

MR. PIZZUTIELLO: And the responsibility for supplying, maintenance and calibration routinely of test equipment, that stays with FDA?

MS. FISCHER: That's with FDA.

MR. PIZZUTIELLO: And the last one was I believe that there has been a provision in the past where inspection reports--after the inspector completes their report--they get uploaded and reviewed by someone at FDA; is that correct, or was that just in the beginning of the program?

MS. FISCHER: No. Their report is not--

MR. PIZZUTIELLO: The inspectors' reports are not reviewed?

MS. FISCHER: --not reviewed--not reviewed by us.

DR. FINDER: I think you may be talking about in the beginning, we did audits of the inspectors--

MR. PIZZUTIELLO: Right. That was in the beginning.

MS. FISCHER: We still have FDA audits of all inspectors.

MR. PIZZUTIELLO: Okay. So the FDA audits, then, would still apply to the inspections done at the State level.

MS. FISCHER: Yes.

MR. PIZZUTIELLO: Those are three things that I thought were important to be retained centrally by FDA, and

I just want a clarification that that is what was happening.

MS. FISCHER: That's what is happening at this point, yes, and we maintain a national database, and the computer systems and maintenance and so forth, that's what goes into that.

DR. MONSEES: Yes?

MS. MCCARTHY: Kendra McCarthy.

You mentioned that you will start getting applicants next year. What do you think the rate will be? Do you think that all the States are going to want to do this, or do you have a sense of how many will not?

MS. FISCHER: Definitely, all are not interested in the program. And again, a lot depends, I think, on the ability of what the State is able to charge or not charge its facilities. Right now, part of the fee is--for example, what we are doing right now--\$509 is a fee that FDA levies each facility in the States as Certifiers for its inspection-related support services, which Bob was just outlining.

Then, for example, in the State of Illinois, for all of their inspection/compliance/certification services, they have a fee of \$750 for their facilities. Combined, that happens to be less than the national fee. In the State of Iowa, I believe the combination of fees comes out to be almost the same, if not the same.

So it is a question of whether they can provide these services in a way that is cost-effective for the facilities, number one, or if they have the personnel available to handle expanded responsibilities. I think that looking at between 10 and 15 States to come in within the first three years of the program is realistic.

MS. BROWN-DAVIS: Carolyn Brown-Davis.

I am wondering if you could just give us some information, more information, on why States don't want to participate. You mentioned that cost might be a factor.

MS. FISCHER: That might be a factor. Some States are really quite content with the system the way it is, contracting with FDA to perform the inspections and just keeping that contract situation going. You do have to be able to have a data system which is compatible with FDA, and there is a lot of work that goes into the decisionmaking and issuing of the certificates, being able to handle the additional volume of facility inquiries that would be coming directly to you as opposed to the FDA hotline and so forth. So there are a number of operational issues as well as financial issues.

And State regulations--that's a very good point, Vicky--you need to have State regulations which are equivalent to the MQSA regulations, and you need enabling legislation, so you if you don't have enabling legislation,

then you know it takes considerable time to get your legislature primed and ready to do that. the regulatory process in many States is not any quicker than it is at the Federal level, so it is quite a commitment to have that foundation in place, too. So there are a lot of things that would go into the decision.

We are also looking for a high-level commitment at Cabinet level, or director of the department level, so that you are in it for the long haul, so there wouldn't be flip-flopping back and forth. That also is subject to budgetary constraints.

DR. MONSEES: Thank you.

Are there any other questions?

[No response.]

DR. MONSEES: We'll move on, then, to "Final Regulation Implementation - Problematic Issues."

DR. FINDER: Basically, what I wanted to try to get from the Committee is what problems, if any, they have encountered since the implementation of the final regulations on April 28th, any issues they want to bring up that we haven't already talked about either in this guidance or in the previous guidance documents, anything that has come up that you think would be important for FDA can know about so we can deal with these problems at an early stage rather than waiting until they get to involve all the

facilities, or inspections, or anything else.

DR. MONSEES: Yes?

DR. SICKLES: Just from talking to radiologists at meetings I attend or where I teach, I think there is still a moderate amount of confusion about patient reporting. I think they are not completely sure that what they are doing is within what the inspectors will expect of them.

The facilities where I have talked to radiologists where they have already been through an inspectin--which is the minority, because there just hasn't been enough time-- have told me they haven't had any problems because they were doing it right. But there is uncertainty out there, and some anxiety that maybe they are doing it wrong, and I think that will solve itself over the course of the next year as people realize that are either already in compliance, or if they are not, then the inspectors will tell them, "You should have done it this way," and they will do it that way the next year.

DR. FINDER: This is somewhat similar to what happened when the interim regulations started and the initial inspections started--there was a lot of uncertainty, and people were very worried about it. Once they got familiar with it, then we decided to change what we were doing to them, so now we can start it all over again.

DR. SICKLES: Yes. I remember maybe a year and

half or so ago, you showed a slide of the number of different level citations. We can expect this year that there will be more, because there are more regulations, and people just aren't familiar with them. But one of the reasons for increasing the standards is that you increase the level of performance, and that's good.

DR. FINDER: Right. We expect that there will be increases in the levels of fines, just as we have found every time a new regulation, even under the interim regulations, went into effect, so that is not going to be surprising. We have tried to inform the facilities as best as possible as to what to expect. We have put out many documents, including "Preparing for the MQSA Inspection," which is up on our web site, but until the inspector actually walks in and they go through the inspection, there will still be that anxiety.

DR. DEMPSEY: Along those lines, I would like to echo something that Bob said earlier, and that is that I think the FDA ought to be congratulated on the level of effort they have gone to to prepare guidance publications which basically, I think, provide a reasonable translation of the Federal Register regulations. I think that any problems I have heard people asking me about, it's just that they haven't taken the trouble to get the publications, which are easily available, which very clearly translate the

regulations.

So I think the FDA has certainly done their part to get guidance out there, and it is just a question of the people using--it's kind of like when you buy a new appliance--when all else fails, you have to read the directions.

DR. MONSEES: Yes?

MR. PIZZUTIELLO: I think the only problem that I see from facilities are those that don't have access to the FDA web site. Clearly, it has been a very valuable and effective way to communicate information, much more quickly than by mailing and much less costly.

A lot of the small facilities I think would benefit if there were some sort of a justification statement that might be available that showed here is what it used to take us to get a guidance document out, and this is what it used to cost--this is now how we do it, and this is what our turnaround time has been, and we have been able to get all these things. If you could do something in a simple, one-page summary, and then maybe put a note in "Mammography Matters" saying if you are interested in obtaining this, call our hotline--because these are largely small facilities that don't have access to all the support, and if they could get something faxed to them which says, look, these are all the benefit to us of spending \$2,000 on a computer and \$50

on a modem and an internet provider, that might be just the kind of legwork that would help a lot of the small facilities get into the internet system, if nothing else, just to be up with what's happening with the changes in mammography regulations. It probably wouldn't be that difficult to do something fairly simple along those lines. That's just a thought that occurred to me.

DR. MONSEES: I think we have talked about this before, but do we have any idea what percentage of facilities do not have access to the internet?

DR. FINDER: I don't have a number to give you. We haven't done a formal study/survey to find out. If you listen to the television commercials, millions of people a month are joining the internet. We do assume that we are talking about one of the more technologically advanced segments of society, considering we are talking about radiology facilities. But there is no question there are still facilities out there that do not have access to the internet--or, I should change that--do not have easy access, because usually in a facility, you have multiple people working there, and at least one of them has access to the internet, and if they don't, there is either a local medical center, hospital, library that they can use. It is not necessarily always the most convenient way to do it, and obviously, it is much simpler to be at home and just tap in

from your home unit. But we have heard several complaints, especially in areas out in the West, where some facilities say that they do not have access. We do have other mechanisms for them to get this information, although I will say, especially one we get the esarch engine on our web site, the best way to do it is going to be from the web; trying to do it in paper documents really is not the way to go, because even if we mailed out all these documents, you would be dealing with six inches of paper to try to wade through, which is not the best way to try to get this information.

DR. MONSEES: How about CD-ROM?

DR. FINDER: CD-ROM I guess is a possibility if somebody wanted to. But again, right now, you don't even need CD-ROM. The actual search engine that was just given to our inspectors to use--they are testing it right now before it goes up on the web--can go on a floppy disk, all the guidance that we have right now; whereas if you put it out in paper, it literally comes out to about six inches.

So it is not necessarily that it is that big a file; it can be put out, actually, on floppy disk. But we would then have the problem of, well, I don't have internet access because I don't have a computer, so giving you the floppy disk isn't going to help you, either.

We do have a system where they can actually get

some of this information by fax. We've gotten the response back: Well, I don't have a fax machine. We tell them you can call in for individual questions. I haven't heard anybody tell me they don't have a telephone yet.

As I said, there is no question there are problems with certain people being able to access this information from the internet, but as it stands right now, that's the best method we have--it's not the only one; they do have other options--but it is the best method from my point of view and from FDA's point of view and from the people who have used it.

DR. MONSEES: Are there any other comments?

[No response.]

DR. MONSEES: No other early experience. Okay.

We have one other item issue, and that is in the document that came from--let me get the right title--Institute for Mammography Research, there was Item 4, "Potential for Future Problems." This addressed MQSA compliance for facilities in a demonstration program. It was on page 3 of 4 of that document, at the bottom of the page.

The Mammography Quality Standards Reauthorizing Act permitted FDA to establish a demonstration program for less frequent inspections, less frequent than annual inspections. And it was suggested that there be a possible

way for mailing in to remotely monitor changes in kVp, half-value layer, AEC, and dose. Do you see that in the document?

Mr. Galkin was suggesting that the Committee "recommend that funds be provided to conduct a field test to determine if this method is an adequate test for validating that facilities remain in compliance."

So the question is not so much allocating funds-- we wish we could allocate funds; right--from this Committee, but let's talk about whether or not such a method is something that we would want to suggest or that might even work.

Does anybody want to talk about that? Yes?

DR. SICKLES: Well, the background of this, I suppose, is the issue that the Committee has dealt with before, of looking for ways to allow facilities that pass routinely not to have to go through annual inspections, but to perhaps skip a year. This might be a way, if the FDA chose, to monitor such a facility in the off-year--although I don't think that was the intent initially. Initially, the intent was just if you do well for a few years in a row, we are confident enough in you that we don't even need to see your data for an off-year. This would be a way to get that data in the off-year, or it might be a way for the FDA, even for facilities that only had Level 3's, to ask people to

mail in something for Level 3's and then do this. There are a variety of ways in which it could be used. I think it is an intriguing concept as long as it is technically sound, and the technically sound part is beyond me.

DR. MONSEES: Just let me interject before I go to you, and that is that there is a physicist going and doing these sites on a yearly basis, so needing to have the FDA have that information when you have a qualified physicist already attesting to it, I wonder if it is really needed-- that is my question--when you already have someone signing on the dotted line, somebody who is purportedly qualified to do so, and testing these exact same things. So that's what I would raise.

Do you want to raise another issue?

MR. PIZZUTIELLO: That's exactly the question I have, and even before that, I might say that at the bottom of page 3 of the letter, it is suggested that "this mail-in system be a method for ensuring compliance between inspections." I'm not sure I see the connection between the--even if FDA wanted to do that, I'm not sure I see the connection between this test device and assuring compliance, since only a small percentage of the compliance issues relate to the kinds of things that this system test would determine, and everything within that is already tested by a qualified medical physicist who visits the facility once a

year.

So I'm not sure I see what this system adds that the qualified medical physicist doesn't already do, among many other things, by being present in the facility once a year.

DR. MONSEES: Such a system could be used between yearly inspections by the physicist--you could use it and have the facility send this type of information quarterly or twice a year or whatever.

MR. PIZZUTIELLO: In fact, I would suggest for background purposes, in our practice, we visit almost all of our places twice a year, at the choice of our clients. We let them know that it is only required once a year, but in the history of New York State regulation, it used to be required twice a year. We looked at our data and presented it to our clients, and they said it looks like you are finding valuable things more often than once a year--so keep on coming. But if other physicists wanted to use this as a supplement to their annual survey, that would be between the physicist and the company to determine.

DR. MONSEES: Any other comments from the Committee on this?

[No response.]

DR. MONSEES: Mr. Galkin himself is going to make a comment.

MR. GALKIN: Ben Galkin from Institute on Mammography Research.

What I tried to do in the previous correspondence was to point out that even though facilities are in compliance, the tests that are intended to monitor the equipment are not sensitive enough to do a good job, and there are parameters that go undetected; even though the physicist may come in once a year, it is throughout the year that these things may go undetected and uncorrected, then, for a facility that is, let's say, inspected once every two years or once every three years.

Now, sure enough, the physicists are going to come in and check, but that has nothing to do with the dialy quality control having to do with contrast test, which is intended to monitor the equipment.

Let me add one other thing. I sent a document along which shows that the FDA did check this out, and their conclusion was that it is a more sensitive test, and it has merit for monitoring multiple parameters in a facility. It is a very simple test to do--it doesn't take any more time than what the technologist is doing now--with the same two density measurements, so it is a very easy, quick, cost-effective way to monitor the equipment throughout the year in addition to what the physicist does annually.

DR. MONSEES: Okay. Are there any other issues

that we should discuss in the final regulation implementation, problems that people want to alert the FDA to that may avert some problems down the road?

[No response.]

DR. MONSEES: Okay. Then, we'll move on to "Reivew of the Summary Minutes."

Dr. Finder?

DR. FINDER: Basically, the summary minutes have been mailed to everybody. If people forgot about it, I do have extra copies, or you could have gotten it off the web page.

The question is does anybody have any comments or corrections to these summary minutes from the last meetnig.

[No response.]

DR. FINDER: If not, we can go on and talk about future meetings.

DR. MONSEES: Is there anybody who doesn't have access to the internet on the panel?

[No response.]

DR. MONSEES: Okay--just a little humor.

We want to talk about future meetings now. Dr. Finder passed around a list of members of the panel and when your term is up, and so on. I don't think we need to discuss it, but that is what that is; right?

DR. FINDER: Yes, just to remind everybody that

this is not a lifelong commitment, and for good behavior, you get off early.

[Laughter.]

DR. MONSEES: Okay. Next, future meetings.

DR. FINDER: Right. It's July now. I'm thinking about the next meeting probably sometime around November, in that kind of time frame. What I want to hear from people right now is if there are any dates that you know you cannot make. We will obviously have to send out a request or some kind of statement like we have in the past, asking for which weeks you are free, but if there are some weeks that you know you can't do, I'll just exclude those as possibilities.

DR. MONSEES: We know RSNA; you can eliminate that.

DR. FINDER: Which week is that?

DR. MENDELSON: Right after Thanksgiving.

DR. SICKLES: It's always the week after Thanksgiving.

DR. FINDER: I just don't happen to know the date.

DR. MONSEES: You'll have to pull up your computer calendar.

DR. DEMPSEY: It's the week of November 29th.

DR. FINDER: Okay, the 29th.

DR. MONSEES: Are there any other major meetings or times--that will exclude Thanksgiving, happily, so we

won't have to worry about that.

Yes?

DR. LEE: I've got a conflict from November 8-11.

DR. FINDER: And the other question I have is how has this one-day meeting worked out for everybody; was it okay?

DR. MENDELSON: Very good.

DR. SICKLES: Good.

DR. DEMPSEY: Wonderful--as long as you keep ending at 4 o'clock.

DR. MONSEES: Now, the other question we had-- didn't we, Charlie--is if we have a one-day meeting, do people prefer to have it like we did today, rather than in the middle of the week, so that you come in on a Sunday?

DR. SICKLES: I am all for doing it on Monday and traveling on Sunday. Coming from the West Coast, it takes me a day to get here. I don't know how the rest of you feel.

DR. MONSEES: Right; it takes time away from your personal life rather than your office.

Does this Monday business seem to work well for people? Does anybody prefer otherwise?

DR. NISHIKAWA: I prefer the middle of the week.

DR. MONSEES: Okay. Do we have any other items to discuss?

DR. FINDER: No. I think we can avoid the break.

DR. MONSEES: Okay. From the audience, are there any major implementation problems or issues that the panel needs to discuss or that FDA needs to hear about?

Does anybody have any issues that they see coming down the pike that we should mention now?

[No response.]

DR. MONSEES: Okay. I think we're done--wait. You raised your hand, and I didn't see it.

DR. MOURAD: Wally Mourad, FDA.

I know you discussed the issue of under what conditions should the phantom be tested weekly, and I got the impression that the Committee was leaning toward if you do it in the auto kVp mode, full auto mode, and you end up finding out what the kVp is, and then you pick that kVp and do it. I want to remind the Committee that the regs do say that the phantom should be taken at a typical clinical condition, meaning a clinical condition used at the facility for the average breast that is represented by the phantom.

So if you decide to check what the kVp is and then do it at that kVp, that really throws a monkey wrench into what is required. I just want to open it up again.

DR. MONSEES: Okay. Do you have any suggestions about how to resolve that? You can't just raise problems without giving us suggestions, too.

Dr. MOURAD: The way we resolved it was that in the guidance, it says do it at the same typical clinical conditions that you do clinically for the average breast, and that's the way it was written.

DR. MONSEES: Okay. Yes?

MR. PIZZUTIELLO: I think when we discussed this earlier, waht we said was that, yes, maybe if you very strictly interpret the regulations, with a little bit of flexibility of interpretation, given the significnat complexity that comes about from doing the test in automatic kVp mode where the kV may change, and given the fact that because it is complex, it may actually make it harder for a facility to detect a problem with this test, that a very good compromise would be to interpret the clinical conditions as the resultant conditions of the image, which would be you pick the kV, and let the automatic exposure control choose the mAs.

Other than that, as far as the wordsmithing and waht the legal counsel says, I don't have any input there.

DR. MONSEES: Is there any way to do this?

DR. FINDER: Well, the other point that had been brought up in the discussion was do we lose anything by doing that, and the issue is very importnat, because if your system is working fine when you set it manually, but it isn't giving you consistency when you are in the auto mode,

you won't know it. That is the basis for the regulation stipulating that it has to be done under the clinical conditions.

Now, do we have some leeway? I honestly don't know. If a good enough case can be presented that it is that important and that the changes that could occur in a typical case where you are testing under the auto mode are going to cause huge problems, I think we can look at it. If it is a more theoretical aspect to it, I would rather try to stick with the simple thing which says if you are going to shoot at a certain clinical technique factor using either auto or manual or whatever, that that's how you do the test--because again, we want to try to simulate as much as possible what is going on.

The other thing is if there is that much variability with the phantom, and slight movements of the phantom in this thing, what is going to happen when you have an actual patient in there? Even if it is the same patient, are you expecting to see that much variability?

MR. PIZZUTIELLO: I'd like to clarify two things. First, we are talking about a 1 kVp variation in the way the auto kV sets it up, and I don't think there is a radiologist in the country who could tell the difference between an image taken at 25 and 26 for that kind of patient.

But the second one, you just gave me an idea for a

compromise. How about if we said do the test in whatever your clinical mode is; however, if you have one of these situations where the kVp alt flips by one, and let's say your routine data comes out at 25; you do your auto Kv measurement, and it comes out at 26. We have demonstrated that the auto kV is good within one kV. Then, you can repeat the phantom by manually setting 25 kV and chart that point. It would require a second image, but it is not all that often--it may be one time out of three or four--and it might be a compromise that is better than keeping two sets of data.

DR. MONSEES: I like that. Is there ever a situation with the 4.2 cm phantom where the filter material changes?

MR. PIZZUTIELLO: No, no.

DR. MONSEES: It is always going to be molly-molly [ph]; right?

MR. PIZZUTIELLO: Yes. And I should say some machines might flip between 24 and 25 kV, or 25 and 26, depending on the screen-film combination.

DR. MONSEES: But it's going to be a kV adjustment, not a target--

MR. PIZZUTIELLO: Correct, or a filter.

DR. MONSEES: --or a filter. right. So we are only talking kV. I like that.

Does that sound okay to you? Is that workable?

DR. FINDER: I will pass it along to the people and see what we can come up with.

DR. MONSEES: Okay.

MR. GALKIN: Could I ask one more question without going over there?

DR. MONSEES: Yes--you have to go to the mike, because it has to be on the tape.

MR. GALKIN: Bob, are you referring to those machines that have the automatic kV sensing device? There are an awful lot of machines out there that don't do that. You set it up manually, you set the kV up manually, and the automatic exposure controls are for the mAs. In fact, I would think there would be very few machines out there that have the automatic sensing device.

MR. PIZZUTIELLO: Well, I have a pretty broad experience, and there are a lot of machines that have auto kV. Basically, any machine that has been designed since about 1994 or 1995 has some sort of capability to automatically choose the kVp, and I would guess that the universe is probably split 50-50. There are lots of machines where you manually set the kV, but there are also lots of machines out there where it automatically selects the kVp, and sometimes the target and filter combination as well.

DR. MONSEES: For the ones that don't have that

choice--

MR. PIZZUTIELLO: it's not an issue.

DR. MONSEES: --it's not an issue. And many people have the choice but don't use it that way anyway. They may set the kV.

All right. If there are no other issues, we are adjourned. Does anybody have any other issues?

[No response.]

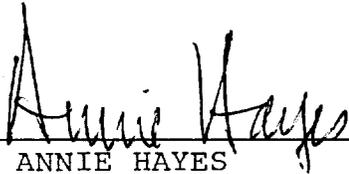
DR. MONSEES: We are adjourned. Thanks very much.

[Whereupon, at 4:12 p.m., the proceedings were concluded.]

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C E R T I F I C A T E

I, ANNIE HAYES the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.


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