

1 other, so I feel like this is a somewhat subjective
2 process and that the more objective data is really
3 already acquired by the inspectors.

4 So, I am not sure there is a lot to be
5 gained. I think that the number of facilities it
6 would actually help for the inspector to actually
7 lay eyes on the images would be very, very low for
8 the amount of time and money that would have to go
9 into a program like that.

10 MS. HARVEY: Dr. Barr.

11 DR. BARR: I just wanted to point out some
12 of the things that Etta started before I did, and
13 that is, that we do have objective indicators that
14 do have triggers, that if they are severe enough,
15 they trigger looking at films, and in our
16 experience it is mostly the other way around from
17 what you are saying, say, a phantom image failure
18 triggers looking at films, and in all the phantom
19 image failures we have had, we only know of one
20 case where that actually translated into poor image
21 quality, so it is sort of the flip side that
22 sometimes we find violations in an inspection where
23 the clinical image is still good.

24 I haven't seen a documented case where the
25 severity of the films, such as you are describing,

1 would not be caught by one of the inspection
2 parameters. In the case you cite, I would just
3 like to point out that neither the accrediting
4 body, the ACR, nor the FDA ever had a chance to
5 evaluate the image quality, so that's still an
6 issue of whether a case like that has actually come
7 about.

8 Thank you.

9 MS. HARVEY: Any other comments on the
10 future?

11 DR. YOUNG: I would like to offer what I
12 hope is a constructive comment when we look at the
13 future of MQSA, and I would hope that we would move
14 forward--and I think the phrase has been used in
15 some of the handouts--total system resolution with
16 a particular emphasis on the clinical images, and
17 by that, I mean not just measuring a focal spot,
18 not the filter, not looking at your image receptor,
19 your source image distance, all that stuff to
20 processing.

21 Anecdotally, I had a problem with one of
22 my units a couple of years ago where the molybdenum
23 filter went bad, and I can't remember what happens
24 from the standpoint of physics, it is like when
25 window glass turns different colors, and it took us

1 about a week, and our clinical images just
2 deteriorated on that unit to the place we quit
3 using it, and even the company had a hard time.

4 We took that problem to them finally, and
5 those are the sort of things that this idea of
6 total systems resolution relative to the clinical
7 images, continuous quality improvement, things like
8 that, that is what we need to keep in mind, and not
9 burden some regulations that we are just doing a
10 bunch of paperwork for paperwork's purposes.

11 MS. HARVEY: Yes.

12 DR. KARELLAS: I agree with Dr. Young. I
13 believe that the agenda for the years to come would
14 be perhaps some increase in the efficiency of what
15 we do. I think we can cover the same ground, not
16 necessarily recommending any elimination of
17 anything unless everybody agrees to that, but I
18 believe we can do things smarter and more
19 efficiently.

20 There has to be a way that some of these
21 things we can do them better and with relevance to
22 what the ultimate goal, as Dr. Young suggests. It
23 is perhaps premature to know exactly where we are
24 going. The technology is changing, communication
25 is easier now between the various parties,

1 accrediting bodies, physicists, facilities, and I
2 think that now we know the rules, we know how to
3 live with the rules, I believe now that we can make
4 it more efficient, and I believe that everybody
5 feels that way.

6 MS. HARVEY: Dr. Lee.

7 DR. LEE: I strongly encourage you to
8 continue looking at the access factor because you
9 can have the best staff and the best machines in
10 the world, but if you don't get that woman to that
11 machine and to that staff, you are not going to
12 really make a dent in breast cancer morbidity and
13 mortality. So, I hope you really continue looking
14 at access.

15 MS. HARVEY: Any other comments?

16 MS. ELLINGSON: I don't want to pass up
17 the chance. One of the weakest links that I see in
18 every-day practice is the quality control
19 technologist. In a large facility, you may have a
20 choice of a volunteer, somebody who has a
21 background and they are interested in it, and
22 that's great. Sometimes you just get named to be
23 that person. You don't want to do it, you don't
24 understand it, it is not something that you are
25 even remotely trained to do.

1 We have CE, specific CE for modalities. I
2 would like to see somehow require some basic
3 documentation that these QC technologists have some
4 kind of training, and I think it would help them.
5 Then, they would say to their doctor, you know, I
6 have to have this, you have to send me someplace or
7 even develop a self-learning module that would be
8 specific to the tests.

9 I know it is in the QC Manual, but people
10 are asked to do this that don't understand what
11 they are doing, and it is fine if the numbers are
12 right, but the day something goes wrong, they don't
13 know what to do. They are not trained in
14 troubleshooting.

15 I would like to see that strengthened
16 somehow, and I don't know if it is our place to do
17 that, but if we required some documentation that
18 they have had--some of the physicists around the
19 country have developed a program, when they do
20 their annual inspection, and they have applied to
21 ASRT for approval of that course, and if it is a
22 format is documentable, and so forth, and it is not
23 just following them around watching them, we have
24 approved courses, and things like that could be
25 mandatory that they have had some kind of training

1 that is documentable to help them understand
2 average gradient, all those kind of things. Some
3 people don't understand it. They just hope the
4 numbers turn out right, and, woo, it did, but what
5 if it doesn't.

6 That, I identify, and some of the time
7 that is taken away from their mammography duties is
8 because it is taking them three times as long to
9 figure out what has gone wrong, when they could do
10 it quicker if they were better trained. Just a
11 suggestion.

12 DR. IKEDA: I also have a comment about
13 that. I have several mammography technologists,
14 some of who are named and some of who volunteered
15 to do this. Our lead technologist, who has the
16 most expertise in it, learned how to do it on the
17 job with another lead technologist as she took over
18 the other person's job, but we have several other
19 technologists who do much of the charting, for
20 example, because we have multiple units. As former
21 director of a private practice who had 19 sites and
22 25 mammographic units, we had to go through many
23 different people to get the right person and to
24 train them.

25 Although it is possible to have such

1 training, I don't know if it exists, for example,
2 on the web, because I don't want to limit access in
3 the small rural communities, for example, who may
4 have one technologist or a couple technologists,
5 and they need to learn what they are doing, of
6 course, and I don't know if that exists now.

7 MS. HARVEY: Let's move on to the last
8 agenda item of the day. Dr. Finder.

9 **Review of Summary Minutes of**
10 **September 2000 Meeting**

11 DR. FINDER: Once again, last chance. Any
12 federal liaison, any AV rep want to give me their
13 mailing information and e-mail address, polls close
14 in 15 minutes, last chance.

15 Next, review of the summary minutes from
16 the last meeting. Anybody have any comments?

17 MS. ELLINGSON: Radiologic technologists
18 are quite sensitive. We don't like to be called
19 technicians. In the minutes, we were called
20 technicians again, so please call us technologists.

21 DR. FINDER: That was definitely an
22 oversight. We didn't catch it when it went out.
23 So, that will be corrected.

24 MS. ELLINGSON: Thank you.

25

Future Meeting

1 DR. FINDER: Any other comments?
2 Future meetings. I don't want to try and
3 set any specific date because several of the
4 members will not be here, we will have new members,
5 and we have to arrange times with them, but I would
6 want to get to try and get a feel from the current
7 members in terms about which day of the week do
8 they want, beginning, end, something like that, or
9 middle of the week is better, because we can try
10 and plan the meeting for that.

11 The other thing is we are probably going
12 to be looking for another meeting sometime in the
13 spring.

14 Does anybody have any preferences for
15 beginning, middle, or end of week?

16 DR. PISANO: End of the week is more
17 difficult to get home because the airports tend to
18 be more crowded, so I would prefer to avoid
19 Fridays.

20 DR. FINDER: What about Monday? That is
21 when we used to usually have the meetings. Anybody
22 have any problem with the middle of the week? We
23 have heard in previous panels that they had
24 problems because they had to travel during too many
25 workdays, but if that is not a problem with

ajh

1 anybody--

2 DR. IKEDA: It's all bad.

3 DR. FINDER: Well, that's another problem
4 we can't deal with, the airlines, it is not a part
5 of MQSA.

6 So, basically, I have heard that the only
7 thing we don't want to do is on Friday.

8 With that, does anybody else have any
9 other comments? I would want to thank two of our
10 members who this will be their last meeting - Dr.
11 Dowlat and Ms. Brown-Davis have served on our
12 committee for the last four years. See how time
13 flies when you are having fun.

14 I would like to thank them for their
15 service. While I don't have it with me, when your
16 term officially ends in the end of January, you
17 will be receiving a letter and a plaque for your
18 service, but we don't send them out at this point,
19 so you won't be getting them right now, but you
20 should be receiving those.

21 Once again, I and the entire Division want
22 to thank you for the efforts that you have put in,
23 in serving on this committee. So, thank you.

24 [Applause.]

25 MS. HARVEY: I believe that is it. Thank

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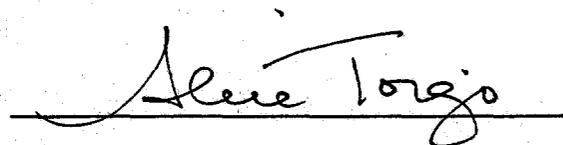
1 you for coming. Thank you for serving. The
2 meeting is closed.

3 [Meeting adjourned at 3:30 p.m.]

4

CERTIFICATE

I, ALICE TOIGO, 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.

A handwritten signature in cursive script, reading "Alice Toigo", is written over a solid horizontal line.

ALICE TOIGO