

1 need to have women with dense breasts. Even if the majority
2 of your women have fatty breasts, you still need to submit a
3 dense breast example. I think it would cover all situations
4 if you simply referred a footnote to these special situation
5 cases which are not common, still have to go through
6 accreditation, still have to use standard breasts in order
7 to pass that accreditation and to base your tests on that
8 kind of stuff. It will cover everything, and you will not
9 have to go into great detail.

10 DR. MONSEES: Clearly, the panel is saying
11 word-crafting needs to be performed here on this table
12 because it was not understandable, but I think we now
13 understand it, now that it has been explained, and I think
14 we have given you some suggestions for that.

15 Any other comments on this table?

16 [No response.]

17 DR. MONSEES: The last item, "k" of "KvP" needs to
18 be a small "k" and not a cap.

19 Anything else on this table?

20 [No response.]

21 DR. MONSEES: From the audience, please.

22 MR. USINOFF: Hi. I am Bob Usinoff with Fuji
23 Medical Systems.

24 In the table in the area of "Uniformity of Screen
25 Speed" and "Screen-Film Contact," the way I am reading it, I

1 am wondering how we would address a facility that
2 used--let's say they had two services of screen film in its
3 receptor, and they use two films. It is called F-1 and F-2,
4 and they use two screens. I will call them S-1 and S-2.
5 The two combinations might be S-1 with F-1 and S-2 with F-2,
6 but looking at the screen-film combination test with each
7 unit, I read "All clinically used screens (cassettes)," and
8 the specification for one film type. I think that might
9 cause some problem of interpretation.

10 I think the intention would be for each class of
11 service to be tested. So you would want to evaluate S-1/F-1
12 and S-2/F-2.

13 DR. MONSEES: Basically, it carries into the next
14 item as well when there is more than one. How would you
15 solve that? We are looking to you, Mr. Pizzutiello.

16 MR. PIZZUTIELLO: Thanks.

17 [Laughter.]

18 MR. PIZZUTIELLO: In thinking this through, the
19 way I interpret this is that what has been written is you
20 only have to test one film type.

21 I am trying to think of a situation where if your
22 screen speed were acceptable with one film type, could it be
23 not acceptable with another? I do not know, but certainly
24 our general rule of thumb in testing is when in doubt, test
25 using the clinically relevant combinations, and that is what

1 Bob was just saying and I support that.

2 So his example, if that were to be the case, would
3 make sense to test them under the clinically used
4 screen-film combinations.

5 DR. MONSEES: So take out one film type.

6 MR. PIZZUTIELLO: Right.

7 DR. MONSEES: Just take out the wording, and it
8 should solve it, right? "All clinically used"--well, it
9 should say "screen-film combinations," right?

10 MR. PIZZUTIELLO: Yes.

11 The other thing is that the screen-film contact is
12 a characteristic of the cassette and the screen, not the
13 film.

14 DR. SICKLES: It has nothing to do with film.

15 MR. PIZZUTIELLO: If you tested all of the
16 cassettes with one film, if you were to use that cassette
17 with a second film, it does not occur to me that it could
18 change because it is a physical characteristic of the
19 cassette. So, in that case, the one film would apply, and I
20 think that is probably what the example is that is intended
21 here. I see Wally nodding.

22 DR. MONSEES: So separate them out.

23 MR. PIZZUTIELLO: Separate them out.

24 DR. MONSEES: Have one be screen speed and the
25 other one be screen-film contact, and the screen-film

1 contact could be done with one film type and the other one,
2 every clinical combination.

3 MR. PIZZUTIELLO: Yes.

4 DR. MONSEES: Does that make sense?

5 Yes.

6 DR. MOURAD: Walid Mourad, FDA.

7 The uniformity of screen speed is a test at the
8 screens. So you do not need to do it for films, really. We
9 tried to simplify it by asking for doing it only with one
10 film type.

11 Now, if the committee thinks that another film
12 type that is clinically used should be added, that is fine,
13 but that is an added burden. We tried to avoid that.

14 Regarding the other one, the screen-film contact
15 is a test of the cassette, and it is a physical property,
16 really. You do not need any other film combinations.

17 DR. MONSEES: Right.

18 DR. FINDER: I think the thing that we are
19 addressing may not be exactly what you are talking about.

20 What we were trying to say is if you happen to be
21 using multiple films with the same screens, different types,
22 we are only asking that you check with one of the ones that
23 you use clinically because the situation could be if we
24 leave out the one film type, then we are saying that you
25 have to test it with every single film type. Since we are

1 only testing the uniformity of screen speed, which is mainly
2 the screen, not the film that we are really looking at, we
3 did not see a reason to have you test with all the film
4 types that you have and that you use with that screen. You
5 would only have to test with one. So we are trying to keep
6 the number of tests down.

7 If you think that is not good enough, we can
8 always relook at it.

9 MR. PIZZUTIELLO: I think that makes good sense.
10 There are other factors that are important to know if you
11 are using different films, but they do not happen to be
12 addressed by either of these two tests. They are more
13 addressed by the image quality and the dose test. So they
14 are using all clinical combinations, but, here, with that
15 clarification, I think it is acceptable the way it is.

16 DR. MONSEES: All right. Since the last page of
17 this document is likely to be somewhat contentious and may
18 go on, I think we will break for lunch here, if that is
19 okay.

20 Do we want an hour or an hour and 15 minutes? Can
21 I see a show of hands of people who think that we can resume
22 in an hour?

23 What does this mean, Ed?

24 DR. SICKLES: Less.

25 DR. MONSEES: Less than an hour?

1 DR. SICKLES: I have to leave at about 3:00.

2 DR. MONSEES: All right. People may need to check
3 out and do some other things. So we will resume in one hour
4 which will be 1:00, okay? Is that all right?

5 [Whereupon, at 12:00 p.m., a luncheon recess was
6 taken, to reconvene at 1:05 p.m., this same day, Monday,
7 January 31, 2000.]

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A F T E R N O O N S E S S I O N

[1:05 p.m.]

DR. MONSEES: Good afternoon. Thank you for coming back after lunch.

We are going to continue with the document that we were discussing prior to lunch, and we are up to the verification testing table which was the last page of that document.

The question is to what extent should the medical physicist be involved in the following repairs that are listed down below, and the following items on the list would be considered a major repair and must be evaluated by the medical physician following the repair and prior to clinical use of the equipment. I think this is important stuff, and we ought to go through it item by item. We are going to rely heavily on our physicists, and we may need some input from people in the audience.

How about compression device adjustment? Any comments here?

[No response.]

DR. MONSEES: So this is not required?

MR. PIZZUTIELLO: No.

Can I make a general comment as to what I see as the criteria for involvement?

DR. MONSEES: Sure.

1 MR. PIZZUTIELLO: I think this applies to all of
2 them.

3 In my view, anything that could have a significant
4 impact on radiation dose or image quality needs to have more
5 involvement of the medical physicist. Anything that does
6 not have that needs to have less involvement with the
7 medical physicist. So, with that as a criteria, then, when
8 we go down, that is how I would view them.

9 DR. MONSEES: So compression device adjustment, we
10 agree not required?

11 MR. PIZZUTIELLO: Agreed.

12 The reason I think why (b) does require oversight
13 is because that is related to the very next item which is
14 the collimation.

15 DR. MONSEES: So the first two items, compression
16 device adjustment, compression paddle adjustment, we are
17 okay with?

18 MR. PIZZUTIELLO: Yes.

19 DR. MONSEES: The definition of "oversight" is
20 sufficient, consult with a medical physicist to determine
21 whether this represents a major repair for the facility's
22 specific unit and how the evaluation is to be performed, is
23 that okay?

24 MR. PIZZUTIELLO: Actually, I think that is
25 something that could use a little work.

1 What I sense from the text that is here is that
2 you are focussing strictly on the words in the regulation is
3 a major repair. That may be the appropriate mandate from
4 FDA. What I do not see anywhere in here is professional
5 judgment. I would like to see that phrase someplace in this
6 sentence because that is always a thing that the medical
7 physicist has to use. It is hard to put things in black and
8 white.

9 In fact, I am going to make some suggestions
10 further down that we try to resist putting too much in black
11 and white, but to say that the medica physicist must be
12 involved and must use their judgment.

13 DR. MONSEES: All right. Let's go to collimation
14 adjustment, then. Are there any comments on that?

15 Do you have a comment on that?

16 MR. PIZZUTIELLO: No problem.

17 DR. MONSEES: AEC adjustment. Should those all be
18 conducted in person? Can somebody else do it and they be
19 supervising that? This means they have to do it in person
20 themselves, right?

21 MR. PIZZUTIELLO: Right.

22 I think this is one of the things that could be
23 changed. I think that to require each of these adjustments,
24 to have the medical physicist visit the facility and do
25 these in person is a significant change from the current

1 practice. It would require a lot more time on the part of
2 the facility and the physicist and increase the cost. In
3 some cases, it is justified, but in other cases, I think it
4 is not. So this is an area where I see that the medical
5 physicist must be involved, but that the professional
6 judgment of the physicist should be the determining factor.

7 The example is one that I think I used earlier
8 this morning. You learn who the personnel are in the
9 facility, and sometimes you can instruct the personnel to
10 make certain measurements and send you the data. If you
11 have confidence in that person because you have worked with
12 them before or you have supervised them, then it may not be
13 necessary to physically go to the place.

14 On the other hand, if you have a facility where
15 you do not have that confidence in the personnel, then you
16 might say as a medical physicist, my judgment is that I need
17 to be there to be sure that it was done correctly. Because
18 of the professional nature of the practice of medical
19 physics, I would prefer not to have it be specified, but to
20 allow the physicist some flexibility to use their judgment.

21 DR. MONSEES: Any other comments from members of
22 the panel on this?

23 DR. SICKLES: I would defer to the people who are
24 doing the work. If the situation of being able to rely on
25 skilled helpers is acceptable, I would certainly go along

1 with it.

2 DR. MONSEES: Are there any specific ones on the
3 AEC adjustment? Would you treat them all the same, or would
4 you isolate one or two of them and have it be different from
5 the others? Do you think they should all be treated the
6 same here?

7 MR. PIZZUTIELLO: I am comfortable treating them
8 all the same. In fact, I would like to add one item that is
9 very frequently, in fact most frequently, performed, and
10 that is to adjust the "normal density up or down," because
11 it is relatively common that you find that facilities have
12 their images more often too light, but occasionally too
13 dark. It is very easy to say to the service engineer, take
14 the density that is normal that used to be 1.4 and make it
15 1.65. If they do that and shoot a phantom to verify it,
16 then I do not think there is any need for a physicist to go
17 there, but since that is the most common change, I would
18 like to see it listed in the examples.

19 DR. MONSEES: So how would you suggest the wording
20 be, "to the extent by the medical physicist"? How would you
21 advise FDA?

22 MR. PIZZUTIELLO: I think you could use the word
23 "oversight," but if we put the "professional judgment" into
24 the phrase of the definition at the bottom, "physicists must
25 be consulted and then should use their judgment to

1 determine," and this is the question about regulations
2 versus the practice. If you need to make the issue a major
3 repair, that is probably less of a judgment. The question
4 is how do you verify that what has been done is correct.

5 DR. FINDER: I think one of the things we have to
6 keep in mind is that we are dealing within regulatory
7 limits. If we call something a major repair, then within
8 the regulations, we have very little leeway. The medical
9 physicist has to be there.

10 So, if you are going to define something as not a
11 major repair, then we cannot require the physicist to come
12 whether they think it is in their judgment or not. Once it
13 is no longer a major repair, it is outside the realm of they
14 have to be there. So we have to be careful.

15 The situation, obviously, is one thing if you are
16 dealing with everybody who feels comfortable with everything
17 else, but when you come into other situations where the
18 facility will then say, "Well, I do not have to bring in the
19 medical physicist because I am not required to," we lose any
20 kind of leeway in dealing with that situation.

21 If you think that these are not major repairs--and
22 we have tried to base it on what you were talking about--is
23 an adjustment or repair to this, will it affect clinical
24 image quality, will it affect dose, if it does, our feeling
25 was this is a major repair. It is worth having the medical

1 physicist check on this and make sure that it is okay. If
2 it is not a major repair, if it does not affect those
3 things, then we have a lot more leeway in what we can
4 recommend. Again, once it is not a major repair, anything
5 we say is a recommendation. It is not a requirement.

6 MR. PIZZUTIELLO: When you look at the AEC, it is
7 defined in the regulation as a major repair. If it is
8 replacement of the entire AEC system or sensor, these would
9 be considered AEC adjustments. So perhaps we might want to
10 create another category where the oversight verbiage stays
11 the same because it refers to major repairs, but to create a
12 third category that says professional judgment, consult your
13 medical physicist and the physicist should use their
14 judgment, and that would apply to items that are not
15 enumerated as those being a major repair. These AEC
16 adjustments would fall into that category.

17 DR. MONSEES: Since this is a major item here, do
18 we have any comments from ACR or anybody else who feels
19 differently about this?

20 Yes. Please come up to the mike.

21 You might want to comment on the guidance.

22 MS. BUTLER: I think in support of what Bob was
23 just saying in the manual--we have a table and this was
24 developed in concert with the FDA, what consisted a major
25 repair. We have got X-ray two replacement, collimator

1 replacement, filter replacement, AEC replacement, referring
2 to the sensor or system controller.

3 I think we are throwing some new things into the
4 mix with this table. There is really only the filter
5 replacement in there and maybe possibly addition or
6 subtraction of the filtration, if you consider that a
7 replacement, that would fall under what we have in the
8 manual.

9 So I would support Bob's point that these other
10 things should not be discussed in terms of major repair. If
11 the FDA would like to provide guidance on these QC tests
12 that failed, whether a medical physicist needs to be there
13 or not should fall back on the professional judgment of the
14 medical physicist.

15 DR. MONSEES: Thank you.

16 So perhaps this table should include other items
17 that are in fact real major repairs, and it should include
18 not only these, but the additional items.

19 This is such an important point, really, when they
20 call them and when they do not. Maybe it should be more
21 inclusive in this particular table.

22 MR. PIZZUTIELLO: This particular table is labeled
23 tests that fail, when you fail a QC test.

24 DR. MONSEES: Right.

25 MR. PIZZUTIELLO: That is not quite the same as

1 those things which require a mammography equipment
2 evaluation. So maybe a little explanation that says
3 remember that if it requires mammography evaluation, see the
4 other reference in this area. If you just picked up this
5 table and glanced at it, it would be easy to confuse the
6 two.

7 What this is saying, if I go in as a physicist and
8 I find that the photo timer needs some adjustment, do I have
9 to then go back physically, personally, retest it, or if I
10 tell the service engineer to fix it and they send me some
11 data and I look at it and I have instructed them as to what
12 to do, would that be acceptable? I think that is a matter
13 of professional judgment.

14 DR. MONSEES: I think it might be better if the
15 title were changed, then, also, and it were more inclusive
16 and it was guidance as to when the medical physicist should
17 be involved and then list all of these things plus more, the
18 things that were perhaps in the manual that are clearly
19 replacement, and then make sure and delineate every
20 particular item.

21 If it is not all in one place where people can
22 look it up in a single place, it is going to be difficult
23 for them to navigate the system. I think it will be
24 clearer.

25 DR. MOURAD: Walid Mourad, FDA.

1 May I suggest, then, that the committee would
2 perhaps suggest that we create a new question to expand on
3 what does not constitute a major repair here, such as AEC
4 adjustment and other things that we have lumped into the
5 major repair category. This way, then we could easily do
6 these as oversight, as you said.

7 In other words, AEC adjustment, you have just told
8 me that that is not a major repair, and perhaps there are
9 other things here that may not fall under a major repair,
10 even though they are in the realm of or close to the issue
11 of a major repair.

12 DR. MONSEES: To clarify what you are asking us to
13 do, are you asking us to write a question now, or are you
14 asking us for feedback? What does FDA need on that?

15 DR. MOURAD: Give us some thoughts, and we can
16 formulate the question and answer.

17 DR. MONSEES: Thank you.

18 So suggesting that we give some feedback, not
19 necessarily now, in writing, would you be willing to do some
20 of that?

21 MR. PIZZUTIELLO: Yes.

22 DR. MONSEES: I think we have a question from the
23 back here.

24 MR. McCROHAN: John McCrohan from FDA.

25 I do have a concern, and I am not sure what your

1 reaction is to it. I think we can find ourselves in a
2 logical conundrum if we say that certain things, let's say,
3 don't constitute a major repair. You found a problem. The
4 fix of that problem is not a major repair. Therefore, the
5 medical physicist does not have to come back in, but you
6 want somebody to check on that.

7 The check is, in essence, a test which the medical
8 physicist is responsible for doing as part of the annual
9 survey or the equipment evaluation. We have come to the
10 conclusion that the medical physicist has to do those tests
11 because only a medical physicist is qualified to do those
12 tests.

13 So, if there are circumstances in which we see
14 the right to do those tests to someone who is not a
15 qualified medical physicist, I am not sure where that ends.
16 I think we may create for ourselves some difficulty in
17 drawing a clean line on when the medical physicist is
18 required to physically be on site to do the work and when
19 not.

20 We have had a lot of questions about can medical
21 physicists send in surrogates who are not themselves
22 qualified medical physicists, but with whom they may be very
23 familiar or they may have supervised them and so on and so
24 forth to do certain of those tests with medical physicists
25 not on site. We have seen that as problematic. It is just

1 a concern.

2 I understand what you are saying, and I am not
3 suggesting that that does not make sense, but, I think we
4 can cross over that line and get into a situation where it
5 is going to be difficult to defend the position that medical
6 physicists and only medical physicists can do certain things
7 in certain circumstances.

8 MR. PIZZUTIELLO: I think I have a logical
9 solution to that. We have already made the case in the past
10 that when a facility gets--when a medical physicist does
11 their annual survey, we test the screen speed. When a
12 facility gets a new batch of screens, a new batch of
13 cassettes, those cassettes can be tested by someone who is
14 not the medical physicist because that test is not being
15 performed as one of the enumerated annual tests that can
16 only be performed by a medical physicist. Those data get
17 sent up to the medical physicist.

18 In the example that I gave, the physicist does the
19 annual survey. The annual survey is complete. Then there
20 is some follow-up work which is done, which any follow-up
21 work would not be done in the context of an annual survey.
22 It gets follow-up. It is something else.

23 The professional rationale is that the difference
24 is I as a medical physicist have already made some
25 measurements on this machine recently. So, when I get some

1 other data in from a surrogate, I compare them with what I
2 know the machine was doing a week or 2 weeks before, and I
3 know if it is reasonable and consistent or not. Whereas,
4 the annual survey, it has been a year since the last thing
5 has been tested. So there is no way to make a comparison.

6 Does that logic help?

7 DR. FINDER: Yes.

8 DR. MONSEES: I think probably another draft could
9 be drawn up here with some input. Then it could be passed
10 around and shown back to the panelists for comment. Does
11 that sound like a good plan here?

12 DR. FINDER: I would be very interested if you
13 would come up with a list. We would be happy to take a look
14 at it.

15 MR. PIZZUTIELLO: Certainly.

16 DR. FINDER: Again, this is a document that is
17 still in its early stage. Of course, the sooner you get it
18 back to us, the sooner we can actually get it out for public
19 comment.

20 MR. PIZZUTIELLO: Just so I understand what you
21 are asking me to do, it is to come up with a list of things
22 which are not major repairs, but require some follow-up.

23 DR. FINDER: While you are at it, since you are
24 going to be doing this, why don't you come up with a list of
25 what is a major repair that requires a physicist there, what

1 is not a major repair, what could be a major repair, all the
2 possibilities.

3 I do not want to be facetious about this, but
4 these are the conundrums that we try and deal with in terms
5 of every time we think of a situation, somebody else comes
6 up with more situations. So we either try and make it as
7 complete as possible, or we stay more in generalities. If
8 it is the feeling of the committee that we should go down to
9 the specific level, the more detail probably the better.
10 Then we could have one table that somebody could look at it
11 and just scan it and see what they need to do.

12 DR. MONSEES: Or, to have another question that
13 follows this one, what is considered a major repair, and
14 then everything the committee does, perhaps review all of
15 those things that are in the ACR QC manual, et cetera, so
16 that there is some consistency.

17 Are there any other comments regarding this last
18 table? Otherwise, we are done with this document.

19 Yes.

20 MR. PIZZUTIELLO: Another comment is should there
21 be some comment about the time limit for evaluating the
22 appropriateness of the corrective action. I am thinking in
23 particular because if we have a mammography equipment
24 evaluation, the facility replaces an X-ray tube, the
25 physicist needs to come in and verify certain specified

1 performance parameters before the first patient.

2 My question is in these areas, where they are not
3 major repairs, perhaps there should be a time frame, but I
4 do not believe it should be before the first patient. I
5 think that would be unnecessary. I would think something
6 like 30 days after the corrective action is taken. Whatever
7 we say needs to be done to verify that the corrective action
8 has been taken, this is when a QC test fails, that it be
9 done within 30 days of the corrective action.

10 DR. MONSEES: Isn't there already a table that
11 stipulates the corrective action timeline--

12 DR. FINDER: Yes.

13 DR. MONSEES: --for the QC tests that fail?

14 MR. PIZZUTIELLO: That is the corrective action.

15 Now we are talking about the medical physicist being
16 involved at some level in verifying that the corrective
17 action has been done.

18 I do not think anything has been said heretofore
19 about that, and I just want to be sure that we do not have
20 inspectors interpreting this as saying, "Well, when an MEE
21 is done, the physicist has to do it before the next
22 patient," wouldn't that apply here, and I think it would not
23 apply here.

24 DR. MONSEES: So how should we handle that?

25 DR. FINDER: I think I see where you are going.

1 Not having a chance to really spend a lot of time thinking
2 about that specific topic, I think we would significantly be
3 constrained because there is no regulation regarding this.
4 Anything that we would come up with probably would end up
5 being a recommendation, unenforceable.

6 For example, I could imagine the following
7 situation where one of these tests goes astray. If under
8 your scenario the medical physicist consulted either side,
9 it is not a major repair, he tells them how to fix it, it
10 gets fixed, that might not be looked at again by the medical
11 physicist for another year.

12 MR. PIZZUTIELLO: Exactly. Is that what you want?

13 DR. FINDER: Is it what I want? No, but the
14 question is under the scenario you are talking about,
15 probably we would be limited to enforcing because I do not
16 think we can come up with an arbitrary thing and say within
17 30 days the medical physicist has to do some type of
18 verification, and the question then is what kind of
19 verification. Does he have to come in and repeat the test?

20 Think about it.

21 MR. PIZZUTIELLO: The problem is we are now saying
22 that there needs to be some verification of the corrective
23 action, which we have never said before and is not in the
24 regulation. So perhaps the only thing that you could say in
25 the guidance document is that there is nothing in the

1 regulation about the timeliness of this, but I suspect that
2 you would find places saying, "Well, it will only be 11
3 months until you come back again. You can check it out
4 then." I think there is a flaw in that logic because, if it
5 is important enough to conduct some verification that the
6 problem was fixed, then I do not think it was reasonable to
7 wait 11 months because what if it was not right.

8 DR. FINDER: Exactly, exactly. I do not know how
9 we get at it, but we can look at it and see what we can come
10 up with.

11 DR. MONSEES: Mr. McCrohan, did you have a comment
12 on that?

13 I will get to you, Dr. Sickles, next.

14 MR. McCROHAN: McCrohan, FDA.

15 This is more in the nature of a question, and that
16 is, when in your view is the corrective action taken or
17 complete? Apparently, it is complete before anybody has
18 done any verification, but it was done correctly.

19 I think one could equally well argue that the
20 corrective action is not complete until some verification
21 has been made. I think the question has been who does the
22 verification. I think you have made some cogent points
23 about there are circumstances in which the medical physicist
24 ought to be consulting with some other individual who is
25 actually going to make the repair and I would have presumed

1 done some verification. So I guess that raises the
2 question, then, does the medical physicist only consult at
3 the front end or do they actually look at the data after the
4 verification is done and is that the point of closure when
5 the medical physicist looks at that information in their
6 consultative capacity and says it looks okay to me.

7 If that is the case, then I think that sort of
8 plays into the issue of the 30-day or
9 before-the-next-patient time frame, depending on what test
10 it was that led to the issue in the first place, all in the
11 context of the repair is not a major repair.

12 DR. MONSEES: Dr. Sickles?

13 DR. SICKLES: As I understand this, hearing the
14 discussion, it would seem to me if the medical physicist is
15 making a professional judgment about how he or she gets
16 involved in the specifics of the particular case, if it is
17 that person's judgment that this can be done remotely and
18 they are willing to outsource it, if you will, then they
19 could specify certain action limits to the person who is
20 doing it or to the facility saying if these parameters are
21 maintained, it is okay to start doing patients, if they are
22 not, it is not okay and I will have to come.

23 You can probably figure out a way to put that into
24 the language of the table, and that is really what you
25 should be looking to do.

1 DR. MONSEES: Does that sound like it is workable?
2 MR. PIZZUTIELLO: I think that is okay as long as
3 it is clear that it is the medical physicist who makes the
4 decision. Ultimately, I think that means looking at the
5 data because it is hard to say up front what all the
6 possibilities are. The practical answer, as I think John
7 mentioned, is if you consider that the corrective action is
8 complete, when it has been verified that the work has been
9 done properly, that is a pretty reasonable interpretation.
10 Then it solves the problem about what kind of time frame it
11 is.

12 It makes it a little bit tougher because it means
13 the corrections have to be not only made, but evaluated
14 within the 30-day time frame. I think it is the cleanest
15 solution.

16 DR. MONSEES: It also raises the question of what
17 we talked about before regarding the equipment evaluation
18 report. Does this need to be in writing? Is verbal enough?
19 Is it okay for the facility to just document what the
20 physicist said, or does something need to be in writing and
21 in hand before they can proceed?

22 Would you like to comment on that? Who is
23 documenting that this is done?

24 MR. PIZZUTIELLO: The physicist needs to make a
25 determination as to whether the corrective action was

1 sufficient, needs to let the facility know. The facility
2 needs to document that. I think that is all we should say.

3 I personally think it would be a good idea for the
4 medical physicist to issue a short note, but I do not know
5 that we need to require that because the same sort of
6 technologist documentation could be done. This test failed.
7 I talk to the physicist today. He reviewed the films that
8 we sent and the data, and the physicist says everything is
9 okay. I think that handwritten documentation from the
10 facility would be reasonable, and I do not want to make it
11 unnecessarily complex.

12 DR. MONSEES: I agree. I just want to make sure
13 that it was discussed.

14 DR. SICKLES: I agree with all that, but I think
15 you have to leave the physicist the option to require more
16 in a specific circumstance. That is the lesser end of the
17 spectrum, but there may be a more stringent end, depending
18 on the circumstance of the case.

19 DR. MONSEES: Any other comments on this document,
20 then? I think we are at closure here for this document.
21 Any other comments on this?

22 DR. FINDER: I just want to check one thing. So
23 there is agreement that the artifact caused by filter, the
24 medical physicist has to be there. Is that correct? Same
25 for kVp adjustment, an addition or subtraction of

1 filtration?

2 MR. PIZZUTIELLO: I would not agree with the kvP
3 adjustment. I think, again, that could be a matter of
4 professional judgment. It is not a major repair. If the
5 physicist is confident that the service engineer made the
6 adjustment and agreed, fine.

7 Sometimes what happens is you make a measurement
8 of kvP, and the service engineer says, "Yes, you were right.
9 I made the adjustment." In that case, that is probably
10 sufficient.

11 But if the service engineer says, "I think you are
12 nuts. I am perfectly happy with the results," then I think
13 that would not be sufficient. Then the physicist needs to
14 be back in.

15 DR. MONSEES: Any other specific ones you want to
16 go through?

17 [No response.]

18 DR. MONSEES: Any other comments here? Last
19 chance on this document.

20 [No response.]

21 DR. MONSEES: Okay, we are complete here.

22 We are going to make an adjustment here, and Dr.
23 Finder is going to go to the next item which will be the
24 awards, I guess, presentation of awards, near the end. When
25 we are done with that, we are going to do the full field

1 digital mammography certification update.

xx

2 DR. FINDER: I just wanted to mention our thanks
3 to three of the members who are completing their terms at
4 the end of this meeting. Actually, their terms expire at
5 12:00 midnight tonight. So we have to make sure that we get
6 them home beforehand. Otherwise, they yank them of the
7 plane and that is it, they have to stay wherever they are.
8 So we have to make sure that they get their awards and are
9 on their way home sometime.

10 The people that are leaving are Dr. Laura
11 Moore-Farrell. I would like to give her an award, and I
12 will read these in a second. Ms. Patricia Wilson.

13 DR. SICKLES: You just have to mail it.

14 DR. FINDER: And Dr. Edward Sickles.

15 Actually, let me keep this for a second so I can
16 read what it says. Really, I just do not want to give it to
17 Ed.

18 [Laughter.]

19 DR. FINDER: It is a certificate of appreciation,
20 and it is being given to these three people in recognition
21 of distinguished service, National Mammography Quality
22 Assurance Advisory Committee, signed by the Commissioner of
23 the Food and Drug Administration.

24 [Applause.]

25 DR. FINDER: In addition to those plaques, they

1 also are receiving letters, and I just would like to read
2 what it says: "I would like to express my deepest
3 appreciation for your efforts and guidance during your term
4 as a member of the National Mammography Quality Assurance
5 Advisory Committee. The success of this committee's work
6 reinforces our conviction that responsible regulation of
7 consumer products depends greatly on the participation and
8 advice of the non-governmental health community. In
9 recognition of your distinguished service to the Food and
10 Drug Administration, I am pleased to present you with the
11 enclosed certificate. Sincerely yours, Jane Henney,
12 Commissioner of Food and Drug."

13 DR. MONSEES: Thank you. We will miss you. We
14 will miss you.

15 DR. FINDER: I do want to say one thing. I want
16 to give my own sincerest appreciation for all the work that
17 you have done and the effort that you have put into it.
18 Just the fact that you are here at this meeting indicates
19 the perseverance that you have put into this meeting, to say
20 nothing of the fact that when I told you that if you did not
21 come to this meeting, you would have to stay for another
22 year. I guess that does work.

23 With that, thank you very much.

24 [Applause.]

25 DR. MONSEES: Now we are going to move onto full

1 field digital mammography certification update.

2 Helen Barr. Do you want to state your title, or
3 should I?

4 DR. BARR: I am Dr. Helen Barr. I am the deputy
5 director of the Division of Mammography Quality and
6 Radiation Programs with the FDA.

7 My presentation is going to be very brief. I was
8 one of the kids who did count on school today. So I did not
9 do all my homework.

10 I am pleased to announce that on Friday, January
11 28th, 2000, after about 5 years of strenuous labor, General
12 Electric gave birth to the Centigraph 2000-D full field
13 digital mammography system on the market. The system went
14 through the pre-market approval process and was approved for
15 marketing this past Friday. It is reported that FDA and GE
16 are both doing fine.

17 When it became clear to us that eventually a full
18 field digital would be approved for marketing, of course, we
19 were looking to how that was going to fit in with the rest
20 of our program.

21 Last fall, the American College of Radiology let
22 us know at that point in time that for the near foreseeable
23 future, they did not see an accreditation process being in
24 place. So we were left with several options to look at,
25 which we have done since that time, of when digital came on

1 the market, what we would do with it, vis-a-vis MQSA.

2 After looking at many options, we decided that the
3 best way to proceed was to specify that full field digital
4 mammography units could only be used in already MQSA
5 screen-film-certified facilities. Without an accreditation
6 program, this was at least a way that we would have some
7 oversight as to some quality control aspects of digital
8 mammography as well as personnel requirements.

9 What FDA has told GE is that until such time as an
10 FDA-approved accreditation process is in place, full field
11 digital mammography can indeed only be used in
12 screen-film-certified facilities, already certified by MQSA.

13 What we will do is require a number of the
14 facilities to submit to us some pieces of information which
15 will then extend their current MQSA certificate to include a
16 full field digital unit, and the general categories of what
17 we would be requiring from the facilities are a list of
18 current personnel and those working in digital mammography,
19 both on the interpreting and technical sides, both prior to
20 April 28th, 1999, and after April 28th, 1999, and the
21 personnel after the April 28th date would need to have
22 verification that they received the 8 hours of new modality
23 training.

24 The FFDM machines would also require an equipment
25 evaluation, and the facilities would also be required to

1 follow the manufacturer's guidelines for quality assurance
2 and quality control tests, and those are the general
3 categories of what we would be asking for.

4 The full field digital units are exempt at this
5 time from an accreditation process, but do need to meet
6 these other requirements.

7 We hope that this will be a relatively seamless
8 process for the facilities. The facilities that already
9 have digital units in place will be continuing to use those
10 full field digital units while the information that we
11 require to be submitted is being evaluated.

12 There was no magic on Friday afternoon where those
13 facilities already with digital units would have known that
14 the color of the unit changed and it was now under MQSA. So
15 we expect and endorse that they will continue to be using
16 them while we evaluate their information.

17 Facilities that will be newly purchasing or
18 acquiring a digital unit after the equipment evaluation is
19 performed, just as in the accreditation process, the
20 facility will be able to use the unit while the remainder of
21 the information to extend their certification to include a
22 full field digital unit is evaluated.

23 DR. MONSEES: I would like to ask a question. Did
24 you mention whether or not they are accredited for use for
25 hard-copy display only? Could you comment on that,

1 hard-copy versus soft-copy display?

2 DR. BARR: At the current time, with the ODE
3 approval, only hard-copy interpretation is approved at this
4 time.

5 DR. MONSEES: Another question. You said that
6 they are exempt, but that it has to be at facilities that
7 are already certified. Are you stipulating as well that the
8 personnel have to be the same personnel, and that additional
9 personnel cannot come work at that facility unless they are
10 listed among the qualified personnel?

11 DR. BARR: Additional personnel would have to meet
12 the MQSA requirements, and if interpreting digital
13 mammography after April 28th would need to meet the
14 additional modality training requirements.

15 DR. MONSEES: The personnel are not exempt?

16 DR. BARR: Right. Both the facility and,
17 therefore, the personnel would need to remain under the
18 certification. The facility would have to maintain its
19 certification as a screen-film facility and, i.e., therefore
20 its accreditation.

21 DR. MONSEES: What I am getting to is that they
22 cannot hire a tech to come do the digital who is not also a
23 qualified tech listed--

24 DR. BARR: That is correct.

25 DR. MONSEES: Okay.

1 DR. BARR: Also, the full field digital units will
2 be at some point in time in the near future begin to be
3 subject to inspection at the time of the annual MQSA.

4 DR. MONSEES: Do we have any other questions or
5 comments from the panel?

6 Yes.

7 MR. PIZZUTIELLO: This is the GE 2000-D that has
8 been approved.

9 DR. BARR: Yes.

10 MR. PIZZUTIELLO: Can you comment on the status of
11 any other digital systems that might be in the pipeline for
12 approval?

13 DR. BARR: I cannot. Sorry.

14 DR. MONSEES: All right.

15 DR. BARR: I would like to ask Penny Butler to
16 step forward and talk about the ACR's program. Then, if you
17 have any questions after her presentation for both of us, we
18 can answer them.

xx 19 MS. BUTLER: And I thought I was going to get out
20 of this.

21 I wanted to talk a little bit about the digital
22 mammography accreditation activities and maybe start off a
23 little bit, because we have a number of people who are on
24 the committee who are not really familiar with the ACR
25 accreditation process, just talk a little bit about the

1 accreditation process in general.

2 We currently have a limited number of
3 accreditation programs that are available right now. There
4 is a mammography accreditation program which is, of course,
5 the largest and one of the earliest. We also accredit
6 ultrasound facilities and MRI as well as radiation oncology
7 and nuclear medicine. We are also in the process of
8 developing accreditation programs for computer tomography,
9 radiography, fluoroscopy, and interventional vascular.

10 These accreditation programs have been developed
11 over the years with committees which are assembled
12 consisting of professionals who have been involved with the
13 modality for a considerable length of time. They have lots
14 of experience of the clinical aspects of the procedure that
15 needs the requirements, the quality control aspects of the
16 procedure, and all the problems associated with them.

17 Even MRI, which is one of the relatively more
18 recent new technologies that are out there, there was a
19 number of years that went by before we started accrediting
20 MRI.

21 So, when we started looking at digital, we ran
22 into a problem in that we did not have a clinical in-use
23 widespread basis for coming up with standards that pertain
24 specifically to digital mammography because obviously it was
25 not approved by FDA yet and the clinical studies were still

1 going on.

2 So, recognizing the need and working with FDA on
3 what their time table was to approve this new technology, we
4 had a meeting with the Mammography Accreditation Committee
5 at RSNA to talk about how we can fast-track this
6 accreditation and the best way to approach this.

7 The Mammography Accreditation Committee decided
8 that rather than developing a separate accreditation program
9 for digital, it was going to be in module under the existing
10 mammo accreditation program. This way, we could utilize a
11 lot of the similarities between the two modalities.
12 However, there would be a separate whole series of questions
13 and perhaps types of tests that would have to be done as a
14 result of that.

15 We set up a digital subcommittee to address some
16 of these specific issues, and they are now in the process of
17 designing a pilot program. We have got to look--and in
18 fact, the subcommittee has sat down and looked through some
19 of the manuals that we have been able to get a hold of, the
20 quality control guidance that is available from the
21 manufacturers to look at what QC tests they are
22 recommending, because we are going to be basing our
23 requirements on what the manufacturers are requiring at this
24 point in time.

25 There are also other technical challenges in that

1 at least one of the manufacturers has an X-ray tube which is
2 significantly different from the others. So our
3 measurements of dose is going to have to be a little bit
4 different, and we have to get the calibrations in place.

5 So we are currently devising the administrative
6 and technical tools to run the pilot tests. Once we
7 conduct the pilot test for this module, we are going to not
8 only include the General Electric products, but we are also
9 going to include the major digital imaging systems for
10 mammography, full field digital, that are currently
11 undergoing clinical testing. So, when they get approved
12 down the road, we should be ahead of the game.

13 Also, going along with what Helen just said, we
14 are going to be requiring at this point in time some issues
15 of hard copy for clinical image evaluation. We have to make
16 sure that our reviewers are trained and experienced in
17 digital imaging. So there are a number of other hurdles to
18 leap over.

19 Our estimated guess at this point in time, we are
20 doing the pilot program, evaluating the results, making the
21 modifications that always come at the end of a pilot
22 program, and then getting approval through our organization.
23 We are talking about probably being ready in between 18 and
24 24 months with an accreditation program.

25 We are trying to move this along as quickly as we

1 can. We hope to do better than this, but I am looking at
2 that on the outside.

3 That is all I have got.

4 DR. MONSEES: Thank you.

5 Any questions or comments from the panel for Ms.
6 Butler?

7 Dr. Sickles has a comment.

8 DR. SICKLES: I just want to make a comment. I do
9 not mean for it to rock the boat, but as a current user
10 experimentally of digital mammography, it is my intention
11 never to read hard copy. I will be willing to provide
12 hard-copy images for accreditation so that people can judge
13 image quality, but if digital mammography were forced to be
14 used hard copy, it is a dead technology. It will work only
15 with soft-copy viewing because that is how it will become
16 worked into the daily process of a department. It is not
17 cost effective any other way.

18 So, ultimately, if there is no easy solution to
19 clinical image review by some kind of electronic means,
20 every department will still have to have a hard-copy system
21 to be able to at least satisfy accreditation.

22 MS. BUTLER: Just to comment on this, the college
23 recognizes the trends in all of imaging now to go into
24 soft-copy reads. We also have a situation of dealing with
25 the reality. We have got to get this program going as soon

1 as possible. Our ultimate goal is to be able to do that.

2 DR. MONSEES: Yes.

3 MR. PIZZUTIELLO: I might also mention that we had
4 this same issue with the stereotactic breast biopsy
5 accreditation program, and while facilities largely do
6 digital imaging, they need to submit hard copy, even though
7 not every facility has the hard-copy capabilities. The
8 manufacturers have come up with a method where the facility
9 provides them, the manufacturer, with electronic images, and
10 the manufacturer generates the hard-copy images which can be
11 submitted and reviewed for accreditation.

12 So the accreditation by hard copy does not in any
13 way restrict the interpretation by soft copy because,
14 clearly, the stereotactic images are accredited largely in
15 soft copy.

16 MS. BUTLER: I do want to point out one other
17 thing regarding the hard copy/soft copy issue. Under MQSA,
18 there is a requirement that the original films be available
19 to the patient so they can take them when they are moving
20 and going to another facility. There is going to be a
21 number of years before the rest of the facilities across the
22 United States are able to catch up. So some mechanism for
23 providing this hard-copy film to patients is going to have
24 to be available for a while.

25 DR. MONSEES: Yes.

1 DR. SICKLES: Not just for a while. Probably
2 forever because there will always be places which are not
3 digital, and there certainly will be non-interpreting
4 physician providers who will need to look at these images
5 who will have no access to a work station. So there will
6 always be the need for a hard copy.

7 You should and you must put this on a fast track
8 and get it going as soon as possible. That is priority one,
9 but also, I think it would be shortsighted to think in terms
10 of requiring use, not accreditation, but use only on the
11 basis of hard copy because use is going to be soft copy.

12 DR. MONSEES: Thank you.

13 We are going to move on, then, to the presentation
14 on States as certifiers.

15 DR. FISCHER: Kay is snowed in.

16 DR. MONSEES: Oh, she is snowed in.

17 Ruth Fischer is going to make this presentation.
18 She is the chief of the Mammography Standards Branch.

xx 19 DR. FISCHER: This is going to be extremely brief.

20 The program is going along well. We still expect
21 the State of Texas, who is here represented today, to join
22 the program sometime this year.

23 The one area that we are seeing will be critical
24 for the regulatory program is adequate staffing, and we may
25 make some changes in that area based on the demonstration

1 project.

2 The proposed regulation is now in its last hurdle,
3 which means it is at the Office of Management and Budget.
4 It went there December 21st. So we expect it to be out
5 March 21st, and publication for 90-day comment in April. So
6 I think we are going to make that.

7 That is it.

8 DR. MONSEES: Thank you.

9 Any questions from the panel? Comments?

10 [No response.]

11 DR. MONSEES: Thank you.

12 We are going to move to the discussion of the
13 voluntary stereotactic accreditation programs, and we are
14 going to call upon Penny Butler from the ACR again. I
15 believe on the original, Dr. Winchester was going to present
16 for the American College of Surgeons, but I do not think he
17 could come as well because of weather. Dr. Finder is going
18 to make some comments as well.

19 Do you have slides or verbal presentation?

xx 20 MS. BUTLER: Verbal, just verbal.

21 Since the last time we met, there has not been a
22 significant change in the status of the accreditation
23 programs in terms of the number of facilities that have
24 applied.

25 We currently have 473 facilities that have applied

1 for accreditation or is in some stage of the accreditation
2 process through the American College of Radiology and 365
3 that have been accredited.

4 We are not seeing a tremendous influx of
5 applications.

6 DR. MONSEES: Can you break down or give us any
7 information regarding surgeon's use of the equipment and
8 accreditation? Do you have any numbers there?

9 MS. BUTLER: No, although I do have the number
10 from the American College of Surgeons.

11 DR. MONSEES: Okay.

12 MS. BUTLER: Charlie is going to be presenting
13 that.

14 DR. MONSEES: The total universe is what, and,
15 therefore, at what percentage are we at here?

16 MS. BUTLER: About 3,000 that we expect across the
17 United States.

18 DR. MONSEES: So we are still a low percent, under
19 15 percent, something like that?

20 MS. BUTLER: Yes.

21 DR. MONSEES: Any comments here or questions?

22 MS. BUTLER: One thing I would like to say is that
23 at RSNA, we did make available the quality control manual
24 for stereotactic which Bob Pizzutiello was heavily involved
25 with. It has gotten a very good reception, and it is

1 currently being mailed to all facilities that are in the
2 process of accreditation or who are accredited.

3 DR. MONSEES: So those facilities that have not
4 even applied would not have access to the manual unless they
5 knew about it and requested one.

6 MS. BUTLER: That is correct.

7 DR. MONSEES: Do you have any other comments
8 before we see what Dr. Finder has to say from Dr.
9 Winchester?

10 MS. BUTLER: No.

11 DR. MONSEES: Dr. Finder, do you have something to
12 read, a report from Dr. Winchester?

xx 13 DR. FINDER: This is Dr. Finder.

14 I am just going to read a list of accomplishments
15 that were sent to me by Dr. Winchester regarding the
16 American College of Surgeons stereotactic breast biopsy
17 accreditation program. This covers the years 1998 to 1999.

18 Jointly developed and approved, physician
19 qualifications for stereotactic breast biopsy in February
20 1998. This was published in the Bulletin of the American
21 College of Surgeons in May of 1998. The statement can be
22 viewed on the ACS web site. It is www.facs.org.

23 Also, accreditation services agreement between the
24 ACS and the American College of Radiology became effective
25 July of '98. In October 1998, 13,200 practicing general

1 surgery fellows of the ACS were surveyed to assess their
2 experience and/or interest in stereotactic breast biopsy and
3 participation in verification and accreditation.

4 They held an administrative planning meeting with
5 the ACR in October of 1998, developed an accreditation
6 packet and internal process for verification review,
7 reporting, and accounting procedures in December of 1998.
8 They established a committee chaired by David Winchester and
9 held conference call meetings in January, March, June,
10 September, and December of 1999. They have developed a
11 stereotactic database and processed applications from three
12 facilities which were forwarded to ACR for survey in 1999.
13 They have published their survey results in the May 1999
14 bulletin, provided program updates and resource information
15 to the fellows via electronic news service, Newscope, in
16 May, June, and July 1999.

17 They recommended 27 qualified surgeons to serve as
18 instructors to the Education and Surgical Services
19 Department. They have standardized courses that satisfy all
20 requirements and have been taken by over 1,000 participants
21 at regional spring meeting and clinical congress since 1996,
22 and two courses will be offered again in the year 2000.

23 They have prepared slides and handouts and
24 introduced the ACS stereotactic accreditation program at the
25 Virginia College Chapter and Commission on Cancer meetings

1 in 1999. They have appointed three surgeon reviewers for
2 team surveys.

3 In answer to your last question, they have mailed
4 out 200 application packets in response to requests so far.

5 DR. MONSEES: So did I hear those numbers right?
6 They sent out 200 applications, but only three facilities
7 have been forwarded to the ACR?

8 DR. SICKLES: Those are the ones they have passed.

9 DR. FINDER: So far, and that is an old number.
10 Let me see where that came from. That was probably earlier
11 in terms of--I do not have an exact date when those three
12 facilities went through, but like I say, they have sent out
13 200 application packets.

14 DR. MONSEES: Some of them where the surgeon is
15 practicing in conjunction with the radiology may have been
16 submitted not through the American College of Surgeons,
17 correct? Are we undercounting here how many surgical
18 facilities have applied and been approved?

19 MS. BUTLER: This is Penny Butler from ACR.

20 We currently have three active applications
21 through the American College of Surgeons at ACR, and one
22 facility accredited. I believe there are some surgeons that
23 are included in the ACR applications, and we do not have a
24 breakout of that.

25 DR. MONSEES: So we do not really know how many of

1 the interested surgeons that answered this survey would have
2 already been accounted for by applying with radiologists,
3 correct?

4 MS. BUTLER: That is correct. I do not have that
5 figure with me.

6 DR. MONSEES: So, of the 27 qualified surgeon
7 teachers, one would hope that all of them are accredited.
8 Clearly, there are not 27 applications through the American
9 College of Surgeons that have been approved.

10 MS. BUTLER: No.

11 DR. MONSEES: Hopefully, they are in conjunction
12 with radiologists.

13 Comments from the panel on this?

14 DR. SICKLES: I do not believe there is a
15 requirement that a teacher has to be part of an accredited
16 program.

17 DR. MONSEES: That is correct.

18 DR. SICKLES: It is quite possible that some of
19 the people who are experienced enough to be teachers simply
20 have not gone through the accreditation process. That is
21 quite possible.

22 DR. MONSEES: Right. I was just making an
23 observation. I was not saying there was a connection
24 necessarily.

25 Do you want to make a comment as to what the

1 surgical community maybe can do or what they are doing to
2 try and increase participation with voluntary accreditation?

3 DR. DOWLAT: My overall impression is that the
4 surgeons are somewhat like radiologists. They are reluctant
5 to go yet through another administrative paperwork, not
6 mentioning the fee which has to be paid. The overall sense
7 is that there is too much burden on them through the managed
8 care, and this is yet something else to do.

9 I think, having spoken to radiologists and to
10 surgeons over the past month, that is the impression I get,
11 how we can encourage them to go forward with this program.
12 It is a little bit of a dilemma.

13 Maybe we can crack that nut over the coming
14 months. Hopefully, it will not be regulated by FDA.

15 DR. MONSEES: Do we have any other comments from
16 the panelists?

17 Yes.

18 MR. PIZZUTIELLO: For the last 4 years or so, I
19 have been teaching as part of the surgeons training program
20 for stereotactic procedures, teachers in physics, and my
21 observation when this subject has been brought up has been
22 very much in support of what Dr. Dowlat said. There is in
23 general a reticence to do more.

24 So, while we had hoped that there would be a
25 greater support of the voluntary program in order to avoid

1 the Federal regulation, I think in fact we have found the
2 opposite. There has not been a great interest in support of
3 the program, and I have to say that I would not limit that
4 to surgeons either because the numbers at the American
5 College of Radiology program support the same result. So it
6 appears to me that there is not a big mandate from the
7 stereotactic breast biopsy community to voluntarily
8 self-regulate, much to my own personal disappointment, but
9 that is apparently what the reality is.

10 DR. MONSEES: Is there any knowledge of the number
11 of adverse events that are occurring on a national level and
12 whether or not there should be a push for regulation of
13 this?

14 DR. FINDER: We did have a presentation at one of
15 our previous meetings where this had come up. We had looked
16 at the issue from the databases that FDA is privy to. We
17 also had talked with representatives from the States and
18 tried to get a sense of what the problems that they were
19 encountering were.

20 I do not have the exact numbers in my head
21 anymore, but at the time, we did not have hard data that
22 showed a large number of problems that had been reported to
23 us, and especially problems that we felt that we would be
24 able to address through an MQSA-type program.

25 Obviously, there are problems out there that one

1 hears about, but some of them are not necessarily amenable
2 to regulatory fixes.

3 DR. MONSEES: Could we hear some comment from the
4 FDA regarding their intentions on this and whether we should
5 continue to encourage our colleagues on the basis of the
6 threat that regulation will follow if voluntary
7 accreditation is not near 100-percent complied with?

8 We had heard that from FDA a number of years ago.
9 Can we be advised as to what should we be telling our
10 colleagues?

11 DR. FINDER: With the data that we have just heard
12 today about the current status, we have to look at it again
13 and see what our standard is going to be.

14 Obviously, we are still hoping that the voluntary
15 programs will accomplish the goal without regulation.
16 However, if they do not and they do not appear to be
17 accomplishing what we like as soon as we like, we obviously
18 are going to look at the issue about starting a regulatory
19 program to deal with this situation, but I do not want to
20 commit to any time tables right here. It certainly is not
21 encouraging, the information that we have received today.

22 DR. MONSEES: Yes.

23 MR. PIZZUTIELLO: Just to comment on the States,
24 in the State where I practice, in the State of New York, the
25 Department of Health did institute its own separate

1 regulatory program and began inspecting interventional
2 breast X-ray facilities probably in about April of last
3 year.

4 My understanding is that they have found some
5 problems, and it might be helpful to FDA to contact New York
6 State and any other States through CRCPD who have done some
7 regulatory process on their own. The issue is, in a
8 nutshell, places that are doing only stereotactic work or
9 places that are doing only interventional breast procedures
10 were completely out of the regulatory loop in many States
11 because, while the States had mandates in their regulations
12 to inspected all X-ray machines, many other States amended
13 their regulations around the time of 1994 to say as long as
14 facilities are complying with the requirements of MQSA, we
15 will not get involved further with regulation of X-ray
16 breast imaging.

17 So then there was this little gap in the
18 regulations, and since some of those facilities were
19 operated by individuals who were not at all familiar with
20 X-ray regulation and radiation safety procedures, that is, I
21 think, where the big benefit has been in educating those
22 facilities about radiation safety, dose image quality, and
23 all the factors that the regulatory process seeks to assure.

24 DR. MONSEES: So, in essence, there were more
25 findings in the facilities that did not otherwise practice

1 mammography and were not adhering to MQSA guidelines for
2 their standard units?

3 MR. PIZZUTIELLO: That is my subjective
4 understanding from just casual conversation with some of the
5 folks in the Department of Health.

6 DR. MONSEES: Thank you.

7 Yes.

8 DR. MOORE-FARRELL: I work in a private-practice
9 setting, and in my town, we have two stereotactic units that
10 are shared on both sides of the town by surgeons and
11 radiologists. Those doctors are not necessarily connected
12 in any other way. They have their own private practices and
13 their own clinics, and they only share that machine.

14 I am sure it would be difficult, but in the
15 future, if we have to certify or accredit, to do it possibly
16 by the individual and the machine, hooked up with that
17 equipment. I think to lump a machine and then try to keep
18 all those doctors who are completely disconnected in any
19 other way, make them accredit under one umbrella is just too
20 much to ask because all it takes is one or two that do not
21 want to do it or to participate that keep everybody else
22 from being able to get accredited.

23 DR. MONSEES: That is a good point. That is a
24 very good point.

25 Yes.

1 DR. DOWLAT: Is it not true that the facilities
2 get accredited independently through ACR for the facilities
3 as such?

4 DR. FINDER: In terms of the accreditation
5 process, the entire certification process is based on the
6 facility. It is a facility-based certification.

7 Accreditation tends to be more unit-based, but the
8 certification under MQSA is a facility-based issue. You are
9 right, if you have got a situation in a stereotactic unit
10 where even one of the people does not want to get involved,
11 that one people could torpedo the whole thing if we went
12 down that road because it has to be by the facility.

13 DR. MONSEES: Dr. Sickles first.

14 DR. SICKLES: If it eventually comes to FDA
15 regulation, I do not foresee that as a problem because, if
16 it is facility-based, as I would assume it would be, a
17 particular provider who chose not to be involved simply
18 would not be allowed to work at that facility and that
19 person would be shut out economically and otherwise. They
20 would very strongly feel the need to become part of it.
21 Otherwise, they would have to set up on their own and do it
22 on their own.

23 DR. MONSEES: On the other hand, they would not
24 show up in the stats now.

25 DR. SICKLES: They will not show up now.

1 DR. MONSEES: Right.

2 DR. SICKLES: Absolutely not.

3 DR. MONSEES: Because they will not have applied,
4 because they cannot comply.

5 MR. PIZZUTIELLO: Just to follow that point with a
6 concrete example, I participated in an ACR stereotactic
7 breast survey, site survey, went out to a facility that had
8 applied. One of the things that is reviewed in that site
9 survey is the credentials of all the physicians providing
10 the service. There were six or seven physicians providing
11 the service. All but one met the criteria. One of those
12 physicians did not meet the criteria.

13 So the American College of Radiology informed the
14 facility that either that physician needed to meet the
15 criteria or they needed to prevent that physician from
16 performing the procedures or they would lose their
17 accreditation. Those are sort of the three choices.

18 If you are accredited as a facility, then all your
19 personnel must meet the requirement. So the facility then
20 has the administrative control to say you cannot do this
21 procedure until you meet the requirement which is really the
22 essence of credentialing in a hospital on any procedure.
23 So it is not a foreign concept, but it does require some
24 administrative responsibility on the part of the facility.
25 Since MQSA is a regulation, fundamentally regulates

1 facilities and not individuals, that seems to me to be the
2 way this would proceed.

3 DR. MONSEES: Ms. Butler?

4 MS. BUTLER: I was just going to point out that in
5 support of what Bob was just saying, the accreditation
6 really evaluates not just the unit, but the entire system,
7 including all the personnel that are involved with this that
8 is at the facility.

9 Yes, if a facility has an individual who does not
10 meet the criteria, in order to be accredited, that
11 individual either has to show us that they have met the
12 criteria or that individual may not be involved with the
13 procedure.

14 DR. MONSEES: Thank you.

15 I cannot see in the back there, but I understand
16 there is somebody who has had their hand up. I apologize.
17 I could not see your hand. The podium is between us.

18 MR. FLATER: I am Don Flater with the Iowa
19 Department of Public Health.

20 We have a full certification program for
21 stereotactic units. We have 17 facilities that have them.
22 Two of those facilities are surgeons alone, and they meet
23 our criteria which we modeled after the surgeons' criteria
24 that they provided us.

25 We started the program about 4 years ago, maybe 3

1 years ago, where we got surgeons and radiologists together.

2 To elaborate a bit on what Bob said, the surgeons
3 really did not take it seriously. We kept telling them they
4 needed to.

5 I got a call 3 days ago before I came out here,
6 and they finally admitted that because the rules are in
7 place. We have inspected all our facilities at no charge,
8 and now they start the charging process as of January 1 of
9 this year.

10 We have an inspection form, a full set of rules,
11 and the program seems to be going quite well at this point
12 in time.

13 All the other facilities are surgeons and
14 radiologists together. They are from the same institution.
15 The radiologist reads the film, makes the recommendation,
16 and in most cases is in fact in the facility when the biopsy
17 is done.

18 We have two units that are the ABBI-type units.
19 Both of those are in surgery facilities, but are starting to
20 go away. There is one that has not been used in about 2
21 years now. The other one has been.

22 DR. MONSEES: Thank you for your information.

23 DR. MOURAD: Which part of the country are you
24 from?

25 MR. FLATER: State of Iowa, right in the center.

1 DR. MOURAD: All 17 facilities are in Iowa?

2 MR. FLATER: Yes, sir, they are.

3 Thank you.

4 DR. MONSEES: Thank you, sir.

5 Any other comments from anybody out there? I
6 cannot see. You will have to stand up if that is the case.

7 [No response.]

8 DR. MONSEES: We shall move on, then. The next
9 presentation is from Walid Mourad who is going to talk about
10 the final regulations, the early inspection findings. We
11 saw a preview of that this morning in our first
12 presentation.

xx

13 DR. MOURAD: Thank you.

14 In the next half hour or so, I would like to give
15 you a rundown on findings under the final regulations over
16 the last 6 months or so.

17 I would like to start with a little background and
18 move onto the evolution of finding levels across facilities
19 over the last few years, and then concentrate on the
20 findings under the final regulations over the past 6 months
21 and then pay special attention to the most serious findings
22 and then briefly talk about inspection time and then a
23 couple of comments on future outlook for the inspection
24 program.

25 Next, please.

1 A brief background. You all probably know this,
2 but for those who do not, MQSA was enacted by Congress in
3 October '92. The FDA was delegated the responsibility of
4 implementing the MQSA program. So, in the spring of '94,
5 FDA published the interim regs which became effective in
6 October '94. The inspection program started with the first
7 inspection about mid-January of 1995, and the final regs
8 finally were published in October of '97. They became
9 effective in April of '99. MQSA was reauthorized by
10 Congress in October of '98, and the implication of that
11 reauthorization for the inspection program were two things.

12 Number one, the lay summary must be sent to all
13 women, and the FDA had the mandate of doing the
14 demonstration program which John McCrohan talked about in
15 some detail this morning.

16 Moving on to the evolution of the finding levels
17 across facilities. I present you with this table which has
18 a summary of what we have found over the last few years.

19 The column on the left shows you all the fiscal
20 years, fiscal year 1995 to the present. The last item is
21 fiscal year to date, 2000, which means it starts October
22 1st, 1999, and the data that was collected for this
23 presentation ends on January 7th, 2000. So it is about 3
24 months and a week or so.

25 On the extreme right is the number of facilities

1 presented in each of these fiscal years, and in between, we
2 have finding levels, L1, L2, and L3. In case you did not
3 know, L1 is the most serious finding. What it means is that
4 if a facility has a Level 1, it automatically gets a warning
5 letter from the FDA within 2 weeks of the inspection, to
6 which they must respond telling the FDA how they are going
7 to fix the problem.

8 L2 is what we consider also a serious finding, and
9 if a facility has L2 only as the highest level, then they
10 must write to the FDA within 30 days of the inspection date
11 to tell the FDA how they propose to fix the problem found.

12 L3 is what we consider a minor finding. We expect
13 facilities to correct all findings regardless of level, but
14 we do not as a matter of fact check on Level 3 findings
15 until the following inspection year.

16 The fourth column in there is called no finding.
17 That is facilities with no findings whatsoever.

18 So the table basically lists the percentage of
19 facilities of the total on the right that have been found to
20 have the highest finding at a given level.

21 So, for example, the first row indicates at L1 in
22 fiscal year '95, we had 2.6 percent of the facilities with
23 the highest finding of Level 1, likewise 19.9 at the Level 2
24 as the highest finding, et cetera.

25 If you look at this table, you will find that over

1 the next 3 years, 5, 6, and 7, we had a nice trend going on
2 whereby Level 1 findings went down and all the others also
3 went down. At the same time, the number of facilities with
4 no findings kept going up, which was a good sign.

5 In fiscal year '98, there was a little glitch on
6 Level 2 findings simply because some continuing education
7 and continuing experience programs took effect for
8 personnel, and that is why you see a jump in there.

9 There is another jump in fiscal year '99. You can
10 see L1 now jumped up to 1.8, and L2, 23.4, et cetera, and
11 the next slide will explain why we have that.

12 Fiscal year '99, as it was mentioned before, is a
13 combination. It is a hybrid year. It is a combination of
14 inspections under the interim regs and for about 10 months
15 of the year, and then the last 2 months or so where we
16 implemented the final regs in early July. That was we
17 inspected under the final regs.

18 You can see a jump there in L1 from .9 to .43
19 percent, the facilities, and L2 jumped also, of course,
20 almost a factor of 2. L3 went down, and no findings
21 basically came down to about 49 percent. The hybrid of the
22 year, then, is summarized on the third line which is copied
23 from the previous slide. That is why you see the average of
24 the whole year is what it is.

25 We are going to move on now to talk about the

1 inspection findings under the final regulations, what have
2 we found. First of all, we are going to talk about the
3 number of facilities versus the highest inspection findings,
4 and then we are going to talk about the various finding
5 levels starting with the minor and ending up with the most
6 serious.

7 Next, please.

8 This slide shows, again, the percentage of
9 facilities according to levels that have been cited, and
10 this is over the past 6 months, in other words, from July
11 6th, 1999, when the new software program implementing the
12 final regs too effect, to January 7, so roughly 7 months
13 under the final regulations.

14 You can see the number of facilities cited at L1
15 is about 4.4 percent. L2 is, again, as has been alluded to
16 before, 35.7 percent, and Level 3 is 10.4, et cetera. No
17 findings is about half the facilities. Total number of
18 facilities inspected is about half the total population of
19 facilities, about 4,800 and some change.

20 I want to caution to those of you who are
21 mathematically minded. If you try to add up the percentage
22 number sometimes, they may not add up to exactly 100
23 percent. It is strictly an averaging process. So do not
24 worry about it too much.

25 This slide shows the number of occurrences of a

1 given finding. In other words, this is not the number of
2 facilities, but, rather, how many times we have cited at a
3 Level 1, how many times we have cited at a Level 2, and how
4 many times we have cited at the Level 3. You can see the
5 numbers in the middle and the percentages of the total of
6 findings, again, on the right. So, again, 4.4 percent is
7 the total number of findings at the Level 1, and Level 2 is
8 about 60 percent. The balance is Level 3. This adds up to
9 about 679 occurrences, but these occurred at 4,841
10 facilities. That is natural, of course.

11 The last item there is number of inspections with
12 findings. In other words, of the 4,800 facilities, about
13 half of them were found to have all these 6,000 findings.

14 Next, please.

15 Let's talk about the minor findings. I am
16 starting with the minor here just to get them out of the
17 way.

18 A quick comment is that in general, there is not
19 much really to talk about here. The ones underlined are the
20 ones that we have noticed some change from the previous, and
21 the first one is performance test. These include all the
22 tests that the inspectors do on site when they visit a
23 particular facility, and these are namely the collimation
24 test, the dose test, and whatever is associated with it,
25 then the phantom scoring and the STEP test and the fog [ph]

1 test.

2 The total of all of these is about 15 percent of
3 the total, and I underlined one item here because we noticed
4 a slight jump, actually a good-sized jump of the
5 misalignment of the paddle with respect to the image
6 receptor on the chest wall side. It went up about by a
7 factor of 7, but the total finding is from 4 to 27. So it
8 is not a big deal, but it is due to the fact that the
9 regulation now states that that alignment has to be within 1
10 percent, not 2 percent. So there is a number of changes
11 there.

12 The other stuff is very much like what you see in
13 the interim regs. The incomplete survey refers to a lump of
14 citations here whereby if certain number of tests or one
15 item that belongs to a number of tests that we consider to
16 be not as important as the other, we classify them as Level
17 3. It gives you an incomplete survey period. So that is
18 about 10.7 percent.

19 Then the new item that came under our minor
20 finding here is the personnel documentation. The final regs
21 specified that facilities are required to keep personnel
22 documents on hand for inspections when requested. So
23 facilities have not gotten used to that yet, and we find
24 many of the inspectors citing facilities for that. So you
25 can see this is about the biggest, one of the largest items,

1 that is cited singly, namely 23 percent.

2 The next two slides present the findings of a
3 serious nature, but not the most serious. That is L2, and
4 here, because there are so many of them, I had to break them
5 into two slides. Otherwise, you could not read it.

6 Again, there are no surprises here except the
7 sheer volume of these, and I will explain later why that is
8 the case.

9 The biggest single item on that line, I believe,
10 is the QC records, and that is the daily and weekly tests.
11 All of these have been elevated, if you will, from a Level 3
12 under some of them, under the interim regs, to a Level 2 and
13 Level 1, but the ones that belong to Level 2 constitute
14 about 23.8 percent.

15 There is also the QA program. There are two
16 responsibilities there, the infection control procedure and
17 the complaints program that facilities must have, and those
18 also constitute a new big percentage because facilities,
19 again, are not used to it.

20 The survey and equipment evaluation lumped
21 together constitute still a relatively small portion of the
22 total findings at Level 2, and then there is a category
23 which we called initial qualifications. That is all
24 personnel categories at Level 2, which means part of the
25 initial requirements like you did not have the 60 or 40 CMEs

1 for the IPs, you did not have the training for the
2 technologists, and you did not have the training for the
3 physicists, and also the continuing requirements like
4 continuing education and continuing experience all lumped
5 under--sorry, that will come in the next slide. I am
6 jumping ahead of myself here, but the initial qualification
7 part is on this slide. The subtotal here is 2000 and some
8 change.

9 Next one. This is the second part of the L2
10 findings, and, again, here, the continuing experience for
11 the personnel are listed. You can see the percentages.
12 Again, no big surprises.

13 The next item is the medical report contents.
14 Here is where we found a big jump compared to the interim
15 regulations. Again, facilities have not gotten used to the
16 idea that they have to specify only one of those categories,
17 and it has to be said in a certain way and not in any old
18 method. So we are seeing a big number of citations because
19 of that, even though we did publish guidance on enhancing on
20 the six categories that were published according to the
21 BIRADs, but still our people are finding violations there.

22 Medical audit system. It used to be partly under
23 the L3 and partly under L2. This year, under the final
24 regs, we made it all L2. So there is, again, a number of
25 citations there.

1 So the number of occurrences is about 3,600 and
2 some change, and, again, they do not really give us any
3 surprises in that sense because we anticipated that.

4 Next one. Now we are going to talk about the most
5 serious findings.

6 By the way, all of these results I am showing you
7 here pertain to the first 6 months, that is, July 6th of '99
8 to January 7th of 2000.

9 Under here, I want to point your attention to the
10 percentages. If you look at the first line, personnel
11 initial qualifications, this encompasses for the doctors the
12 license or the certification, that is, the lack of, for the
13 physicists, the lack of the degree, for the technologist,
14 the lack of certification or license. So, if none of these
15 are met, this is a Level 1 under the final regs. The total
16 of these is like 16.5 percent.

17 Look at the next item, processor QC, phantom QC,
18 results communication, and underprocessing. Underprocessing
19 is a new issue. We used to have underprocessing always at
20 Level 2. We broke it up into two levels. That is, if the
21 facility was severely underprocessing, then it is a Level 1,
22 and we cited a few cases. Low phantom score, of course, it
23 used to be also two levels. That has not changed. So there
24 is no surprise there.

25 No valid certificate. This is something we can

1 cite for under the final regs because a facility is supposed
2 to be certified, and if they are not, we can still inspect
3 uncertified facilities and cite them for that. So, again,
4 we found a few.

5 The unit not accredited at Level 1, this is a new
6 thing that we required under the final regs. That is, if
7 the facility is using a unit for a year or more and they
8 still did not accredit that unit, that is a Level 1 and not
9 a Level 2. It used to be always a Level 2.

10 What I want to say about this slide is that the
11 first line, personnel issues, used to be like 80 percent of
12 the total of Level 1 findings. Because of the way things
13 have changed under the final regulations, it became now a
14 minority.

15 Moving onto the next one. To drive the point
16 home, I showed you here a comparison between the last 6
17 months of implementing under the interim regulations, that
18 is, from 1/6 to 7/5/99, that is, for 6 months of 1999. That
19 is all under the interim regs on the left. Implementing the
20 final regulations, that is, from July 6th to January 7th of
21 this year, the next 6 months, that is all under the final
22 regulations.

23 Notice this is now strictly talking about the
24 Level 1 findings. You will notice here the total
25 occurrences were 72 occurrences under the interim regs.

1 They jumped to 267 under the final regs. So that is a big
2 jump.

3 If you look at the distribution again, you will
4 find that while we have the initial qualifications for the
5 different categories, if you do not look at details but add
6 up the numbers, you will find that they dropped slightly,
7 which is nice, but it is not the big surprise. Again, the
8 big surprise is how things like processor QC, which used to
9 be like 3 occurrences under the interim regs to 70 under the
10 final regs. Again, it is because we upped the level. We
11 upped the ante here. It did not happen by accident.

12 Yes, Bob.

13 MR. PIZZUTIELLO: Could you clarify the change in
14 the processor QC from Level 1?

15 DR. MOURAD: I will do that. Since you asked it,
16 I will answer it now.

17 If the facility did not do a processor QC under
18 the interim regs for the whole year, if they never did it,
19 in other words, they were negligent totally about it, that
20 used to be a Level 1, not just missing 1 month or 2 months
21 or anything. So it has to be 100 percent and over the whole
22 year.

23 Under the final regs, we cite a facility at Level
24 1 if they missed 30 percent or more of the QC. The QC is
25 not required to be daily. It is required to be on the days

1 that you process mammograms. In a given month, if you
2 process mammograms 12 days out of that month and if you
3 missed four, that is 33 percent. That is a Level 1. So we
4 really upped the ante quite a bit. That is why you see
5 those jumping up.

6 The other one is the phantom QC. That also is 80
7 percent. There is on corresponding amount to it under the
8 interim regs. This is, in other words, if you missed under
9 the interim regs 2 months or more, it was considered to be
10 Level 2 at best. Now if you missed 4 weeks or more under
11 the final regs, it is a Level 1. If you miss 4 weeks, not 4
12 months. Two things changed in the phantom. The requirement
13 became weekly, and, of course, the penalty has stiffened.

14 The other item was, of course, the results
15 communication, and now we see 47 of the findings which is a
16 big percentage, of course.

17 Results communication was always a Level 1. What
18 happened here under the final regs are two things. The lay
19 summary and the rest of the report has to be sent to either
20 the woman or the referring physician within 30 days, and
21 then communication of the serious results as soon as
22 possible, meaning either 3 or 5 days as guidance. But also
23 a big part of that was a judgment call. That is why we had
24 to review some of these, and I will talk about the review
25 process. In other words, facilities are not used to the new

1 stiff requirements. So that is one reason we are seeing a
2 big jump here.

3 Go back to the previous one. Thanks.

4 Now I will talk about some explanation as to why
5 we are seeing the level changes that have been manifested in
6 the slides.

7 Quite a few Level 3 findings were bumped up to
8 Level 2's by design, and, of course, this did not take place
9 on our own by ourselves. We got input from the CRCPD
10 working group, and, of course, we ran all of these by the
11 advisory committee before we implemented any of that.

12 Some Level 2's were bumped up to Level 1's. So,
13 as a result, actually Level 2 became a lot more populated
14 than before, and Level 3 became less populated. So it was
15 natural for us to see a jump in Level 2. Also, to add to
16 that category on the level changes, we have new requirements
17 meaning new items that were not even required under the
18 interim regs. Now they became required under the final
19 regs. The result of all that is we have seen an increase in
20 Level 2 and Level 1 findings.

21 We noticed some of these changes as we started
22 getting inspection results back, and some things jumped at
23 us right away. We noticed two things. The level of QC
24 citations was up, and so, as we looked at ourselves and what
25 we had told the inspectors, we noticed that there were some

1 things that were happening because the program could not
2 differentiate sometimes between when a noncompliance as far
3 as QC records are concerned occurred before April 28th or
4 after April 28th.

5 For example, if you went to inspect on July 15 and
6 you looked at a facility's record for one year, let's say
7 they missed 5 days in February of 1999 out of 10 days of
8 processing. That is 50 percent, right? If the inspector
9 was not careful enough to notice that this was not required
10 until April 28th, the program blindly will cite that as a
11 Level 1 because the program will calculate the percentage
12 automatically. You just put down how many days were
13 processed, how many days were not recorded, and so you
14 automatically get 50 percent, bingo.

15 We recognized that about a few weeks into the
16 inspection process under the final regs, and we said
17 opportunities, we apologize.

18 An apologize is not good enough. So what do we
19 do? We scrambled, of course. We issued guidance to the
20 inspectors. We could not make the change in the software so
21 quickly because the software did not have the intelligence
22 to differentiate between that. So we issued detailed
23 guidance to the inspectors how to deal with this problem.
24 This is one example, I am giving you, of course.

25 The phantom QC was another problem for the same

1 reason. If they cited sometime a facility for missing 3
2 months in, let's say, February of '99 as an example, some
3 inspectors took that as 3 months times how many weeks. So
4 they added it up, and, of course, the program cited at Level
5 1. So, quickly, we issued guidance to the inspectors to
6 tell them to please be careful, to make sure the finding
7 took place after the final regs and not before.

8 Well, in spite of what you say, unless you write a
9 detailed guidance for every little item--and there is no end
10 to it--it becomes very complex. Nobody can read it if it
11 gets too detailed.

12 So, to make a long story short, there were some
13 compliances, then, that were issued inadvertently, if you
14 will, oversight, whatever. So these are what we called
15 questionable Level 1 findings.

16 What do we do? We took a big scan of the data
17 starting in September. First of all, we could not do
18 anything about it in the software because there was an
19 agency mandate that we could not come up with any new
20 software between October 1st of last year and January 31st,
21 today, as the deadline. The agency could not come up with
22 any new software and implement any new software programs
23 because of the Y2K problem. So our hands were tied. The
24 only thing we could do was issue guidance, more guidance,
25 and hope for the best.

1 In the meantime, what we had done is take a scan
2 of all the Level 1's that have been cited in the areas where
3 we thought there is room for error either on the part of the
4 inspector or the inspection software, or both, namely the
5 results communication, the QC records, and the unit not
6 accredited at Level 1. We looked at all these issues. So
7 we had a long list of inspection findings that were cited at
8 Level 1. Yours truly with assistance from some able people
9 in the branch, we were able to make a validation of roughly
10 about 50 percent on average came out to be about correct
11 citations and the other 50 were not. So we went to the
12 records, to the database and corrected all those that we
13 have stumbled on so far.

14 Of course, we will resume the work as soon as this
15 presentation is over. What do we do about it? We corrected
16 the record. We intend to follow up with the facilities for
17 further action, as needed, because we do not want this to go
18 on anybody's record as a permanent record unless it is a
19 valid and appropriate citation.

20 So much for that. Inspection time. Many people
21 were wondering about how the inspection time has managed or
22 averaged over the years, and, of course, we started high
23 back in '95 and then we started slowly, drifting and
24 stabilizing, at about a little under 5 hours or so. That is
25 what we call on-site inspection time, meaning how much time

1 the inspector spends at the facility when they do the
2 inspection.

3 This slide is for a facility with one unit only.
4 So you can see there are three numbers in there, three
5 columns, that is, the V1.1 program, that is, the old
6 software. That is 6 months from 7/1/98 to 1/8/99. On
7 1/8/99, we implemented the V2 software program which was
8 still under the interim regs, but it was a Windows 95-based
9 program. So that was, again, to compare the two--you can
10 see it increased slightly, so no big deal there. These
11 times are in hours, by the way.

12 Under V.3, it jumped from 4.9 to 5.2, and then the
13 other time is how much time the inspector prepares to input
14 the data or do any follow-up regarding the inspection. That
15 is also in hours. The final number down there is the total
16 time, meaning inspection time on site and others. You can
17 see the numbers are not terribly bad for a one-unit
18 facility. The number did jump up a little bit between V.2
19 and V.3, but the interesting thing here is that when we
20 switched from the interim regulations to the final
21 regulations, the total inspection time did not really change
22 much, as you can see.

23 Next slide. Here, this showed on average, if you
24 averaged all inspectors and all facilities, meaning
25 facilities with one unit versus facilities with many units,

1 it averages per facility perhaps 1.2 units. So the
2 inspection time does go up a little bit, but notice how it
3 is consistent regardless of which software we are talking
4 about. So we did not really change much, bottom line.

5 Next. What is the future outlook? There are
6 three things here that we want to implement. Repeat
7 findings, so far we have carried them over to the interim
8 regulations. We kept track of repeat findings so that we
9 can escalate the response, but when we started with the
10 final regs, we could not do that anymore until we get the
11 first year under the final regulations underway. Simply
12 because of the fact that there are new requirements, we
13 could not just keep going as is. Many requirements also
14 changed between L2 and L1. So, in other words, the level
15 change made it difficult for us to judge a finding as a
16 repeat.

17 What we are going to do is implement the repeat
18 finding again into the software program next July. The
19 demonstration program was presented this morning. So I do
20 not want to say too much about it, except that, of course,
21 it may have implications for the software, as some of you
22 suggested today.

23 Of course, when the new mammographic modality
24 becomes approved, namely digital full field, we are talking
25 about sometime next year perhaps being able to put some

1 expanded inspection questions in there.

2 Thank you very much. If you have any questions, I
3 will be happy to answer them.

4 DR. MONSEES: Thank you.

5 It is very interesting to see that. We worked
6 pretty hard in helping FDA to develop its guidance, and it
7 is nice to know that the guidance probably worked some, that
8 people seemed to have understood it.

9 One comment that I would like to make, not
10 pertaining to your presentation, but pertaining to something
11 I spoke to Dr. Finder about the other day, is that we are
12 moving more towards electronic distribution of guidance
13 materials. I frequent the web site to look at how
14 frequently it has been updated, and the guidance document
15 has not been updated since last June. I would just like to
16 make a request that maybe that could be turned over more
17 frequently as new guidance becomes available.

18 One of the reasons for having electronic guidance
19 is that it can be updated very frequently and very quickly
20 and expeditiously. I think maybe the web site has fallen
21 behind there, and I think that might help the people who are
22 looking to that web site for the guidance.

23 DR. MOURAD: I could comment on that, but since
24 Charlie is the guru of this, I will let him.

25 DR. MONSEES: We have another comment here.

1 MR. McCROHAN: This is John McCrohan, FDA.

2 I would let Charlie answer this, but it is kind of
3 his baby. So I think I will take him off the hook a little
4 bit.

5 We appreciate the comment, and I think it has a
6 considerable degree of validity, but I think Charlie might
7 be loath to point out how long it does take to get guidance
8 cleared. In fact, he could give you chapter and verse on
9 how long it took to get the second guidance document out,
10 but I think it was once we went it into the clearance
11 process, it was probably a good 8 to 9 months before it came
12 out.

13 So we would love to be able to update the guidance
14 much more frequently, but relay up to this point, it has
15 been dictated by how frequently we have been able to get a
16 guidance document fully through the clearance process.

17 I think we can probably anticipate speeding up a
18 little bit in the future because I think and hope and pray
19 that we have run out of brand-new questions, and as we get
20 into questions where we are modifying existing guidance or
21 amplifying existing guidance, that is going to be of the
22 type that is called Level 2 which does not require quite
23 such an extensive review process. So we would be able to
24 hopefully get that out quicker and update the web site more
25 frequently.

1 DR. MONSEES: I might add that I think that the
2 guidance document that is on the web site is wonderful. It
3 is very easy to use. It is intuitive, and it gives good
4 information. So I think it is a very good way to distribute
5 information.

6 DR. MOURAD: If it makes you feel any better, our
7 guidance and the inspectors is much faster.

8 [Laughter.]

9 DR. MONSEES: Yes.

10 MR. PIZZUTIELLO: I would like to amplify what Dr.
11 Monsees just said. I would commend the agency on the search
12 engine because it is extremely easy to use.

13 DR. MONSEES: Right.

14 MR. PIZZUTIELLO: The only place I think where
15 perhaps you could do a little better is to try to get the
16 word out to people to actually download it and use it
17 because I have been doing this in lectures since it first
18 came out, 6 months. I found out when you give people
19 step-by-step instructions of exactly how to do the download
20 procedure, they do not always understand that when it is
21 finished that it resides on their local computer. So maybe
22 a little more detailed explanation of how to do that, step
23 by step--and I always recommend they find a 13-year-old if
24 they need help on the Internet.

25 DR. MONSEES: I had a problem unzipping or zipping

1 or whatever there was that you had to do, and I had to get
2 help with that process. I have loaded it in the view room.
3 I have loaded it on our administrator's computer, our tech's
4 computer, and my desktop. It is a very, very valuable
5 resource. So I would like to see it continually updated on
6 a timely basis. It is, I think, really wonderful.

7 Did you want to make a comment, Dr. Sickles?

8 DR. SICKLES: No. I use it, too.

9 DR. MONSEES: I think we are nearly done here. Is
10 that right, Dr. Finder?

11 DR. FINDER: Yes.

xx 12 DR. MONSEES: Do we need to review these minutes?
13 We have done the awards. We want to talk about a review of
14 the minutes.

15 Does anybody have any corrections to the minutes
16 that were distributed?

17 [No response.]

18 DR. MONSEES: No. So we will accept those
19 minutes. They are approved.

20 The awards have been done.

21 Do you want to talk about future meetings? During
22 any natural disasters, we will hold our next meeting.

23 [Laughter.]

24 DR. FINDER: Yes. I think after this meeting, we
25 are coming to the conclusion that March and September look a

1 lot better than January and other months.

2 I will say that it probably is not worth while to
3 spend a lot of time talking about the future meetings since
4 three of the people who are at this meeting right now will
5 not be attending the next meeting because they have finished
6 their terms. So I think the best thing to do is just to
7 send out a list of dates when we think that we can have a
8 meeting and just fax them out like we have in the past. I
9 think we are done with the issue of the future meeting.

10 I would hope to have one maybe during the summer
11 sometime, but I will get back to you on that.

12 DR. MONSEES: If any of the panel members have any
13 ideas about what they think are pertinent for discussion,
14 either address them to myself or Dr. Finder and I am sure we
15 will be advised in advance of what items the FDA needs input
16 on.

17 So, if there are no other issues, we will adjourn
18 this meeting. Again, thank you to the people leaving the
19 panel. We are adjourned.

20 [Whereupon, at 2:56 p.m., the meeting was
21 adjourned.]

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CERTIFICATE

I, **THOMAS C. BITSKO**, 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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