKLEY: As another consumer rep here, I have a couple of comments to make. One, I agree to Tammy very much in that many, many women are self-referring. I saw that in our own facility, and they give a physician's name, and then I have gotten a phone call back, and the physician has no record that this patient has ever been through the doors. So, Tammy, I do agree with that, that that can be a real problem.

The other thing is I represent a large number of women, and how I am here on this committee, and those women were very strong in that they wanted to have some kind of communication. I agree with Amy that I think we have totally gone beyond what the original intent was, and it doesn't have to be as elaborate and it doesn't have to be as costly, and my real concern is that the consumers truly do want to be notified.

Now, again, in agreeing somewhat with Amy, I think we need to be able to do it and perhaps do it less costly, my fear is if all of these numbers, if \$14 million now, and then where does it wind up five years from now, if all of those dollars turn out to be something that is going to be

real, not just a projection, but a real, that we are going to find facilities that just they can't afford it, they cannot afford, as you had up there, Ellen, a \$37,000 cost. They can't afford it if they are a small facility, somewhere in the next five years they are going to elect to shut down, and all that does is make it more difficult for women to get a mammogram.

So, I am concerned. I do want to see women get results. I want it somehow to be some kind of consistency, and I guess I want to be sure that no facility decides we are not going to do it, it is not really in the reg, we really don't need to do it, we can avoid it.

I have seen that already happening where people are trying to skirt around it, go around it, and I am really concerned that what women across the country want is to know that they are going to be protected with a result.

DR. PATTERSON: Esther.

MS. SCIAMMARELLA: I think I partially agree with Amy and what you say, Marsha, but the other issue is that I think is we want to tailor it to the clients is to ask at the time they do the self-referral, they go for mammogram,

to ask how they want to know.

I mean if they want a letter, some people are very mobile, maybe they cannot receive the letter, or the institution or the mobile unit, sometimes we do a lot of things to help there, is to give a number they can call, because it is very important how you explain, there is a need of emphasis, that not everybody, if they need to come back for a second mammography because they have something they are not sure, people are afraid they maybe have a cancer.

So, I think at the moment the person come in each institution, whatever the point of entry is, to explain what are the alternatives for the patient, so then maybe that way they can be tailored and less expensive that we are talking about.

DR. O'MARA: Rita.

MS. HEINLEIN: When this was first discussed, initially, the verbiage was that the facility would have a system for communicating the results of the patient. It was not indicated that it would be written notification.

Perhaps if we went back to that verbiage, just

saying that the facility must have a system for communicating the result, that at least give them the flexibility to say they can give it to them verbally or they can give it to them through written notification. That might be a way to simplify it.

DR. O'MARA: Flo, did you want to make a comment?

DR. HOUN: I guess there might be some misremembering of the discussion. I led the discussion. I was very specific, was verbal communication acceptable. I got the response no, and we had proposed written notification in this response because that was the clear message voted on by the committee, but I understand that in light of the public comment, the bottom line is that women should know their results and that it was felt in other committee meetings that the only way to assure this was written.

However, I think that in these discussions, and in light of many excellent facility responses on how they communicate, that weren't written, but that were also documented in the medical record or other procedures, that what I am hearing is that in terms of answering the first

question, I think it was the first question, one of the first questions submitted to you folks in terms of are other systems acceptable, you are saying yes.

DR. CHRVALA: I have several comments that I wanted to make about this. One is that I think one of the reasons why mammography centers are concerned about the cost is that they also like to use their postage to notify people to return for rescreening, which is a way for them to keep their patient population, but regardless, I think it is incredibly important that we do have a system of patients notification.

In the system that I worked with in Colorado, we had numerous, numerous instances where women were not informed of their results, and we would be sending them a reminder letter to come back for an ultrasound in three months or repeat exam in six months, and they would call us and say we didn't know that this was the case.

The standard right now in Colorado is not to notify the woman, it is to notify the doctor, and what was happening was the doctor was not conveying that information to women. That really concerns me.

I think this relates to an earlier issue we talked about, that women have to know what their results are, as well as what is recommended for follow-up according to the radiologists, so that they can discuss it in an informed way with their physician promptly.

I have some concerns that we have seen that women with abnormal results are more reluctant to return for their follow-up, and they require extra effort, and at that point we may be dealing with verbal communication and verbal follow-up, and it would be those women who are not returning for the follow-up.

So, I think that some of the cost issues are related to the fact that mammography centers are using their dollars to prompt women to return for rescreening, but not to notify women of their results and the recommendations that they receive is a mine field, I think, for the quality of mammography.

DR. O'MARA: Dr. Monsees.

DR. MONSEES: I strongly support notification of women of their results. That is the way we practice at our institution. But I think there may be some need to separate

screening and diagnostic results here. I think it is very important.

Screening is where we are talking about where we worry that people will fall through the cracks, where people may not know that they have an abnormal result, and there are so few abnormal results compared to normal results that it is possible that a woman could not understand that something is going on if she hasn't received a letter.

So, I strongly support for screening patients that we have some method of notification. In our institution, we are so paranoid that we not only send a result to the patient, but we also hand them a card at the time of their exam, and we say if you don't hear from us in seven days, call this number, because you should have gotten the report which could have been lost, and we also send duplicate reports to the physician if the patient gives us a name.

But I do have a problem with diagnostics and sending some sort of direct notification to the patient. Here is where it is very difficult in the lay language to communicate what is going on, and where I fear, for example, a woman who comes in for a diagnostic exam, for evaluation

of a palpable mass, if she gets a negative report, that she may just walk away thinking there is nothing needed to be done.

This is where the referring physician is really important and needs to bear the responsibility. At least at our institution, we do not accept diagnostic patients, symptomatic patients who are self-referred.

If a woman comes into the system and self-referred, when she comes back in for her additional workup, because she will be given one of these assessment categories that she needs some additional workup, it is a face-to-face communication, and a referring physician or surgeon is found for that woman, and the woman hears from our lips that she needs to go on and do this or that.

So, those situations where a diagnostic exam is done on a patient, a patient is symptomatic, I fear that it is going be very difficult to communicate to the lay public via a letter, and I would like to distinguish screening from diagnostic workups in methods of communication.

DR. O'MARA: Elizabeth.

DR. PATTERSON: The fact that nowhere in the

regulations is screening and diagnostic defined we are not going to be able to unless you wish to go back into that kettle of worms, which then you get into all kinds of changes because there are some Medicare terminology for diagnostic that really isn't, and so I really think that you are getting into all kinds of problems by trying to separate that terminology.

DR. O'MARA: Tammy.

DR. BASSFORD: I think the critical issue here is the mandate that the facility have responsibility for ensuring that all examinees receive the results of their mammogram. Given that we don't separate screening and diagnostic in the regulations, I agree that trying to impose how certain things are going to be communicated for screening and for diagnostic and for every situation, in terms of method of communication may be problematic.

I am not comfortable with leaving it to the patient to call in for those results, because it takes the responsibility for some attempt to communicate the results away from the facility and puts it back where it has been all along. Women have always had the option of calling in

for their results.

I am not even sure that it would be less costly. To me, it takes more manpower to try and reach a patient by telephone than it does to sign one of those little cards that go out that says your mammogram or your pap smear is normal.

So, I think we could address some of the concerns about how specific facilities handle communication in specific situations if we just had a simpler regulation that said every facility needs to have a documented system in place that ensures that examinees get their results from the facility.

When we look at the cost of that -- and I don't know what the overall cost of the total regulations has been estimated at -- but when we throw these numbers around, it is important to remember what contribution direct notification will make in terms of the total cost of the regulations.

I don't want to see direct notifications be the scapegoat for the increased costs of the regulations in general. You know, I don't think we just need to focus on

the cost of direct notification to the exclusion of the general costs.

DR. O'MARA: Carl.

DR. D'ORSI: Just as an aside, there were several comments that I received with the letters that were sent to me about the absence of the definition of screening and diagnostic, so we will probably come back to that again. There are some very good comments in that, and maybe we will think about this when we talk about that other definition section.

DR. O'MARA: Amy.

MS. LANGER: Two things. As we try to establish a documented system, as Tammy has just articulated, I think we shouldn't lose sight of the fact that a written notification is a very important and preferable element in a lot of cases. Since we know in breast cancer, constantly women talk about not being able to hear or understand if they are being told something is wrong, you know, you will say, well, what did the doctor say, and they will say, er, ah, I can't remember, I was so upset.

So, let's be very clear that It is the lay

notification by letter is something that is a good thing, we don't want to take it out now, but rather just trying to build in documented flexibility to the system.

The second thing is given the disparity, for example, that Ellen illustrated, between the experience of Massachusetts, who thought it was fine, and Ohio, who thought it was dreadful, has there been any effort by FDA staff to understand what the HCFA experience has been and what sort of positive and negative responses have followed the requirement of lay notification under Medicare screening?

DR. HOUN: Yes, and actually the public comments reflect what the objections were. The HCFA process, people felt was costly. They felt that they did get complaints from referring doctors saying don't talk to my patients. FDA still gets an occasional letter in red ink saying why is this mammography facility trying to steal my patient away. So, that is a concern.

Also, people objected to the quality of the notifications. They confused people, radiologists got called because the notices really upset patients, they

didn't know what they were about.

So, I think the more government gets prescriptive in communication, the problems we are going to run into, and I think that Dr. Monsees' situation where if her institution does well with the written for screening, but verbal notification with documentation that this discussion happened, if we revise the regulation to be more general in the sense of assuring that patients receive results through some documented system, and then we explain in the preamble that --

MS. LANGER: By the facility. That is the distinction. We don't want to go back to, as Barbara said, the physician can fulfill that requirement. That is not what we are talking about.

DR. HOUN: Right. The facility has that requirement to assure, and there are different means that they can assure that the patient receive results, and written notification, we can emphasize, you know, is the easiest way of documentation, and a very clear way to meet that requirement.

DR. O'MARA: Carl.

DR. D'ORSI: I think, having been involved in the Massachusetts notification program, I think during HCFA times what was specifically stated was the lay translation of the physician's report, in other words, with a fair amount of specifics placed into lay language vis-a-vis biopsy, follow-up for a mass.

The notification letters that I think we are all speaking about are more generalized, require a follow-up and it is a recommendation type of an oriented letter, so the woman knows what the next step is, and if she has questions about why that next step is to be taken, she can call up the facility and say, look, I have got this letter, you want me back in six months, what is going on.

So, I think that was the big problem with the HCFA letters requiring that a specific reason be placed in each letter, in other words, just a translation of the reports, and that is what many of the physicians were reacting to. I think the letters that we have now are more action oriented, which is the bottom line. You want a woman to follow the correct action.

DR. O'MARA: Dr. Kopans.

DR. KOPANS: I just wanted to not let Dr. Monsees' comments go by too quickly, particularly in light of the fact that someone said we are going to discuss definitions soon.

I absolutely support sending out or some direct communication of screening results. It gets very complicated with diagnostic cases. You may be in the process of doing multiple diagnostic evaluations, and every time you send a letter out, you may have already done what you are sending the letter out for, and you start getting all kinds of confusing signals back and forth.

So, I would hope -- and I don't see a major problem with defining screening and diagnosis, the Medicare can define whatever it wants, but that is purely a reimbursement issue, and I think we should be able to define what screening is all about -- so I would hope that you wouldn't completely dismiss the dichotomy between screening reports and diagnostic. I see more confusion with sending out written diagnostic reports than benefit.

DR. O'MARA: Cass.

MS. KAUFMAN: One of the problems that we have

seen when you do differentiate between screening and diagnostic is that if there is an easier route to go for one versus the other, that then the facilities, some facilities will call everything screening or everything diagnostic.

For example, if their reimbursement rate is higher for diagnostic, then, they tend to call things diagnostic. That is one problem with doing that.

The second point that I wanted to make is that I think we need to focus in on how the women themselves will best be benefitted, and not get into issues of relationships between various physicians. We need to focus in on what is good for the women of America.

For example, if I am referred to a cardiologist from my primary care physician, I expect that cardiologist to deal with me directly, and I think that is generally the way it works, and I think radiology is one area where that has not occurred in the past, but I don't think it is a bad thing to have the consulting physician communicate directly with the patient.

Once the primary care physician has referred you to that physician, then, that is a relationship between you

and the patient and that physician, and I think they have every right and obligation to communicate directly with the patient.

DR. O'MARA: I understand what you are saying, and I think that in a practice that I was in when we had patient surveys, we often got comments about the fact that the patients never met the radiologist, and it is a different relationship between being sent from your family physician to a cardiologist, where you see that doctor face to face as opposed to being sent in for a screening mammogram, and honestly, I mean I have known patients who don't even understand that it is a physician who reads that film, and for all they know the tech processes it and goes and reads it or that it comes out of the processor with an answer, so I disagree a little bit with your comment there.

MS. KAUFMAN: I guess this might be a good opportunity for people to understand what a radiologist does do.

DR. O'MARA: I think that, as a patient, I might feel that I have never met this person, I have no relationship with them, and I have a sense of trust in my

referring doctor. I basically support what we have been saying here in terms of lay notification. I am just commenting on what you said in terms of the relationship between the physician and the patient.

Yes, Dr. Finder.

DR. FINDER: I just wanted to bring up two facts. One is people are talking about the costs and everything. In your packet, there is a little, brief summary of some of the costs, so you can look at that and get an idea of what we are talking about.

The other thing is I would hope that we could answer the last portion of that question at some point in this discussion - can requiring written instructions rather than the actual final assessment to the patients on how to get their results, is that an alternative, or is that nothing to be considered. So, if we can get an answer to that from the committee.

DR. O'MARA: Tammy.

DR. BASSFORD: I would say based on the sense that I am getting from the discussion, that that would not be an alternative. The crux of it, what I think I am hearing is

there may be some room for flexibility in how the results are directly communicated, but that everybody would like to see or the recommendation would be that in the regulation is a requirement for direct communication of the results by the facility to the patient. Instructions for how you can get your results does not meet that need.

Particularly, I want to allude back to Amy's comments about the considerable amount of denial that women can be in regarding these things. I don't think that that is going to fulfill the intent of the original regulation or of the original legislation that was designed to improve a quality assurance system in mammography.

So, no, I don't think that would do it, and the other -- now I have forgotten what else. Elizabeth?

DR. PATTERSON: I always find that so often people, if you can do it an easy way, then, you will use this method, and so I can see in a waiting room a sign up there posted saying, if you want your results, you can call this number, and I think that that is not the intent of the legislation.

DR. O'MARA: Amy.

MS. LANGER: I do think it could be viewed as suspenders, you know, where the belt is what we have all been sketching out, so that it is another way to be absolutely certain that the letter was sent, that the verbal communication was actually delivered, so that you can do it as a supplementary addition to the direct communication.

Some other people might have comments on this, but I would like to get back to the section of the comments that I saw where medical professionals indicated a tremendous discomfort with our language pertaining to sensitivity to ethnic and cultural issues in communication of results.

When you are ready for that, I would like to make some comments about that.

DR. O'MARA: Esther, did you want to say something? You had your hand up before.

MS. SCIAMMARELLA: My comment is that, Flo, I think nobody disagree here that we need to send information in writing to the patient. The issue is how we prepare the patient for what they are planning to receive. I don't have the numbers and the statistics now, but I think it is around 40 percent in general the doctor doesn't send to the patient

information about the diagnostic condition even if the results are not good.

So, I think the idea is reassurance in this particular case that the patient receive the information in writing, but I think it is important to explain what happened and what they will receive and for what reason. So, this is the relations between individual patient and the provider, how is the process, and I think sometimes consumer doesn't know what is going on, and I think you will need to be sure that that is explained in the way the patient want to know.

DR. CHRVALA: I just wanted to add that in terms of notifying women of the results of the mammogram and the radiologist's recommendation, oftentimes -- and this is again from experience in Colorado with a statewide tracking and follow-up system that did medical audits -- there were variations between what the radiologist recommended, so if a letter went out saying that your mammogram was interpreted as this, and we explain what that meant, and this was the recommendation, when the woman went to her physician, alternative activities happened, and I think the letter

would have to acknowledge that this is what the radiologist recommended and it is important that you discuss this recommendation, as well as other procedures for follow-up, too, because there is a dramatic difference between what the radiologist recommends and what actually happens.

DR. O'MARA: Tammy.

DR. BASSFORD: I think a lot of this, positive suggestions for better letters than went out with HCFA and stuff, could be in the guidance document and kind of make it easier to encourage written notification by providing -- I mean providing some examples of things that are really I think generally well received.

I think any letter from a mammography facility that says we notified your doctor of these results and we encourage you to discuss them with your physician could hardly be seen as an attempt to steal patients.

I mean I think that is what was missing from a lot of the HCFA letters or letters that were generated in response to that requirement earlier. I think a lot of the how's and why's could occur in guidance as long as the regulation is firm on the responsibility of the facility to

communicate the results.

DR. O'MARA: And apparently there are letters out there that the ACPAR committee had available that could be put into guidances, suggestions for how to send these letters out, too.

Amy.

MS. LANGER: Why don't I just make a suggestion, because it comes off your point. I was on the ACPAR panel, as well, and we did model letters, and maybe they are not fabulous or perfect for every facility, but they are a starting place.

As I say, it was my impression reading through letters from facilities around the country, that they are quite concerned to fulfill, obviously not a requirement, but the encouragement of the FDA to deliver the information in a culturally appropriate fashion, sensitive to considerations of each woman and of course a language that she could understand.

I wonder if it might be a future project outside of regulations specifically to develop model letters in collaboration with organizations that represent groups of

women that are ethnically diverse and see if we can help facilities in this way specifically again using the expertise of women's organizations that represent these various populations.

DR. O'MARA: Elizabeth.

DR. PATTERSON: I just want to bring you back to one point again. Is the committee recommending that the word "written" be kept in the regulation? I am hearing -- I think I heard some way, well, there might be alternatives, and then I think we are back to saying written.

Can I have the consensus from the committee?

DR. BASSETT: I do share Barbara's concern a little bit about patients who already have an abnormality, you have informed them of that, and now they are coming back for workup of that.

I know what we do in our practice is the same. If someone is called back for something additional or because there is a problem, we talk to them directly, because at that point they are going to want to know, you know, you are not going to want them to leave without some understanding of what transpired.

Whether you need to send something in the mail after that, I am not so sure about.

DR. FINDER: Well, let me just say that the way this is written right now, you wouldn't have to send something written. So, that is the question again.

We started off at least I heard that we were going to be more flexible and allow oral, and now we are saying, no, that is not acceptable, so we need some kind of consensus which way you want us to go.

DR. O'MARA: Maybe a show of hands, Charlie? I think you are going to go around in circles making these comments again.

Rita?

MS. HEINLEIN: Both Dr. Bassett and Dr. Kopans and Dr. Monsees, all of them have used the word "direct," that they speak to this woman directly when it is a diagnostic exam. Perhaps the word, instead of being "written," needs to be "direct," that there should be direct communication with the woman, and that can be through written communication, through verbal communication, et cetera, but I think direct communication by the facility to the patient

of the results that is documented.

DR. BASSFORD: My sense is that would meet the sense of the committee and then, in guidance, we could make a comment to the effect that in most cases, written notification will be probably preferable and an easiest way of documenting, to kind of encourage written notification for women who present for screening examinations.

But I think the key words are "direct" and "documented" and by the facility.

DR. O'MARA: Marsha.

MS. OAKLEY: Again, as a consumer rep, my initial preference was it was written, but I think what I am hearing here today, and from some of the physicians, that as long as this includes direct and documented that I could probably support that.

DR. SMITH: I think the emphasis has to be on direct, and I think that there is a real opportunity here to provide guidance and, in fact, show that you have responded to the letters and the critiques that have come in. I think that this is going to be a real good opportunity.

DR. O'MARA: Do we have an overall sense here now

that you think that we can close on this issue? Okay. I have a little bit of a problem and I really am going to have to leave, but maybe Amy can take over leading the discussion.

I thought what we could probably do is go through the rest of the transparencies, which I can leave with you, if you want to refer back to them, but just nobody has to struggle understanding my cryptic notes, and if Amy wouldn't mind doing me the favor of just leading the rest of the discussion, and that would work probably for me.

DR. PATTERSON: That is entirely between the two of you how you wish to do it. You are pressed for time, and I realize that. How much more on your transparencies do you have?

DR. O'MARA: We need to get through the section on the notification of physicians and then recordkeeping. I think that actually that discussion is going to be fairly small, but I am well past the time that I need to leave, unfortunately.

MS. LANGER: I can fake anything, but I have not concentrated on those sections, Ellen. Thank you for your

confidence in me.

DR. O'MARA: I thought you made the comment before about having had an interest.

MS. LANGER: I stopped reading at a certain point, but I just would point out there is a third FDA question in this section, as well, that needs to be addressed, about original films.

DR. PATTERSON: That is still part of it.

DR. O'MARA: Kind of go through those comments. Flo said she would help. That's okay. I had asked Flo before.

DR. PATTERSON: If Any can wing it on your transparencies, why don't we do that.

DR. O'MARA: I thought it would be probably reasonable to go through the transparencies.

DR. PATTERSON: And then hold the discussion until afterwards?

DR. O'MARA: Yes.

DR. PATTERSON: Okay. Fine.

[Overhead.]

DR. HOUN: This one was a fairly short segment.

Communication of results to health care providers. Comments were of a general nature. Requests to define immediate communication for suspicious or highly suggestive lesions with regards to those categories.

One facility wrote in and said that their radiologist read only two times per week and how were they to deal with this "immediate" communication.

Some of this is redundant to the other section. Again, 30 days was unreasonably long to notify a physician of results. On the other hand, 30 days was reasonable unless there was delay in obtaining comparison films. More of the letters supported the second comment than the first comment.

A question was raised what is meant by the responsible designee of the health care provider, spell out the qualification of the person capable of receiving the mammography report.

Again, the electronic signature, referring docs receiving the mammo report should acknowledge by electronic signature that they received the report, and this should be kept on in the electronic file indefinitely was one of the

comments made.

Next section. We will delay that then for comments.

[Overhead.]

DR. HOUN: Recordkeeping. General comments.

Facilities should be allowed a nominal fee for transfer of films. The FDA should develop guidelines for charges for copy, film, and postage, and fees for transfer should not exceed costs. The proposal that fees for transfer should not exceed costs was considered price fixing.

There was positive support for this section. Transfer of original films should be done upon examinee request. It should be a written request indicating whether the transfer is temporary or permanent. Transfer of original films may conflict with state and local law, and there was a question about how that should be dealt with.

The FDA should add a statement in this section regarding that the films should be transferred in a reasonable time frame. The original film transfer was felt important by one respondent. The copies were often of poor quality and not helpful, that others felt that the original

film should be returned within 30 days if it was a temporary transfer, and it was also noted that this, too, was a previous HCFA requirement.

There were some suggestions to modify this section and that one respondent said that mammo films should be kept indefinitely to spare a woman an unnecessary biopsy. Another suggested that there should be a one-time standard recordkeeping time for all films five to seven years, and then another comment was made that a facility which took the most recent mammogram should maintain ownership of the originals for future comparisons.

[Overhead.]

DR. HOUN: The negative comments regarding the recordkeeping section. They felt that this section on the transferring of original films should be deleted, that the films were the property of the physician or institution which generated them, that only copy films should be sent out. Transfer of original films would disadvantage the physician's ability to defend against claims.

A question was posed does the FDA indemnify the radiologist in the event of malpractice action in lost films

if the films had been sent out. There is obviously a potential for loss of breach of confidentiality. Would prevent comparisons at the original institution if the patient returned for another mammogram, and the films had been lost.

Several letters said that they felt it was no value to have copy films, which is one of the suggestions, for comparison if the originals were lost, and that copying originals retained in the jacket just results in more increasing costs, as well as a delay in sending out the films to the facility requesting them for comparison.

[Overhead.]

DR. HOUN: Some other general comments on the section, again, not my statements, but an intrusion into practice of medicine, just delete the whole section.

There was concern about the use of the term "examinee" as opposed to the use of the word "patient," that third-party payers may not recognize the term "examinee," that the use of the word "patient" was tied in with malpractice protection, and also we talk about the doctor-patient relationship and the ethical protection of

that.

Others wrote in and said they agreed with the term "examinee." There was just another note about a typographical error that was I guess actually written as "topographical," something I don't think we need to get into.

Is that the last sheet? Okay. That is the beginning, so we got through them. Thank you.

Should I open the floor up? Do you want to go back to maybe the notification of physician would be a good place to start.

I am very sorry about this.

DR. PATTERSON: You are forgiven. If Amy is willing to lead the discussion on that aspect.

MS. LANGER: Could you put Ellen's overhead back up. I think it was green, and it started talking about physician notification.

[Overhead.]

MS. LANGER: Yes, thank you. Okay. The first issue pertains to defining the timing of notification. Does someone want to comment on that, on the committee?

DR. KOPANS: Is there anything in that first line there defining "immediate"? I don't remember seeing anything in the regulation that actually gives minutes.

MS. LANGER: I think we left it very general, didn't we?

DR. HOUN: That's right. We did not specify what is immediate, and I think the reason is that we did not want to be unreasonable in a situation where you need to be flexible.

DR. KOPANS: It would seem to me that immediate is fine, just leaving it that way. Thirty seconds is good.

MS. LANGER: Immediate in a batch environment obviously is very different than on-line reading.

Marsha.

MS. OAKLEY: I just have a comment on that word "immediate." It isn't in there I don't think. I have had the experience, and again I represent consumers, of women who have been called at 4:30 on Friday afternoon because someone said we have to notify this woman immediately.

At 4:30 on a Friday afternoon, there is no way this woman is going to find anybody who is in an office that

they can talk to, and again, that word isn't in there, but immediate to me from a medical point of view, also has some common sense behind it. Unfortunately, I haven't seen that with some physician offices.

I think that, you know, immediate to me means reasonable immediate, and again my point being if you use the word "immediate," and somebody takes it literally, 4:30 in the afternoon is not reasonable for a woman to then have to go all weekend with no answers and nobody to get ahold of.

MS. LANGER: The word "immediate," just to clarify, is actually in the regs.

Tammy.

DR. BASSFORD: I think we are talking about notifying health care providers here, if I understand it. I just think we had a lot of discussion about whether to put a specific time limit or not, and unless any of the comments have changed the committee's consensus, I think we had some pretty explicit reasons for why it would be imprudent to regulate a specific time limit in this case.

MS. LANGER: Dan.

DR. KOPANS: I think, just to answer that question, you can't legislate common sense. It is going to happen no matter what you do. I would just leave it the way it is.

MS. LANGER: Moving on to the 30-day question, I did read some of these, and it was amazing. You would read one, it would say that was terrible, and one would say it was fine. So, does the committee have any suggestions in terms of a change or should we maintain the 30-day? It is fine as is?

This was interesting. What is meant by "responsible designee of health care provider"? There were quite a few letters that were concerned about who on the physician side would be receiving this information, and then, in turn, communicating it to the examinee.

Any suggestions here? It doesn't strike me as something we can regulate.

Anything further that we need to discuss here?

DR. CHRVALA: In terms of the 30-day, I think it is important, in light of our discussion about notification of the consumer, that there be some lag time put in there,

so that the provider gets the report before the consumer.

MS. LANGER: That is in a separate section, and I think there is that suggestion. Is that not right, Flo? Flo, isn't that correct, there is some guidance saying that there could be a lag time?

DR. HOUN: We didn't want to be prescriptive on the actual issuance sequence.

MS. LANGER: Could we see the next overhead, please.

Dan.

DR. KOPANS: I am just curious, and this sounds a little silly, but if your average time is 34 days, do you go to jail or what happens?

DR. HOUN: Federal prison.

MS. LANGER: Marsha, could you maybe help this gentleman. It was the one after this one. I think it pertained to recordkeeping, films. Yes, that is it.

[Overhead.]

MS. LANGER: This is really a good question, whether you send out and release the original films, obviously, there is a trade-off. Any discussion? Dan.

DR. KOPANS: I think it is interesting that the comment that said they don't want to send out the originals because if they keep the copy films, the copy films are inadequate to compare to subsequent studies, but it is okay to use copy films to send out for the other facility to compare.

In my mind, the care of the individual should come first. It should be a requirement to send out original films. You can document that the patient agreed to that, that she agreed to the transfer. If they are lost, then litigation comes up. It is unfortunate, but she agreed to the transfer, and that should be, I would think, some sort of defense for the radiologist, but that is such a low potential I think for a problem anyhow that I think FDA should definitely require originals. Copies I think are useless for comparing to new films unless they are perfectly done copies, and it is very hard to do that.

MS. LANGER: Is there any knowledge here about, for example, transfer of orthopedic films? Is that done standardly with originals? Why would that be different?

DR. KOPANS: The detail is much more important

with the mammograms. I don't think you can compare it to anything else really in terms of transfer of films.

MS. LANGER: Yes, Joel.

DR. GRAY: From the technical point of view, the duplicating film cannot reproduce all of the densities that are on that original film. So, you are sending less information than it there.

MS. LANGER: Flo?

DR. HOUN: I have a question for folks involved in new technology because I don't want this reg to necessarily be outdated quickly. Is new copy technology that is of high quality coming out soon, or in terms of other kinds of transference of mammography films, let's say, through telemammography, what is the original?

I know we could handle that through alternative standards and this variance procedure, but is there a way to say maybe original copy quality? I just want to make sure that we are broad enough, we don't outdate ourselves too soon.

MS. LANGER: Elizabeth.

DR. PATTERSON: I would like to address that. If

I remember correctly -- and I think it was Larry that made the comment when we initially discussed this -- if your copies are as good as the originals, then, you can keep the copies and send the originals, if I have quoted you correctly.

So, I think that if you use the terminology in there of copies, then, you are always going to end up with everybody who makes copies is going to send out these copies which are completely useless, and I think that we really need to keep it for comparison for the patient's benefit the originals.

As you questioned with some of the newer technology and always the possibility of digital and et cetera, then, the alternative standards would be able to look at that and answer that question.

MS. LANGER: Before we go further, I thought I would mention that I noted that both in the American Cancer Society and National Breast Cancer Coalition letters, there is a suggestion that the woman be notified as to where her films are, the original films that is I would assume, and how she might obtain them at any point in time, so that just

throws a bit of another layer of complication on when films are transferred.

Carl.

DR. D'ORSI: Can the FDA just reiterate the policy of what happens when federal law and state law conflicts require that original films never be sent, and only copies used, and what the policy is, and is that policy defensible for someone in a state where this may go to litigation?

DR. HOUN: General counsel has looked at a few state laws, the states that had issues that wrote to us, like practitioners in those states refusing to send originals, and in the case of Florida and California, in reviewing those laws, our counsel doesn't feel that there is an exclusion for this provision of original transfer.

If, however, let's say, a practice in Florida disagrees, I mean what happens is that it is a suit in court, and the court decides. But in looking at our position, states can have stricter laws, but the stricter laws in MQSA refer, not to protecting -- it is for protecting the patient for advancing quality, and so FDA's regulation that you must transfer originals would be viewed

as stricter than you can only submit copies for transfer.

MS. LANGER: Joel.

DR. GRAY: I would like to address Flo's question regarding the digital imaging aspects. When we are talking about film, we have been talking about originals and duplicates. I don't think you can equate that in any way whatsoever to the digital world.

Unfortunately, whatever you decide today in the digital world, it is like the computer you buy today, it is going to be outdated within six months anyway. The original in the digital world can exist in many places at one time, an undegraded duplicate, if you will.

On the other hand, I suspect that most of the people getting into digital are going to be looking at data compression techniques, which means you now no longer have an undegraded original data set anymore, so it is going to be a whole different ball game, and I think you will just have to address that separately, unfortunately.

MS. LANGER: So, it is the committee's feeling that we should stand with our requirement that originals be sent for comparative studies?

[Affirmative responses.]

MS. LANGER: Thank you. There is one more overhead.

[Overhead.]

MS. LANGER: We, as a committee, worked pretty hard to craft this term "examinee" with the idea that many, many consumers of mammography are healthy women. I think the only question raised that I saw is if there is any kind of breach of the patient-doctor relationship for medical malpractice interpretive purposes to allow someone to somehow hide behind the term, which is an interesting question.

Was that looked at by the FDA staff at all?

DR. HOUN: We discussed it and we felt that that was probably a very important argument that examinee term did not have some type of historical base in protection and recognition in courts if we were going to have to come before them on records or other issues.

MS. LANGER: Tammy.

DR. BASSFORD: I wonder if there is any precedent with increasingly common use by again managed care and

corporations that are providing insurance of patients as consumers' covered lives. I mean there is just a huge range of terminology out there, and this is the first time I have ever heard a concern expressed referring to your patient as a consumer of health care, which at least on an organizational level is done all the time now would be a problem in terms of liability and confidentiality.

It isn't the only instance where terms other than patient are being used commonly I guess is what I want to say.

DR. FINDER: I think the "patient" word has just a longer track record in terms of understanding some of the other issues attached with medical-legal issues.

MS. LANGER: Larry.

DR. BASSETT: Could that be addressed in the introductory definitions, that this is a term traditionally, the term "patient" had been, but it used "examinee" because of the difference between healthy and patient, and I think that would settle it.

MS. LANGER: That sounds like a good suggestion. It also occurs to me that once there is a financial

transaction under standard codes, for example, that would convert the examinee to a patient for legal reasons.

Aside from the big typo problem, are there any other issues under this section? No? Thank you.

DR. PATTERSON: Thank you very much, Amy.

At this point, being that we are really running on time -- I am being facetious, tongue in cheek -- we are going to take a break for lunch, and we need to be back here at 1:30 promptly.

Has anyone heard from Ed? Is Ed coming, do you know?

DR. SMITH: Ed had an emergency.

DR. PATTERSON: Joel, are you prepared to go on?

DR. GRAY: Not at this time. I would suggest that after the public discussion this afternoon, we proceed with the Quality Assurance-Equipment 900.12(e).

DR. PATTERSON: We will need to go back onto the Quality Standards sometime today. It will have to be covered today because it is on our agenda for today.

DR. GRAY: I am not prepared to do it today.

DR. PATTERSON: Okay. We will look at what we can

ajh

do with that.

So, back at 1:30 following lunch.

[Whereupon, at 12:10 p.m., the proceedings were recessed, to be resumed at 1:30 p.m.]

AFTERNOON SESSION

[1:40 p.m.]

DR. PATTERSON: If everybody will resume their seats, so that we can continue on with the session for the afternoon.

We are going to have to do some juggling on our scheduling agenda items. The topics under Quality Standards under Equipment -- I have got all the manufacturers back there screaming at me right now -- we are not going to be able to do today. Unfortunately, one of the individuals is detained, and the other, I think they sort of split up the things, so we are not going to be able to do that today.

Now, we will do that discussion tomorrow. I don't know how many of the equipment people back there are unable to be here tomorrow for this discussion. Can I see a show of hands of any of those who will not be here tomorrow?

[Show of hands.]

DR. PATTERSON: Okay. Let's go the other way. How many of the equipment people can be here tomorrow?

[Show of hands.]

DR. PATTERSON: Three.

Back on the drawing board. We will come back on this comment later. We are going to have to rethink this one.

In the meantime, we will go ahead with the public session, and we will allow 15-minute presentations.

The first to talk is Richard Graves, who is a representative of the American Mammography Software Association. There are some handouts that are at your seats that have been handed out by Mr. Graves.

OPEN PUBLIC HEARING

MR. GRAVES: Hello. Can you all hear me? My name is Rick Graves. I am here representing the American Mammography Software Association.

[Overhead.]

MR. GRAVES: We want to cover four issues. One is the lay language results notification requirement. Based on the committee discussion this morning, I would change that to direct documented notification to the patients facility requirement.

The second is the adequacy of FDA's proposed final regulations on the missed cancer issue.

Third is ACR statistical definitions, and fourth is accreditation body commercial conflicts of interest.

You should have five documents from AMSA. One, the April 1996 handout to the December letter to the Advisory Committee. Three, supporting materials to the December letter. Four, our January 13 handout. The people up front should have a separate piece of paper which I distributed this morning, which is a supplemental handout, Quality Mammography Comparison, Feature by Feature.

For people in the audience who picked up the materials, the January 13 materials, I brought some this morning, but obviously not enough. I will bring more tomorrow. If you are interested, look for it then.

Before we go on -- no, this slide is fine. The only thing I would like to say on the lay language results notification requirement or the direct, documented notification by the facility requirement is I think it is sensible to allow facilities flexibility to tell people in person their mammography results.

If FDA wishes to -- in our December letter, we have set forth some suggestions on how to counter the

objection raised to the written requirement. Since you are going to emphasize written notification would normally, well, I assume if you follow the Advisory Committee advice, you are going to emphasize that normally a written notification would be appropriate. I urge you to consider those comments.

Also, I would like to announce that AMSA endorses the American Cancer Society proposal to expand the things that facilities should tell patients about their mammograms.

So, on to the next. Could we get the next overhead, please, the missed cancer issue.

[Overhead.]

MR. GRAVES: MQSA provides in part, "The Secretary shall establish standards that require the maintenance of a quality assurance program at each facility that is adequate and appropriate to ensure the accuracy of interpretation of mammograms."

I may have read this to you five times now, but we believe that FDA's proposed final regulations fail to comply with this aspect of the law passed by Congress. We know what Congress meant by "accuracy of interpretation of

mammograms" because Congress said MQSA would help solve the problem encountered by Mary Stupp. Her mammograms were read as normal, but they were misinterpreted, the cancer was missed with tragic results.

Secretary Shalala, FDA's big boss, clearly understood what Congress intended in her opening remarks before this committee three years ago. She told the story of Nina Hyde, a distinguished Washington Post fashion writer whose mammogram was misinterpreted with tragic results.

She went on to say, "This is why the Mammography Quality Standards Act is so important."

Could we go to the next slide, please.

[Overhead.]

MR. GRAVES: This is FDA's proposed medical outcome audit regulation. The emphasis is entirely on positive mammograms, but Mary Stupp's and Nina Hyde's misinterpreted mammograms were negative. FDA is focusing on only cancers that mammography finds, but Congress was most concerned about cancers that mammography misses. There is a big difference, and I would also like to add at this point that Brock Adams dedicated MQSA to the memory of Mary Stupp.

She passed away before Congress adopted the Act.

At best, the FDA regulation would only address the misinterpreted mammogram or missed cancer issue in an indirect way, but not for all radiologists and only after a long delay. At worst, the FDA regulation would encourage radiologists to focus on positive predicted value only, and thus fail to detect cancers at an early curable stage, the opposite result from what Congress intended.

I explained these points in my December letter. I don't have time to go into them in detail now.

Could we go to the next overhead, please.

[Overhead.]

MR. GRAVES: AMSA believes that its proposal from our April '96 handout would fulfill the legal requirements of MQSA and would address the heart of the problem that Congress sought to achieve through the Act. During the April advisory committee discussion, radiologists described reviewing prior mammograms in cancer cases as our greatest learning tool and as the best way to learn how to detect cancers at any early curable stage.

That is what we are asking for. AMSA believes no

valid reason has been offered yet as to why FDA should decline to require that radiologists utilize this learning tool. However, FDA points out that the only advisory committee members who have spoken on this issue are opposed. Is there any valid public policy reason why FDA should decline to require that radiologists utilize our greatest learning tool and the best way to learn how to detect cancer at an early curable stage? Would each of you please address this issue and let FDA know where you stand.

Could we go on to the next slide, please.

[Overhead.]

MR. GRAVES: Statistical definitions for mammography. Consider the usefulness of determining the probability of detecting cancer when a cancer exists. This would allow one to compare a new cancer detection technology with mammography. Researchers and investors could decide to proceed with new technology on this basis.

Could we go to the next slide, please.

[Overhead.]

MR. GRAVES: I would like to tell you about a study Dr. Ken Heilbrunn and I did back at the end of 1995.

Our objective was to determine for mammography the probability of detecting cancer when a cancer exists. To do this, Dr. Heilbrunn reviewed prior mammograms for a random sample of 128 breast cancer cases to determine whether the cancers were visible in retrospect. Obviously, if they are visible in retrospect, they must have existed at that time.

Our results by totaling the numbers and dividing, we estimated that the probability of detecting cancer when a cancer exists for mammography is 58 percent. The false negative definition that allows you to validly determine the probability of detecting cancer when a cancer exists is a simple one. The test was negative, but patient had cancer.

If someone limits the false negative definition with a time limit, computes a percentage, and calls it sensitivity, that percentage does not mean the probability of detecting cancer when a cancer exists, because with any time limit based on when the cancer is discovered, you are undercounting cancers when a cancer exists.

If you have got a time limit that says you only discover the cancer in one year, otherwise, you leave it out, you are leaving out cancers when a cancer exists.

In our April handout, AMSA explains why it believes that the sensitivity figures published in the radiology literature are meaningless. We also know that the sensitivity figures published in the radiology literature are higher than the probability of detecting cancer when a cancer exists. AMSA believes that the sensitivity figures published in the radiology literature are thus misleading.

ACR has, in effect, acted to extend the effort to mislead the public about the effectiveness of mammography. ACR's BI-RAD's statistical definitions omit more missed cancers from the when a cancer exists count than any other approach as far as AMSA is aware.

Let's think about a hypothetical. Suppose researchers discover a new cancer detection technology that is actually superior to mammography, but not as good as the sensitivity figures radiologists have been publishing.

The researchers and financial backers could decide to abandon their efforts incorrectly believing that the new technology is inferior to mammography. I think it is fair to say radiologists have a public relations problem here.

People making money from mammography are thus

maintaining an artificial barrier to the development and acceptance of new cancer detection technologies, and ACR has acted to raise that artificial barrier higher.

These could be considered wrongs against women's health. I think it is fair to say no one of us can know whether the development of a new promising cancer technology has already been discovered and has already been abandoned because of the meaningless sensitivity figures radiologists have been publishing.

Now, true, we are here because of the Mammography Quality Standards Act with the emphasis on Mammography, but AMSA believes we owe a higher duty to women's health. We owe it to American women that if any new technology should be discovered, that they should be considered fairly on their merits.

Now FDA knows that the ACR's statistical definitions are an artificial barrier to the development and acceptance of new cancer detection technologies. AMSA hopes that FDA will not acquiesce any longer.

Can we go to the next slide, please.

[Overhead.]

MR. GRAVES: Accreditation body conflicts of interest. ACR has dropped its commercial product, but the issue remains whether FDA should close the door or keep it open for future commercial ventures by accreditation bodies. Right now FDA's door is open.

In considering this issue, we think it is fair to assess the success of the ACR software venture. With the benefit of hindsight, AMSA believes that ACR's commercial software venture was detrimental to quality mammography, to free enterprise, and to ACR's track record as a professional organization.

On that basis, we believe FDA should prohibit commercial ventures by accreditation bodies. First, ACR's commercial venture was detrimental to quality mammography. AMSA believes that ACR put off requirements for medical outcomes audits and follow-up on the disposition of problem cases to save the market for its commercial product.

This caused medical outcomes audits requirements to be delayed for about eight years and the requirement for follow-up on the disposition of problem cases to be delayed over three years. On this point, there is an inaccuracy in

my December letter. When I wrote that, I had forgotten that FDA had included in its interim regulations a requirement for follow-up on the disposition of problem cases. So, the correct point there is that the delay there was for just over three years.

Could we go to the next slide, please.

[Overhead.]

MR. GRAVES: Now, you should have a handout that looks like this overhead. That is the one I distributed and that is the one that some of the people in the audience may not have. As I said, based on the discussion this morning, the box on the lower left might be better labeled "direct, documented communication of results to the patient by the facility," but that is a little long, but anyway we support that.

We believe the ACR product cannot be justified on quality mammography grounds. Prior to ACR embarking on its commercial venture, products were commercially available that would fulfill FDA's upcoming requirements for overall assessments, medical outcomes audit, follow-up on disposition of problem cases, and direct documented

communication.

Furthermore, before ACR launched its product, ACR knew that commercial software was available incorporating these features. Based on FDA's judgment, as embodied in its regulations, proposed regulations, we therefore believe that the reasons ACR embarked on its commercial venture were not for quality mammography.

Interestingly, FDA's medical outcomes audit standard is highly similar to a 1990 ACR Council resolution, performance standards for screening mammography.

Could we go to the next slide, please.

[Overhead.]

MR. GRAVES: This comparison is included in the January handout. The ACR Council is a representative body comprised of hundreds of members that establishes policy for the organization. It is like the Congress of the ACR.

On this basis, we believe ACR could have adopted standards in 1990 similar to FDA's Medical Outcomes Audit Standard. Instead of adopting accreditation standards in compliance with the Council resolution, ACR embarked on a commercial software venture.

Now, consider this. Congress passed MQSA and FDA is working on regulations. The ACR Council adopted this resolution, and ACR could have adopted Medical Audit Standards. Well, think of it this way. What if Congress passed MQSA and FDA did not come out with regulations, but instead announced it was coming out with a product, well, there is a valid analogy here to what ACR actually did.

Of course, it is ridiculous to think of FDA coming out with a product, but ACR came out with a product.

Could we go to the next slide, please.

[Overhead.]

MR. GRAVES: I would like to read something that a radiologist on the advisory committee, who was also a member of both the ACR Mammography Committee and the ACR BI-RADS Committee, said about the FDA proposed regulation.

"I would like to say that I think the FDA Medical Outcome Audit requirement does make an important step forward because before this there was no requirement for medical audit. Another thing it is doing is you are required to keep track of the women who are positive. This is a major step forward in monitoring and follow-up, so

women won't fall through the cracks when they have a positive exam."

If the FDA Medical Outcomes Audit and problem case follow-up requirements were important major steps forward when they go into effect in 1998, then, they would also have been important major steps forward in 1990.

Okay. There was a light flashing here, I am sorry.

DR. PATTERSON: Yes. Your time is just about up. I will give you two minutes more.

MR. GRAVES: Okay. Two minutes.

DR. PATTERSON: Your time is up. I will give you two minutes. That's it.

MR. GRAVES: Two minutes. Okay.

FDA's regulation will help save lives by preventing positive cases from falling through the cracks.

ACR declined to make this an accreditation requirement in 1990. AMSA believes that as a result of the commercial conflict of interest, ACR inadvertently put saving the market for its product ahead of saving women's lives, and we wonder, instead of adopting audit standards in

1991, as ACR had already done in the quality control areas, what did ACR hope to accomplish better by developing and selling mammography audit software?

We have always found it hard to explain the ACR commercial venture. Perhaps the ACR Mammography Committee members in attendance would like to shed some light on this issue.

Second, the ACR venture was detrimental to free enterprise. This is covered in the December letter.

Third, the ACR venture was detrimental to the track record of ACR as a professional organization. The independent software developers had been promoting quality mammography since before ACR embarked on its commercial venture, and we are still at it, championing the same issue before you now. ACR has chosen to be our adversary. We believe this is because ACR was promoting commercial interests to the detriment of women's health. The commercial software ventures were the only ones who stood up to ACR over this obvious conflict of interest. To counter criticisms by commercial ventures, ACR made false statements to Congress, the press, FDA, and the Advisory Committee.

Commercial conflicts of interest can cause good people to do bad things, and we believe the ACR commercial venture is a case exactly on point. AMSA believes that a responsible professional organization would not subject its people to commercial conflicts of interest.

ACR did not do this. Thus, we believe it would be folly for FDA to keep the door open for accreditation bodies to engage in a broad range of commercial activities.

Could we go to the next overhead, please, and I am almost done.

[Overhead.]

MR. GRAVES: These issues we have raised were covered on the back of the April handout. We still think they apply. You should have them before you, but we think these are the issues you should be focusing on.

Could we go to the next overhead, please.

MR. GRAVES: On the back of the January 13 handout, we have prepared these discussion questions 1997. We hope these facilitate your consideration of these three issues. We urge each and every one of you to speak out on these issues for the sake of quality mammography and women's

health. If you do not speak, FDA may believe that the status quo meets with your approval.

And that's all. Thank you.

DR. PATTERSON: Thank you, Mr. Graves.

Are there any questions from the committee?

Yes, Carl.

DR. D'ORSI: I just want to understand your definition because it was a little unclear to me looking at it for false negative.

If a woman has a mammogram that is read as normal, and 10 years later is found to have a cancer and no mammogram in the interval, that mammogram 10 years ago is a false negative by your definition, is that true?

MR. GRAVES: Well, no, that is not true. I mean not necessarily.

DR. D'ORSI: But that is a time limit.

MR. GRAVES: Well, no. I mean if you looked at that mammogram and it was 10 years old, and if you honestly couldn't see anything there that looked like the cancer, then, according to the definition we use, that would be a true positive then. But even if it is 10 years old, if you

can see, in retrospect, look, there it is, you know, now we can see it --

DR. D'ORSI: So, in other words, any film in which in retrospect you can't see anything, it is not a false negative if the woman has cancer?

MR. GRAVES: Well, that is the definition we applied, right. We looked at the mammograms in retrospect to see if we could see the cancer in retrospect. What we didn't try to do is say should the radiologist have ordered immediate workup back then.

Now, there is a study in the radiology literature which I quoted in the letter, which our study was consistent with and an extension of, and what we did is put numbers together. What that other study did is just come to the conclusion that looking at mammograms retrospectively, you can see things that you would not call suspicious prospectively, and that does not indicate negligence.

DR. D'ORSI: But that doesn't fit with your table here. You say a false negative is a test that is negative, but the examinee does have cancer.

MR. GRAVES: Right.

DR. D'ORSI: So, if you read a mammogram that is negative, and five years later she is discovered to have cancer, by your definition, that is a false negative.

MR. GRAVES: Well, did you know she had cancer five years ago?

DR. D'ORSI: If I knew, I would have treated it.

MR. GRAVES: Well, no, that is not what the study I cited in my letter concluded. The study I cited in my letter said that to look at mammograms where you know the patient had cancer, to look at those retrospectively, you will see things that you would not call suspicious prospectively, but in retrospect, you can see that they were cancer.

DR. D'ORSI: Who makes that decision?

MR. GRAVES: Well, the radiologist looking retrospectively.

DR. D'ORSI: Any radiologist.

MR. GRAVES: Well, there again, I am citing a study in AJR.

DR. D'ORSI: I don't want to get into this because it doesn't fit your definition that you have stated right

here.

MR. GRAVES: Well, no, it does fit. I think everything is consistent. I mean the definition of false negative is a situation where the test was negative, but you know that the patient had cancer.

I mean extreme examples are Mary Stupp and Nina Hyde. Now, those were misinterpreted, but it is our belief that of all false negative misinterpreted mammograms are in the minority.

DR. D'ORSI: Just one last point. I do not want to belabor this. If it is read as negative, and in retrospect it is negative and the woman develops cancer, you do not count that as a false negative.

MR. GRAVES: That is correct.

DR. D'ORSI: Okay.

DR. PATTERSON: Yes, Cass.

MS. KAUFMAN: I just wanted to correct something for the record, because you said that at previous meetings no advisory committee member had supported the concept of looking for missed cancers, and that is incorrect, because I have in the past stated my concern about this issue.

Although I am well aware of the problems inherent in it, I have indicated some concern about the fact that this is an area that we have not addressed.

MR. GRAVES: Well, Ms. Kaufman, I am fully aware that you have been aware of this issue, and I apologize if I misinterpreted your remarks, but the remarks that I reread in the FDA transcript, I did not interpret as directly endorsing our proposal.

MS. KAUFMAN: And I would say that that is correct, that I don't directly endorse your proposal.

MR. GRAVES: Okay.

MS. KAUFMAN: I just endorse the concept of taking a look at this issue and coming up with some kind of a plan to address the issue.

MR. GRAVES: I would like to make a plug again for the AMSA proposal. I think it is a sensible proposal. I think it is sensitive to the legal concerns of radiologists, and as I say, it is has been described as our greatest learning tool.

DR. PATTERSON: Yes, Dan.

DR. KOPANS: I am sorry, I apologize if the

committee already knows this, but who is AMSA?

MR. GRAVES: The American Mammography Software Association.

DR. KOPANS: No, but I mean how many members do you have, do you have a list of the membership?

MR. GRAVES: I can get you a list. It was 13. Not all of them are still active now.

DR. KOPANS: Thirteen?

MR. GRAVES: Yes.

DR. PATTERSON: Any other questions?

Yes, Bob.

DR. SMITH: One of the things that you have addressed today, it speaks to the difficulty of this issue. I really do disagree with at least the tone of your paper that there is an almost methodologic conspiracy that protects the performance measures of radiologists.

I mean what we have in terms of estimating sensitivity is a convention. We have talked about this before. What happens in that convention almost certainly as well is that some cases get counted as false negatives that, in fact, even within that year, you know, do not have any

lesion visible.

So, what hasn't really occurred although it is going to start occurring because more and more people are actually scrutinizing films retrospectively instead of just simply relying on the time interval, and concluding actually under the best of circumstances with an independent review of two or three radiologists with mixed films, so that there is no way of actually seeing something, as you pointed out, that it is very easy to see something, over-interpret, under-interpret.

I mean this is one of the problems with retrospective review if you are trying to estimate a false negative rate, and see that this convention actually in some cases works against radiologists, just as if you happened to fall outside of that one-year interval, say, a lesion that would be obviously visible, but it was a mammogram taken 15 months or 14 months before, doesn't count against the radiologist in terms of their rate.

I don't think anybody on the committee disagrees with you that retrospective film review is a very important thing to do, but the problem is, is when you are doing that

to calculate a false negative rate, you encounter a whole list of new problems that are no different than the ones that you encounter by exclusion or inclusion when you simply go on the one-year convention.

MR. GRAVES: Well, Dr. Smith, I would like to discuss this with you just briefly. I would like to point out that from my perspective, you are looking at this a little differently. You are looking at this from the perspective of should the radiologist have ordered additional workup on that prior mammogram.

That is a separate issue from whether the patient had cancer, and as I say, the study I cited in my December letter is about that except they didn't put numbers together. It is one thing to know in retrospect, to know that the patient had cancer and then look at the mammogram and then see whether you can see it.

It is another thing for the limits of mammography to be able to let you know when you read that mammogram the first time whether that was a suspicious lesion. You are merging those together, and they are really separate, I believe. I would like to discuss this with you further.

DR. PATTERSON: I will take one more question and then we are going to have to close on this.

MR. GRAVES: Could I make one more comment to Dr. Smith, please?

DR. PATTERSON: No. We are going to take Dan's comment and question, and then we are going to close out.

DR. KOPANS: I am just a little concerned also that you suggested that the FDA regulations would stifle the development of better ways of finding early breast cancer. I don't read that in any of the regulations, and I didn't understand your argument.

You are somehow basing it on the sensitivity argument. Is there any way you can clarify that, how that is going to stifle development of better techniques?

MR. GRAVES: Well, in the April handout, which you may or may not have, I included in that handout the argument that FDA was acquiescing in the sensitivity definitions, and if FDA is, in fact, acquiescing in sensitivity definitions, that do present an artificial barrier to the development and acceptance of new cancer detection technologies, then, we believe FDA should not acquiesce.

That is what I was saying, not that the regulations themselves, but the fact that FDA has given ACR its official seal of approval and is holding ACR out as its national accreditation body, and ACR has been promoting statistical definitions, which I believe it is fair to say are raising the artificial barrier to the development and acceptance of new cancer detection technologies.

DR. KOPANS: I would love to see a written argument as to how the last part of what you said actually could take place. In terms of the sensitivity, you know, epidemiologists determine sensitivity issues, radiologists generally don't even get involved in that, and the ACR has probably adapted what epidemiologists suggest.

It seems like it is pretty tenuous connections that you are making, but I would love to see your argument, because I am concerned if something is going to reduce our ability to find better ways of finding cancer, but I don't see it in your argument.

MR. GRAVES: I will bring to you our December letter just as soon as we are done, and the last point I would like to make is -- I am sorry, I lost it -- I don't

know what the last point I wanted to make was.

DR. PATTERSON: Okay. If there is no additional questions, then, we will close up. Thank you again.

I have one other person who was scheduled to talk, Eleanor Sherman. I do not see her here. Is there somebody here who is speaking for her?

[No response.]

DR. PATTERSON: If not, then, we will close the public hearing session.

DR. PATTERSON: We are going to move now to the Quality Assurance aspect under Equipment with Penny and Joel. Then, we will move on to the Medical Physicist requirement.

We will have to hold the Equipment aspect under Quality Standards until tomorrow. If there are any questions or comments that the manufacturers wish us to address, please see that one of the other representatives -- I understand there is a number of you will be here, of if you bring your questions to us, we will see that they are addressed. I am sorry I can't do anything else about that at this time.

Quality Assurance-Equipment

MS. BUTLER: Before we get started, I just wanted to make some general comments and get back to Charlie and one of the GAO questions.

First of all, I would like to make one comment that reviewing the tons and tons of material that we received just before Christmas, not that it was reviewed then, that the ERG summary was really quite excellent, and I think they did a real nice job putting it together. However, I would like to say that I still found it necessary and really essential to read the entire letters and many of the letters really to understand the writer's tone and their opinions and recommendations, and I think doing that was valuable. So, my comments are going to try to reflect both of these.

First, and this is a personal opinion, as a member of the committee I strongly urge that the final rules be streamlined in this section, and all procedural details be left to the ACR manuals under guidance documentation, and I really do think we should discuss this.

My reasons are as follows. Many of the commenters

remarked on the extraordinary time and consequently cost it takes for facility personnel just to read and then maybe understand the rules in its entirety.

In addition to that, several commenters said that the ACR system is working well, why are we changing it. The effective QC procedures is not fixed in time. We have seen this. There have been three versions of the ACRQC manual published over about the past five years, each with improvements in testing procedures. Some of these changes provide more clinically relevant performance indication. Some of these procedure changes provide more efficient methods of accomplishing the same results.

The QC manuals and guidance documents can be more readily changed although it is still not easy, but it is certainly easier to change this type of documentation than it is to change something that is codified in rules.

The next thing I wanted to talk about was the issue regarding the large image receptors, and the question from the GAO as to whether QC testing should be included which specifies the testing of the large image receptor.

The proposed final rules as they are currently

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written are not written in such a detailed manner to specify which selection of focal spot filtration or compression paddles should be tested. Likewise, the image receptor size has not been specified. These CTLs are described in the ACR manual and should be included in guidance. This is my feeling.

The '94 ACR manual specifies that both the large and small image receptor be tested for the following tests. For the technologists' tests, screen cleanliness, repeat analysis, equipment check list, and screen film contact. For the physicists' tests, they are included in the mechanical equipment checks, the automatic exposure control test, the X-ray field/light field/image receptor/compression paddle alignment test, the screen field uniformity, and the artifact test. Additional testing should be left to the judgment of the QC tech or the physicist.

The point I am making here is the large image receptor has not been ignored, and it has been addressed in the ACR manuals. Again, I feel that there is no reason to include them in the rules as they are written.

Is there any discussion on these two topics before I turn it over to -- Cass?

MS. KAUFMAN: I have a couple of comments. One -- and I am speaking from a regulator standpoint -- is that the ACR manuals are guidance, they were never written to be regulatory, and therefore they are often not clear in terms of what might be required versus what might be recommended.

So that is one problem with it. The second problem is that anytime you write regulations, you have to reference a specific manual. So, for example, that is why we had to add in the Federal Register the 1992 version -- I forget which year -- the 1992 version, because we had previously mentioned the 1990 or 1991 version.

So, you can't just make a general statement that you are going to follow the most current one. You have to specifically mention a date that people have to abide by, and the real problem, though, is that the very facilities, if you don't make something mandatory, if you don't make it required -- and this is particularly applicable to your comment about the large-size grid -- is that if you don't make it mandatory, the very facilities that are most

problematic, that these regulations are really written for, are the ones who won't do it.

I offer as an example the one facility in the nation where sanctions have been applied was a facility where we were having problems with the large-size cassette, because they did not have a grid for it, so the image quality was terrible with the large-size cassette, and that had never been tested by their board-certified physicist, and it wasn't required in any regulation or anything that they do that. What they ultimately ended up doing was shooting a large breast on two small films rather than getting a grid for the large-size cassette.

So, that is the problem. I think we always have to remember that these regulations are not written for the good facilities who are doing everything right. They don't need these regulations. It is written for those smaller facilities or poorer facilities, whatever, poor quality facilities, I don't mean monetarily, who are not going to do it unless it is mandated.

MS. BUTLER: Any other comments?

DR. KOPANS: Just a general concern, and I think I

am seconding what you are saying, and that is that if you require things in minute detail, then, I think it is going to be a problem in terms of moving the technology and the science forward in the future.

For example, we are all convinced that we should be doing high-contrast mammograms and a lot of our phantoms are set up in that way. In fact, no one has ever done a randomized control trial comparing high contrast mammography to wide grey scale mammography, for example, we happen to think it probably won't work, but, in fact, we don't know for a fact that it won't work.

So, I would like to see general image quality issues addressed as much as possible. I think certain requirements, the grid/no grid has been demonstrated scientifically and that it should be required to have a grid with a large detector, and so on.

But as I have looked through the regulations myself, getting down to the minute detail of the equipment and the processing and all that, I think is a mistake, and I am also concerned about future developments being stifled, although Dr. Houn has assured me that there is a mechanism

for industry, and those of us interested in development to move things forward, I am concerned once you get regulation, it is tough to change them.

DR. FINDER: I just wanted to bring up this point to have it on the record basically in terms of the GAO's concern. Do I understand that the consensus of this committee is that we should not, in regulation, be asking for phantom images on large image receptors?

MS. KAUFMAN: Not in my view.

DR. FINDER: Well, I am asking.

MS. KAUFMAN: I think we specifically need to look at phantom image on the large size.

MS. BUTLER: And I disagree because I think it is overly burdensome. I think certainly if there is reason to believe by either the QC technologies or the physicists that phantom images are necessary to test the large grid, that it should be done, but we are testing film-screen contact. We are doing all these tests on this. I think if there was a problem, there would be an indication that would point us in that direction, but to mandate it by law, by regulation, I think is overkill.

Maybe we should take a vote.

DR. FINDER: We don't take votes, we take consensus.

DR. PATTERSON: We take consensus.

MS. BUTLER: Change my terminology.

DR. PATTERSON: Is it possible to use the language of the phantom images should be done on the system that is used, in other words, leave it sort of wide open? In other words, whatever combination of factors is used on that image, something of that sort, in contrast to specifically?

MS. KAUFMAN: I think that is certainly better than leaving it out altogether, but I guess my only concern about that is I don't know what kind of impact, using, for example, new filter, target filter combinations might have on that particular phantom that we have today.

All I know is that if you should be able to visualize certain things with a smaller size patient, if you use that same phantom with the large size, it ought to be even easier to visualize, and therefore, you need to test it with the larger size.

MS. BUTLER: Rita.

MS. HEINLEIN: My concern with saying that they should test the system that they are using is that they may then decide, well, we just won't use this large buckey, we don't need one, so we will just do everybody on the small film and do two or three images on the large breast if that is what we need to do.

I think it does leave a very huge loophole for that.

MS. BUTLER: I would just like to make the point that in reviewing these comments, I reviewed a large number of comments that expressed a lot of concern that they were being overburdened with quality control tests, and I think adding one more quality control test on there, doing the large cassette in addition to the small cassette, is really something that hasn't been shown by any evidence to be necessary.

MR. SHOWALTER: What if it were in lieu periodically of the smaller cassette, that is, the proposal proposed that weekly phantom image testing be done, what if every three weeks you did the small cassette, and every fourth week you did the large cassette, is that a reasonable

compromise or not?

MS. BUTLER: I don't think that is reasonable, and the reason I don't think that is reasonable is because you are talking about, for one reason you are talking about different emulsion batches between small film and large film, and so you could be throwing another variable in there, and we have seen changes in emulsion going just from one box of film to another box of film, and we are able to track that down because we can track the box changes.

I think by throwing a different variable in there, you are going to be making some of these changes, these things more difficult.

MR. SHOWALTER: Let me clarify. I wasn't proposing that one compare the images developed on the small image receptor with those developed on the large, but since right now the ACR manual calls for a monthly phantom test, you would effectively be continuing a monthly phantom test on the large image receptor and comparing one large image receptor with another, that is, you know, tracking the large one independent of the small one, so you wouldn't have this comparison of different emulsions, and so on.

I am not advocating that. I am just throwing it out as an idea that might get away from the comment that this is overly burdensome.

MS. BUTLER: Joel.

DR. GRAY: I guess I am getting a little confused at this point. We do the screen-film contact test on both the large and the small cassettes at this time. That will tell us if there is any change or any variation in the image quality in those cassettes. Otherwise, nothing else is going to change on the large cassettes.

MS. KAUFMAN: [Off mike.]

DR. GRAY: If you do the screen-film contact test

--

MS. BUTLER: And the artifact test.

DR. GRAY: -- and the artifact test, basically, you are not going to see any changes over time other than screen-film contact anyway. I don't care what the image quality or resolution is, if the contact test shows that you have good contact, then, the resolution has not changed.

MS. KAUFMAN: But nobody has ever tested the resolution.

DR. FINDER: I want to bring up one realistic case that we had where the small image receptor was okay in terms of phantom image scores, and the large image receptor was not.

DR. GRAY: And what was that?

DR. FINDER: I cannot answer that, but I can tell you that that was the case.

DR. GRAY: I would suspect it was screen-film contact. That is the only thing that can be different.

DR. FINDER: The only thing I can say is that the other tests supposedly had been done and were okay, but the end result was not.

DR. GRAY: If you are going to argue that point, then, then we must carry out that image phantom test on every cassette in the facility. That is the purpose of doing the screen-film contact test, to eliminate bad cassettes. I don't care if it is a different grid or not.

MS. BUTLER: In order to address the grid, we do do the artifact test.

MR. SHOWALTER: It strikes me that we have no consensus on exactly -- we have differing opinions, we have

no consensus that we need to add the large image receptor, periodic testing of the large image receptor. That is what I am hearing.

DR. PATTERSON: Let's get a consensus from the committee on that.

MS. KAUFMAN: Penny said we have no evidence, and that is not true. We have plenty of evidence that it is a problem, that unless you require people to look at the large cassette, that many will not look at it at all, period, they just don't even look at it, and we have several cases where it has been very problematic.

I don't think you can say the large-breasted women, we are not going to make sure that it is okay for you.

DR. PATTERSON: Penny, ask for a consensus of the committee on looking at the large cassette in addition to the other, either periodically or on a regular basis.

DR. GRAY: In what manner?

MS. BUTLER: Do you mean by doing a phantom test?

DR. PATTERSON: By doing a phantom.

DR. GRAY: Because we already do screen-film

contact.

DR. PATTERSON: By the phantom, strictly on using the phantom.

MS. BUTLER: Okay. Those who feel that a phantom test should be done periodically on the large cassette, raise their hands, please.

[Show of hands.]

MS. BUTLER: Four. Those who feel that phantom tests should not be required to be done periodically on the large cassette, raise your hand.

[Show of hands.]

MS. BUTLER: That is a no consensus.

DR. PATTERSON: Thank you, Penny.

DR. GRAY: Going over the comments regarding quality assurance, if we could have the first overhead, please.

[Overhead.]

DR. GRAY: What I have tried to do on these is provide the wording in this particular case right of the regulations and then some comparative wording, and I will try to point out where this is specifically my personal

opinion. In this particular case, I don't know if you could call this a personal opinion.

There were a lot of questions raised by people writing in because the FDA proposed regulations say that facilities with screen-film systems shall perform a processor performance test before any examinations are performed that day.

This is not going to work in a lot of cases, and I think the wording in the ACR manual basically corrects that. It says, "before clinical films are processed."

If you think about it, if you were in a mobile facility, you would have a real problem in this case because you would have to perform the test at the processing site before you could perform any examinations, and the coordination of that would be extremely difficult.

Likewise, I don't see any reason to hold up on examinations just because the processor may not be functioning properly. What would happen here, first thing in the morning, you might have a group of patients lined up, and you would have to have them sitting there until somebody took the time to correct the processor problem.

So, I think consensus of the comments that we received, as well as the wording in the ACR standards basically clarifies the situation, so we should be looking at before clinical films are processed each day.

Could we have the next overhead.

[Overhead.]

DR. GRAY: Basically, in the first set of comments that I received, seven out of seven agreed that a change is needed, and these are some of the comments. It is not the performance of the exam in this case that is important, but whether the films are processed. Three people made that comment. And, again, the ACR comment itself.

I guess we can open it up for discussion on this one.

Cass.

MS. KAUFMAN: I agree in principle with that change, but as we mentioned before, I think we do need to put some kind of a time frame in there, because we just had an incident where the facility's processor broke, and they had to wait for a part, and so they held the films for 10 days while they waited for the part, and subsequently, had

to repeat every single one of them.

So, I think we need to put in some kind of a reasonable time frame during which the films need to be processed, because they shouldn't hold them forever.

DR. GRAY: Rita.

MS. HEINLEIN: I agree with the change. I think it should definitely say before clinical images are performed.

DR. GRAY: Performed or processed?

MS. HEINLEIN: Processed, I am sorry. Thank you for correcting me -- before they are processed.

Didn't Art Haus with Kodak do a study to show the length of time before you really have a detriment to the film, and wasn't it fairly long?

DR. GRAY: You have to be careful because that is film dependent, and I can tell you right now at least three films out there that I have seen are significantly different. One particular film will show a detrimental decrease within hours, others can go for days to weeks.

MS. HEINLEIN: So you are saying that the study he did was only on one type of film.

DR. GRAY: Yes.

MS. HEINLEIN: I don't know that, I don't know the answer to that.

DR. GRAY: Cass.

MS. HEINLEIN: The study that Art did, I forget the exact percentages, but there was actually a rather serious degradation after about four hours on that particular film, and after like eight hours it starts leveling off a little bit, but there is a pretty significant loss of contrast.

I have never seen any film that lasted weeks without processing in the area of mammography, so I think we do need to think about some kind of a time frame.

MS. HEINLEIN: I do think that if we are going to suggest a time frame in regulation, that we need to have some scientific data that we base that upon instead of picking a number out of the hat.

I remember when we had the discussion about mobile mammography and batch processing. I don't recall, though, if there was -- do you recall, Mike, if there was any type of an actual time limit that we suggested at that point?

Does anybody remember that?

MS. KAUFMAN: We had talked about 24 hours only because we thought that that was a reasonable period of time in which to process the film in case they were off in some other location, and even though these was some pretty serious degradation, the films would probably still be clinically diagnostic, and you could make a technique adjustment, i.e., increase the dose to the patient, but it wouldn't be significant enough where people might complain about it.

MS. BUTLER: Again, I hate to see us write a regulation for every single situation that we are going to encounter out there. I think this is going to be atypical and very abnormal, and to create a rule to address very rare incidents, I think is unreasonable.

MS. KAUFMAN: I don't want to belabor the point, but I don't think it is all that rare, number one, and number two, I think again we need to focus on the woman who has that film, and if I were one of those women who had to have my mammogram repeated simply because that facility's processor was broken and they didn't want to go to another

facility to process their films, you know, I would be an unhappy camper.

Again, we write regulations for the worst facilities. A good place never would have done that.

DR. GRAY: Esther.

MS. SCIAMMARELLA: I feel some concern and I think for new providers, what is going on with the films and how long they take, the courier take the film and deliver, I am concerned for that people that maybe take it not too serious. I think here there are a group of very well intent and professional institutions who I agree they know what to do, but there are many providers in communities that I am not sure about that.

DR. GRAY: Any other comments on this?

DR. BASSETT: I might have said otherwise before, but in our practice we would endorse what you are just recommending, and that is that the films can be performed, but should not be processed.

Now, we actually in our mobile have a processor onboard, so we process as the films are done, but there are occasions when that processor is not functioning properly or

various things can happen to it, and in those cases we do process them at delayed time back at our base facility, so I would say that my recommendation would be what you have already enunciated, and I am only thinking that I said it the other way by mistake in the record sometime, but that the examinations should not be processed until the processor quality control tests are done and verified it's within limits.

In terms of the time period, our experience in a national survey we did was that it was very much the exception to the rule in the minority that if it was greater than 48 hours in terms of how long a delay was done for mobile facilities, sending films in, and so on, if it is of any value.

I think I shared that with the group at an earlier date, a very long time ago, but that was our experience. It was very unusual to be over 48 hours.

DR. GRAY: Anyone else? Okay. The next overhead.

[Overhead.]

DR. GRAY: The next refers to the selection of the mid-densities for phantom imaging. The mid-densities shall

be within plus or minus -- I am sorry, for sensitometry -- shall be within plus or minus 0.15 at the established level, of no less than 1.2 optical density. That is how it appears in the proposed regulations.

The ACR manual specifies that a step has an average density closest to 1.2, which would of course allow it to be less than 1.20.

Next.

[Overhead.]

DR. GRAY: This is a personal perspective, but I wanted to point out where that figure of 1.2 came from. It really wasn't pulled out of thin air. The American National Standards Institute specifies 1.0 above base-plus-fog level as a point for monitoring the speed of the film. Base-plus-fog is usually about 2, therefore, the mid-density turns out to be 1.20.

Normally, people think that with lower densities, you get a lot less contrast and a less sensitive test. If we looked at the results between 1.0, 1.10, and 1.19, which are all less than 1.20, the difference in the test results would basically be insignificant. So, I don't think it

really makes all that much difference in the long run.

Next overhead.

[Overhead.]

DR. GRAY: Several comments suggested deleting of no less than 1.2 from the regulations or changing the control limits to plus or minus 12 percent, but this would allow an unacceptably broad limit of plus or minus 0.2 if the density is 2.0.

Some comments also suggested adopting the ACR manual guidelines of accepting whatever step is closest to the density of 1.20.

Next.

[Overhead.]

DR. GRAY: In the public comments, nine people indicated that they want the closest to 1.20, and one indicated that they wanted it greater than 1.20, and these are some of the comments just summarized here basically.

Next slide.

[Overhead.]

DR. GRAY: The FDA summary suggested including plus or minus 12 percent as a limit, and again I think this

is very broad. Density is a logarithmic value, so a percentage of a logarithmic value really don't have any meaning, and when you are looking at logarithmic densities around 2, your control limits gets pretty broad in that case.

Any other comments regarding the 1.2 as a mid-density point for sensitometry?

MS. BUTLER: I recommend that we stay consistent with what is already written in the DACR manuals.

DR. GRAY: Rita.

MS. HEINLEIN: I agree.

DR. GRAY: Dan.

DR. KOPANS: On your first slide, was there a confusion between -- were they confusing the sensitometry with the ACR phantom?

DR. GRAY: No, I don't believe so. I think it was fairly clear from the comments that they were talking about the sensitometry.

Okay. If there are no other comments, could we have the next overhead.

[Overhead.]

DR. GRAY: Weekly phantom test. There were a lot of comments about this. Weekly phantom images is appropriate, et cetera. Basically, 19 people spoke in favor of a monthly test, and 20 spoke in favor of a weekly test. So, I guess that puts it back in your lap, Charlie.

There doesn't seem to be any real consensus here. I think the problem is the ACR manual specifies a monthly test, and I think what happened is that most of the facilities ended up doing weekly tests, more as a convenience, more as a fact that you sort of get in the swing of doing it. Maybe you do it every Friday or every Monday, or whatever, and that is probably where the weekly test came from, but I don't think there is any strong argument one way or the other for this other than it does take a little more time.

Are there any other comments regarding the weekly phantom test?

Cass.

MS. KAUFMAN: My only comment is that the reality is that the phantom image test really isn't all that sensitive to variations that may be significant in clinical

images. We have never quite finished that study that determined that, but it would seem to me that if we are looking at areas to reduce cost, that this might be one test that might not give you a whole lot of information.

DR. GRAY: I would have to agree with the comment. One of the problems with the phantom, for those of you who may not be familiar with it, is it really only looks at one density level out of a range of, well, if it was densities from zero to 3.5 or greater, you are looking at one level, so it is not really a good systems test in that case.

Any other comments or questions?

Okay. The next overhead.

[Overhead.]

DR. GRAY: The system test. This is using the phantom for presumably eliminating the possibility of doing some of the other tests. Basically, there were 21 comments against this and only 3 for it. We can go through and take a look at some of them.

It is impractical. Using the phantom will not indicate what part of the system is not operating properly. Since processing is an area that is most difficult to

maintain within operating limits, it seems imperative to continue doing processor QC, which is a daily test. That comment was by one of our state regulators.

Next overhead.

[Overhead.]

DR. GRAY: This is from the American College of Radiology. They say that it is premature to discuss alternative performance and outcome measures of mammography and quality control. There is not sufficient experience with these types of measures to know their validity or reproducibility. The current phantom could not be used as a single system performance evaluation criteria. That is from the organization that was primarily involved in developing the phantom.

Next overhead.

[Overhead.]

DR. GRAY: Phantom imaging testing as a proposed complete system test cannot indicate the subtle trends demonstrated by daily processor quality control. For the past several years, we have done at our facilities, performed a daily phantom test in addition to the other

daily QC tests. We found that phantom image quality is very subjective. The majority of poor image quality is due to processor problems.

Phantom image testing is not sensitive enough to indicate many subtle processor-based problems which can be remedied before the magnitude increases to the point that image quality is compromised.

Just as a personal comment in support of that idea, what we would like quality control to do is correct the problems before they become visible on the viewbox to the radiologist. So, if our test tool isn't sensitive enough to do that, we should be looking elsewhere.

Next overhead.

[Overhead.]

DR. GRAY: Another one. A single system test is not a good indicator. Testing individual components has long been known to be a better measure of quality assurance. Furthermore, a total system test would not save a significant amount of time. Therefore, we opposed development and use of a total system test. Somebody from Eastman Kodak.

Next overhead.

[Overhead.]

DR. GRAY: Daily phantoms and processor films are a waste of time, film, and money. I thought I would give you an opposing view here to a certain extent. Daily film strips, yes; bimonthly phantoms would be acceptable. Using your figures this would cost 2 million a year. The film companies would love it. I thought the government wanted to reduce the cost of medicine. No, I didn't write that one.

Is the FDA going to review all 240 phantom films at inspection time?

Next overhead.

[Overhead.]

DR. GRAY: If the image is to be done weekly, it may be necessary to redesign the phantom. The idea of a top wedge in the phantom would eliminate the need for additional film to be used in daily processor quality control.

Personal perspective. You can't do processor QC with an X-ray-exposed film because of the variability from the X-ray generator.

So, we have some conflicting ideas here, but I

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think these are all issues that we have dealt with and thought about before.

Any other comments on the system test? No comments on the system test. Okay.

Do we need a consensus on that? Does everybody agree with that?

[Affirmative responses.]

DR. GRAY: No system test, yes.

[Overhead.]

DR. GRAY: The next has to do with repeat analysis. This regarded whether we wanted to put limits on repeat analysis or not, and whether we wanted to use it for monitoring. This is a rather interesting issue to deal with, and from a personal perspective, setting limits is a very difficult thing to do because there is always a way to reduce your repeat rate below any limit you set.

Let's say we set it for 5 percent. Well, I have once heard it said that a good radiologist can read anything that comes out of the processor, so that means that a radiologist that is willing to accept any quality film will have a zero repeat rate.

Another way of reducing the repeat rate is to make sure that the films don't appear in a place that can be counted, and I am not saying that this would happen consistently, but I know when we first started to do this in one hospital when I was in Toronto, we found the repeat rate was close to zero, but there were a lot of films appearing at the homes of some individuals. They were just basically taking the repeat films home with them.

So, by trying to enforce something like a limit on repeat analysis, you have people trying to do things which they probably shouldn't be doing.

Writing a documentation criteria based on a 2 percent change from the prior repeat rate is statistically flawed. The proposal to monitor the repeat rate will not be accurate, a zero repeat rate could be obtained for a facility with many problems by accepting everything that comes out of the processor, something which I just alluded to.

Repeat rate is not a good outcome indicator because suboptimal films are usually still utilized and not rejected. In some places I am aware of, all films go in the

patients' jackets anyway, so you need some other mechanism which we have been discussing how to handle those situations.

Next overhead.

[Overhead.]

DR. GRAY: One individual said please list an acceptable range for repeat percentage. Simply utilizing a 2 percent change gives one too broad of an interpretation of what is acceptable and what is not. In other words, if you were operating at a 10 percent rate, and you only saw 1 percent change, that would be acceptable. Well, a 10 percent rate in my mind is not acceptable to start with.

I agree with what is written, but think there should be a second part which states total repeat rate should not exceed 5 percent, so this is taking it in a different direction.

Next overhead.

[Overhead.]

DR. GRAY: A statement should be added that indicates additional films that were needed to be taken because the first film was not optional and are included in

the examinee's file are to be counted as repeat films.

This is something that some of us are trying to work on right now. We have come up with a little table to try to do this.

Repeat analysis for each technologist should be evaluated. Philosophically speaking, that is something we try to avoid because unless there is one technologist which it is obvious that most of the repeats are coming from an individual, this becomes more like the policeman looking over the technologist's shoulder.

We like to think of the repeat rate as a tool for continuous quality improvement, and not specifically directing it at one person.

Any other comments on repeat analysis?

Rita.

MS. HEINLEIN: I agree with the comment that there should be a suggested upper limit. I have been to facilities that, you know, again, you could have the repeat rate be up to 8, 9, 10 percent, and the comment is, well, we are doing it, you know, we are looking at it. So, I think that whoever wrote that comment brought up a very important

point.

I think a range would be a good idea to say and also to suggest a minimum, because I have been to facilities also that have a 0.10 percent repeat rate, and that is because they accept suboptimal images, so they don't count those films that did go through with the patient's jacket. I mean at one place I said you only have one film in your throw-away box, did you just do your repeat analysis, and they said, no, in fact, it is due tomorrow.

I said one film and all these patients, why am I here, and then that morning they repeated a couple images and just put everything through, and I said, well, you have to have a method of counting them. No, we only count what is in the box, but the radiologist wants us to put everything through.

So, they in effect were not doing a repeat analysis at all.

DR. GRAY: I think we have to be careful in specifying a range, because if we specify a minimum, and I don't make that minimum, that means I have to do more repeats, I don't meet the FDA standard for the minimum

number of repeats.

[Laughter.]

DR. GRAY: Cass.

MS. KAUFMAN: I think the way it is presently written is probably the best route to go because it says if you see a change, you have to look into it. I think the notion of having a maximum is an appropriate item for guidance documents because whatever regulation you set, everybody can meet that. This is not a good area for regulation, but I think it is appropriate to say if you say that kind of a change, you will at least look at it and see what the problem is.

So, I think the way you have it is probably about the best route to go.

DR. GRAY: Penny.

MS. BUTLER: I actually agree with Cass on this one. The only other thing I would like to add is I have concern for the 2 percent variation for low workload facilities with the statistics of these low numbers can easily cause significant changes from evaluation period to evaluation period, and I am not exactly -- FDA will look

into it? We will look into it. Okay.

DR. GRAY: I think that is one thing we have to be sensitive to are the variations in these numbers. When I first read it, I wasn't sure what the 2 percent meant. Was that a 2 percent variation in the rate that I have or was it -- in other words, I have 5 percent, and 2 percent of 5 percent comes, what, 0.01 or something. If it is 5 percent, does that mean it can vary from 3 to 7 percent without causing any problems?

MR. SHOWALTER: That is what we intended. Whether that is the way it reads or not, I would have to go back and reread it, but that was certainly the intent.

DR. GRAY: If that was the intent, then, I am a little uncomfortable with the 7 percent side of things as being relatively high, and I am not willing to propose a number less than 2 percent because that may be too tight, but 7 percent is getting pretty high.

Rita.

MS. HEINLEIN: Actually, I think the way it is written is best, because it just says that the reasons for the change shall be determined and corrective action and the

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results shall be recorded. I think that it is written very well the way that it is right here.

You have got this change, figure out why, and correct it.

DR. GRAY: I think that is the whole purpose of repeat analysis, is to do that.

Are there any other comments on repeat analysis?

That is about all I have at this point.

Elizabeth.

DR. PATTERSON: Before we move on, in everybody's packet, there was supposed to be a sheet that looked like this. It starts off Table 3-2, Compliance use for national-level, et cetera. Does everyone have one in your packet? Does anyone have it in your packet? It is by itself, and it's number sheets maybe, I don't know, six, seven, eight sheets.

Charles Finder is going to pass it out to everybody because it was supposed to have been in the packet.

MS. BUTLER: Elizabeth, I am doing the second half of the QC-Equipment.

DR. PATTERSON: Yes. I just wanted to bring this to your attention at this point.

Okay. You are on, Penny.

MS. BUTLER: I want to talk about the semiannual QC tests, and you will have to bear with my little comments that I have up there handwritten in, I apologize.

Most of the comments on the darkroom fog test tended to request more specific procedural details, and again, this is the issue that I brought up in the very beginning, are we going to be including these procedural details in the regulation or is this something more appropriate for guidance.

For example, one of the comments asked that we specific the test be under the conditions that the mammo film was processed, place the film on the counter top emulsion side up, et cetera.

Are there comments on darkroom fog?

I would like to recommend, then, that the requirement go in as is, and no procedural changes be made.

Shall we discuss the emulsion side up issue?

DR. GRAY: The emulsion side up issue is an

interesting one. The ACR procedure does not specify that. We have found at least in two facilities in Minnesota that that has been a problem. People don't understand the test or why they are doing it. You tell them to expose the film, they put it in the sensitometer. You tell them to lay it on the counter top, and they do.

It happens that the exposure device for many of the sensitometers is on the bottom, so the film is laid on the counter emulsion side down, and consequently, it gets no fog exposure.

Well, that is a question. Flo raised the question do you want directions or education in the reg. I think this is part of the direction really in telling them how to do the test properly.

DR. HOUN: Do you want the reg to be prescriptive that way or do you want to encourage more education? I don't think we do exactly the steps of how you place the phantom and da-da-da.

DR. GRAY: Good point.

DR. HOUN: I just want to know if you want it in law.

MS. BUTLER: I agree with Flo. It certainly is an important issue that Joel brought up, but I don't think its place is in the regulation, and there is going to have to be a lot of education that goes on with the implementation of all these regulations that we are talking about here.

Rita.

MS. HEINLEIN: I agree that this is something that could be put into guidance, but I think it is very important that guidance does include education, because I have been to facilities that do the darkroom fog test with the emulsion face down, and they wonder why they have low contrast images when they have 15 lights on in there, and you could go in there and read a book, but yet they turn them all off except for one when they do the phantom test.

So, I think that the educational part can move into guidance.

MS. BUTLER: Okay.

MS. SCIAMMARELLA: I agree with you.

MS. BUTLER: So, no change.

Screen-film contact. I think one substantial comment that was made was a clarification of using a 40-mesh

copper screen. My question to the group is do you think that is necessary to include this in the requirement. I mean we do specify using a 40-mesh screen. Should we specify copper? Joel.

DR. GRAY: Copper is the only material or high Z material like perhaps platinum or gold, which would be a little expensive, but this is the only material that the test will work properly with. If somebody goes out to the hardware store and buys aluminum or fiberglass screen, the test won't work.

MS. BUTLER: I have no problem with this inclusion.

DR. GRAY: It's only one word.

MS. BUTLER: That is why I have no problem with its inclusion.

Compression. I want you to note my handwritten comment there. The way the compression test is currently written, all three commenters that were summarized, they cringed at this rule primarily because the way it was written, it required the testing of everything that was described in the equipment regulation part of the rules.

Several commenters recommended that the compression force be tested semiannually as currently recommended by ACR, and the alignment tests of the compression be done by the medical physicist on an annual basis.

I would like to recommend that rather than just referring back to what was in the equipment regs, that we just specify these two tests in their appropriate places.

Any comments?

MS. KAUFMAN: Penny, I am not quite sure what you are suggesting, that we just take it out of here because it is previously mentioned under --

MS. BUTLER: No, I am not saying that we take the tests out of there, but if I can -- bear with me -- it says, "The compression device shall meet the specifications described in 900.12(b)(12)," and it is my understanding that that is a big section that has a lot of details regarding the design of the compression.

Really, what we are really interested in having included in the quality control tests is essentially the measurement of pressure and also the measurement of

alignment of the chest wall edge of the compression paddle with the image receptor.

MS. KAUFMAN: I guess I still not quite sure what you are recommending, because the reason why it is under here is because that is supposed to be a semiannual test?

MS. BUTLER: That is correct.

MS. KAUFMAN: That just puts the frequency in? I think that is the only thing it does right here.

MS. BUTLER: No, it does more than that. It says, "The device shall meet the specifications described in 900.12(b)(12)," and there are a lot of specifications in that section.

MS. KAUFMAN: Right. Is there a problem with the specifications then?

MS. BUTLER: Including all the specifications in the semiannual test. That is my problem.

MS. KAUFMAN: Okay. So, do you think that some things under (b)(12) need to go under this section instead?

MS. BUTLER: I think some of the things under (b)(12) really shouldn't be included in the quality control test. Just the pressure test on a semiannual basis.

MS. HEINLEIN: This is the quality control test that the technologist performs.

MS. BUTLER: That is correct. Well, yes, and then there will have to be something added in the annual tests.

MS. HEINLEIN: Right.

DR. PATTERSON: Penny, are you trying to say, then, that the wording that is under the previous section should be spelled out here, and not referred back to it, is that what you are trying to say?

MS. BUTLER: No. What I am trying to say is Part 12 in the equipment regs, they say compression, they say (i), application of compression, power driven compression, fine adjustment compression, "compression device shall provide maximum compression," decompression, manual emergency compression, remote compression release, the "compression paddle shall be flat and parallel," chest wall edge.

There are a large number of specifications in the mammo equipment section, which this part of the QC stuff refers to. We really don't want to test all of that twice a year, and some of that stuff we don't want to test at all.

What we really just want to test is the maximum compression force.

DR. HOUN: So that is 12(i)(C).

MS. BUTLER: Yes.

DR. HOUN: And?

MS. BUTLER: And the part about alignment needs to be moved to annually. Where is that?

DR. GRAY: (iv).

MS. BUTLER: (vii). Does that make sense, am I being real confusing? This should streamline things a little bit and make it consistent with the ACR manual.

MR. SHOWALTER: I understand the recommendation.

MS. BUTLER: Thank you.

Annual QC tests is the next one, please.

[Overhead.]

MS. BUTLER: There was one comment about including measurement of viewbox illuminance during the physicist survey. Currently, this is under the appendix, in one of the appendices in the ACR manual and really hasn't been addressed, although it has been discussed, and I don't think it should be really in the rule.

Joel.

DR. GRAY: This is one issue upon which we have virtually no good scientific data at this point, so I don't think it is wise to put into rule things that we can't back up.

MS. BUTLER: There were several comments that the limits should be the same as the accrediting body, and I think for the most part we are doing that.

Specifically, the automatic exposure control performance, and again, a lot of the comments were in an effort to request more procedural detail, which could be included in guidance.

One person recommended that a technique chart be available for everyone, for every unit, which is currently required within the ACR manual.

There was another comment that suggested that plus or minus 0.3 is too broad for the AEC performance test.

Any discussion on this? Joel.

DR. GRAY: The proposed role in Section 12(B), I believe it is, allows for plus or minus 0.3 until October 1st, 2000, and then requires plus or minus 0.15 by October

1st, 2005.

So, I think the intention is to move the manufacturers in that direction. I know there are quite a few units out there without a technique chart, will not meet the plus or minus 0.3 at this point, but I think we are working and moving in that direction. I think it is probably fine the way it is right now.

MS. BUTLER: Any other discussion?

Then, our recommendations are to basically leave this as is.

All right, kVp. There were a significant number of comments that the accuracy and reproducibility standards should be consistent with the ACR manual, which is 5 percent of the actual, and so I think that is a self-evident recommendation that should be changed.

In addition to this, there were several comments that remarked that the lowest and highest clinically used kVp should not necessarily be tested due to the kVp meter limitations, and again suggested using the language in the ACR manual, which I can't remember exactly what it is, but it basically said test the most clinically used kVp and

several others, and something like that, or several other clinically used kVp.

That is my recommendation. Any changes on this?

Okay. Next slide, please.

[Overhead.]

MS. BUTLER: On the system resolution, again, there were a number of comments requesting more procedural details, and that I think we can leave to guidance. By the way, you know, every time I bring this up, this obviates the need for revisiting a lot of these comments when the guidance documents are written.

Now, Kish called me last week and asked me to bring up the issue regarding system resolutions and the requirements for 13 and 11 line-pairs per millimeter performance within this test, so I would like to ask for some discussion on that.

I would like to remind everybody that currently the ACR manual specifies that if the system resolution test does not meet 13 and 11 line-pairs/mm, then you are obliged to actually measure the focal spot size using the NEMA specifications to check the focal spot size.

So, the question is should we include this backup statement as we have in the ACR manual with the system resolution tests or should we leave the system resolution test as is.

Cass.

MS. KAUFMAN: I think we should just leave it as it, and the physicist ought to know that if it doesn't meet this, that they need to take a look at the focal spot size.

MS. BUTLER: But if it is in a regulation, if it doesn't meet the 11 and 13 line-pairs/mm, no matter if you get a 0.01 focal spot size, is still doesn't meet the regs.

MS. KAUFMAN: What we really care about, I think, is system resolution more than focal spot size, and reality is if you have got that focal spot size, it is unlikely that you are not going to -- that that is not the source of the problem if you are not meeting 11 and 13.

But I think what we ultimately care about is resolution, not focal spot size even though they are both clearly interrelated. So, I think the way we have it is the correct direction to go in.

MS. BUTLER: Joel.

DR. GRAY: I guess I am going to have to agree with Cass. What we are really interested in is the resolution. You can have a focal spot size that is smaller than it is supposed to be and still get poor resolution with it. So, I would like to see the specification stand as resolution, and maybe we can encourage the X-ray tube manufacturers to move in that direction also.

MS. BUTLER: In my experience, some of the reason for not meeting the 11 and 13 line-pairs/mm may be how the test is done. So, I think it would be unreasonable to insist that a tube be changed because of something else going on associated with the lack of being able to achieve 11 and 13.

I would like to recommend that we sort of hold off on what we recommend on this particular issue until we get to the equipment section, and perhaps have more discussion on this, because I have a feeling that some of the equipment manufacturers will have something to say.

MS. KAUFMAN: My only comment would just be that I see those same problems with measurement of focal spot size that you just mentioned in terms of resolution, in terms of

people doing the test incorrectly and that is why they are coming up with inaccurate results.

MS. BUTLER: Joel.

DR. GRAY: I would like to point out that deciding not to decide is to decide. Seriously, this is truly a system test, this is not a focal spot test. This takes into account the buckey, phantom, scatter, grid, possible motion vibrations, everything. So, if this test doesn't come out right, then, it is going to be up to the physicist to determine what the source of that is, and they have to make a focal spot measurement to do that.

MS. BUTLER: I don't think there is really any problem with half-value layer test except several commenters pointed out that we should include both upper and lower limits, and I think that would be a good recommendation.

Any comments on this? Yes.

MS. MCBURNEY: I just have a question for SEA, as a matter of process, when you add a limit to a final rule if it has not been proposed, can that be done.

MR. SHOWALTER: It largely cannot, but then sometimes it can.

MS. MCBURNEY: Thank you for that definitive answer.

MR. SHOWALTER: I am always happy to be definitive. No, it depends on whether you can develop an argument that it is an outgrowth of the proposal. If you can do that, and you can say this logically flows from what we proposed and what the comments are, and it is not too great a change, then, counsel will often let you add it. If you can't make that argument, then you have to re-propose.

MS. BUTLER: Charlie, I would also like to propose that we are currently living under upper and lower limits through adoption of the ACR manual.

MR. SHOWALTER: I think the issue here revolved around whether it was really necessary to have an upper limit. Nobody is arguing with an upper limit as being good practice, but is it really necessary to have an upper limit as a regulatory matter, you know, are there other ways of dealing with that, such as you are seeing low contrast, and I guess when we wrote the proposal, we were not persuaded, not that it was not a good idea to not have a real high half-value layer, but we required some additional persuading

that it was a good idea to have it as a regulatory change with the comments.

MS. BUTLER: Cass.

MS. KAUFMAN: I can only speak from experience that when we see a high HVL, usually, there is also a problem with phantom image quality, but I don't know if you have a different experience with that. But it seems like they fail on that if they have a really excessive amount of filtration although we rarely see that problem.

MS. BUTLER: I suggest that we be consistent with the ACR manual and add a regulation.

Okay. Breast entrance exposure, dosimetry. There were several comments. Three comments suggested recommending lowering the dose limit to less than 300 millirads.

Before we discuss this I would like to just bring out that Orhan Suleiman made a very interesting presentation at the RSNA this year, where he showed between the first inspection round and the second inspection round, that the average glandular dose does seem to be increasing over time, and he speculated that one of the reasons because of this is

because facilities are tending to use higher densities in order to increase the contrast of the image.

I recommend that we leave the rule as it is, at 300 millirads and we don't make the change, but I would like to invite discussion.

Cass.

MS. KAUFMAN: I think even with the increased densities, that the average or the mean glandular tissue dose is currently somewhere around 150, 160 millirads, something like that, so that leaving it at 300, what we are allowing is twice what the mean is. I guess I am not convinced that you need that high a dose.

The only thing that I can say anecdotally is that when we see doses that high, there are always other problems at the facility unrelated to dose, but, for example, the processor isn't working right or something, you know, the processor temperature is too low or film is expired or something else has gone wrong.

So, my own personal opinion is that I would be very comfortable with 250 millirads, but I wouldn't be comfortable with something lower than that.

MS. BUTLER: Joel.

DR. GRAY: I would like to support the 250 millirad suggestion -- since it was my suggestion in the first place -- from the point of view that Cass raised, that we are allowing some of those ladies to get twice the dose on average, and we are not talking about the dense breast or the large breast at this point, we are talking about the average.

So, the average patient going in could get up to 300 millirad right now and still be considered acceptable, and that is twice what it really has to be. I think the real key to this is that we are using a limited number of screen-film combinations, we have optimized equipment, presumably we have optimized processing, and I don't see why anybody should be in excess of 250 millirad.

MS. BUTLER: Carl.

DR. D'ORSI: There is no separate dose requirements for Xerox, this will include everybody?

MS. BUTLER: That is correct.

I would just like to go on record saying I disagree with that, and I think it should remain at 300.

X-ray field/light field/image receptor/alignment.

That is the next overhead, please.

[Overhead.]

MS. BUTLER: Again, the same comment applies here as applied to the compression paddle in that the rule I believe made reference to -- or did I get this wrong -- yes, it made reference to paragraph (b)(5) of this section, which is a lot of material. So, I think what we are looking for is basically to be consistent with what is the ACR manual right now without going through all those details.

One question was brought up, was will the equipment currently in the field meet the requirement of having compression paddle edge alignment within 1 percent of SID. I personally in my testing have found most facilities to come within that 1 percent of SID, and those that fall outside of that with one minor exception has been able to be corrected.

I would like to hear comments from others. Cass, go ahead.

MS. KAUFMAN: I agree on the alignment of the compression paddle, that we rarely see them beyond the 1

percent. That seems to be fairly easily achievable by most units. But now are we also talking about alignment of the X-ray field in the image receptor? I am not sure what we are talking about.

MS. BUTLER: Yes, I think we are talking about alignment of anything you can align - X-ray field, light field, within the X-ray field with the image receptor, and then the image receptor with the compression paddle.

MS. KAUFMAN: Okay. Could you mention something about following ACR's recommendations for beam alignment with image receptor? I don't remember what those said relative to the nipple and right and left side.

MS. BUTLER: Everything is 2 percent SID.

MS. KAUFMAN: Two percent.

MS. BUTLER: Anything else on that?

MS. KAUFMAN: If it is 2 percent, then, I agree with that.

MS. BUTLER: Okay. Screen speed uniformity.

[Overhead.]

MS. BUTLER: One commenter pointed out that the screen difference which is currently in the proposal, of

0.3, is too large, and they recommended 0.15. I would like to point out that 0.3 is currently in the ACR manual.

So, my question is should we reduce this by regulation. Any questions? This is a pretty simple, brief one. Cass.

MS. KAUFMAN: I don't think that you can really see density differences below 0.3, can you, visually? I mean does it make a difference in the clinical images or we are talking about that much of a dose difference, but --

MS. BUTLER: Joel.

DR. GRAY: You see can you see differences if the films are on the same viewbox side by side. If I put one up on the viewbox on one side of the room, and one on the other side of the room, you won't see it really.

MS. BUTLER: So, I think the consensus is we will leave this as is.

System artifacts. Most of the questions had to do with including procedural details, and I think they can be easier left to guidance. My recommendation is that the artifact test should be left as is.

Are there comments or discussion? Okay.

Next, please.

[Overhead.]

MS. BUTLER: There weren't any comments tabulated for QC tests of other modalities. If anybody would like to bring up discussion on this? If, not, we will move along to mobile units.

[Overhead.]

MS. BUTLER: There were 21 comments in all summarized. Several of the commenters inaccurately interpreted the proposed rule to mean that images had to be taken and processed prior to examining the patients at each location.

Most comments were generally supported, appreciated the flexibility in choosing their own test methods, but also requested guidance from FDA on what would be acceptable.

My personal feeling is the way it is written right now is okay, and that some of the questions that commenters have, they could be provided in guidance documentation.

Anything else on that?

Okay. The next one, please. The use of test

results.

[Overhead.]

MS. BUTLER: This next set was fairly controversial. I had to do with immediately repeating all of tests. There were 13 comments that were summarized. There was essentially no support for this requirement as written. Ten commenters felt that it was not necessary to repeat all tests. One felt that this requirement should be deleted, and one felt that the tests should be repeated, but not necessarily immediately. Several commenters felt that the medical physicist should decide whether a test needs to be repeated.

Since the repeat of tests is covered in the ACR manual and also perhaps, hopefully, in the guidance manual, perhaps this is a section that could be deleted in its entirety. I would like to hear discussion on this.

Cass.

MS. KAUFMAN: Reference to the repeating of tests, that is the only part we are talking about actually deleting?

MS. BUTLER: That is correct.

MS. KAUFMAN: I would agree with that. I think this is up to the judgment of the medical physicist.

MS. BUTLER: So, we could totally delete Section (i)?

MS. KAUFMAN: No, just the last sentence in Section (i).

MS. BUTLER: Let me just read this. There is so much here, you know, you forget what one rule is when you go to another rule. [Pause.] Okay. Delete that last sentence.

Rita.

MS. HEINLEIN: Where is it?

DR. PATTERSON: We are talking about page 14920, and first column under (8). It is the last sentence before the (ii).

MS. HEINLEIN: All right.

MS. BUTLER: Let me read this for a minute and tell me what you think.

It says, "After completion of the tests specified... of this section, the facility shall compare the test results to the corresponding specified action limits;

or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility."

Do we really need to say this?

MS. KAUFMAN: Yes.

MS. BUTLER: I mean why are we giving them all the performance standards to start with if they are not going to be comparing what their test results are?

MS. KAUFMAN: It happens every day. I mean, for example, the phantom image test, we see this all the time, it is not even unusual, in facilities where they are doing it monthly, and monthly it is showing degradation, but they are not doing anything about it, or they are comparing it to the previous month rather than to an original film, so they don't see slow degradations over time.

MS. BUTLER: Joel.

DR. GRAY: The only item in that, that I would have an issue with is the pre- and post-move test that you are talking about mobile units?

MS. BUTLER: No, it is post-move preexamination.

MS. KAUFMAN: Pre-patient examination.

DR. GRAY: Okay.

MS. BUTLER: That's okay. But perhaps I am being naive, and I ask the regulators about this, but if you go into a facility and they do the test, and it doesn't meet the specifications that is in the previous page, and you fail them on that, wouldn't they sort of get the idea without actually having to have it written that they do have to compare it to what the specifications are?

MS. KAUFMAN: We ran into this before with medical physicist reports where there was nothing in the regs that said that they had to correct deficiencies that the medical physicist had found, and so they didn't. So, if you want them to do something, unfortunately, you do have to spell it out. I think we have got it in here under medical physicists, too, but that was a frequent finding where medical physicists had noted a lot of deficiencies, but the facility had never done anything about it, they just ignored it. So, I think we need to say this is what you are going to do with those tests. You are going to compare them.

And then it goes on to say if you find

unacceptable results --

MS. BUTLER: But that is in (ii).

MS. KAUFMAN: Right.

MS. BUTLER: Maybe we can just sort of like make this one statement then, that you compare the tests and then you make corrections. Does that sound reasonable? If that is your point, and, you know, again I think that particularly the making corrections is a valid point.

MS. KAUFMAN: It says what you are going to compare it to, and I think that is probably a safer route to go than just leaving it open.

MS. BUTLER: Rita.

MS. HEINLEIN: Well, since you have taken out that last sentence that says that they have to repeat immediately, then, in (ii), you would have to take out the first section of that sentence.

MS. BUTLER: Yes.

MS. HEINLEIN: So that, then, (ii) would just read, "the source of the problem shall be identified and corrective actions shall be taken."

So, I know what you are saying. You are saying

could it be one big long, long sentence. Is that what you are saying, Penny?

MS. BUTLER: No. I am just saying you would combine the two sections because the other thing that I am proposing for (ii) is that it says that, "If the repeated tests continue to produce unacceptable results, the source of the problem shall be identified and corrective actions shall be taken" -- and here is the important part -- "before any further examinations are performed."

We need to discuss -- Elizabeth.

DR. PATTERSON: Yes. I don't want us to get into micromanaging the verbiage of the FDA in the regs. I think the concepts of what we want should be in there, and not get them -- you know, we want a comma here and a period there, and put it one sentences or put it in two sentences.

MS. BUTLER: I agree. Okay.

MS. KAUFMAN: At an earlier meeting where we went over the regs, we went over each item specifically that we thought would require that they discontinue use of the unit, so I think in earlier meetings we have already addressed this issue.

MS. BUTLER: Those items were processor, screen-film contact, and average glandular dose, and that still holds.

The next one, please.

[Overhead.]

MS. BUTLER: Surveys. There really weren't any major comments. There was a lot of discussion under Item (10), which is mammography equipment evaluations, which basically says that if there is a new unit or new processor or major change of component, that a qualified individual should perform a mammography equipment evaluation, and it was not clear as far as what the qualified person would be.

There were 44 comments summarized, and most of the comments supported the need for additional evaluations of equipment when new equipment or major equipment components were installed.

There was considerable discussion of who should perform these equipment evaluations. The vast majority, and that is 27 of the comments regarding responsible personnel, felt that the medical physicist should conduct these evaluations, and I think there was general agreement at the

April committee meeting that that should be the case.

Facility cleanliness. Yes.

MS. KAUFMAN: Did we get any comments relative to a definition of what major components include?

MS. BUTLER: Yes. There were not a lot of suggestions, but there were several suggestions, and without digging through this pile, I think they were primarily an X-ray tube, buckey assembly -- and what was the other one -- were they new cassettes? No, I don't think so. But new processor, that is not a component, but that is a whole new piece of equipment.

MS. KAUFMAN: It says "or processor equipment or change," but at some point we need to define what major components are. It could be in guidance, but at some point we need to do that.

MS. BUTLER: Thirty-five comments were summarized on facility cleanliness. Seven supported the requirement, three wanted to see it deleted, and nine wanted specific protocols and more details available from the FDA. I think it is okay as written, and we don't need to include any additional details in this reg.

(12) Calibration of exposure measuring equipment.

By far, most of the commenters recommended that exposure measuring equipment be calibrated every two years.

Joel.

DR. GRAY: I would just like to make one comment to emphasize that point, and that is that for radiation therapy, ionization chambers, calibration is required every two years. Doing it more frequently than two years just doesn't seem to make sense for mammography where, compared to therapy, we are working at 1 percent or half-percent levels.

The other issue is, is that every time that that device goes back, it takes somewhere between one week at a minimum probably to two to three weeks for that calibration to occur. That means the physicist is without that device during that period of time.

MS. BUTLER: Okay. The final issue that was addressed had to do with infection control, which is not on there. There were 10 comments that were summarized. Eight of these comments indicated that this requirement was unnecessary, and two indicated that additional requirements

were needed.

[Overhead.]

MS. BUTLER: Oh, I guess I do have it. Okay. I don't want to touch this one. My personal feeling is the way it is described in the regulations is adequate, and probably needs to be in there for good reasons, but anything more than that, I think may be too much.

If there is any discussion, I would like to open it.

Okay. Thank you.

DR. PATTERSON: Thank you, Penny, and Joel.

Yes, Flo.

DR. HOUN: Before we end this discussion on the QA for equipment, I just want to know if you want to -- you began your section by saying you were concerned about cost-benefit and the need to streamline, and right now you have recommended a deletion of the one sentence in (8)(i), and I am wondering, in looking at all the tests and regulations that you have commented on, is there anything you feel that needs to be streamlined, any details that can be limited, any places where flexibility should be allowed.

MS. BUTLER: I had actually opened up a couple of issues which weren't supported by the committee, and perhaps we can address this.

Honestly, when we were asked to review the comments, basically, we were asked to review the comments and present them rather than putting thought into making recommendations on modifying what is here, so my mind frame was not going in that direction, but I certainly think it is a valuable thing to open up.

DR. PATTERSON: Penny, I just have one other question I would like to bring up, and that is under the questions that the FDA had, which they wanted you to address, Question No. 1, the first part of that was addressed. The last part of that, which talks about the remaining tests, how long should a facility have to make correct actions on those, I don't believe any mention was made of that.

MS. BUTLER: My personal feeling is I am not sure it should be specified under regulation. I think there are certain extenuating circumstances that make easy correction of some things and difficult corrections of other things.

Certainly, the issues that we brought up regarding dose, film-screen contact -- and what was the other one -- processor QC, by the fact that they can't do mammograms or process films, really you don't need to put a time limit on correcting it then, because they are going to move on it if they can't do mammography. The others, I think we should leave to the judgment of the facility, but that is my feeling again.

DR. PATTERSON: Are there any other questions or further discussion for Penny or Joel on that aspect?

Okay. Thank you very much.

We will now go to Tammy on the Quality Assurance-General, and that is on page 14881, where we are talking about 900.12(d).

Quality Assurance-General

[Overhead.]

DR. BASSFORD: I reviewed about three inches worth of letters for this area, and actually felt that the ERG summary was extremely accurate.

I have organized the comments under the three FDA questions, and then I have got an additional couple of

overheads for some nonspecific comments that didn't seem to fall under any of the three FDA questions.

I will start with the first question, which deals with assigning primary responsibility for the facility quality assurance program to a physician, the lead interpreting physician as we have defined it in the proposed regulations.

The comments around the assignment of responsibility for overall QA program to the lead interpreting physician basically looked at three issues. There were several comments regarding the position of contract physicians or physicians who are less than full-time employees of the facility or physicians who interact with the facility from some physical distance, and whether they, in fact, had the authority to enact changes as they saw fit when a quality assurance problem came up.

Specific suggestions fell into one of two categories: allow the facility to choose somebody, not necessarily an interpreting physician, to be in charge and have the ultimate responsibility for QA, or make it be the CEO of the company, because increasingly this is a business

decision.

There were also a fair number of comments that supported the idea of switching over all responsibility for quality assurance programs from the medical physicist, as was implied in the original legislation, to a physician.

There were a few comments on the competence of mammographers to oversee quality assurance in terms of their training and also their will to be concerned about quality assurance. None of these were from physicians.

There were two comments that basically expressed that the mandate of the original MQSA legislation, as they understood it, was for medical physicists to be in charge of quality assurance, and they felt that the regulations were exceeding the authority or the mandate given to them by the original enabling legislation by switching primary responsibility to the interpreting physician.

We might want to start with the authority liability issue. I know that that was discussed in terms of some of the difficult contractual relationships and who would be most likely to be able to enact changes necessary for QA. I will open it to any comments and discussion.

Cass.

MS. KAUFMAN: This was a problem in the HCFA regulations in that it said that the medical physicist was responsible for assuring that the QC program was adequate, and all that kind of stuff.

That is really not an appropriate responsibility because in many, if not most, instances, the medical physicist is hired on an annual basis, or something like that. They don't really have control over the facility or the way expenditures are made, so that they can make a lot of recommendations, but to put the responsibility on them to assure that what they have advised is implemented, I think is legally and ethically incorrect.

DR. BASSFORD: I am sorry. I think you said medical physicist. Did you mean physician?

MS. KAUFMAN: No, I meant medical physicist.

DR. BASSFORD: You meant physicist. So, you are speaking in support of the regulation as it stands, making it a physician?

MS. KAUFMAN: Correct.

DR. BASSFORD: Okay. Does anyone have any

response to the comments that question the wisdom of making this physician, assigned to a physician? Does anyone want to respond to that? Rita.

MS. HEINLEIN: I agree that the responsibility for the facilities quality assurance program should remain with an interpreting physician or remain with the physician who takes on that responsibility, because the quality assurance is not just the QC tests.

I mean certainly even though they may not be trained in the performance of those tests, they certainly are knowledgeable in looking at the results and whether something is in or out of compliance, and I think that is where there is a real team approach between the medical physicist and the interpreting physician, but I think it is the interpreting physician that has to also be able to go to the board or whomever to say these are purchases that need to be made. I don't think that is something that the medical physicist really would have the authority to be able to do. I agree it should remain with the physician.

DR. BASSFORD: I think some of the concerns expressed confused the immediate consequence of having an

inadequate QA program in terms of consequences to the facility, which would be lack of obtaining a certificate, with liability or legal liability, which could be considered perhaps a more indirect consequence, and I think probably comes under some of the liability comments that were received with regard to the audit, and would perhaps best be addressed there. Does that make sense?

MS. HEINLEIN: I think that makes sense, and I also think that I don't know any group that would want the medical physicist responsible for coming in and assessing a medical audit and then suggesting any type of corrective action plan.

DR. BASSFORD: Joel.

DR. GRAY: I would like to make a suggestion here as to why this occurred, and I think part of it may be due to the confusion of the terms quality assurance versus quality control. I can see no reason why the physicist shouldn't be responsible for the quality control program, but I agree to have them responsible for the quality assurance program, which is a whole other issue.

Hopefully, we have gotten those terms straightened

out, and if people still have a question, maybe we should
redefine them in the beginning of the document.

DR. BASSFORD: Cass.

MS. KAUFMAN: So that means that under Section
(iii) where it talks about medical physicist, you would be
comfortable if it said "related quality control practices"
rather than "quality assurance practices," the way it
presently reads?

DR. BASSFORD: Well, here it says "equipment
related quality assurance." I am hearing a suggestion to
change that to "equipment related quality control"?

DR. GRAY: Yes.

DR. BASSFORD: Is that the general sense?

MS. HEINLEIN: That is the correct term.

DR. BASSFORD: What I hear is it is the sense of
the panel that we support the designation of the lead
interpreting physician as the person ultimately responsible?

MS. HEINLEIN: Yes.

DR. BASSFORD: Okay. There was a question
regarding (d) on 14881, when it described the quality
assurance-general, "Each facility shall establish and

maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services," there was a question regarding the definition of safety, if that meant infectious safety, radiologic safety, or more general, equipment safety, et cetera.

I am just reporting. I don't know if anyone has any comments on that.

There were several comments that seemed to be confused under the duties of the lead interpreting physician. There is a statement in the proposed regulations that, "No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for the assignment are adequate."

A lot of people took that to mean that the lead interpreting physician would essentially be designating out all his responsibilities, and questioned the usefulness of even having that physician if all the QA tasks were divvied up.

I think what this paragraph was meant to do was strengthen the position of the lead interpreting physician

in terms of being able to ultimately approve who carried out the tasks.

So, I think that was just a misunderstanding in terms of what the paragraph was really trying to say.

Next overhead.

[Overhead.]

DR. BASSFORD: The next question FDA has posed is the role assigned to the other interpreting physicians, interpreting physicians other than the lead interpreting physician, and there was a lot of confusion about the feedback issue.

There were about 12 comments inquiring if the interpreting physicians needed to provide feedback to the mammography technologists after every single image, which is how they interpreted the regulations to read, versus after. There were several suggestions to replace that with "after technically inadequate images."

Related to that was confusion as to whether the purposes of QA would best be served by immediate feedback to the technologist performing the mammogram or more general feedback to the lead QC technologist or to the lead

interpreting physician or LIP, as I have on the overhead.

Rita.

MS. HEINLEIN: I think one of the comments about versus technically inadequate images only, I think feedback is not just negative. In fact, I think they can get a lot more oomph out of all the people that are working with them if some of that feedback was positive.

I think the issue of whether it should be after every single image, I mean they have gone from one extreme of every single image to the other extreme of only talking to them when it is technically inadequate.

DR. BASSFORD: Does anyone have any recommendations as to how to clarify that?

MS. HEINLEIN: Where exactly is it in here, because the wording in here could be just right, just saying that there should be feedback.

DR. BASSFORD: It is under (ii). It says, "All interpreting physicians" --

MS. KAUFMAN: As written, it's pretty good. It is a general statement that they will provide feedback. It is not relative to any specific exam.

DR. BASSFORD: Maybe, Flo, we could just put in the guidance section that it doesn't have to be after every single examination, since there were so many comments that seemed confused about it.

DR. HOUN: Well, my question is, it is written general that feedback should happen. We are not prescriptive in saying every or bad ones or good ones or minutely, hourly, whatever. Do we need this as a regulation regulating communication between the doctor and technologist? Do we need this? It is a good thing, everyone knows that. It is a very good thing. That is a good thing to happen. Is it something that you need by law to happen?

DR. BASSFORD: Dan.

DR. KOPANS: By the tone of your question, I would suspect that you agree that it probably doesn't need to be mandated by law. I mean it is like again legislating common sense. You know, there is leadership. The radiologist is supposed to exercise some leadership in their practices, and that involves feedback, good and bad.

It almost goes without saying. You might want to

put it in guidance, but I don't understand why you would legislate. I mean how do you measure it, then, do I have to sign off every time I feed back to a technologist or she feeds back to me?

DR. BASSFORD: Like HCFA did that monthly.

MR. FLETCHER: As Cass has said many times, regulations are normally written for the exception rather than the rule, and in most of the cases you are exactly right, this won't be necessary, but if you don't have some kind of guidelines in law, that are going to cover those instances where individuals are not going to do it, then, you open yourself up for greater difficulties down the line.

DR. BASSFORD: Cass.

MS. KAUFMAN: Where you need this most often is with off-site radiologists that never go to the facility, and there is virtually no communication between that radiologist and the technologist, that is really where you need this kind of a requirement.

I can tell you that with off-site radiologists, currently, there is probably no communication whatsoever, and sometimes we will look at just terrible images, and when

we bring it to the radiologist's attention, they will say, oh, yeah, I know, I didn't think that was very good either, and you will say, well, did you talk to the technologist about it, and well, no, I didn't.

So I think you do need it for those facilities.

DR. BASSFORD: Betty.

DR. PATTERSON: My only comment about this is the fact that you are talking about all interpreting physicians, and unfortunately, in some facilities, you know, it is not my job, it belongs to the lead individual and I don't have to deal with this. That is the only reason why I could see keeping this in regulation.

DR. KOPANS: I have no problem with it, but how do you document that? You just gave an example of where there is poor quality imaging and the radiologist didn't tell the technologist. Does that mean that when the inspector comes through, they have to find an episode like that and say did you document that you fed back? It just seems to me it is unmeasurable and unenforceable.

DR. BASSFORD: Cass.

MS. KAUFMAN: I think this is one of those

regulations that you only use it when you need to use it. I mean we have got lots of regulations on the book that you don't really look at during every inspection, tube-head leakage, for example, we almost never inspect that, but it is a regulation that you do want somewhere on the books.

I would anticipate that this would be something that would only be used under that condition that I just described, where then you could go back and say you didn't communicate to the technologist, but it would not be something that I would expect to see documented or routinely asked during an inspection.

DR. KOPANS: The only way you could measure it -- sorry to be argumentative here -- the only way you could measure it is if the interpreting physician never spoke, because if you said to the interpreting physician, well, don't you feed back to the technologist, oh, I do it all the time, but maybe I haven't done it for the past two months or something like that, and you wouldn't know that.

It just seems to me it is unenforceable.

DR. BASSFORD: Just something to consider, and I don't know if it will work or not, but another point of

contact to bring distant interpreting physicians into the loop is through the annual audit and the interaction between the lead interpreting physician and the other interpreting physicians, when conceivably that might be an opportunity to address some of these issues.

I just mention it. It is a longer term sort of corrective action, but I just mention it as a possibility and wanted to hear some comments on that, since I think it would be easier to document those annual conversations than how often somebody calls the technologist.

MS. KAUFMAN: Off-site radiologist, it is usually one radiologist, so the lead interpreting physician is going to be the interpreting physician, so that you are not going to have that kind of communication.

DR. BASSFORD: Well, I would say then they will have responsibilities as a lead interpreting physician that are going to necessitate more frequent communication anyway.

MS. KAUFMAN: With whom, communication with whom?

DR. BASSFORD: Well, if they are ultimately involved with the QA program for the facility, and they identify problems, it is their responsibility, if they are

the lead interpreting physician, to take corrective action and document it. Correct?

MS. KAUFMAN: Not with the technologist's performance.

DR. BASSFORD: If the only physician, be they distant or on site, is the lead interpreting physician, and they are ultimately in charge of the QA program, and they have primary responsibility for taking corrective actions, how are they going to do that without talking to people?

MS. KAUFMAN: I think the only time we require corrective action is in the medical outcomes, the audit, where we say they have to, under this particular section --

DR. BASSFORD: Under (i), "The facility shall identify a lead interpreting physician who shall have the general responsibility of ensure that the quality assurance program meets all requirements," so if you are saying that those outlying physicians are not going to have conversations with the lead interpreting physician as part of the audit process, because they are the lead interpreting physician, then, as the lead interpreting physician, they have actually a more well-defined and increased

responsibility as the lead interpreting physician to assure that quality assurance program.

MS. KAUFMAN: I agree with that, but I guess what I am saying, though, is they don't communicate with the technologists.

DR. BASSFORD: Well, then, they will get dinged as the lead interpreting physician because they won't have adequately maintained and assured quality assurance program.

Esther.

MS. SCIAMMARELLA: Going back to the question, I think this needs to be kept here, so give a good clarification for the institution who are not too careful to maintain good quality.

DR. BASSFORD: Carl.

DR. D'ORSI: I kind of agree with what Dan said and what Florence intimated. It is, as it stands, relatively unenforceable and meaningless. One of the things you can do -- and some states have done this -- is to require at least a semiannual meeting between interpreting physicians and technologists that may last a half-hour, and then you can go over conglomerate problems at that time. At

least that is something that you can see and check off, yes, I have had my semiannual meeting.

But if you are going to leave it like this, it is meaningless. It is just putting something in that is not going to be checkable, but if you put in a meeting that may be required, at least that is something that could be checked on and accomplish the same thing.

DR. BASSFORD: Rita.

MS. HEINLEIN: I think something has to be in there, so that there is communication between the radiologist and the technologist.

Again, it is not uncommon if there is a physician who is off-site, where they do not communicate at all with the technologist, so the technologists therefore assume that all of the images are just fine, and yet I know of a facility that had great difficulties with accreditation, and when I went to visit with them and I said what does the physician say, they say we don't know, we have never seen him.

So, I think it is important to have something, and I think actually, Carl, your suggestion is a good one,

something maybe that is a little bit more easy to document.

DR. BASSFORD: With the idea that if people are using physically distant radiologists, an actual meeting might not be the most efficient way. I wonder if it would be sufficient if what I am hearing is that what needs to be specified is evidence of communication between the technologist and the radiologist.

MS. HEINLEIN: Whether it is conference call or something.

DR. BASSFORD: And then we can leave it up to each facility perhaps to decide how they are going to document communication? Dan.

DR. KOPANS: Then, for the regulators, how much evidence is sufficient? I call once a month, I call once a week, I call once a day. You know, I think someone is going to say, no, you are not doing it frequently enough, and unless you are going to write into the regulation it has to be done once a day, once a month, once a year, again, it is unenforceable.

I am sure even in the case, Rita, that you were mentioning, I am sure if you talked to the radiologist, the

radiologist would say, oh, I stop in there periodically.

MS. HEINLEIN: No, he just said he had never been there.

DR. KOPANS: Then, it should be never. That way would be enforceable, if you have never had feedback, but I don't see how you can enforce it any other way.

MR. FLETCHER: Once again, you are talking about a situation where -- you are going to have some experience with these facilities. I mean these facilities don't just do mammography, and these individuals don't just do -- you know, it is not just one area.

You are going to have a track record or they are going to have a track record, so you are going to have an idea as to how well they manage their radiation safety programs, and you will be able to establish guidelines based upon your own experience with these facilities.

Whether you allow that institution or facility to establish a frequency of contact, and you double-check that, or you require it to be in writing, there are already rules on the books for other areas that they are already following, and I think in most cases you will just follow

the guidelines you have already established with most of these facilities.

DR. BASSFORD: Florence, do you have what you need in terms of the sense of where the committee is at?

DR. HOUN: I think so. I think you are saying that if this requirement stands, it should be more prescriptive by giving a periodicity.

DR. PATTERSON: Is it possible that could go into guidance, more descriptive?

DR. HOUN: I think that right now it is written general, and the guidance in the preamble will say how wonderful and helpful communication is, and it should be frequently, and blah-blah-blah.

DR. KOPANS: I still have a problem, because these are laws, these are regulations that I can be fined for, go to jail for, I don't know, have something happen to me, and I want to know what I have to do to fulfill the requirement of the law, and there is nothing in this part of the regulation that gives me any clue except I have to mumble something to a technologist once a year or once in the entire relationship that we have.

So, I am saying that I understand the intent, and in my practice we talk to each other constantly, we never shut up, and that may be a problem, too. Maybe you should put a postscript at the other end.

DR. BASSFORD: Could we limit the amount of communication?

DR. KOPANS: I think if you are going to require us in law to have these interactions, then, you have to spell out what is that level, so that you, as a regulator, can come in and say you are not performing at that level or you are performing at that level, but this is just too general. It is unenforceable.

DR. BASSFORD: I think a difficulty also if there is a facility with tons of crummy images, the appropriate amount of communication for that facility would be different than a facility where the images aren't as problematic, which I think is difficult in setting, I would think would be difficult in setting an absolute limit that would be broadly applicable. I don't know what you all think.

Joel.

DR. GRAY: I think this discussion is getting

entirely too serious. I would propose that we develop a regulation on the quality of communications.

DR. BASSFORD: Well, we know they need to be sensitive and appropriate.

Penny.

MS. BUTLER: Ignoring that, I would like to support Dan and Carl. I think this is common sense. I think it is something that does need to be in guidance, but I am really afraid that if it goes into regulation, and there is documentation requirements associated with it, so they can be potentially inspected against, that it is just another additional burden which is going to take time away from the conduct of good mammography.

DR. BASSFORD: Marsha.

MS. OAKLEY: I guess my question on this one is if you go back to, you know, I don't want to make it burdensome, but it would seem if I were having a mammogram in a facility where the tech and the physician have never seen each other, don't talk to each other, and as you say, didn't do well on inspection, I sure wouldn't want to have my mammograms done there.

So from the point of view of the woman who is going into that facility, in order not to try and make it more burdensome, there must be something on a monthly basis that is being done anyway where this could just be simply checked off.

I can't imagine that in a month's time, in most facilities -- now, that is excluding off-sites -- but it would just seem to me there ought to be somewhere you could just initial you had one conversation in a month, and maybe I am incorrect on that.

DR. BASSFORD: Dan.

DR. KOPANS: Maybe I am not being clear. That is fine. If you want to set a regulation down that says that you have to check off once a month that you had an interaction with one or more technologists, that is fine. At least it is something that I can say, okay, I have had the interaction, I am checking it off.

But the way it is worded here, there is no guidance. It is you should have an interaction, and what does that mean. It may mean to say, you know, the technologist says I don't think this is a good film, I want

to repeat it, and the radiologist says shut up and don't talk. That is an interaction, but does that count as a useful interaction?

So, I am saying you need to define, if you are going to make a requirement that we interact, what is the definition of that requirement and how do we document it, because otherwise, quite frankly, what I am concerned about is that this is kind of an open-ended thing where an inspector could come in -- not that this is going to happen -- but decide by himself or herself that the interaction isn't sufficient, because the technologist says he never listens to me or something like that, and you don't know what the interactions are, but it is an open-ended regulation, and I don't think that is a good idea from a regulator's point of view.

DR. BASSFORD: Do the other radiologists in the group have any comment on this? Mike, Larry? Do you come down on one side or another?

DR. BASSETT: I think there are reasons, and I think that someone should be designated as responsible, and that should be on paper because the inspector or the

accrediting party may want to contact that person for a specific reason. I don't think it is unreasonable to have somebody designated.

Whether you can document all these meetings and everything, I think is a little bit of a problem. I think it is going to lead to just kind of every month you go by and check something off, and it is not going to have much meaning.

DR. BASSFORD: Mike?

DR. LINVER: I agree. I think that is how I feel about it, too.

DR. BASSFORD: Overly prescriptive?

DR. LINVER: Yes.

DR. KOPANS: And then Cass, then Esther.

MS. KAUFMAN: One thought, and it is interesting, Dan, because the statements that you are making are exactly what I said earlier this morning, that you need to be cautious that you don't get too general, because facilities do want to know what they have to do, and the more prescriptive you are, the clearer it is to them what they have to do.

Now, one thought in terms of this particular section would be to say that they either have to have an ongoing interaction or that they have to at least once a month communicate with the technologist or something like that, because, for example, in a hospital situation where it is not unusual at all for the technologist to show every set of films to a radiologist, so that is an ongoing interaction that shouldn't have to be documented, so that might be an alternative suggestion.

DR. KOPANS: Again, it's fine if you define what is the requirement. I think Rita's point is that the radiologist never communicates, maybe you could say the radiologist at least once a year, but there needs to be a definition, otherwise, it is unmeasurable, I don't know if I am in compliance until you come and tell me I am not.

DR. BASSFORD: Esther.

MS. SCIAMMARELLA: Well, I think again from the consumer I go back to what we were discussing here about the consumer point of view, that I encounter, too, like Rita mentioned, facilities where nobody communicate with each other, and like you said, people can chat and talk about

what is the next movie, but the issue is that we can discuss a case with you once a month, once every six months, but I think there needs to be that communication that is an educational conversation or case review in areas who are deprived, and are not good institution.

They follow certain guidelines, and my concern is again that the more we regulate it for the poor or rural areas or underserved population, we have more guidelines, and people if they don't perform, they cannot continue to perform poor, lousy job on the underserved population.

So, I think I want to see certain, like six months a case review, because university, you do all the time, but not in the community clinics.

DR. BASSFORD: So, for FDA, it sounds like the committee agrees that communication is a good thing, but it is somewhat split on whether it should be a very precise regulation or delete it from regulation entirely, but it sounds like there is some consensus that a general regulation would be the worst.

Does anyone feel it is important that it is the specific technologist who performed a specific mammogram

that gets the feedback or could it be periodic feedback to the QC technologist, because as it reads now, it appears to be the specific technologist who helped create the image?

DR. KOPANS: From a quality perspective, it is clearly the technologist who did the imaging, and the ideal feedback is between the interpreting physician and the technologist.

Again, I have no problem, you know, if you want to write that every month or -- I mean we do that now, most of us, but as you are pointing out, in some practices it is not something that is done routinely -- but you have got to describe what the requirement is, not just leave it general.

Again, my preference would be directly to the technologist performing the study.

DR. BASSFORD: So, if a physician is interacting with multiple techs, and we are going to go the precise route, then, it sounds like we need to say how often you have to interact with each tech, or would that be based on what percent of the images you review? I mean I think this is where the prescriptive stuff can get a little --

MR. FLETCHER: Well, another option is, once

again, is to word it such that the facility sets the frequency, but it must be at least, you know, a certain time period, once annually, for example, and they will be checked against that frequency, and if that is not sufficient, then, a more realistic frequency will be set.

DR. BASSFORD: Have we wrapped this part up?

Okay.

We will move on to the next question from FDA, which is, in view of the comments, should any change be made in defining the qualifications of those who perform the quality control tests.

I will just draw your attention to the description in (iv) of the quality control technologist, which says that, "Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to quality control technologists."

One question or one area of considerable comment was whether the QC technologist, currently this person is required to be an X-ray technologist, but not required to meet the qualifications for a mammographic technologist.

Comments ranged from support for the requirement that a person be an X-ray technologist to suggestions that he or she also be required to be a mammography technologist, to a request that at least for performance of some of the tasks, one does not need to meet the qualifications of a QC technologist in some of these tasks particularly related to processor QC, darkroom cleaning, test strips, and a couple of comments said virtually any QC activity with proper training could be actually designated or given out to less qualified, cheaper personnel.

So, we had a real range in terms of what people thought the requirements of this position should be and whether this person needed to perform all the QC tasks or whether this person could just be responsible for overseeing less highly trained personnel in their performance of the QC tasks.

Joel.

DR. GRAY: I guess I would have a question to the FDA about that. When I read that, I assumed that quality control technologists meant the mammography technologist that was doing quality control, and not necessarily somebody

coming in off the street. What was the intent?

MR. SHOWALTER: My recollection is the intent was that it is the X-ray technologist that is doing quality control, not necessarily the mammography technologist.

DR. BASSFORD: And that is how the regulation, as it was put out, read. Did you have an observation about that? There were some comments who felt that it should be a mammography.

DR. GRAY: I would be very uncomfortable having the typical X-ray technologist that might be doing quality control trying to interpret the tests for mammography since they would not be really familiar with the equipment, the artifacts, probably not know what a good mammogram should look like in the first place.

DR. BASSFORD: Dan.

DR. KOPANS: I just second what Joel was saying. We have actually been there and done that, had the department quality control person doing it, and they don't have the expertise for doing mammography quality control. I think it should be a mammography technologist.

DR. BASSFORD: Rita.

MS. HEINLEIN: I agree it should be a mammography technologist for the performance of most of those tests. I know that in reading all of the letters that I read from technologists, many of them made the comment that they have darkroom or quality control technologists for the department who then go around and perform the daily processor QC, and that these are people that have an expertise in processor QC, so therefore they just go ahead and do the mammography processor.

I personally don't have an issue with that. I mean I think if there is someone who has an expertise in processing QC and they can do all the processors in the department, I don't feel that in order for them to do the one in the mammography department, that they would have to be a mammography technologist.

DR. BASSFORD: Marsha.

MS. OAKLEY: I would just like to see it be the person who certainly has the most experience with mammography. I was in a facility where it literally was kind of assigned on a rotating basis amongst eight to 10 techs, and it was not always the person who even did

mammography, and I go along with what Joel said about really understanding what that person was doing.

I had questions as to somebody who is working in the unit, you know, is it okay just to do all the processors and you really understand all of it, or is there more to it, and based on what Joel is saying, it sounds to me that there really should be more to it, and because of that, then, it should be perhaps someone who is doing mammography.

DR. KOPANS: Maybe a little bit of a qualification, and that is that it should be a mammography technologist who supervises it. I have no problem with someone being trained to run the sensitometer as long as there is someone who is supervising that, but I think that, again, the quality control should be overseen by a mammography technologist. I mean you can use other people in the department just as the interpreting radiologist supervises, I wouldn't have a problem with supervised work.

DR. BASSFORD: Cass.

MS. KAUFMAN: That is exactly the way the regulation is written, is that the quality control technologist has the responsibility for the individual task,

and the quality control technologist has to be a mammography technologist.

DR. BASSFORD: No.

MS. KAUFMAN: The definition of quality control technologist, that is page 869, "means an individual meeting the requirements of 900.12(a)(2)(i)," and if you look under (a)(2)(i) -- oh, and then we go into (ii), but under (i), it says "and" at the end of (B). So, that usually means both.

It is kind of confusing.

DR. BASSFORD: What page are you on?

MS. KAUFMAN: The definition is on 869, and that refers to 907, (i) has an "and" at the end of it.

DR. KOPANS: Which page is the one that has the (i)?

MS. KAUFMAN: 907, (2) radiologic technologists. It references (i), but if you go to (i), and the end of (i) it has an "and."

DR. BASSFORD: "All mammographic examinations shall be performed by radiologic technologists."

MS. KAUFMAN: Right. The definition of the quality control technologist on page 869 says that they will

meet the requirements of 900.12(a)(2)(i).

MS. MCBURNEY: The general requirements, not the specific mammography requirements.

MS. KAUFMAN: I think that is what it is supposed to mean, but when you look under (i), it has got an "and" at the end of that paragraph.

DR. BASSFORD: I think where it goes to (2)(i), that is where it would stop for a quality control technologist.

MS. KAUFMAN: Even though there is an "and" at the end of (i)?

DR. BASSFORD: Roger can clarify. I think you are in the wrong section.

DR. BURKHART: Roger Burkhardt from FDA. The way it was intended was just to apply to (i). If we had meant it to apply to all of the requirements, we would have just said (a)(2).

DR. BASSFORD: So, in this case you would ignore the "and" at the end of (i)?

DR. BURKHART: Right.

DR. BASSFORD: So, currently the QC technologist

does not have to meet the qualifications of a mammographic technologist. There was a lot of comment about that. That is one level that the FDA needs feedback from the committee on.

The second level is whoever that person is, can they supervise less qualified people to perform some of the tasks, and if so, does the committee want to say which tasks they are comfortable with lesser qualified people performing or not.

So, it is kind of three levels. The first is should the QC technologist, should the current description of that person stand, which is X-ray technologist, should it be less stringent or should it be more stringent. I have heard some feedback that some people feel it should be a mammographic, it should meet the qualifications for a mammography technologist.

Does anyone want to make a strong argument otherwise? Okay. Cass.

MS. KAUFMAN: I don't have a strong feeling about this other than the fact that I know there are a lot of facilities that do have quality control people who are

specifically trained and assigned, and that is their full-time job is to do quality control, and I don't know that they are right, but I think they would be upset at having to take time away from their mammography technologist to do some of the other tests.

DR. BASSFORD: If you look at a relatively small facility, they may have one mammography tech who is busy doing mammograms, so should that person be taken away to do, say, processor QC. I think that is somewhat what we are looking at.

Dan.

DR. KOPANS: Again, I would suggest that she should supervise. As I say, you can train someone to do the sensitometry and run it through the processor, and then go over it together, but I think the mammography technologist should be the supervising quality control person.

DR. BASSFORD: Joel.

DR. GRAY: I agree with that. We have about 10 quality control technologists at our facility, and 9 of those I wouldn't trust going into mammography. They haven't seen the artifacts, they are not getting any continuing

education in mammography, they don't understand the problems.

Yes, they can do sensitometry, but they sure can't look at a phantom film, and they sure can't look at patient films and determine what is wrong with them, and look at the films for artifacts and that sort of thing.

DR. PATTERSON: So, you are saying that it should a mammography technologist supervising?

DR. GRAY: I would go a little further than supervising.

DR. PATTERSON: You are saying that it should be a mammography technologist?

DR. GRAY: The problem is in allowing for the fact that sensitometry can be done by almost anybody that understands the basics. It is the eyeball and the brain education for artifacts, image quality, phantom images that I don't think you can delegate to someone that is not working in that area and understands what is necessary.

Now, if you can say that they can supervise somebody, does that mean they can supervise a chest technologist to look for artifacts? I don't think so.

DR. PATTERSON: So, that goes back to you say it should be a mammography technologist who is doing the quality control.

DR. BASSFORD: Who does all the quality control tests.

DR. GRAY: I am hedging in saying that sensitometry can probably be done by someone else.

DR. KOPANS: I think I would agree again with Joel, that the mechanical parts of QC can be supervised. Again, I agree, you have got to know what you are looking at to understand image quality, as well as phantom images. So, I would agree with Joel.

DR. BASSFORD: So, the sense of the committee is the QC technologist should be a mammography technologist, but that certain tasks could be performed by personnel with less qualifications provided they had adequate supervision by the QC technologist.

Other than sensitometry, what else would be a task that would be considered appropriate for less qualified personnel? Rita.

MS. HEINLEIN: Darkroom cleanliness.

DR. BASSFORD: How about darkroom cleanliness?

DR. PATTERSON: That sounds like a good one.

DR. BASSFORD: Anything else? Cass.

MS. KAUFMAN: Relative to these regulations, it sounds like the very least that you do want to add (ii) to this quality control technologist, because that is the person responsible.

DR. BASSFORD: If we make it a mammographic technologist, then, all we need to do is say that they meet the qualifications as defined for the mammography technologist, so you would just refer it, as Roger pointed out.

MS. KAUFMAN: I am saying you would add (ii).

DR. PATTERSON: You eliminate the (i).

DR. BASSFORD: Just eliminate the (i), and then it would be the entire definition of a mammographic technologist, but you guys can figure that out. I mean I don't think we need to.

Ruth.

MS. MCBURNEY: I don't know if it is a problem or not, but in a very large facility, would that person be able

to -- if you make it required for them to be a mammo tech --
would they have time, if they were totally QC, time to get
in the number of exams that they would need to continue
being a mammo tech?

DR. BASSFORD: Joel.

DR. GRAY: That is exactly the reason for
specifying this is to say that this task is so important
that if the radiologist expects the technologist to do 20
exams a day, then, this person should do less than 20 a day
and have the time given to them to carry out these tests.

DR. BASSFORD: Okay. So, what we have done is we
have strengthened or made more stringent the requirements
for QC technologist.

DR. PATTERSON: That wasn't your comment.

DR. BASSFORD: And we haven't allowed very many
tasks open for less qualified people than a mammographic
technologist. So, we have really made the regulation a bit
more stringent than it was in response to the comments.

DR. HOUN: I had a question in terms of you are
asking to prescribe tests which cannot be delegated to
non-mammographic technologists.

DR. BASSFORD: Currently, as it reads, it appears that all the tests should be done by the QC tech.

DR. HOUN: And right now you are saying that the QC tech should be defined as a mammo tech.

DR. BASSFORD: Correct.

DR. HOUN: But that person, I thought the recommendation was is responsible to see that the QA program happens. But do you want to prescribe what that person can and cannot do versus the 11 QC tests?

DR. BASSFORD: Well, here is what the reg says, "responsibility for all individual tasks," and maybe the question is, to clarify, what does responsibility mean. Any tasks that aren't assigned to the physician or the medical physicist are then left for the quality control technologist under (iv).

MS. KAUFMAN: But they don't have to actually do the tests, they have the responsibility for them.

DR. BASSFORD: But there is no clarification of what that means, and there is nothing that addresses who should be performing the tests here. That is why we got such a broad range, I think, of comments on it, because

people were unclear on who could perform some of these tests.

What I am hearing from the committee is most of the tests they feel should be actually performed by someone who meets these more stringent guidelines for a QC tech. Am I interpreting the sense of the committee correctly?

Rita.

MS. HEINLEIN: First, to get back to somewhat that Ruth brought up, yes, I do believe that even if it was a mammography technologist doing all of these quality control tests, that they would still have sufficient time to meet the experience requirement that would be in the regulation.

I don't think that would be a problem. I mean at 100 mammograms a year, as it is right now, I think it would be more than enough time to do 100 mammograms a year in addition to the quality control requirements.

Back to this, I think that the quality control technologist -- and I support Dr. Kopans on this -- who is responsible for all these individual tasks, should be a mammography technologist, and maybe if it is stated like that, then, it would give the facility some flexibility in

that if they did have a processor technologist, you know, someone who just did sensitometry, they could do that.

They may also have a bioengineer in their department or a medical physicist in their department that does the screen contact tests. I mean if we said that only a mammography technologist could do it, that may say that the physicist would not be able to do those tests that the technologist is responsible for.

So, I agree with the quality control technologist shall be responsible for the supervision of the quality assurance program, not assigned to the lead interpreting physician or medical physicist, and that that person should be a mammography technologist.

DR. BASSFORD: But you are saying that certain other tasks, like processor QA, could be assigned to less qualified personnel. Yes, with supervision?

MS. HEINLEIN: With other qualified personnel.

DR. BASSFORD: But not necessarily meeting the qualifications of a mammography technologist?

MS. HEINLEIN: Correct, but the person who is responsible for making sure that everything is done

correctly and assessing the QC program would be a mammography technologist.

DR. BASSFORD: But I am not hearing universal agreement on whether processor QC falls in that "okay to delegate" category or not.

DR. HOUN: But maybe that should be left up to the facility because each one will have different strengths with their different personnel.

DR. BASSFORD: Do you want to leave that up to which tasks get delegated, do you want to leave --

DR. PATTERSON: As long as there is a supervising QC tech is responsible for what is done and the interpretation of it, I don't see where we should micromanage how each facility operates.

DR. BASSFORD: Joel, then Esther.

DR. GRAY: I agree with your comment about micromanaging, but on the other hand, if we don't define what the responsibilities are, then, the managing QC tech could delegate the phantom imaging and the interpretation of them to the darkroom tech, who is not even an RT.

There is a fine line here between micromanaging

and having the job done by somebody that knows what they are doing.

DR. BASSFORD: Esther, did you have your hand up?

MS. SCIAMMARELLA: I agree with Joel. I am scared with managed care with who perform what, in particular in communities that they don't have any staff and qualified people they could delegate to, I don't know, a person with poor skills.

DR. KOPANS: I was going to suggest you might be able to rephrase it in a way that suggests that the QC requirements other than those requiring image analysis or phantom image analysis may be delegated with supervision.

The other question, Larry, you did I think a study on the cost of all this QC. Do you have any data on how much time it takes, so is it possible for a QC technologist or the only mammo technologist in a group to do the QC and also keep up with the clinical load, did you have any data on that?

DR. BASSETT: Well, only in the sense that we counted up the hours and, you know, tried to translate it into how much time per year.

DR. KOPANS: How many hours was it?

DR. BASSETT: If she did all the tests herself, probably about four weeks a year just doing QC activities, but now you have to remember if you have a lot of technologists, that that is not as time-intensive per technologist.

DR. BASSFORD: But for a smaller facility, there is a minimum, and that is four weeks.

DR. BASSETT: Well, no, I am talking about -- that is not correct -- I am talking about when you have three mammography units, and we specified the exact -- I can't remember specifically. Let's just say it's a lot.

DR. KOPANS: But that four weeks is 160 hours, is that right?

DR. BASSETT: Right.

DR. KOPANS: So, 160 hours out of --

DR. BASSETT: But not everyone agrees with that time estimate, I must say. When Dr. Smith who did that came here, she was told that it was excessive.

DR. KOPANS: But what I am saying is you could do a calculation that would say that this should require one

hour a day of a technologist's time or 30 minutes of a technologist's time, or something like that.

DR. BASSETT: Cass, do you have a feeling for how much you expect them to do per day, I mean how many hours or whatever? Has anybody got that?

MS. KAUFMAN: No.

DR. KOPANS: I would think that it is manageable. It might put a burden on, but it is manageable. You know, you don't have a technologist -- even in large practices, the technologist isn't doing QC constantly, so that I think you could do those calculations and figure out that it is possible to be the QC technologist and do the mammograms, although the load for mammography may have to be reduced.

DR. BASSFORD: Betty was next.

DR. PATTERSON: I guess the question becomes what does the term "supervise" mean, and I guess that is the problem.

DR. BASSFORD: Guidance?

Joel, did you have a comment?

DR. GRAY: A comment based on what Larry and Dan were just saying. We are talking about less than 0.1 FTE,

it is like a 0.08 FTE, and that is not an excessive amount of time. That is 0.08 times 40, that is 3.2 hours a week. That is less than an hour a day.

DR. BASSFORD: What do people think of Dr. Kopans' suggestion to allow everything except things requiring image analysis, be it phantom or clinical image, to be delegated with supervision? Is that something we could hand FDA as a consensus along with the increased requirement for the QC tech? Penny.

MS. BUTLER: No, I wouldn't agree with that. Just because something, for example, the equipment check list, it doesn't involve any images, but it certainly involves a knowledge of the equipment, and I think that really needs to be done by the mammography technologist.

Personally, I think all the tests need to be done by the mammography QC technologist with the possible exception of processor quality control and darkroom cleanliness.

DR. BASSFORD: Barbara.

DR. MONSEES: I would like to say that I think we should take the high road here and have the QC technologist

probably be responsible for all of it and probably do it except maybe a few things, such as doing the sensitometric strips.

I think it is not only a question of doing them, and doing them right, but putting it together as a package with the clinical images, knowing when the processor is clean, know when the images look different, et cetera. If you have too many people involved, there is going to be a lack of communication and you are not going to catch things as quickly.

I think it doesn't sound like this is overburdening the facilities, and I think it is in the best interests of the technical quality of the examinations.

DR. BASSFORD: That moves us on to our next small set of comments about the QC technologist. Some people said this should just be one person because they are going to be supervising everything that is going on, and they need to be one person to put it together, versus people that said this should be multiple people because we will need multiple people to meet the QC needs of our facility.

There isn't anything in the -- the language just

kind of has an "s" on the end of technologist, implying it could be more than one. So, I got comments both ways.

Does anybody have any comments on that? Barbara.

DR. MONSEES: For purely practical reasons, you can't just have one person because of vacation, sick leave, et cetera, and these things need to be done, some of them on a daily basis. So, there needs to be more than one person. There needs to be a backup. How many backups, I don't know whether we need to put a limit on that, but in the high-volume facilities, it is very possible you need more than one backup, as well.

DR. BASSFORD: Penny.

MS. BUTLER: I really think this needs to be left to the discretion of the individual facility and what their particular situation is.

DR. BASSFORD: Betty.

DR. PATTERSON: I agree with both of the comments. I think that everyone, you have to have a backup, otherwise, if your QC tech calls in sick, you are going to not do anything because you don't have somebody to do the processor. So, you have to have a backup for it, but I

don't think that should be legislated as to how many backups and when and why, and et cetera.

DR. BASSFORD: Joel.

DR. GRAY: I think one person is responsible, but more than one person can be involved in doing the tests. My concern would be getting into a situation where, as Betty points out, you only have one person there.

Perhaps this is something that is better put in guidance, that if you have 10 technologists, you probably don't want all 10 of them doing quality control because none of them will develop the expertise they need.

DR. BASSFORD: One final question was some comments on whether, if the QC technologist is unavailable, whether physicians and physicists are qualified to perform the QC tests. This person felt vehemently that they were not.

Why don't you go ahead to the next comments.

[Overhead.]

DR. BASSFORD: I just wanted to cover some additional comments that didn't fit easily under any of the questions that FDA put to us.

One was just a comment regarding quality assurance records, that this was too much burden. There were several comments that said the QA manual should be the same manual in every practice and it should be the ACR manual, and then some comments on who should sign off on the manual.

Currently we have the physician, and the lead interpreting physician and the physicist signing off on the QA manual. There were several suggestions, although some of them were xeroxed copies of each other, to add the QC tech to the sign-off sheet, and several suggestions that the physicist sign-off should be limited to equipment-related QC, so that there wouldn't be an implication that the physician I guess or the physicist was taking responsibility for kind of approving the entire QA manual.

Then, several comments on the frequency of signing off the manual, suggesting that the QA manual should be reviewed annually, presumably updated, and then have everybody sign off again.

I kind of lumped those together. I don't know if there are any comments in terms of making any suggestions based on these comments or if the committee feels that the

way the QA manual is described is adequate.

Rita.

MS. HEINLEIN: I do agree that the QC technologist should have their name on the sign-off also. I mean they are responsible for doing the QC tests. I think they should put their name to the page.

DR. BASSFORD: Any other comments? How about the idea of an annual sign-off, any feelings one way or another?
joel.

DR. GRAY: I believe that already exists because as part of the physicist's review, he is supposed to review the technologist's tests and note that as part of the report that that has been done and that they are being carried out adequately, so that in effect is there.

DR. BASSFORD: There was a suggestion -- and I will just read it because I wasn't really clear that I might understand completely, there were several xeroxed suggestions -- "Recommend that the requirement for a technique chart be added to the manual and that the term be defined to include, but not limited to, the typical techniques the facility would use. If exams are performed

in the manual mode, the technique chart shall include manual techniques."

DR. GRAY: To back up, I stand corrected. It is the ACR manual that requires that the physicist review and sign off on QC tests. It is not in the regulations.

DR. BASSFORD: So, currently we don't have any recommendation for periodic sign-off on the QA manual.

What about the idea of a technique chart, does anyone have any feelings about that being added? This would be a totally new addition to the QA manual.

Rita.

MS. HEINLEIN: Isn't there somewhere in here that there is a technique chart available at the equipment? I think somewhere in the equipment requirement there is something about a technique chart. I don't know for certain. Do you know if there is? Do you remember anything about that Penny?

MS. BUTLER: There is something in the AEC section that if you don't meet the plus or minus 0.3, you need to have a technique chart, but obviously, if you do meet plus or minus 0.3, the way it is worded right now it is not

required to have a technique chart. I personally think it would be a good idea to have a technique chart required.

MS. HEINLEIN: I think it is important to have a technique chart. I don't know that the best place for it is in the QA manual. I think the best place for it is in the mammography room next to the equipment.

Dan.

DR. KOPANS: Maybe I am wrong. Isn't an automatic exposure control required for equipment?

DR. BASSFORD: Yes.

DR. KOPANS: And then the only time I think you would need a technique chart is if you are doing implants. So, why would you require a general technique chart? I mean if your AEC isn't working, then probably that machine shouldn't be used.

MS. BUTLER: But not all mammography equipment select kVp for you, and some of the units you have to manually select the kVp, and then your mAs is determined. So, a technique chart would include --

DR. KOPANS: If you were using 26 kV, and the breast was too thick, you would have a technique chart that

would tell you to get back -- I don't know, I have just never seen that really come into play in practice, but maybe there is some facility where it does.

DR. BASSFORD: Rita.

MS. HEINLEIN: I think it definitely comes into practice particularly with equipment that may be a few years old where it doesn't really -- I hope I am using the correct physics term here -- track, is that correct? So, you would have to make adjustments in the kV. It doesn't automatically adjust the kV for breast density or thickness.

DR. KOPANS: There is a requirement for linear tracking, though, of AEC, isn't there?

MS. HEINLEIN: It is the same, that if it doesn't meet that requirement, then, there would have to be a technique chart.

DR. BASSFORD: Would the technique chart be better discussed with equipment or do you think it needs to be part of the QA manual? If it is going to be very equipment-specific, then, maybe we should discuss it with equipment.

MS. HEINLEIN: I don't think it is necessarily

equipment-specific, so this may be the best place to discuss it, but I don't know that it should be in the QA manual as much as it needs to be posted with the equipment.

DR. BASSFORD: Joel.

DR. GRAY: I think the point that Dan makes is a very good one. You basically -- you don't have much control over these machines. You don't need a detailed technique chart. You may want to have one that says if the breast is over 8 centimeters, then, go up in kV or something.

I think this would be better left for guidance, and maybe put a comment in here that a technique chart should be used or -- I don't know want to say should or shall, I don't want to say maybe -- a technique chart is good practice.

DR. BASSFORD: Cass.

MS. KAUFMAN: I don't know whether it is important whether it is a major issue, but I can tell you that it is quite common to see a facility with multiple technologists, and each technologist uses a different technique on their routine patients in terms of not only kVp selection, but density.

So, if you ask what they use for a 4.2 cm, 50-50 breast, you may very well get three different techniques, and it may be that radiologists have different preferences, you know, and that is why they are doing that.

I mean I am not offering an opinion on that, I am just saying that that is a common thing that we see.

DR. BASSFORD: Penny.

MS. BUTLER: Currently, the ACR manual requires that you have a technique chart. It is something that every facility has, every inspector checks. I don't think it is a burden to continue having it a requirement in the regulations, and I think we could have a statement here that an accurate technique chart is required, or something like that, and should be posted near the equipment.

DR. BASSFORD: So, we are recommending that a technique charge be available or posted visibly, but not necessarily be part of the QA manual?

MS. BUTLER: Sure.

MS. HEINLEIN: I think the way Penny said it is correct, just that there be a technique chart --

DR. BASSFORD: -- available. Yes. Okay.

Dan.

DR. KOPANS: If you are going to have a technique chart requirement, then, the place for it is at the equipment, I absolutely agree with that. I think, though, the issue of requiring technique chart is something that maybe you should think about a little bit more. It is fine to say that ACR requires it, but maybe ACR needs to rethink and see do we really -- I think that was back in the days when there wasn't linear tracking of the automatic exposure control systems.

DR. BASSFORD: Penny.

MS. BUTLER: Perhaps I can clarify this a little bit more. Many systems that are currently out there will not preselect the kVp for you depending on the breast density and breast thickness. This is something that the technologist has to do, and what they will do is check the thickness of the compression, if they have old films, they look at the density of the breast, and they select 22 kVp or 30 kVp depending on what they are working with.

The technique chart would specify based on those parameters what they should dial in. On the column next to

the kVp column, it would say the density control. If you have a system which the AEC is tracking well, everything would be normal. On the system that is not tracking quite as well, you would have variations of plus 1, minus 1, something like that.

DR. KOPANS: Do we want within MQSA systems that aren't tracking properly? I mean it seems like you are specifying a requirement for equipment that is not operating properly as a backup. I understand the point you are making.

It would seem to me that then you could just say, for a breast that is this thick, because most of the time if you have old films, you can't tell what percent fat and what percent fibroglandular tissue.

So, maybe if it is a 6-centimeter breast, you have got to go up to 27 kVp with that piece of equipment, but I am not even sure the technique chart really helps you that much because you don't know the actual density of the breast, but I don't think we should specify technique charts to get around having properly functioning automatic exposure control.

DR. BASSFORD: Maybe a final comment on technique charts?

DR. GRAY: To address Dan's concern, the regulations do state that by the year 2000, all systems will function within plus or minus 0.3 in density, and that should cover the entire range, and by 2005, it will be plus or minus 0.1. So, we are focusing in on that and trying to get down to that.

I agree, at that point, the only reason you would want to go up on kVp for the denser breast is to perhaps reduce the overall exposure time.

DR. BASSFORD: There was one comment that noted in paragraph (iii), that one of the requirements for the QA manual is that all staff members, who are assigned responsibility for the QA program, are qualified, and just a comment that if these individuals have already had their qualifications included in the initial application, that it shouldn't have to also be in the QA chart.

I think I have one more. Let me just run through these, because there are just two. Well, I will let you do this now.

MS. KAUFMAN: I just wanted to make sure that Dr. Kopans realizes, too, that in these proposed regs, that when was say 2000, it isn't 2000, it is five years after the final regulations. Wasn't that the 2000 year?

MR. SHOWALTER: Yes, that is the intent.

MS. KAUFMAN: Since these are going to be finalized in 1997, we are really talking about 2002 and 2012.

DR. BASSFORD: And then just a final comment regarding the medical physicist responsibility as defined in (f)(iii), the middle of the middle paragraph, several recommendations -- again, that all seem to have been written similarly -- to revise having the medical physicist survey mammography equipment, to survey and evaluate the mammography equipment.

This would be under the responsibilities of the medical physicist under quality assurance-general.

And then one wording comment on page 14908, when the medical physicist QA responsibility is being described, but uses the more general wording of quality assurance rather than equipment-related QC. So, just a comment to

make that fit the wording that we have decided on for the medical physicist responsibilities.

DR. HOUN: I am just playing devil's advocate. So far in this meeting, we have gotten good additions, some revisions, but I haven't seen anything really in terms of anything to cut back, and yet the overwhelming concern from facilities is it is too much, too much regulation, it is not broken, don't fix it, it costs too much.

So, in looking now at this section, I asked this before from the QA-Equipment, and we couldn't think of anything to delete, is there anything here where you don't need it as law? It is very good practice, it makes good sense, maybe it's the role of the professional society to do more education, it's the role of the medical society to step up to the plate and talk effectively to patients, as well as to technologists, whatever.

I just want to know from people's bottom line, what is essential for regulation, what is essential for regulation.

DR. BASSFORD: Penny.

MS. BUTLER: There was a lot of discussion about

(ii) in this communication issue with the interpreting physician and technologist, and again, I would like to throw this in as a possibility.

Again, I think it is common sense, I think it is something that should be done, I think it is something that could be stressed in guidance, but I find communication like this to be a very difficult thing to regulate and enforce.

I would like to see this go in the guidance.

DR. BASSFORD: So the suggestion would be to delete the words "shall provide feedback on the quality of the mammograms they interpret to the radiologic technologist producing those mammograms," but to keep "shall participate in the facility's medical outcomes audit" so the entire definition of interpreting physicians would basically read that they should participate in the audit? Would that be the deletion you are suggested?

DR. HOUN: Well, even that is somewhat redundant in that I think the audit says that there is a lead person identifying issues and contacting the other interpreting physicians for issues and results and discussion.

DR. BASSFORD: So, we could delete, then, that

entire paragraph describing the interpreting physician as a position in this quality assurance section if the committee feels that that communication bit can be deleted.

Rita.

MS. HEINLEIN: If I was told what could we delete in this section to try to get rid of some regulation, I would say that is it. That could go out.

DR. HOUN: The other controversy was this technique chart and whether it should be in the manual. That is also somewhere.

MS. HEINLEIN: It does not have to be in the manual.

DR. HOUN: How about this manual? We are now telling people what is in this manual. I just don't know. I mean I was just wondering whether the current list of people, the sign-offs, the records of responsibility. Some of it, can that be left to guidance, and what is a model manual?

DR. BASSFORD: Let's think of it differently. Is there any parts of these that are really critical elements of any QA manual that would need to stay in might be a good

way to look at it.

Dan.

DR. KOPANS: I was actually going to do it the other way, and that is that a lot of this recordkeeping is very time-consuming and repetitive. I don't know what the solution is, but I mean we have huge notebooks, and when our inspectors come in, they have their check lists, and if you don't have that page with that signature in the appropriate time frame, you get a little -- of course, we are always up to date -- but if we weren't, we would get a little check that we weren't.

I would really have to go through almost item by item and say does this really need to be in this manual, and have a check after it, but I am not prepared to do that right now, but it's big, it's too much.

MS. SCIAMMARELLA: I don't know. People follow more. If there is something to discuss what to do, people go by the law, and the Federal Register, more going to the guidelines, and I have a concern to have precise information here that the people, and not only in this regulation, but any kind of regulation, people like to refer to the Federal

Register more than the guidelines.

So, I think we need to be precise to include things as simple as possible in the regulation in general, I would say, I don't know.

DR. BASSFORD: I have to say personally with regard to QA manuals in general, that the key elements are pretty much what is here in terms of who is doing it, what the action levels are, and what you do, and documentation that you have taken the appropriate action when you hit an action level.

Those are kind of the key elements of any quality assurance documentation, so at least those three things really kind of need to be there: what you are doing, when you are doing it, whether the problem resolved.

DR. HOUN: What about language like that, the quality assurance manual shall contain --

DR. BASSFORD: -- the following five key elements.

DR. HOUN: Issues impacting on quality, the corrective action documented. I mean here we are saying sign-off pages, and not exactly what you are saying.

DR. BASSFORD: It's wordier, but if you read it,

even though you guys put a lot more language in, that is what it kind of comes down to. So, I don't know if the language is so confusing to people that it is the language that needs to be pared, because I think the elements are pretty basic. That is my opinion.

Joel.

DR. GRAY: I guess, first of all, I would like to make a comment to Flo. The mind-set I had in going through here was not reduction of words or regulations. I got the impression from previous meetings that we were sort of, shall I say, stuck with what we have here, and we were going to massage this a little bit.

If you want to know what can be eliminated from this, then, I think we should go back and go through the process where we through and redline things that we think are unessential.

With that in mind, and relative to the QA manual, we are back in this conundrum again where if there is no regulation, there is no check-off for the inspector to check. I would like it to say, period, there should be a QA manual, end of discussion. It should be there. But if you

don't say what should be in that QA manual, then, what are you going to inspect against?

DR. KOPANS: The corollary to that is then you leave it open to the inspector to decide whether or not you are doing things correctly. So, it is a two-edged sword, I agree. From my perspective, the regulations are important to make sure we are providing high-quality services, but they should not be punitive for people who are doing a good job, and if you don't then spell out what is right and what is wrong, we have seen this in the past with HCFA inspectors, who are just deciding on their own what was correct and what wasn't, and it caused a lot of problems.

So, I support the effort to try and reduce the regulation, but whatever is regulated needs to be spelled out carefully, so we know what is right and what is wrong for the regulators.

DR. BASSFORD: Roland.

MR. FLETCHER: Normally, at least the first time around, I think you need to have perhaps more rigid, more regulations than you are going to anticipate in the long run, because people need that firm grasp to get started. It

ajh

is a lot easier to back off from regulations later as experience tells you they are not necessary than to try to introduce regulations later that you haven't established the first time through.

DR. HOUN: I guess the interim regs have been in effect since October 1, 1994. Inspections are happening now. They are on very general things in terms of the QA manual. I mean we are not inspecting are there sign-off sheets. Here, we have a regulation sign-off sheet. This opens the opportunity to require that inspection.

I am just saying you are saying it is a two-edged sword, and if you say we want a QA manual and then a guidance that describes what it should be, you have to be careful to think that what is happening in inspection, you need to separate a little bit from what is happening in regulation, because then the regulation saying that there should be a QA manual, the inspection would be on the presence of the manual, you are right, well, that leaves it open to facilities of poor quality to just have an empty notebook with white pages, that is the manual.

The conundrum we are facing is that the reason why

Dr. Friedman is saying look at cost effective, look at essential -- and these are not new words -- two years ago, in fact, we borrowed from what Dr. Kessler said, he said the same thing, you know, what is essential for quality, what is enforceable, you know, what needs the force of law for these regs.

It is just that we are coming down to the bottom line where people are going to have to live under this rule, and the best rules don't necessarily mean the most rules, so this is an opportunity to think about what is best, and not necessarily to think just is there and how can we reword it.

DR. BASSFORD: If you look at what is here, it is the procedures, the action levels, list of individuals who are doing it, records to show the qualifications of those individuals, which we are requiring qualifications, the problems directed, the corrective actions carried out, and the effectiveness of the corrective actions.

DR. HOUN: That is fine. I just want to make sure we have that opportunity because a lot of the public was commenting it is too burdensome, so we have gone through the QC section on equipment, the QA section, and we haven't like

made major changes, which is okay, but I just want to make sure we have that opportunity.

DR. BASSFORD: Any other comments before we close this?

MS. BUTLER: I would like to support Flo in her comments. I would like to remind here that we are sort of in a quandary here because, on the one hand, the comments I reviewed was asking for a lot more stuff in there, so we are sort of struggling with one group of comments -- just like FDA is -- on how can we make the regulations effective, important, but simple to understand and simple to enforce, and just add things -- by taking out unnecessary things and if we find it necessary, to include things that many of the commenters said was really important.

DR. BASSFORD: Unfortunately, for this particular section, the burden comments were all like throw out the whole idea. I mean they weren't like, gee, I really don't think that we need to document corrective actions, you know, so there wasn't a lot of specifics to people's comments about burden, unfortunately, for this particular section. I can't speak to the rest of it.

Cass.

MS. KAUFMAN: I think this issue actually is relatively easy, and what we need to do is with every single requirement is what I have suggested all along, is that we focus in on what needs to be done by the facility. You don't focus in on inspections, you don't focus in on the burden of facilities.

You focus in on what needs to be done to assure quality mammography. If this particular item is required to assure quality mammography, then, that is what we need to focus in on.

DR. BASSFORD: I would add, though, that you need to focus on what the facility should do and can we inspect against it and reasonably reassure ourselves that they are doing that. If we can't, then it is silly to put it into regulation.

MS. KAUFMAN: But those are secondary issues.

DR. KOPANS: Just a comment on that comment. Facilities are looking toward inspection. As a matter of fact, all these regulations are a burden. I think they are a necessary burden, many of them, but the questions that I

get as I talk around the country is really, you know, what a nuisance it is to do all this, and how can we do it most efficiently.

So, it is a problem. I think the quality of mammography has improved dramatically in the United States, and I think a lot of it has to do with these kind of efforts, but it is naive to think that people are -- these regulations are spurring people on to do higher quality mammography. The regulations are spurring people to not break the law. Hopefully, the education is what is going to make them do better mammography.

MS. KAUFMAN: For the worst facilities, it is the regulations that is making them do quality mammography.

MS. SCIAMMARELLA: Unfortunately, it is that way.

DR. BASSFORD: Thank you.

DR. PATTERSON: Thank you, Tammy.

We will now move onward into tomorrow's agenda, and the first that we are going to do, because she has assured me it will only take a few moments, is Amy Langer on the Additional Clinical Image Review and Examinee Notification.

We are look at page 14882, at Section 900.12(i).

Additional Clinical Image Review

and Examinee Notification

[Overhead.]

MS. LANGER: This has to do with the ability under the regulations for there to be additional clinical image review if there is evidence that poor image quality is posing a sufficient risk to human health.

As well, if it turns out that that risk is widespread enough, it would require the facility to notify the public, which would include examining their designees, and I am sure medical providers, as well, such as referring physicians, so that, "they make take appropriate remedial action which might include, for example, repeat examinations at another facility.

There were, you will be pleased to know, very few comments on this particular section. The comments, however, were pretty consistent. The first thing is that the entire paragraph, which is right there, is too vague.

Among the aspects needing clarification would be who performs the additional clinical image review.

Accreditation bodies and other entities as specified by the FDA is what this says, but there was some confusion, for example, what then could be or would be the role of the states, actual FDA inspectors, and who else might be designated by the FDA.

What is a serious risk to health, and how is that defined? Who are, for example, the designees of the examiners which are included here, and I think that we felt we knew what we were talking about when we suggested that language. Just to make it, for example, a family member or someone else, but it confused the public.

Then, how are affected parties notified? The actual mechanism was left vague here, and it really did pose a question. I am certain that we had in mind a whole range of activities, but that was questioned in the comments that came forward.

The second slide, please.

[Overhead.]

MS. LANGER: The second comment was that this might be okay for specific complaints or concerns, but as written it is a little broad, that if there were one

particular type of risk or something that would have adverse consequences that we could specify, it would be more understandable.

Then, there was the question of how the provision would be enforced. Lastly, there was some confusion over the relationship between activating this provision and having an appeals process when the facility is actually on the way to being shut down.

Some of the people making comments said that it, "sounds like a consent decree." I wasn't exactly sure what they meant.

However, there were a few consumers or their representatives who, "applaud informing examinees," saying that making poor image quality a matter of public record could improve image quality.

So, I think anticipating some of the need for clarification in this section, the FDA has posed questions to us, and it says, for example, should inspectors be trained to do some aspect of clinical image reviews as part of the inspection, and I think another question is the last point there, how we could assess image quality on a more

routine basis, so as to assure that between accreditation and reaccreditation, there is some kind of surveillance of image quality, and if image quality turns poor, posing a risk to the public, there would be some way to determine that.

Would anyone like to comment on the FDA's questions - once again, would there be a role here for inspectors, if not, how could MQSA better address quality ongoing?

Rita.

MS. HEINLEIN: Well, we just had quite a heated discussion on the QC technologist and the importance of the person who would be doing image analysis, whether that is of artifacts or phantom, that they be someone who fulfills the requirements of a technologist and also meets the mammography qualifications.

I certainly feel that since we feel so strongly about that, that whoever then might be doing clinical image inspection on site should also then meet those qualifications of someone who meets either the mammography technologist requirements or that of the interpreting

physician.

So, if there are inspectors that meet those qualifications, then, yes, I think they could certainly take on that additional responsibility of clinical image review.

MS. LANGER: Dan.

DR. KOPANS: I sort of second what Rita is saying, and they would have to maintain their technical expertise. Image quality review is a very, very difficult process, I think. The American College of Radiology -- and I am not actually involved in the accreditation program -- but don't forget, and I assume the other accrediting bodies around the country, require sending in optimized images.

Again, Larry Bassett, I think did a study on how often the so-called optimal factors were seen in, I don't know, 1,000 or more women. Our statistician has suggested that we have to realize that mammography is not making widgets. If you are in a widget factory, you can pull out five random widgets, and if one of them is bad, you know you have got a statistically significant problem, but with mammograms, each woman is an individual body habitus, all different factors. You need to randomly sample about 1,000

cases to have any kind of statistically valid analysis.

So, this problem of ongoing image analysis, to take your questions, Amy, from the last first, is very difficult. Then, the issue of having an inspector come in and pull, you know, 15, 20 cases and tell a facility that the quality of its mammography is inadequate is problematic.

I don't actually know the solution to the question. I mean to a certain extent you can tell a bad mammogram when you see it, but it is more or less the mammograms that are borderline, I think, that you would have trouble with and then who is to decide.

MS. LANGER: So two points so far that the inspectors would have to meet the same training and quality standards, if you will, of an interpreting radiologist --

DR. KOPANS: At least, if not even more rigorous, to come into a facility that is doing 30,000 mammograms a year with great expertise, and tell them that they are doing a lousy job, they had better have a pretty strong background to be able to do that.

MS. LANGER: Could I just ask you and Rita, who have commented so far, who else might do that? If there was

some sense that a facility needed additional clinical image review, it is not an inspector you both say unless that inspector is qualified.

DR. KOPANS: I think in terms of the actual clinical images, I mean I think a technologist certainly can review the artifact issue. Processor issues, I think are fairly standardized. But in terms of the clinical image assessment, you would need a radiologist who is highly trained in reading mammograms.

MS. LANGER: Ruth.

MS. MCBURNEY: The intent of the rule was to provide it to the accreditation body to use in one of their clinical image reviews to look at those. The rule itself says facilities shall provide clinical images as specified by FDA for review by the accreditation body or other entity designated by FDA, and I think it would have to be somebody as qualified as who the accrediting body would use.

MS. LANGER: I think that was the confusion among the public in what would this other designee be.

Mike.

DR. LINVER: I would agree. I think this person

cannot be any less qualified than the clinical image reviewers who otherwise review these images. So, it sounds to me like in order to be consistent, that would be the only way to resolve this.

MS. LANGER: Joel.

DR. GRAY: How do you handle the situation when we have a computer that can now evaluate -- which several people are working on at this point -- to eliminate the subjectivity of the various radiologists? Are we going to restrict that by making a statement such as this?

I am just throwing it out for consideration.

MS. LANGER: Mike.

DR. LINVER: I think we are still a long way from that.

MS. LANGER: Also, we are not talking about that sort of routine image assessment using that kind of intelligence. We are talking about a problem, in identifying a problem, going in to assess through actual review of images if there is a problem, and then taking action.

Flo.

DR. HOUN: The phrasing "other entity designed by FDA," that is also repeated in the accreditation body reg, but in the case where there were no accreditation bodies that were either state or nonprofit organizations, FDA would be an accreditation body, and that is who we would designate, but that is what the intent was, and we can clarify that, because I do think that everyone believes that clinical images should be evaluated by qualified interpreting physicians, but we also have been using the accreditation bodies because they have expertise in clinical image review.

My question in terms of this paragraph that people had concern about, is in cases where we believe a facility has seriously compromised health, let's say through an inspection we have phantom images that are terrible, or we have a complaint from a referring physician that these are the films I am getting as a comparison, they are terrible, we are proposing to ask accreditation bodies to help review, but the public is rightly confused on what should trigger this, should those things be left to guidance, and also what is the mechanism for the review at the facility, is sending

one film in, you know, you contact the facility, we received a complaint from a referring physician or you have received a level 1 in your inspection, submit one film? I mean what is the process to ensure a serious risk to public health isn't happening at that facility.

MS. LANGER: First, to address the confusion, I think the cross-reference to the accreditation body language needs to be repeated perhaps here, because I think that is what threw the people, they didn't go back and track the language and see what it was referring to exactly.

Carl.

DR. D'ORSI: Just to answer part of Florence's question, I think in that instance where there is considerable concern about an adverse event vis-a-vis clinical images, someone must go in there, and this should be an on-site visit by a clinical team, similar to what the ACR does now. I don't think you can ask them to send in another exam to be checked.

I have across this, and I am sure Dan and the other people, the other radiologists have come across, getting films from qualified accredited facilities that are

horrible. So, the only thing I can think of -- and this is not taking into account the variation from patient to patient, these are bad -- so, the only thing I can think of is either they don't give a damn after they pass the inspection or, to be even nastier, they have gotten other films somewhere else to hand in for their accreditation.

I think there is a real value in random on-site visits by a trained team. As a matter of fact, I personally think that could supplant the entire inspection system or at least markedly reduce it if you did something on the order of inspecting three to five facilities at random per year, that that would do more to push everybody into better clinical images than asking them to send in one view. I think that is also good, but I think a random type of a visit is also very good.

So, I think in this instance where there is a serious or the possibility of a serious clinical image problem, that somebody has to go in on site.

MS. LANGER: Bob.

DR. SMITH: I don't really know what you would specify as a solution, but one thing really might be just a

day's work if you want to look at a certain number of images, and it is a little bit like repeat analysis. You could get very little over a long period of time, or a huge number over a short period of time, but a number of consecutive films on any given day might be a reasonable strategy.

But the other thing here is I have some concerns that the definition of who might the interpreting physician be gets set by the accrediting body. We know ACR has very, very qualified people on these teams, but meeting the minimal qualifications of the interpreting physician in my judgment doesn't make you a qualified reviewer of clinical images in a facility that you suspect of being problematic.

Right now that is a real shortcoming here especially if you have the opportunity to designate an entity in the absence of an accrediting body that you might use.

I think what Dan is suggesting and what Carl is suggesting are not necessarily to supplant the accreditation program, but the idea that a team goes in and following an algorithm that doesn't involve a random selection so much or

a certain number of films, but just look at every one done in a row as a reasonable proxy of how you were doing.

MS. LANGER: Ruth.

MS. MCBURNEY: In situations that we have had in which it was necessary to do something like that, I think you can order them to -- you are usually talking about a certain time frame -- the situation I am thinking of was one in which there was no QC done for a period of three months, you could demand that they pull films from a specific time frame and send them to the accreditation body for clinical image review and also to look at the phantom images, as well from that time frame.

MS. LANGER: Tammy.

DR. BASSFORD: I just think you would want the most -- this is a serious decision if you think about the panic for consumers about being notified, you know, broadly in a community that the images that they have had performed are inadequate -- so, to my mind, sending the most qualified people out to make sure that when that decision gets made to make that kind of -- you know, something that at least locally could have significant public health impact if women

lose faith in the mammography being performed in their community -- you would want to be assured on that side of things that it is the most highly qualified group of people possible making a decision that this, in fact, is kind of the mammographic equivalent of an emergency and needs that kind of an extreme response.

So, the SWAT team kind of idea that Carl proposed is, you know, I think there may need to be a recognition that the people making assessments upon which these decisions will be made need another level of expertise, I think is kind of what we are saying.

MS. LANGER: Charlie had said something this morning about random sampling. Do you have some comment to take in this discussion?

MR. SHOWALTER: Actually, I think that will come up when we are talking about the accreditation body one, but this is an issue that was raised by GAO, what is the appropriate -- and I think Flo was addressing that, too -- what is an appropriate mechanism for follow-up for a facility that, for whatever reason -- and there are a lot of reasons that you might get information where you think this

facility may be in trouble, how do you follow-up, how do you verify this, how do you indeed establish through credible evidence that this facility needs to do something up to and including notifying patients, because Tammy is right, that is an extremely serious decision, not affecting just the facility, but all those women who got examined in the facility.

DR. BASSFORD: And other facilities in the area.

MR. SHOWALTER: Yes.

MS. LANGER: Esther.

MS. SCIAMMARELLA: I agree with what Tammy said, and, Carl, I think I agree we need to take serious steps for the two-tier system for the ones who maybe have federal service going and doing a good supervision what they are performing there.

MS. LANGER: Mike.

DR. LINVER: I would agree that a SWAT team approach may well be a good one, but this is one time when you can truly take a final product and look at it, not necessarily on site, but off site, and still apply the same SWAT team standards.

You can have a team that evaluates films, but as Bob mentioned, and others, you really don't necessarily have to be on site as a member of that team to see the final product in a state that you can really evaluate how that facility is doing.

If you do indeed ask for a certain day and look at consecutive films, I think you can get the same good information about how that facility is doing than to send in a rather expensive whole team of people to do it on site. I think it could be done off site and be just as effective.

MS. LANGER: Could I just ask if states currently have some parallel mechanism to this and what the approach is there for image review?

DR. HOUN: I don't know if some of the accreditation bodies from the states want to speak up, but there was an erroneous statement about that accreditation bodies only look at best products, because states like Iowa undergo every facility must have clinical image review done every year, not just at accreditation, and it is not just one film or one dense, one fatty, it is actually a selection from up to usually from four to six films are selected at

random from a day to be looked at to undergo the state requirement for film review.

MS. LANGER: And who looks at those?

DR. HOUN: The same people who do clinical image review for the state, so they are interpreting physicians, and they also have in-service on quality image assessment, and the same folks that do the clinical image review for the states do that.

MS. LANGER: Dan.

DR. KOPANS: If that is being done with four or five randomly selected images, if someone were to try to shut a facility down based on that, they would have no leg to stand on statistically.

I think that even the problem of sending in batches of films, you don't know what the patient population is that the facility -- if they have a lot of elderly women, for example, who are wheelchair bound, who are coming through a facility, they can't be measured in the same standard as a population that is seeing mostly women in their 40's and 50's, who can be optimally positioned in a mammographic system.

I mean I think there are certain things that are obvious, artifacts, you know, poor processor control, I mean those things are quite objective, but when you get into positioning, which is really I think one of the big issues in image review, you have to take into account the type of patients that are being imaged.

Again, a random selection of cases has no scientific basis. It may be something to do -- I know in the State of Massachusetts, we are going through this discussion right now, and our state regulatory agency feels obligated to do an image review. The women in the state are clamoring for it.

The problem is how do you do that in a fair and scientific fashion. Again, it has to do with statistical analysis, that you would have to pull a very large number of cases if you are going to do it on a random basis.

Now, maybe looking at several days sequentially, going to a facility and seeing every case that comes through and knowing the patient population that they are seeing with those cases, I think we could probably get a good idea of how good a job they are doing, but to do it from a distance

and to do it randomly is -- I mean I don't even know if it would hold up in court if you shut someone down based on that.

MS. LANGER: Charlie.

DR. FINDER: I think we are confusing a couple of different issues here. One is the random clinical image review, one is the on-site visit, and the other is this additional clinical image review, and they serve different purposes, they are not mutually exclusive. You can do them all, you can do some. I think it is important to keep that in mind.

I just wanted to bring up another point that I think hasn't been touched yet, and that has to do with the condition or conditions, if any, in which we go beyond clinical image review and talk about interpretation, because while you can say that the artifacts are problems, whatever, some of the issues that are being brought up to us at this point now are that the images are fine, they are just being misread.

I think that if you are going to look at these images, is there any condition under which you would want to

look at the reports and see if they are being read appropriately.

MS. LANGER: But to dispose of part of your question, it does seem that there is committee consensus that there is not a role in this particular section of the regs for inspectors, is that right, to do clinical image review? This is additional clinical image review. They can ask that it be done, but to perform it, no.

Bob?

DR. SMITH: I agree. I just wanted to follow up on a point that Dan was making. From a statistical standpoint, what you have already is presumably a good indicator that something is very seriously wrong, so at that point the issue of sampling is somewhat different.

I mean the question is, if you were to take -- and I really don't know the answer, in fact, I think it is a useful exercise to try out a handful of strategies three or four times and see what you come up with -- if you were to take randomly select films, that is obviously, in my judgment, not very reasonable, because who knows what you are going to get. Just like you say, you just walk down and

pull a film out every three feet, you know, vertically and horizontally.

Let's say that you decide that you are going to take the first film of the day over a two-week period, or that you are going to take every film done over a three-day period, you know, and just look at them sequentially as a measure, now, if those films turn out to be bad, and the question is, is that representative of work done before and after those parameters, it certainly indicates that the women that got those studies done didn't get good studies. You know, so the issue of notification -- and that is where I think all of this becomes much more onerous -- is what are the implications from your judgments as to what you do for the facility, and this is why I think your concerns are very real, but I also think that those questions are reasonably answerable from the standpoint of a determination that there is something wrong with the facility.

DR. KOPANS: Just to respond to that, Bob, how many of them need to be bad before you say that the facility is performing below some standard. I mean is it 30 percent, is it 50 percent, is it 70 percent?

DR. SMITH: No, I think the point is right.

Actually, Charlie's point is not that far-fetched. It may be that the serious harm is a number of missed cancers, that anecdotally come to light. So it may be that the images are great.

Now, the problem of identifying a bunch of false negatives in a random review is really onerous because they are just not going to come out on a chance basis alone.

MS. LANGER: Another aspect of the public comments is sort of a thread running through it was the sense that there could be some arbitrary nature of this interpretation and call, that there was no appeal process, that there was kind of a draconian intent somehow, and I don't know how you make people feel better about that.

To stress again, this is the section when there is a serious problem. Then, the public asks, well, fine, what problem. I think really they were looking for more specific understanding of what might trigger this process.

MR. SHOWALTER: Let me just clarify that any adverse action -- and certainly this could be seen as an adverse action -- is always appealable. You know, it is not

stated here, it is not stated in every section that exists in the draft regulation, but it is always appealable.

MS. LANGER: Right. Ruth.

MS. MCBURNEY: Just to follow up, usually, there is a lot more information that we get either with an on-site visit from the accreditation body or from the FDA inspection that would warrant such action, and usually it goes around a time frame, it is not just everything that has happened over the past six, seven years.

There is usually you gather information that there is usually a period of time that something was drastically wrong, like no QC being performed or just a lot of artifacts and bad images.

So, you can hone down on that period of time in which to take action and whether or not -- I mean you could do other things like have them cease and desist from doing mammograms until this was taken care of all the way to actually being so bad that it would close down a facility.

MS. LANGER: Bob.

DR. SMITH: Back to this issue of what you would do, I mean with respect to retrospective assessment as to

how long have things been bad. If you did your clinical image review within the boundaries of what has alerted you to the problem, then, it becomes a matter of an algorithm of random sampling retrospectively to try to determine when the problem really began.

Then, that becomes a basis for identifying the population that you may need to make the more, you know, I guess onerous decision from the standpoint of the implications to the community level of having to tell women that, you know, these examination were probably not worth it, you probably didn't gain anything from them, so you may need to be redone.

But, again, I think that is a strategy that just doesn't exist yet, and just needs to be worked on.

MS. LANGER: There was a situation on Long Island a couple years ago -- do you remember that -- which really sent people into a complete panic. I think it was a combination of the image quality being poor, but also the interpretation, and there were actually sort of immediately located miraculously some missed cancers among the group of patients of this facility.

I think, again, maybe Flo's group wants some sort of guidance about when we interact with the public on something like this, which is going to be such an immediate hot button and very sort of mediagenic.

Is there a strategy set forth that we can give some guidance on at different levels of problems? We didn't really spend much time on that in our committee discussion.

Yes, Dan.

DR. KOPANS: It would seem that there is at least one model that you could perhaps look at. I don't know much about it, but pap smears, clearly, you know, we all know recently that there were major problems with pap smears, and I don't actually know how that has been handled in terms of alerting groups of women who had suboptimal pap smears.

Again, I don't want to forget Charlie's question, and that is to do with interpretation of mammograms. Image quality review is doable I think if you have the expertise to do it. Interpretive skills get extraordinarily difficult, and I don't think it is a secret. The American College of Radiology has been looking into this, and has spent several years now trying to develop a way of measuring

skills, and you run into the problem that there may be one person in the world -- I don't know who it is -- who is the best radiologist in interpreting mammograms, and every woman would prefer to have that radiologist interpreting her mammograms.

Where is the cut-off? You know, where do you become okay, not so good, you shouldn't be doing it? We haven't figured out how to measure that as yet, those of us who have been thinking about this for many, many years, and so that is not going to be a simple solution, and you run the risk of developing a system that is pejorative and punitive, not based on any kind of scientific reasoning.

So, I think if you can figure out the image quality review, how to do that in the legitimate scientific fashion, that is easy compared to interpretive skills.

MS. LANGER: But I think something the FDA was trying to get at out here is, is there some proactive or kind of preventative way of approaching a deteriorating image quality that could be detected over time, and it doesn't sound like it.

Esther.

MS. SCIAMMARELLA: We discussed the issues of how we want to measure performance, and this is from my consumer perspective, is that how many radiologists are missing diagnostic and how we can rate or have -- I don't want to say punitive -- way of accreditative or have a list of how radiologists are performing on --

DR. KOPANS: It is a very hard thing to do. It depends on the population that you are looking at. You can have tests where you select out cases, but it is a very difficult thing to measure.

MS. SCIAMMARELLA: We discuss this, and I think consumers have a right to know where to go, and exactly the same information where the facility is accredited beyond be accredited by FDA.

MS. LANGER: I know Marsha is going to talk tomorrow about the complaint mechanism, and there are aspects of that having to do with communicating information about facilities.

Were there other points on this particular section? Bob.

DR. SMITH: I just wanted to add a point about the

pap smear issue. It is much easier with the pap smear because you have got such a division of labor that the more worrisome aspects of interpretation aren't bundled up in a whole other long list of quality assurance issues.

Rhode Island is a good case in point, and that is close enough to Boston, you probably remember the story where a lab run by a single cytopathologist -- and many cytotechnologists will tell you that cytopathologists aren't so great at reading pap smears, they certainly aren't as good as they are -- there are obvious parallels.

At any rate, this woman had four consecutive annual smears with very clear evidence of invasive disease, or as much evidence as you can get on a pap smear of invasive disease, misread, which really does call into question all the other interpretations.

In that instance, the state agonized for some time as to whether or not they really did need to notify every woman whose smears had been read in that lab, and they finally determined that aside from the probability that there are other cases of invasive disease, and their reluctance to reread every slide and notify those women who

had some evidence of disease, the easiest thing to do is to notify everybody and say that the quality of your exams was probably not adequate.

But in that point in time, specimen collection problems were scattered all over the referring physicians, so in that instance, it is just misreading.

DR. FINDER: The question I was asking could be phrased a little bit differently. I said are there any conditions, and one of those possibilities is that we find out that the person who has been reading these mammograms never met the qualifications.

MS. LANGER: Like the receptionist or something, right?

DR. FINDER: Well, no, it was somebody who thought they did, but never documented it.

MS. LANGER: Forgot that they didn't go to medical school.

DR. FINDER: Things like that. Not going to medical school because these were people who have been reading mammograms possibly for years and years and years, but don't meet our qualifications. What do we do in those

kinds of cases?

DR. KOPANS: The question was asked why -- I mean I can see someone making a mistake and not realizing that they were supposed to do something, but they are very good at it versus what you are looking for are no matter what your qualifications are, you are very bad at it, or not very good at it.

DR. FINDER: Looking at either. I asked the question, under what conditions, if any, and I know that there are these conditions, and what do we do?

MS. LANGER: Betty, is it appropriate to see if anyone in our audience would wish to comment on this very difficult problem?

DR. PATTERSON: You are running this section, so if you wish to ask anyone from the audience, be my guest.

MS. LANGER: Does anyone want to shed some light on this from our audience?

Please identify yourself and also please be brief.

MR. BAILEY: Two mutually exclusive conditions.

My name is Ed Bailey, and I am from the State of California. We have handled situations where it didn't take

an expert to look at the films to see they were bad. When you look at 4,000 women's films and you can see visually thing wrong with the film, we went out and notified all 4,000 women that we doubted that they had got a good reading at this facility.

In another case, we had a doctor who scored zero, zero, zero on a phantom image, and we had him contact all of his patients and tell them that they were bad, and he got out of the business.

We have another situation going on right now with FDA where we got numerous complaints from people who subsequently saw their films, and they are now looking at that facility to see what needs to be done at that facility and have it re-reviewed.

MS. LANGER: Could I interrupt and ask a question?

MR. BAILEY: Yes.

MS. LANGER: How did they determine the community that required notification?

MR. BAILEY: How did who determine?

MS. LANGER: The facility. In other words, clearly, past examinees, but also, for example, referring

physicians that work with the facility, any other members of the public?

MR. BAILEY: Well, first of all, they had a patient list. We had all the films from the facility. So, that constituted a patient list. Now, if they threw some films away, sure, we don't have those, but for the most part, this was a mobile facility, which had all kinds of wonderful information in their film packages including, you know, the best way to get people to come in was obviously advertise it in the newspaper, if you brought in the coupon, you got \$30 off.

MS. LANGER: Do you have some bottom-line advice for us?

MR. BAILEY: Well, I think that this whole process -- and this is going into the third one -- was that we do have a situation right now of an accredited facility where we have gotten numerous complaints. It has been referred back to FDA.

FDA needs a group to look at that set of films. It may be that a second accrediting body would review films or it may be that the same accrediting body would review the

films, or it may be that they would take one from each accrediting body and have them review the films. I don't know, but they could make up some mechanisms to get that done, and that could be the other people designated by FDA.

I mean they could take this committee or the radiologists on this committee and say we want you to do it if you were willing to accept it.

MS. LANGER: Thank you.

Tammy.

DR. BASSFORD: I just wanted to mention, I was about to raise my hand to say it and then Amy mentioned it, but again, looking at the community impact of this kind of thing, referring physician notification is never measured, and I think one of the unfortunate potential fallouts.

I talk up the mammography facilities to which I refer as a way of ensuring that my patients follow my recommendation and go there. If a facility to whom I refer was shot down and all my patients were notified that their mammograms over the last two or three years were poorly done and needed to be repeated, this would have an impact on my practice, as well.

That hasn't been addressed as far as I can see in the current regulations, and I suspect that huge numbers of referring physicians haven't reviewed these regulations to the same extent that radiologists have, and I just wanted to provide that feedback to FDA.

MS. LANGER: You don't have to identify yourself, but please be brief.

DR. KOPANS: I am curious from the California experience. I think that there is no question, I think there could be situations where anyone looking at the quality of the mammograms would say these are lousy mammograms, and that is what I was saying, is that you can look at artifacts, you can look at processor issues, it doesn't take an experienced radiologist.

That is the most important concern, but the question is where does the review stop. Do you just go after the people that are clearly performing terribly or then you say, well, let's start moving into the community of imaging, and that is where I am more concerned, is someone who is really trying to do a good job, doing a fairly decent job, and you don't have appropriate image review, and that

person is cited.

Now, that may never happen, I don't know, but those people also need to be protected. I am curious, in the California experience, who were the people who reviewed the images?

MS. LANGER: Excuse me. Could you do that privately because we need to wind this up now.

DR. KOPANS: I am sorry.

MS. LANGER: Unless there are other committee remarks. Bob, did you have something?

DR. SMITH: I was just going to say it is sort of Dan's question is really where are the criteria and are they neatly laid out as to what constitutes serious concern.

MS. LANGER: That was one of the questions in the public comment.

MS. EDGERTON: Tricia Edgerton, State of California.

I don't know if the committee is aware, but where we patterned our notification was after a regulation in New York. New York has a regulation that states that whenever the image quality falls below acceptable levels, that the

patients will be notified from that day.

MS. LANGER: That came out of that Long Island experience.

MS. EDGERTON: Right. As a result, we used their -- you know, they have criteria spelled out, and so it has been done out there. We have never had a problem with the people who have been identified and we have sent information to. We haven't had the same hysterical response that you think might happen. They have all been very appreciative.

MS. LANGER: Good.

Carl.

DR. D'ORSI: I think the confusion is exactly what people have been focusing on, what does severely compromised mean. Once you have the definition clearly of what is severely compromised, you should come down like a ton of bricks on that facility. That is not the issue. The issue is what is severely compromised, and this kind of thing kind of falls into our other area that we were speaking about with the lack of clear definition.

If you can get that down in some kind of a codified way, then, I don't think the issue is how you

should come down, you should come down on them really hard, but it becomes an issue of what is severely compromised.

MS. LANGER: Does the FDA require anything else on this section?

MR. SHOWALTER: No, I don't think so. I think Carl is exactly right. I would really love to have a very clear definition of what that means. I don't see any immediate prospect of having one.

DR. PATTERSON: Thank you, Amy.

I am going to leave it up to the committee on this, because I don't want to be shot in the back on this later. It is now 6 o'clock, almost 6 o'clock by my watch. We can quit for today, which will necessitate tomorrow being extremely long because we have a lot of today's work that we did not cover, or we can start on a portion of tomorrow, between now and 6:30, at which time dinner is scheduled.

Can I have a feeling from the committee? Yes, Penny.

MS. BUTLER: Ruth and I can do ours in half an hour, under a half an hour.

DR. PATTERSON: Well, you know, Amy assured me

that we could do hers in like 15 minutes.

MS. MCBURNEY: We can lay it out in half an hour.

DR. PATTERSON: I don't think that you can probably do it in half an hour.

MS. BUTLER: Fine.

DR. PATTERSON: Unless you are going to tell me something differently. Do you think you can?

Yes, Rita.

MS. HEINLEIN: I don't think that we can get anything done in half an hour, so the question becomes does the committee want to stay here longer tonight and reduce the length of time that we are doing tomorrow, or --

DR. PATTERSON: That wasn't a choice.

MS. HEINLEIN: Okay.

MS. LANGER: Dinner can't wait another half an hour?

DR. PATTERSON: Well, that is a possibility is to delay the dinner. I don't know, I will have to check out there to see if we can put it off until 7 o'clock.

If you can do it in an hour, is everybody willing to go for another hour?

[Affirmative responses.]

DR. PATTERSON: We are still probably going to end up going long tomorrow.

Why don't we go ahead, then. Okay, we have got until 7 o'clock. You are on.

Medical Physicists

[Overhead.]

MS. MCBURNEY: The first section is on the Medical Physicists, which is under 900.12(a)(3), page 14908.

The first topic, initial qualifications, ran the gamut on the comments all the way from, they were too restrictive for practicing physicists, and we should allow straight grandfathering meaning anybody that qualified under the interim rules, and some said that these were appropriate, and then other comments said that they were not restrictive enough.

Some comments said that it should be board certification only, that the state approval process is not uniform, that they should be approved or licensed only in the state where they are practicing, and then another comment we will get into a little bit later is that

board-certified physicists should not need to document education since they had to document it for the board certification process.

Penny will go into some of this. A significant number of the comments pointed out that board-certified medical physicists should not have to comply with, and therefore document, the degree and training levels contained within the initial qualifications requirement since they have already met them to qualify for board certification.

MS. BUTLER: Just reading one of the comments the State of New Jersey wrote in, that if the medical physicist is board certified, it seems unnecessary to have them prove that they have 20 semester hours in physics. This is an appropriate requirement if they are qualifying without state licensing or approval, the requirement of physics seems limiting and should include courses, such as radiation biology. If we eliminate this requirement for board-certified physicists, it reduces some of the burden for recordkeeping.

So, consequently, we recommend that B(1) and B(2) of this section for board-certified medical physicists be

deleted, although it still stays in place for those who aren't board certified.

MS. MCBURNEY: If that is doable. I know that in our discussions before, when we talked about that the law says be board certified or state licensed or approved, that when we added the education requirements, it was to make everybody on an equal footing, that it would be for everybody. But I agree with Penny, if that is some documentation that would not have to be looked at because it had been looked at by another entity, that would be fine.

Cass.

MS. KAUFMAN: Is B(2) required for board certification, to become board certified, 20 contact hours in mammography?

MS. BUTLER: I am not sure if it is specifically required, but it is certainly obtained, and it is certainly examined on.

MS. MCBURNEY: I know it is examined on, but I am not sure that it requires them to have actually done that survey of a mammo unit. So, I don't know that we want to eliminate B(2), but B(1), I think we could certainly, if

that is already required for certification. Do you all know?

MS. BUTLER: I know in the list of items that need to be covered during didactic courses. I don't think they have a specific number of hours for each item, but they do have mammography included in all the course work.

MS. KAUFMAN: This is specifically specialized training in conducting surveys.

MS. BUTLER: I understand. I can't answer that right now.

MS. MCBURNEY: But certain B(1), if that is already required for board certification, the education.

DR. GRAY: Does the ABR require 20 hours in physics, or is a degree in sciences acceptable?

MS. BUTLER: I don't know. I don't have the requirements right in front of me.

MS. MCBURNEY: What we could recommend is they look at those qualifications.

Elizabeth.

DR. PATTERSON: In that respect, if you go up to the upper line there, it is certification by a body approved

by the FDA, so it does not necessarily mean the ABR.

MS. BUTLER: ABMP.

DR. PATTERSON: Yes. So, I think you are starting to muddy the waters unless they all have the same requirements.

DR. GRAY: The point I was getting at is if we are going to require 20 hours of physics for somebody that isn't board certified, then the board-certified people should also have 20 hours of physics.

DR. PATTERSON: Right, but what I am saying is we don't know. The ABR may have it, but the ABMP may not, et cetera, so I think it is probably easier just to keep the requirements there.

MS. BUTLER: I am pretty confident that the ABR and ABMP both require 20 hours of physics at least.

MS. KAUFMAN: I guess the issue is since we all agree that ABR-certified people are certainly more than qualified to do this, then, maybe if they don't require 20 hours, maybe we need to revisit the 20 hours.

MS. BUTLER: I will get the information, and I will bring back to the table tomorrow.

[Overhead.]

MS. MCBURNEY: This also gets back to the grandfathering provisions for the bachelor's level physicist, as well as in the master's.

Several comments contained comments that we should add other items to the definition of physical science, to add biology, nuclear physics, radiologic technology, and radiation biology.

Currently, the definition that we have for physical science is physics, chemistry, radiation science including medical physics and health physics, and engineering. I think nuclear physics and medical physics and health physics are all interrelated, and certainly nuclear physics is a physics.

DR. D'ORSI: In the interests of time, this is also in the definition sections. Maybe we can discuss it together in definitions, and just go on.

MS. MCBURNEY: We have a separate item for that.

Are there any comments on the level for the initial requirements? Go ahead. There were several other comments.

MS. BUTLER: One reviewer wrote in he was concerned about physicists that have been out there for a number of years and difficulty in documenting contact hours, and he wanted to know a little bit more what would be qualified as a contact hour.

One of the things that I prepared is I would like to recommend for the requirement for contact hours remain in place, but the FDA interprets it as anything from didactic course work to hands-on training during actual survey by qualified physicists, and this could also include continuing education that has already been acquired.

MS. MCBURNEY: Any comments on that? Cass.

MS. KAUFMAN: I don't object to that as long as we keep in there the requirement about the experience of conducting surveys to make sure that they have some experience actually conducting surveys.

MS. MCBURNEY: This is the one on the contact hours of training, specialized training.

MS. KAUFMAN: The way Penny had defined it, all of it could have been didactic, it might not have been experience in conducting surveys.

MS. BUTLER: But experience in conducting surveys is the next one down.

MS. KAUFMAN: That is what I am saying. As long as we keep that, then, I don't object to what you said.

MS. BUTLER: We haven't discussed deleting it.

MS. KAUFMAN: I know.

[Overhead.]

MS. McBURNEY: On the specialized training required, there was some opposition for experienced physicists, and I think you have already addressed that, so we will go on.

[Overhead.]

MS. McBURNEY: This was a major issue on the number of facilities versus units. Penny.

MS. BUTLER: Most comments remarked that the experience should be unit based rather than facility based. The PFRs specify that medical physicists needed an initial experience of surveys at five facilities and 10 units, and continued experience at three mammography facilities within the preceding 12 months, and there were other rules that were written in the same light.

I would like to read comments from Dr. Berman, I guess, regarding this issue. He said first, in discussions with Massachusetts state inspectors, who enforce both our state mammography regulations and carry out MQSA inspections under contract, I have been told on several occasions that mammo facilities which have generally performed the best have been major teaching hospitals, which are primarily serviced by in-house medical physicists. A good number of these do not perform a significant number of outside surveys in mammography.

For example, the facilities he is at, we received zero citations during our most recent MQSA inspection. It has been the small mammography centers that are visited once or twice a year by consulting physicists that have had the most problems. The problem with small centers are most often the lack of continuous daily attention to quality control that a conscientious on-site physicist can provide.

I do not believe that the quality of mammography programs in hospitals with in-house physicists would improve significantly by requiring them to survey other physicists, as well.

Then, he goes on to say about the difficulty in getting time off in order to survey outside facilities and also contractual arrangements which would not allow them to survey outside facilities in addition to acquiring equipment to do the testing.

This was expressed numerous times by a number of reviewers, and probably was the most responded-to items.

Consequently, we recommend that the survey experience requirements be changed to a unit-based system and that multiple surveys of the same unit be acceptable. For example, if they have one or two units, they do those one or two units twice a year or every year, and count that to what they are doing.

Specifically, we recommend 10 mammography units for initial experience for the alternative criteria, three units annually for continuing experience, and three units for re-establishing qualifications.

MS. MCBURNEY: Comments? Cass.

MS. KAUFMAN: Charlie, I thought -- and maybe I am thinking of HCFA regulations -- but I know I have seen regulations in the past where they had a different

requirement for a physicist who only worked in one facility versus physicists who did consulting, and I don't have any problem at all with a physicist who is working in their own facility.

What concerns me about going strictly to unit based is that if you have got someone who wants to do consulting, that they only have familiarity with one particular system, and that is not always helpful when you are going out to multiple facilities.

So, maybe that is something that could be considered is splitting it up and saying if you are only working in your facility, you have just got to do your machine, but if you want to do consulting, then, you have to do these other, you know, as the additional facilities.

The advantage of seeing multiple facilities is that then you become more familiar with different units, different film-screen systems, different processors, different quality control techniques, that kind of thing, as opposed to just being totally familiar with your own facility.

MS. MCBURNEY: Charlie.

MR. SHOWALTER: We have debated this internally back and forth, and you are exactly right, the in-house physicist who, let's say, does only one mammography unit, they only have one unit, and they do that one unit once a year, but they are doing general medical physics work that sort of supports their knowledge in mammography for the rest of the year.

That is one kind of practice and expertise that is quite reasonable compared to someone who does only mammography, but maybe does 50 units a year all in different facilities, they are going to have a lot more familiarity with different machines obviously.

The one physicist who works in-house and maybe does only one survey a year, but does troubleshooting throughout the year on that machine will probably be very familiar with that one machine, which is better.

We have talked about that. Obviously, we didn't propose in that way, but that is a possibility.

MS. KAUFMAN: That seems to make the most sense to me, is to have a different requirement. If you only do your own facility, you know, and doing your one machine a year

works for you, but if you are doing consulting, you need a different kind of expertise and experience.

MS. MCBURNEY: Joel.

DR. GRAY: There is another issue to address here, and that is the fact that many physicists working at academic institutions are probably more so at private clinics, are contractually restricted from working outside of their clinic, and that is the case at my facility.

I guess I would disagree with Cass that if I only did one unit in my facility once a year, that that would keep me qualified. I would be a little concerned about that. I am not sure how you handle it if you do happen to be in that situation, but it is an issue, and I think the major thing we have to be concerned about is from the manpower issue.

For example, if I am not able to do the mammo units in my facility, because I can't do three facilities, or whatever the number is, then, I am going to have to hire somebody to come in and do it, and I don't know where I am going to find him in Minnesota.

DR. PATTERSON: If I remember correctly on this

long discussion over this, one of the things that I think the physicist said at the time was if you had this requirement that you had to do X number of machines, those that had contractual relationships, they only have one mammo machine, would force the institution and making them go outside to do consultant work, and therefore, your manpower shortage would not be as great a problem in some of these areas that would be otherwise. I remember that long discussion.

MS. MCBURNEY: Right.

DR. GRAY: Well, I think at my institution I can tell you what the reaction to that would be. The policy is you do not work outside the institution, so we will hire somebody to come in and do it.

MS. MCBURNEY: Penny.

MS. BUTLER: In all likelihood, if a diagnostic physicist is employed by a hospital, they will probably have more than one, probably two or three or more mammography units at that facility, because small hospitals don't hire full-time diagnostic physicists.

If a therapy physicist is there and also is

responsible for doing a couple of diagnostic X-ray units and mammo units in this one mammo unit, perhaps they don't have a lot of experience, you know, perhaps they shouldn't be doing it.

MS. MCBURNEY: And they would still have to qualify.

MS. BUTLER: And they would still have to qualify under the rules.

So we discussed this ad nauseam last April, and I believe we came to the consensus, which is what I proposed in the recommendation.

MS. MCBURNEY: Any other comments on this issue? We will go on then.

DR. GRAY: What was our recommendation?

MS. MCBURNEY: Well, we have had several comments. I don't know that there was a consensus.

MS. BUTLER: Do you want me to read it again?

DR. PATTERSON: Yes. What was your recommendation?

MS. BUTLER: We recommend that survey experience requirements be changed to a unit-based system and that

multiple surveys of the same unit be acceptable.

Specifically, we recommend 10 mammo units for initial experience, 20 for the alternative criteria, 3 units annually for continuing experience, and 3 units for re-establishing qualifications.

MS. MCBURNEY: I think what we are doing is taking out the number of facilities. It would just be deleting the number of facilities.

Cass.

MS. KAUFMAN: I don't think that that is okay for people who do only consulting, who see a wide range of facilities or want to begin doing consulting. I don't think have done your units, you know, repeatedly, qualifies you to go out and see a lot of other facilities.

DR. PATTERSON: I want to get a consensus from the committee regarding that.

DR. BASSFORD: Maybe I am being really dim, but if you are consulting and doing whole lots of facilities, then, why do we have to require that you do more than one facility? I mean if you are a consultant, you will be doing more than one facility.

MS. KAUFMAN: That is not the issue. The issue is those physicists who only work in their own facility. The problem isn't the consultants, it is who qualified to be a consultant. That is the problem, is you have got plenty of physicists who only do their own units, and then maybe they want to go out and start working as a consultant after having only seen their own facility.

DR. BASSFORD: So you would like to have them be required to do additional surveys at different facilities under the supervision of somebody before they begin their consulting career even if they have done 10 different units in their own facility for years.

MS. KAUFMAN: I think if they have pretty much only seen one film-screen system and, you know, one processing system, and one quality control system, I think they need to see some other things before they can provide appropriate consultative services to facilities that have completely different arrangements.

DR. BASSFORD: What do the physicists think about that?

MS. MCBURNEY: Penny.

MS. BUTLER: I entirely disagree just because you get a lot of experience working on your own systems, in fact, you see a lot more stuff going on over time because you are right there, and you can recognize a lot of the problems when you walk into a new facility, and even if you have never seen that unit before.

I mean I walk into new facilities all the time where they have got a brand-new piece of equipment, and I have never seen it before, so I have to learn how to use it while I am there, but I am not a dummy, I mean it is something that a physicist is trained to do, to understand to do, so I don't think it is a problem at all.

MS. KAUFMAN: I think there is some self-serving, you know, thoughts going on here. I can only say that my perspective is coming from having responsibility to look at about 300 mammo facilities ballpark figure, and I know what the inspectors have to know to look at the incredibly broad arrangement of units and screens and processing in different systems, and they are not providing consultation.

So, I think I am coming from experience with seeing all those different things compared to maybe you.

MS. MCBURNEY: I think Joel had his hand up.

DR. GRAY: I don't think, Cass, that realistically, five facilities is going to give them that broad a range of experience, number one, and number two, I think we are arguing here about a very, very small percentage of the physicists.

We are talking about a physicist who has been working in an academic setting for two, three, four, five years, and now he has decided to go out and consulting. We are not talking about a large proportion of the physicists in practice out there.

MS. MCBURNEY: Elizabeth.

DR. PATTERSON: This is initial qualifications, correct?

MS. MCBURNEY: It also applies to the continuing experience requirement where we are talking about three units, but, Elizabeth, you are right, it is initial requirements that I am concerned about.

DR. PATTERSON: I think the initial requirements should be separated from continuing requirements.

MS. MCBURNEY: We are talking about the initial

requirements.

DR. PATTERSON: We are talking about initial, and I agree that it shouldn't be on one unit repeatedly for initial requirements.

MS. MCBURNEY: Penny.

MS. BUTLER: Earlier, Elizabeth, you had asked for a consensus from the committee on how they felt about this. Before we start splitting things up, I would like to see how the committee feels about the recommendation that we proposed as I read it.

DR. BASSFORD: I just need a clarification. I think the recommendation that I heard you propose sounded a little different to me than what you just said, Betty.

MS. MCBURNEY: We could split it up.

DR. BASSFORD: You said for initial requirements, 10 different units, correct?

MS. MCBURNEY: No, just 10 units. It doesn't say "different."

DR. BASSFORD: Not 10 surveys on the same unit, correct?

MS. MCBURNEY: Right, having done 10 surveys.

DR. BASSFORD: But if it is 10 units, it wouldn't be 10 surveys on the same unit. Which did you intend?

MS. MCBURNEY: You are doing it for 10 years, you know, or 5 years, you do it twice a year, you only have one unit, or if you have 2 units in your facility.

DR. BASSFORD: So you really mean unit surveys.

MS. MCBURNEY: Unit surveys.

DR. BASSFORD: Not units, right?

MS. SCIAMMARELLA: It sounds like if you work in one facility, I mean my interpretation to you is that if you work in one facility, you only see one type of equipment, but according to what Penny said, all the time your institutions is bringing new equipment, so you need to be up to date. It is like for me I mean --

MS. KAUFMAN: They don't get new units, right?

MS. SCIAMMARELLA: But I mean constantly, if they want to have, you know, competing, I think you maybe have more experience than the other people who go to maybe different facilities, but they don't have new equipment as fast as you have in your institution, I don't know.

MS. BUTLER: My personal situation is in our

institution I deal with five units, and we have three of one kind, one of one kind, and another of another kind, and we have two different film-screen combinations that we work with. I don't think that is uncommon.

MS. SCIAMMARELLA: That means that you have exposure to different type of equipment. Okay.

MS. KAUFMAN: And then you would meet whatever requirements we are proposing if we say you need to see X number of different units.

MS. MCBURNEY: Do you all want to take a show of hands? Does FDA have enough comments to work with?

MR. SHOWALTER: I think so. It is my impression that this is getting to a level of detail that we are probably not going to reach when we write the final regulation.

DR. PATTERSON: Could I just make one comment to what Joel said? You were saying if an individual has been out there doing it for 10 years, and et cetera, they would have already qualified under the interim regs.

DR. GRAY: That is right.

DR. PATTERSON: So, therefore, they don't have to

requalify for their initial requirement.

MS. MCBURNEY: That is right.

MS. BUTLER: No, they would.

MS. BUTLER: Even under the alternative standards, they still have to have done several individual facilities.

DR. PATTERSON: If they have met the requirements under the interim regulations, they don't have to go back up to the point above.

MS. MCBURNEY: But there is an "and."

DR. CHAKRABATI: Kish Chakrabati, FDA.

What they are talking about, initial qualification, there are two routes. In the alternate initial qualification, only the number of facilities that they will survey is different, but then there are continuing qualification requirement, and there, three facilities are required.

So, right now they are talking about initial qualification for the master's degree holder, and board certified, that is going to be five, and for the other one it is going to be 10. Then, there is a continuing experience required that is three facilities per year.

Now, if we go to unit, now that I am here, I have one advice that I am seeking. If we are asking 10 units rather than facilities, then, my question is can they do 10 units experience back to back, that means 10 days?

MS. MCBURNEY: Shall we move on? Are there any other comments on this issue? Bob.

DR. SMITH: Penny was looking for some sense from the committee?

MS. BUTLER: Right. I would like to remind everybody on the committee that I think the vast majority of comments that we received on the medical physics section had to do with this one particular issue.

MS. MCBURNEY: And a lot of them came from in-house physicists, so it was a big concern to them.

MS. KAUFMAN: I think we need to consider the issue of having different requirements for in-house physicists versus people who don't work on their own units.

MS. SCIAMMARELLA: What happens to people, to managed care, and that person has been working in that institution, then, they have no chance to work in another place? I am seeing this from a consumer perspective. What

is the difference between unit and facility if a person has experience?

MS. MCBURNEY: Bob.

DR. SMITH: I guess I am not really persuaded that it is different criteria. You could just as easily inspect 10 different facilities one a day, 10 days in a row, as you could inspect 10 units in your own institution each day in a row.

The difference is that you are keeping a unit functioning well, it seems to me, and I mean there are plenty of examples where people keep something running well, master one thing, or they master anything, but it is not entirely clear. I just haven't yet been persuaded that the distinction is really important.

MS. KAUFMAN: I understand that, and I think that that is clearly spoken by someone who has no experience doing surveys, because the reality is that you see gross and significant differences between facilities, between the way that the unit operates, between the various film-screen combinations -- and there are many combinations -- between the processors, between the chemicals that the facility

uses, between the expertise of their technologists, between the expertise of their physician. There are significant differences between the level of consultation that facilities need, and the physicist needs to have -- the physicist who is providing that consultation needs to have a much broader area of expertise than the physicist who just works on his or her own units every year.

DR. SMITH: But if you will just indulge me a little bit longer. You haven't really told me that a person working in one facility wouldn't recognize those problems just because they are working at one facility. It sounds to me like you are trying to make the argument that you would get such acute tunnel vision from just working on the same unit and the same processor that you would be incompetent dealing with anything outside that institution. I am not sure that is the case.

MS. KAUFMAN: Again, that is spoken by someone who doesn't know anything about doing a survey, and it is not a matter of tunnel vision, it is just a matter of experience and understanding of how various systems work.

MS. MCBURNEY: Penny, you have a quick response?

MS. BUTLER: As someone who does have experience doing medical physics surveys, I would like to contend that an individual working full time in a hospital will have, in one respect, much more experience because they see the day-to-day operation of the equipment and day-to-day fluctuation of the entire system, which perhaps someone who comes in on a consulting basis would not have the experience with.

So, I think it could go either direction. I honestly do not think we need to get to this level of detail, and I strongly recommend the unit-based criteria.

MS. MCBURNEY: Charlie.

DR. FINDER: If I could just say one thing in terms of trying to move this along. This sounds very much like a conversation I heard in April, where we heard the exact same thing, so we have got that all taken care of. Why don't we move on? We have heard it.

MS. MCBURNEY: Okay. Last one.

[Overhead.]

MS. MCBURNEY: The next issue are the alternative standards. We got a lot of comments on both sides of this

issue, especially on the issue of education for those under the alternative standards.

Several felt that the bachelor's degree in physical science was too low, some felt that requiring so many hours of physics in that physical science degree was too high, that we should just go ahead and grandfather everybody that met the interim standards.

Some felt that the alternative standards should be a permanent option rather than just closing out one year from the effective date of the regulations. Some had some alternative language suggested, and many took issue with the experience requirement. That was, what, 20 units?

MS. BUTLER: Yes.

MS. MCBURNEY: Well, especially the 10 facilities, 20 units. So, Penny, do you want to elaborate on some of that?

MS. BUTLER: First, I may as well bring up that probably one of the most controversial issues, although I think after today's discussion, maybe it wasn't, that many commenters remarked that a B.S. degree was insufficient preparation, and it would probably be best to just read some

of these comments.

The proposed rule fails to provide emphasis to some of the most important qualifications for medical physicist. A minimum requirement of a master's degree with board certification by ABR or ABMP is the appropriate specialty, provides the best assurance for medical physics qualifications.

Individuals with only a bachelor's degree may be qualified to perform certain specific tasks in mammographic quality assurance process, but in all likelihood they lack the in-depth understanding of the physical processes involved.

Although there is always the likelihood that individuals with only a B.S. degree may have spent a considerable amount of time in their own education and possibly acquires some in-depth understanding of the physics of X-ray equipment, this is not likely.

In most professions, formal training with an earned degree provides the most important foundation of knowledge which is complemented by practical experience. Conversely, another commenter pointed out that the criteria

for mammography medical physicist should not require that they be certified or have a master's degree in health physics or related field.

Currently, the MQSA inspectors perform almost the same functions as the mammography medical physicist. The criteria should be comparable. The history with the MQSA inspectors for the last year proves that the mammography inspections do not need a person with certification or master's degree.

A bachelor's degree in a related field or equivalent and specific training in mammography plus field experience for one year should be adequate. I am sure that the MQSA inspectors would perform capably as mammography medical physicists.

So, I think we have rehashed this one over and over, and I believe that we have come up with probably the best compromise that we could have, so we recommend that the alternative pathway remain with the sunset date as initially described in the proposed final rules.

MS. MCBURNEY: Then, the other question under this was the degree again, the physical science and what that

would entail, and then the number of physics semester hours. Some had suggested as high as 45, which would be way above a major in physics, and then somewhere around -- I think the CRCPD recommendation that had brought in some medical physicists, as well, it was a collaborative effort from that committee, recommended 15 -- somewhere around between 15 and 20, I think is like a minor in physics. So, if we allow a degree in a physical science, to me, at least whatever a minor would be in physics might be appropriate for the amount of college level physics that would be required under this.

MS. BUTLER: And we recommend 20 semester hours or equivalent.

MS. MCBURNEY: I don't know if that is the equivalent of a minor. In some colleges, I guess it is. Some colleges, it is around 15, I don't know.

Any comments on the alternative standards? Basically, we are saying leave the sunseting in there, allowing many of the practicing physicists to go ahead and practice if they meet these minimum qualifications.

MS. BUTLER: Yes, Dan.

DR. KOPANS: I am sorry. I still don't completely -- you are saying that they are getting grandpersoned in, but after that, are we requiring physicists be --

MS. MCBURNEY: To have a master's degree. Those entering the field would have to be either board certified or have a master's degree.

DR. KOPANS: We rely on our medical physicist constantly and for fairly sophisticated issues that have to do with quality control, and it just seems to me they need better training.

MS. MCBURNEY: Right. Any other comments on this?

Okay. We can move on.

[Overhead.]

MS. MCBURNEY: The next issue was the continuing education. Some of them wanted a definition clarification on contact hours. I can't remember what the exact comment was on that. Do you remember? It was just really minor. There was no real opposition to the concept of continuing education.

So, we move on to the next item, which was the continuing experience.

[Overhead.]

MS. MCBURNEY: There, again, we had the issue of surveys rather than facilities, the concern of the in-house physicist, and I think we have beat that to death, that it should be less prescriptive, and the comments varied on the number of surveys to maintain continuing experience from one to three, and we are suggesting that it stay at three, but be unit based instead of facility based.

Any comments on continuing experience? If not, we can move on.

[Overhead.]

MS. MCBURNEY: Reestablishing qualifications. Several though it should be consistent with the initial qualifications. There were pros and cons on the supervision issue by practicing medical physicists for reestablishment. There was a comment that if there is not any around, that they can watch them, that the lack of medical physicists in an area might be an issue there for somebody to get requalified.

Any comments on this? Did we cover the major questions, Penny?

MS. BUTLER: I just have that final one to give for Flo. No. (4).

Although we weren't asked to review this, Item No. (4) has to do with the retention of personnel records, and this one is for Flo. I think we can delete this and actually take this material and insert it in the QA records section, and perhaps add any additional language that needs to be added. It seems to be redundant.

MS. MCBURNEY: Rita.

MS. HEINLEIN: I actually was assigned that part, to read all the comments on the retention of records.

MS. MCBURNEY: Okay. So, we will get to that tomorrow.

MS. HEINLEIN: But to support what you just said, there were very few of them, and I have my comments right here.

DR. PATTERSON: Let's hold that entire retention of records until --

DR. FINDER: Let's retain that.

MS. HEINLEIN: I am just saying if Flo wanted a comment on it, there were only like 20 comments, and most of

them said only keep them for as long as you need to, make sure you have met the requirement and that you have complied

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DR. PATTERSON: Rita, we are still going to have to go over this again tomorrow, because it is on the agenda for tomorrow.

MS. HEINLEIN: So is what we are talking about tonight on the agenda for tomorrow. Are we going to go over that again tomorrow?

DR. PATTERSON: We may have to, yes, or at least bring it to the floor for discussion. So, I don't want to go off the agenda for anything more if possible.

MS. MCBURNEY: Did we answer the two questions that FDA had? The contact hours for initial qualification for practicing physicists, I think we still wanted them to have that. They can get that at continuing ed. courses.

The first question was should documented contact hours, training as proposed for the initial qualification requirement be required for all medical physicists or should this be required for only for new medical physicists entering the field after the final regulations are

effective. I think we wanted everybody to meet that.

MS. KAUFMAN: And most people were doing it.

MS. MCBURNEY: Right.

MS. KAUFMAN: It is pretty easy to meet that.

MS. MCBURNEY: Okay. That concludes our section.

DR. PATTERSON: We will plan on adjourning for this evening. Let me remind the committee tomorrow morning we start at 8 o'clock, and we will start with the items from today's agenda that we did not do, which is on the Quality Standards for Equipment, starting off in the morning with that discussion.

We also will have to allow into the record that we did discuss these other two areas and that if there are any additional comments on those, we are going to have to allow it since that was part of our agenda for tomorrow.

At that rate, then, we will adjourn for this evening.

[Whereupon, at 6:50 p.m., the hearing was recessed to be resumed at 8:00 a.m., Tuesday, January 14, 1997.]