

1 we're not limiting the interpretation to necessarily
2 the onsite physician.

3 CHAIRPERSON HARVEY: Do we have any
4 thoughts about whether or not the number of hours of
5 continuing education should apply *ad infinitum* to
6 practitioners. I've heard many people say that after
7 doctors or rad techs actually have practiced for many
8 years that perhaps the need for 15 years in a three
9 year period isn't necessary any longer. It could be
10 scaled back to a lesser number of credits. Do any of
11 the rest of you hear this or feel that's the case?
12 Yes. Dr. Karellas.

13 DR. KARELLAS: Andrew Karellas. I don't
14 think five hours a year is too much to ask for. But
15 at the same time, I'm not sure how well continuing
16 education correlates to performance. I'm afraid that
17 the lack of continuing education may not be a good
18 thing altogether, but we all know that continuing
19 education can be very passive. It is very difficult
20 to recommend specifically as to what kind of
21 continuing education would demand workshop like quiz
22 or anything like that. However, I think still at the

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1 level that we are it's reasonable scaling back may
2 send the wrong message.

3 CHAIRPERSON HARVEY: Yes. Dr. Harrison.

4 DR. HARRISON: Miles Harrison. Just a
5 simplistic question. I'm the fish out of water. I
6 have no radiology background. I'm a surgeon. But my
7 concern when I hear moving toward some national
8 initiative to identifying experts and the ability to
9 send images rapidly and being interpreted anywhere is
10 that who gets to define who an expert is? Is that not
11 going to ensue with some issues of restriction of
12 trade? I'm really concerned about that. And
13 understand as a surgeon who absolutely needs accurate
14 reading of mammography, I'm not at all saying I would
15 not like an expert to read the film. But who's going
16 to start calling the shot who the expert is? That
17 concerns me.

18 CHAIRPERSON HARVEY: Yes. Dr. Timins.

19 DR. TIMINS: Julie Timins. Several things
20 that I want to address. One is that I think I would
21 be hard pressed to find some other expert who is going
22 to want to read my charity-care patients wherever I

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1 send them. Most facilities have one mammography unit.
2 I believe surveys have shown that.

3 A lot of small practices are reading
4 mammography that don't have the extensive
5 computerization available. The panel may predispose
6 to people from larger institutions who have multiple
7 facilities, multiple units, but that's not what's true
8 in most of the United States. So we have to keep in
9 mind the mammographic practitioners who are working in
10 the smaller facilities and also reading the 480
11 required a year but not much more than that.

12 2. In terms of education, I think a lot
13 of people feel that requiring six hours per modality
14 especially with the full-field digital is difficult
15 and that there should be a shift towards self
16 assessment of interpretative skills in CME. That's
17 something that bears consideration. I also feel that
18 a total of 15 hours over the course of three years or
19 average five hours per year of continuing education is
20 quite reasonable.

21 CHAIRPERSON HARVEY: Thank you. Amy
22 Rigsby.

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1 MS. RIGSBY: I would like to see rather
2 than so much paper checking when the inspector comes -
3 that's a big majority of it, looking at the paperwork
4 - I think that, like we were talking about experts, we
5 have to be certified every three years. We send in
6 our perfect mammograms and you know. Sometimes that's
7 easy to do and sometimes it isn't.

8 But what about all the other mammograms
9 that are taken every single day? I think it would be
10 great if the inspector actually looked at the
11 mammograms of each tact to see just at random at any
12 certain days what their mammograms look like. Of
13 course that would have to be more training for the
14 inspector. I would think they either need to be a
15 mammographer or perhaps a radiologist.

16 To me that would be a more effective
17 inspection than looking at our records which some
18 people can manufacture those, but still I don't see
19 that as a problem. When we have some facilities that
20 are not good in someone's opinion, I think it's
21 because of the poor positioning or the poor reading.
22 So we need to figure out a way to inspect the reader

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1 and the mammographer in some way however that could be
2 accomplish.

3 CHAIRPERSON HARVEY: So some form of MISA,
4 Mammographic Interpretative Skills Assessment.

5 MS. RIGSBY: Yes.

6 CHAIRPERSON HARVEY: For both the rad tech
7 and for the physician.

8 MS. RIGSBY: You know back in the early
9 days when an R.T. -- I took the first registry for
10 mammography in 1991 and there was no requirement that
11 I even have ever done a mammogram. Of course, I had
12 been doing mammograms for quite some time at that
13 time, but I went and sat for that registry and it
14 didn't require me to even have taken a mammogram. Now
15 of course you do have to at least perform mammography
16 and you have to be a tech at least a year. There are
17 several other requirements. I just think that we
18 should be evaluating that more than the paperwork
19 things.

20 CHAIRPERSON HARVEY: Dr. Karellas.

21 DR. KARELLAS: Although I agree in spirit
22 with Ms. Rigsby, I think there are some practical

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1 problems. For example, the paperwork is there and it
2 is to be inspected. If it's well done, there is
3 documentation. It is less subjective. What you see
4 there in writing is what you report and the paperwork
5 should be absolutely and completely honest.

6 From the point of view of the medical
7 physicist, I believe these numbers are believable. I
8 have seen various reports by many other physicists.
9 I think there is some very, very good work that is
10 happening out there and I do believe sometimes people
11 make certain small errors or some miscalculation, but
12 all in all, what I've seen in the field for the most
13 part, I have been very impressed.

14 Now when it comes to the interpretative
15 skills of the radiologist, I would advise people to
16 really shy away from that because it's very easy to be
17 wrong. I recommend very highly that you look in the
18 recent paper by David Gur from the University of
19 Pittsburgh in Cancer dated April 15th and please also
20 I know you enjoy reading the editorial by Dr. Brem.
21 They are talking about recall and detection rates in
22 screening mammography.

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1 And that can be any of us, not just the
2 inspector, can go in and see recall rates in the 15,
3 16 percent and that may be deemed very bad. These
4 people say in the paper that 12, 13 percent recall
5 rates are probably quite good and acceptable. There
6 is a lot of pressure to radiologists to maintain a
7 recall rate that is relatively low, in the order of
8 five to seven percent.

9 What I'm saying without saying what is
10 right and what is wrong here is that it is extremely
11 difficult for an inspector to work in and make a
12 judgment on the interpretative skills. It's just a
13 dangerous area. I'll have to say that inspectors I
14 have seen I've been quite impressed. I think they are
15 quite good and they are very well trained, but it's
16 just a very tough area. This is why I'm saying that
17 the paperwork when it's well done does speak for
18 itself and that's the only way you can go by.

19 DR. HARRISON: Question.

20 CHAIRPERSON HARVEY: Yes, Dr. Harrison.

21 DR. HARRISON: I agree with you both in
22 spirit and here comes another naive comment, but it

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1 gets at what we're talking about right now. With our
2 recertification situation in surgery right now, not
3 only do we have to take a didactic -- It's not the
4 same recertifying in institution and recertifying an
5 individual for skills - but there is some analogy here
6 that I think may be helpful.

7 There are two phases at this particular
8 time being proposed for us, a didactic phase where we
9 indeed do answer questions and see if you kept up or
10 see if you crammed the two weeks and then there is a
11 practical portion that's being proposed right now
12 because things change so rapidly for surgeons over the
13 last 20 years to make sure that we've incorporated the
14 new skill sets within our practices and are indeed
15 making the appropriate about when to and when not to
16 use that which I'm using sort of as an analogy for
17 interpretation. I realize the difficulty of anybody
18 trying to evaluate another physician's ability to
19 interpret x-ray or anything else for that matter. But
20 I still fail to see in my very naive surgeon's kind of
21 sense how we could relegate that to not being
22 important enough to address.

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1 CHAIRPERSON HARVEY: Ms. Mount.

2 MS. MOUNT: I agree with all of them too.
3 I just wanted to make a comment. We all have very
4 comprehensive programs in place and each institution
5 is basically responsible for their technologists'
6 repeat, reject reports. In that, each facility should
7 be able to tell whether or not each technologist is
8 doing a good job or not. If not, I would think that
9 the supervisor or the director of that facility could
10 handle that one on one.

11 Also we do have outcome audits for the
12 radiologists and I would assume that they would be
13 handled in the same way. That's their report card and
14 use that as a tool for improvement as opposed to
15 having an inspector come in and have that do their
16 job.

17 CHAIRPERSON HARVEY: Dr. Ferguson.

18 DR. FERGUSON: First, I would like to say
19 that Dr. Harrison is the most humble surgeon I have
20 ever heard or seen.

21 CHAIRPERSON HARVEY: I'm sitting with a
22 bunch of radiologists. I have no choice. I have one

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1 vote here.

2 DR. FERGUSON: But there's a couple of
3 points that Ms. Rigsby and Dr. Timins made that I
4 think are very important, some form of centralized
5 credentialing for paperwork. I agree that we spend
6 way too much time on paperwork and inspections and
7 there ought to be some type of random audit of maybe
8 not the interpretative skills because that is very
9 difficult. We need to address that within the
10 radiology community if it's a practical exam with CT
11 or however you decide decision CTs. That's something
12 we need to address. But the paperwork, if the
13 inspector could walk in and know who they are going to
14 see and who the technologists are, state inspectors
15 pretty know that. In my state, they know them all on
16 a first name basis. If the material is there, they
17 can dispense with that part as long as they don't have
18 new employees that aren't on the record and then get
19 to something that's more meaningful as to the quality
20 of the mammogram, the positioning, the technique, the
21 things that we all see and know or maybe they are not
22 optimal on this exam. I would like to see something

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1 like that.

2 Dr. Timins makes a good point on the
3 continuing education. Fifteen hours I don't believe
4 is an excess amount, but when you are doing it for
5 eight different facilities and they all have a
6 different timing of their inspection and you may not
7 be in sync on every inspection, again a centralized
8 system would allow you to look very rapidly and see if
9 you have the proper amount of continuing education
10 rather than trying to have that for each facility that
11 you report. That's my comment.

12 CHAIRPERSON HARVEY: Thank you. Yes, Dr.
13 Timins.

14 DR. TIMINS: Julie Timins. In discussing
15 with my state inspectors what their concerns were, I'm
16 sure there is the option of pulling out mammograms and
17 looking them for technical quality when you do an
18 inspection. That was not their concern. Their
19 concern was in expediting the process and their main
20 stumbling point is the personnel qualifications.

21 One suggestion made was in simply software
22 enhancements because some of the software requires you

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1 to exit the personnel screen, run a missing items
2 report, then return to the personnel screen and it
3 takes time. So one thing to facilitate would be some
4 software changes. Another might be as we said to have
5 a dataset available for individual credentialing and
6 either have it available on computer at the time of
7 inspection or have an annual sheet of paper that
8 updates the technologist's licensure and CME and the
9 physician's licensure and CME so that it's readily
10 available and easily checked.

11 As to our surgeon's concern with whether
12 we should be dealing with interpretative skills at
13 this point on MQSA, I think interpretative skills is
14 something that the professional organizations are
15 grappling with now. For several years there have been
16 voluntary interpretative skills tests available at
17 either the ACR annual meeting or the Radiological
18 Society of North American. There are increasing
19 educational programs to promote interpretative skills
20 and then retest at the end of the CME program. I
21 think that it is being approached and I don't think
22 it's quite ready to put into a form like the MQSA at

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1 the current time.

2 CHAIRPERSON HARVEY: Maryanne Harvey. I
3 would see that as being a substitute for a certain
4 number of continuing education credits. If a doctor
5 chose to take one of the MISA tests, that should be
6 equivalent to some number of continuing education
7 credits and in fact, maybe a little more as an
8 encouragement. You get a reward for doing that
9 because as Dr. Karellas said some continuing education
10 has more value and leads people to at least think a
11 little bit more about something than they've been
12 doing. People sometimes just feel that they need to
13 go through it pro forma because they are required to
14 do it. If we can add a little more meaning to it --
15 Yes, Ms. Martin.

16 MS. MARTIN: I'd like to just make a
17 couple of comments. One, I really would not like to
18 decrease the continuing education and continuing
19 experience requirements, but I would really like to
20 get a recommendation if possible from this committee
21 or at least something that we are going to promote
22 that soft copy documentation will be acceptable. It's

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1 not a requirement that it has to be, but at least that
2 it will be acceptable by the MQSA inspectors.

3 CHAIRPERSON HARVEY: Certainly. I think
4 we have agreement on that amongst the group. So any
5 other points? Mr. Camburn.

6 MR. CAMBURN: Yes. Jim Camburn. I just
7 want to echo a couple of things that have been said
8 here. From our perspective as a state that does the
9 regulations, we see just a huge difference from
10 facility to facility in the time that it takes us to
11 review these records. Some facilities have them in
12 excellent order for all of their sites. The book is
13 a single book that's maintained for all sites and is
14 just transported to individual sites to be there
15 during the inspection. It cuts a tremendous amount of
16 time from our inspections.

17 Other facilities, it's a separate record
18 for each location. They have extraneous material in
19 the records. It just bogs our inspectors down. So
20 there might be a way to streamline the process in many
21 facilities without doing a whole lot if the facilities
22 would just go to a more centralized record and keep

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1 the records up-to-date and available. Long term
2 having everything online and available to do it maybe
3 once would be wonderful. I'm not sure the cost and
4 effort of doing that is something we're going to be
5 able to accomplish real soon.

6 CHAIRPERSON HARVEY: Something to work
7 for. Right?

8 MR. CAMBURN: Yes.

9 CHAIRPERSON HARVEY: As years go by. Any
10 other comments? Dr. Hendricks.

11 DR. HENDRICKS: Carolyn Hendricks. I
12 think since we're going to be trying to respond to the
13 Institute of Medicine there are two lessons that may
14 be learned from JCAHO because they have struggled so
15 much with this with hospital accreditation. The first
16 one is to try to get the paper in before the
17 inspection so the deficiencies would be flagged. I
18 think that's an approach that JCAHO is having with
19 hospital accreditation now. But they've also taken
20 the approach of maybe a limited versus an extensive
21 inspection where some facilities might be subjected to
22 a more limited inspection on several years like maybe

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1 equipment only and that some might be selected for the
2 more extensive or more comprehensive approach. It
3 might be random. It might not. It might be targeted.
4 I know that's going to be the approach because
5 hospital accreditation has become so unwieldy.

6 Also their approach is to just target one
7 area in a hospital. Pain management, for example, is
8 just an example that everyone here is aware of it.
9 But in terms of mammography inspection maybe make a
10 focused inspection, something to look at in the future
11 as one aspect to improve quality.

12 CHAIRPERSON HARVEY: Maryanne Harvey.
13 Would the facility know beforehand what they were
14 going to have?

15 DR. HENDRICKS: The hospital do.

16 CHAIRPERSON HARVEY: Well because one of
17 the radiologists that I spoke to was concerned about
18 it because it's a very large program and it just shuts
19 them down for days. He said, "Oh, it's very
20 burdensome."

21 DR. HENDRICKS: It's like the comments of
22 the gentleman who spoke about the inspections that the

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1 more we let the facilities be aware of advance of the
2 inspection than the more successful that approach
3 would be I think.

4 CHAIRPERSON HARVEY: Right. Ms. Martin,
5 did you have something?

6 MS. MARTIN: Well, I was just following up
7 on Mr. Camburn's comments about if the books are
8 organized the way the inspectors want them. In my
9 experience, we have quite a variety among inspectors
10 as to how they want the books organized. I guess if
11 there's a template that goes out as to how the
12 facilities should organize their records and each
13 inspector actually used that same template, it would
14 help tremendously.

15 DR. RAMOS: Catalina Ramos. Just thinking
16 about moving to the electronic era, maybe not
17 immediately but long term, it will be great if we
18 could make a recommendation about developing some
19 software that actually also every single facility
20 would have the same software, the same template that
21 they just file out and they have everything. So
22 inspectors would the standards. We have what to look

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1 at and not only that but within the software can be a
2 way that they get the results.

3 CHAIRPERSON HARVEY: Ms. Pura.

4 MS. PURA: I like your idea about basing
5 a lot of this comparison to JCAHO because if you go to
6 limited or focused types of inspections at that point,
7 then you can actually ask for some randomized polls of
8 charts or whatever you need at that point and that's
9 an ideal time when it's limited or focused or targeted
10 to a specific area.

11 CHAIRPERSON HARVEY: Dr. Karellas.

12 DR. KARELLAS: I just want to make it
13 clear that the most important recommendation I think
14 is for having electronic form acceptable for the
15 inspectors. This is by far the first and most
16 important step. What I would definitely discourage is
17 having any agency being the safekeeper of anybody's
18 continuing education credits because this is a very
19 dynamic kind of process and it changes all the time.
20 If somebody missed my continuing education credits, I
21 would like to pick up the phone and not being very
22 nice to them for a minute because we pay for the

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1 service.

2 We feel if you don't do it well we will go
3 somewhere else. I believe there are facilities within
4 the hospital. You're computer people or private
5 parties that they would be very responsive because
6 that's the way the system works. I believe that
7 within the government if they had to handle that it
8 would be a very unfair burden to them. They are
9 excellent in keeping records and I have very good
10 experience, but I believe that if they become the
11 safekeeping place, it would not be appropriate thing
12 to do. But we should be able to transmit them
13 electronically to them if they wish and that would be
14 highly desirable to send data to the government,
15 state, FDA or whatever is appropriate electronically
16 at some time in the future.

17 MS. RIGSBY: Amy Rigsby. With ARRT who is
18 the American Registry for Technologists, they keep, of
19 course, everything current. The license is current.
20 The CEUs, we're required to do 24 in a two year
21 period.

22 I had a new employee last week that all I

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1 had to do was go online, put in her name and her
2 number and it said that she had a current license and
3 her CEU was current and up-to-date. It took a few
4 seconds. If we could do that for every technologist,
5 why couldn't we do that for the radiologists,
6 physicists? It would take a few seconds and that
7 would be it. Of course, they like to look at the
8 certificates of the CEUs that were attended rather
9 than a list of what they attended. So perhaps, they
10 still would want to do that, but the checking of the
11 licensure and all that could be really, really simple
12 in that way.

13 CHAIRPERSON HARVEY: Yes. Dr. Ferguson.

14 DR. FERGUSON: Scott Ferguson. I don't
15 know if there's a perfect answer for the centralized
16 credentialing but at least in our state every time we
17 renew our license - and you renew your license on your
18 birthdate - you send to the State Medical Board your
19 continuing education hours which could easily be
20 itemized as to what's in mammography or whatever you
21 want. The state inspectors could be authorized to
22 access that information. Now that seems to me a

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1 pretty simplistic way to do it. They keep up with all
2 our stuff.

3 All the insurance companies have to go
4 through our centralized credentialing service so that
5 we don't have to fill out the forms for every managed
6 care company in the state. It seems like that would
7 be one way to do it on a state-by-state basis. If
8 it's up there on the Internet and I can access it and
9 show it to the guy. Or if they could pull it up, it
10 would be even better.

11 CHAIRPERSON HARVEY: Dr. Timins.

12 DR. TIMINS: Julie Timins. I don't think
13 it's fair to put that burden on inspectors that they
14 would then have to check other sources like go to the
15 state. I think that everything should be right there
16 together for them when they come in. I am from one of
17 the last stalwart states. I think New Jersey is just
18 starting to institute mandatory CME for physicians if
19 you can imagine. However, most of us for whatever
20 purposes have been getting CME certificates from
21 either the state medical society or the AMA for many
22 years.

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1 When I get my CME certificate, it does not
2 state what my CME is in. I am the one who keeps track
3 of what courses I've taken and what my CME is in and
4 it's for me to ultimately know what I've done and be
5 responsible for 15 hours in mammography, 15 hours in
6 ultrasound over the course of three years.

7 CHAIRPERSON HARVEY: This is Maryanne
8 Harvey. I'm not sure that every state requires
9 continuing medical education, does it? I don't know
10 that New York does.

11 DR. TIMINS: No.

12 CHAIRPERSON HARVEY: It's doesn't. Dr.
13 Finder.

14 DR. FINDER: Yes. I just have a couple of
15 questions. A lot of things were talked about and I
16 want to clarify in my own mind some of these issues.
17 One issue I wanted to bring up which had been brought
18 up previously and at other meetings was this issue
19 about mammography modality, specific CME, the
20 requirement that we have basically for new
21 mammographic modalities that you have to have six
22 every three years and that for those people who don't

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1 know we have been basically pushing back on that
2 requirement that was supposed to go into effect in
3 2002. We pushed it back to 2004. Now it's been
4 pushed back to 2006 for a number of reasons basically
5 because of the fact that it's very difficult to get
6 some of these CME courses.

7 At other meetings, this issue has been
8 discussed and the recommendation was that we consider
9 not enforcing this requirement, this specific one
10 about modality, specific CME. We would enforce the
11 initial requirement of eight hours, but not this six
12 hours. Is that still the feeling of the committee?
13 I just want to check on that. I see heads going up
14 and down. I will take that as -- Well, does anybody
15 have a comment against that? We usually don't take
16 votes in terms of that. But if anybody has any
17 feelings against that, I would certainly be
18 interested.

19 Another issue that seems to be coming up
20 a lot is the issue about paperwork, the templates and
21 things like that. We have tried to deal with that.
22 One of the reasons we've published the actual

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1 inspection questions and the order in which they're
2 given is so that the facilities would actually be able
3 to see exactly what we were asking for and
4 theoretically they could look at it and say "This is
5 the question he's going to ask and the order he's
6 going to ask it in so I might as well put it in that
7 order and make things move smoothly." But the issue
8 of putting these paper documents into electronic
9 format, we have been looking at that issue and as I
10 said we will discuss that a little bit more, some of
11 the details, when we get to the Guidance section
12 because I do have a question on that.

13 The other question I had was we in our
14 inspection have asked for documentation. We want to
15 see the certificates. We want to see all this. Has
16 anybody given any thought to whether we should talk
17 about accepting an attestation saying that the person
18 met it and not go into the detail that we do now?
19 What do people think about that?

20 CHAIRPERSON HARVEY: Ms. Martin.

21 MS. MARTIN: I really like the fact that
22 you need some kind of credential that says you

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1 actually were there. It's way too easy to have
2 someone attest that I went to class.

3 CHAIRPERSON HARVEY: Dr. Timins and then
4 we have a question from the audience.

5 DR. TIMINS: Julie Timins. I am against
6 the simple attestation because people often think that
7 they did something more recently than they did. I
8 don't think that it would be specific perjury or
9 intend to defraud, but I think that people lose track
10 of time. I would rather have a requirement to see the
11 documentation so that people can be sure.

12 CHAIRPERSON HARVEY: From the audience?

13 MS. WILCOX: Pam Wilcox, American College
14 of Radiology. Just as an FYI, the ACR and the RSNA
15 are putting together a centralized database where
16 members which means physicians and physicists, not
17 include the technologists, would be able to keep track
18 of all of their CME. So that may be an opportunity.
19 It's very early stages, but it certainly might be an
20 opportunity for this committee to give feedback to
21 that group and I certainly will take it back to our
22 staff who's working on it that electronic verification

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1 of what courses you took should be available broken
2 out by modality and then you wouldn't need either an
3 attestation or the paperwork for all of the
4 certificates because that would be submitted to that
5 centralized repository.

6 DR. TIMINS: And just one step further,
7 but one of the things that the ACR is working on is a
8 generalized needs assessment for an individual's CMEs.
9 So that if one required some assistance in
10 interpretative skills whether it be mammography or CT
11 or whatever that it could be addressed in a learning
12 plan and this would all be online.

13 MS. WILCOX: Exactly. That's also part of
14 maintenance of certification that all medical
15 specialities are looking at. So what Dr. Timins was
16 speaking to was that piece that will give you the
17 maintenance for certification documentation.

18 DR. FINDER: This is Dr. Finder again. I
19 do want to make mention of the issue about trying to
20 check people's credentials, having the inspector check
21 them online. One of the technical problems with that
22 is when they are at the facility they may not have

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1 access to the Internet. We don't necessarily give
2 them access to the Internet and it might be difficult
3 for them all of a sudden to start using the facility's
4 phone lines to connect up. That's one issue.

5 Another issue I wanted to ask about. Has
6 anybody given consideration to changing the way we
7 inspect and also our regulation that deals with these
8 continuing requirements which basically are set on the
9 date of the inspection by regulation? People have
10 mentioned that some of the other organizations go on
11 a yearly basis.

12 Is that something that we should consider
13 and when I mention that I will give one of the reasons
14 that we went with the system we did go with is what
15 are you going to do with the person who didn't meet it
16 by the calendar year but now meets it by the time you
17 go in there and inspect them? Are you going to cite
18 them because they didn't meet it in the past, but they
19 meet it now? That's one of the reasons we went with
20 the date of the inspection, but it does create certain
21 problems. Any thoughts on that?

22 CHAIRPERSON HARVEY: Dr. Karellas.

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1 DR. KARELLAS: Well, you could have a
2 system of rewards. The people who do not do well
3 could have inspections at an increased frequency.
4 Where people who consistently demonstrate compliance,
5 it could be less frequent. But clearly if that
6 applies to facilities that they do not have a good
7 record in the past two or three years, that could be
8 the wrong message. This can be done. I do not think
9 that this is that difficult that if a facility is not
10 doing very well that the frequency is done always on
11 a yearly basis. Where a facility with an outstanding
12 record could skip a year.

13 DR. FINDER: Well, let me just answer
14 that. That's one of the things that we did do with
15 the inspection demonstration program to look at
16 facilities that were without violations over several
17 years and see how they would do if we gave them an
18 inspection every other year. As Dr. Barr mentioned,
19 that program is coming to its end. We're going to be
20 looking at the data, but some of the initial data that
21 she talked about does seem to indicate that these
22 facilities if you're not there every year tend to

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1 become less vigilant.

2 CHAIRPERSON HARVEY: But are they
3 substantive violations or not?

4 DR. FINDER: Well, that's what we're going
5 to have to look at as part of the analysis of the
6 program. Again it hasn't even totally finished yet.
7 There are still some facilities that have yet to be
8 inspected. So that is one of the areas that we're
9 going to be looking at and GAO is going to be looking
10 at to see whether this is a viable option or not and
11 how it plays out.

12 CHAIRPERSON HARVEY: Dr. Reicher.

13 DR. REICHER: I just wanted to address a
14 few things. One is in the quest of safe, accurate and
15 cost effective mammography. It seems that a lot of
16 the discussion is based on the things that we're
17 trying to measure indirectly that we hope will lead to
18 those results like CME, number of mammos read, tech
19 retakes and things like that. But the facilities are
20 required to keep the data which is very different by
21 the way than surgical data where it's acuity-adjusted.
22 Mammography is pretty digital in its outcomes. You

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1 can measure number of cancers diagnosed per thousand
2 cases read and you can measure number of recalls and
3 have some targeted bracket.

4 A suggestion that I would have is that the
5 current guideline is fairly indistinct as to what
6 outcomes need to be measured. Having a single outcome
7 data sheet that everyone used that says this is
8 exactly the data we want you to collect, the number of
9 mammos read by each radiologist - I'll speak on the
10 radiologist side. Similar things could be done on the
11 tech side as well - but the number of cases read, the
12 number of fours and fives, the number of those, the
13 number of biopsy-proven cancers per thousand
14 mammograms read, a very structured form I think would
15 be tremendously beneficial to at least get you by this
16 time next year or the following year to the point
17 where you could do some sort of outcomes-based
18 analysis.

19 I would further that by saying that there
20 could be a carrot in a stick model that you might
21 consider. That would be that if you have data that
22 shows that you're diagnosing at least four breast

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1 cancers per thousand mammos read and your positive
2 biopsy rate relative to recommended biopsies is at
3 least say 25 percent, then maybe the next year you
4 don't have to file your CME forms and you don't have
5 to read 240 mammograms.

6 If the pudding is served, why continue to
7 run people through the cost of the indirect proof? So
8 something for you to consider would be a standardized
9 data collection form that everybody would use and then
10 some sort of carrot that would reduce the required
11 regulations appropriately if your stats were
12 appropriately high. That would reduce costs.

13 The other comment and then I'll sit down
14 is that the comment was made that mammograms could be
15 centrally read. I just want to make it clear that
16 technology does not exist today to allow mammograms to
17 be cost effectively digitized or digital mammograms to
18 be moved because of other topics that need to be
19 addressed like data compression. It's just not
20 practical to do that.

21 CHAIRPERSON HARVEY: Someday. Any further
22 comments before we break for lunch? Ms. Martin.

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1 MS. MARTIN: I was just going to add
2 something that AAPM is also going to offer. Since all
3 the physicists that provide mammography services are
4 not ABR certified, there is another option available
5 to them for a centralized database to keep their
6 continuing education units online and available
7 because AAPM offers that also.

8 CHAIRPERSON HARVEY: Okay. Dr. Karellas.

9 DR. KARELLAS: The only issue about what
10 Dr. Reicher suggested is that if you have several
11 practitioners, they perform at different levels within
12 an institution. It's very difficult to tailor the
13 inspection if all these people would -- They are
14 accepted. It's pretty normal to operate at a
15 different level.

16 However, I totally agree with his
17 assessment that the technology does not exist to move
18 all mammograms to a central facility. We have had a
19 few examples and experiments and at some point, it's
20 probably practice to some low level, but the
21 technology is not there yet.

22 CHAIRPERSON HARVEY: All right. We'll

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1 break for lunch and return at 1:15 p.m. Off the
2 record.

3 (Whereupon, at 12:01 p.m., the above-
4 entitled matter recessed to reconvene at
5 1:07 p.m. the same day.)

6 CHAIRPERSON HARVEY: All right. We will
7 begin this afternoon's session on addressing
8 mechanisms to reduce the regulatory and inspection
9 burdens on facilities, and this concentration is on
10 equipment and quality control in the able hands of our
11 Ms. Martin.

12 MS. MARTIN: Well, I thought I would bring
13 up some general topics, and I'm sure there's enough
14 items in this to hopefully generate some interesting
15 discussion. For those that are looking in their
16 handouts, the equipment actually -- the actual
17 equipment regulations start on page 5 of the Facility
18 Regulations, just so you know what we're talking
19 about.

20 I think the other item of interest is to
21 look at the number of citations that was handed out
22 this morning. And if you go to the page that's item

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1 74 under QA/QC, I assume these are the 9,000
2 inspections, since we have 9,000 facilities. So if
3 you look at that, the percentage actually isn't high.
4 But what I was looking for was the actual number of
5 citations. And if you look at that, the phantom image
6 is still a significant, and the other one that is a
7 very significant item is number 87, where the phantom
8 image was taken out of compliance and absolutely no
9 corrective was taken. So the question that was raised
10 a while ago, do we need continuing education?
11 Obviously, we're still missing the boat somewhere in
12 the idea that we don't just take images, we actually
13 evaluate images. And so if we have 500 citations were
14 no corrective action was taken, we need to do
15 something to correct that so that the staff at the
16 facilities know that they not only take the image,
17 they have to actually evaluate it and take action.

18 The one item I would really like to bring
19 up for discussion that impacts the physicist is for
20 the new facilities that are digital only. And I think
21 this committee needs to make a recommendation. For
22 those that may not be aware, the current physics tests

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1 that are required for new equipment in an all-digital
2 facility still have some film-based tests in them, and
3 new facilities don't have film processors, so it is a
4 Catch-22. There is no way to make some of these
5 tests. And I think we need to look at how we can
6 evaluate the performance of that equipment without
7 requiring those two film-based tests when there are no
8 processors.

9 The idea that we have based our equipment
10 evaluation requirements that we still have to evaluate
11 the resolution of a mammography unit on a film-screen
12 system that's never, ever going to be used on a film-
13 screen system, we don't need that test. And I would
14 make the recommendation we take that out. If it's
15 only a digital unit, I don't see why we have that in
16 there.

17 The other item I'd like to bring up just
18 to open, and I'm really sorry but whatever is in bloom
19 around here is driving me crazy. I think we've got --
20 I would really like to figure out how to take the
21 emphasis of what we do for QA/QC, and I think it
22 correlates with what we said this morning. If we

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1 could make the idea that what we're going for is the
2 best image quality and how to achieve that, we've
3 established certain tests that we're doing. We've
4 established education, we've established training,
5 we've established certain QC tests. And I think I
6 would really like that emphasis to be on the image
7 quality obtained at the end of all of this, not that
8 it's such a paperwork review. And what we can do to
9 change that emphasis of the evaluation is what I would
10 like to hear other people's ideas.

11 I also know I have two technologists on
12 this panel that have lots and lots of experience in
13 QC, so I'm really looking to Amy and to Carol for
14 input on what you, as technologists, have experienced
15 on the day-to-day QC that works and what doesn't work.
16 So it's your's, guys.

17 CHAIRPERSON HARVEY: Okay. The ball's in
18 the court. Carol.

19 MS. MOUNT: I'm Carol Mount. I'll start
20 with one test that I think has become somewhat
21 redundant, and it's simply because we come from a very
22 large institution. But the screen-film contact test,

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1 having to do it every year and only if you have an
2 area of poor contact that does not move, that does not
3 go away after three tries do you throw that cassette
4 out. We have to shoot in excess of 200 films. We
5 have over 200 cassettes, and so we're throwing that
6 away. Throwing the money away, throwing the time
7 away. The person that does it has to work after hours
8 only since it's inception - I think it was probably
9 about in '90 or '91 when the manufacturers became very
10 aware of the fact that a number 8 mesh was not
11 appropriate for testing mammography cassettes, and the
12 standard was set to a number 8. After the time, I
13 believe the manufacturers have really stepped up to
14 the plate. We have found a couple of cassettes as we
15 have entered them into the facility that have had poor
16 contact, that we actually have discarded before we
17 ever starting using them. But since they have been
18 into place, we have cassettes that date back to when
19 the MIN-R2000 was still a thought, and not even a
20 product yet, right onto new cassettes that have been
21 added in our facility within the last year. And we
22 have yet to throw one out in our annual testing.

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1 And so, I would kind of like to see the
2 regulation change so that it is done annual. And any
3 time new cassettes are introduced into the facility,
4 or any time that you believe that there is a problem
5 with contact - and I talked to another large
6 institution and they agreed, they had the same outcome
7 from their facility.

8 We have also, in the event of all this
9 time blown to x-ray tubes because of the 225 cassettes
10 that we test one after the other, which is probably
11 poor judgment on our part, and we should move it
12 around to different machines. But once you find that
13 density that matches you hate to set up another room,
14 so that's one thing that I think we could cut back on.
15 It would save costs, and I don't -- we have never
16 found a problem.

17 MS. MARTIN: I would agree covering the
18 facilities we have, once a year would certainly be
19 adequate for a screen-film contact. The physicist
20 only checks uniformity once a year. I really don't
21 know why we're doing screen-film contact twice a year.

22 MS. RIGSBY: Amy Rigsby. I agree with

1 that. That's certainly the QC test that takes the
2 most time. Even if you don't have 200 and some
3 cassettes, every facility usually has like two sets of
4 cassettes for every room, close to that. It does take
5 a lot of time, and hopefully the technologists can
6 identify if there is a problem with a cassette and
7 then do it at that time, so that's a good suggestion,
8 I think, going to once a year when there's new
9 cassettes brought into the facility, and then if
10 there's a problem.

11 CHAIRPERSON HARVEY: Carol.

12 MS. MOUNT: Carol Mount. Also, I noticed
13 that Melissa was mentioning the violations, and I
14 noticed the screen-film contact violation was fairly
15 high. I'm assuming it's because data was missing.
16 Either they're not doing it twice a year, or they're
17 not even doing it once a year. I'm not sure, but I
18 know the inspector doesn't typically go in and check
19 all the films and look at them, so I'm assuming it
20 just has to be because of data missing.

21 MS. MARTIN: It's data missing, and my
22 understanding -- and those that actually know how this

1 inspection works, but my understanding is if you have
2 80 cassettes and you are missing one, you are given
3 that violation. So it's very easy to get that
4 violation, which again, I see no reason in the world
5 they're doing it twice a year. And you get -- this is
6 what I was saying, the no-brainer stuff that winds up
7 as a "violation". But yes, if you have 80 cassettes
8 it's awfully easy -- it's a large challenge to find
9 them twice a year and get them all done, and just
10 document. I'm not sure that would qualify as a
11 violation that the facility is not doing their job.

12 The other thing I find at least, and I'm
13 not sure -- I'm looking for guidance, the suggestion
14 of the weekly phantom. For those that have GE
15 machines in the automatic modes, the kV fluctuates
16 between 25 and 26 most of the time, so the mass that
17 is recorded, you have to have for the mass for both 25
18 and 26 on a lot of film-screen systems. Is there a
19 suggestion for how to make it easier or make it a non-
20 violation or how to track the mass for those units?

21 DR. FINDER: This is Dr. Finder. There's
22 no regulation that you have to track the mass at all.

1 Okay. Not for regular machines. Now we do have the -
2 - the issue of the mass comes in when you're dealing
3 with mobile units, and you're using that as a test to
4 determine that. And we have actually put out guidance
5 that you could set up your standards for either the 25
6 or 26 kV, and use that as an example. But we don't
7 require that mass be tracked for the weekly testing or
8 anything else, so that's not a requirement, so you
9 can't be cited for it.

10 MS. MARTIN: Okay.

11 CHAIRPERSON HARVEY: Yes. Dr. Timins.

12 DR. TIMINS: Julie Timins. My
13 understanding is that the uniformity of screen-spread
14 is done by the physicist at this point.

15 MS. MARTIN: Yes.

16 DR. TIMINS: And it was suggested to me
17 that this be moved to the RT instead of the physicist,
18 and then have the physicist review it. And that the
19 mAs check had been removed, and that this was
20 something that should be reinstated, especially as Dr.
21 Finder said, for mobile units.

22 MS. MARTIN: For mobile units that is

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1 pretty much the way people track their ability to
2 shoot the next patient. But it is a requirement that
3 has gone away. And I know that they were tracking
4 just density, so as long as you density was okay, that
5 that was the only thing they were really tracking. I
6 guess I was still based on -- I'm amazed at the number
7 of phone calls I get that my mass is different today,
8 or my mass is different this week. Maybe we've just
9 our people trained to call us if anything changes, but
10 it's obviously not a citable offense. It's just a QA
11 option that we've got set up.

12 CHAIRPERSON HARVEY: The FDA is not --

13 MS. MARTIN: I think I'd like to follow-
14 up.

15 CHAIRPERSON HARVEY: Go ahead.

16 MS. MARTIN: The uniformity test -
17 obviously, it's a job. There's no question the
18 technologists couldn't do that test. I think it's a
19 question of who has more time to do that test. And my
20 impression is the technologists don't want another
21 test moved to them, but that's -- it's a question. It
22 is not a test that would require physicists to do it,

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1 but the physicist needs to review it. And a lot of
2 the facilities don't have the piece of Lucite. But if
3 you do, it would certainly be up to -- I mean, I find
4 no reason why it would not be acceptable to use that
5 mode, as long as the physicist reviewed it, and the
6 technologists wanted to take, or were willing to make
7 that test. I think that should be an acceptable
8 practice.

9 CHAIRPERSON HARVEY: Carol.

10 MS. MOUNT: Carol Mount. I agree, that is
11 something that the technologists could quite easily
12 take on. Now are you talking -- you're doing
13 uniformity as a separate test, or is uniformity and
14 screen-speed there together, or they're separate?

15 MS. MARTIN: Screen-film contact you mean?

16 MS. MOUNT: No.

17 MS. MARTIN: The screen-speed is one test,
18 and the uniformity is all one test.

19 MS. MOUNT: It's all one test. Okay.
20 Because I know that we have found again, over time,
21 that we have cassettes that are '90 vintage, and then
22 ones that are the 2004 vintage. And because of the

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1 spread of the speed and the density that you are
2 allowed to have, we do not throw any cassettes out for
3 that either. And so I would like to propose that we
4 could do a -- you do your initial test. You get your
5 baseline, and then every time you introduce new
6 cassettes into the system, you just do a percentage of
7 the existing cassettes with the new ones, and see if
8 that matches. Again, I think the manufacturers are
9 very in tune. When the regulation was first made, I
10 believe it was felt that probably screens would maybe
11 change color, maybe the speed would change a little
12 bit, maybe there would be some inherent quality that
13 would cause them to falter and you would have to throw
14 them out. But again, with the vintage that we have
15 across the years, we have not thrown any out for that
16 either. And maybe that would be a possibility of just
17 testing a portion of them with all of the new ones,
18 and then each time you bring in new ones you just take
19 another handful and test against the next batch. Is
20 that something that would be acceptable?

21 MS. MARTIN: Well, what I actually have is
22 we use the phantom cassette as the control cassette,

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1 and every time they get new cassettes we have them run
2 the new cassettes versus the phantom cassette to make
3 sure they're within the .15. And that's how we've set
4 our programs up, and that allows them to implement the
5 new cassettes, because most of the time the vintage
6 cassettes will age, and you may have to separate those
7 out per room, but you don't toss them. You just
8 designate them for one room.

9 MS. MOUNT: We haven't even had the
10 situation where we've had to separate them.

11 MS. MARTIN: Right. We have too.

12 MS. RIGSBY: Amy Rigsby. I agree that the
13 technologists could do that exam, but why would we not
14 want to keep having physicists do it? I mean, they
15 are there for a certain period of time to do their
16 annual visit, and technologists time - unless that's
17 all they do is QC. Most of the time they're doing
18 patients, and have a hard enough time trying to get
19 everything done anyway, so I really wouldn't -- I
20 mean, they could do it, but I would rather just keep
21 it with the physicist's visit.

22 MS. MARTIN: I don't think it necessarily

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1 needs to be -- I mean, I was just looking for the
2 option. I think it's acceptable either way to do it,
3 either the physicist does it or the technologist does
4 it and the physicist reviews it. I would say that
5 either mode would work. I've got lots of facilities
6 where I'm going to be doing it forever, I can tell
7 you.

8 CHAIRPERSON HARVEY: It's good to be
9 employed.

10 MS. MARTIN: But I've got others that the
11 technologists would be quite happy to do it and get me
12 out of there 30 minutes less time off of her machine.
13 They'll get me out of there. I'd like to come back,
14 if we could, to the digital question.

15 CHAIRPERSON HARVEY: Did you want to wait
16 on digital?

17 MS. MARTIN: Oh, does anybody want --

18 CHAIRPERSON HARVEY: Okay. Go ahead.

19 MS. MARTIN: For those physicist tests
20 that do require film, is there an option? I'm looking
21 to Dr. Finder to just find out. Is there any options
22 at this point, or what do we need to do to take that

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1 out of the current requirement for a new unit to be
2 tested for facilities that do not have a film, or any
3 film, or any film processor? I'm looking for what do
4 we do with that.

5 DR. FINDER: Well, I think Dr. Mourad can
6 probably speak better to the individual specific
7 question about which tests require what, and --

8 MS. MARTIN: Well, there's two that are
9 the problem.

10 DR. MOURAD: Wally Mourad, FDA. First of
11 all, regarding the digital units right now, if the
12 unit has been downloaded as a digital unit, we don't
13 do any physical tests on it. Okay. There's no -- we
14 don't do the collimation, we don't do the dose test,
15 we don't do anything on it. So that's not even there.

16 MS. MARTIN: You don't, meaning the
17 inspectors?

18 DR. MOURAD: The inspectors do not do
19 that.

20 MS. MARTIN: Oh.

21 DR. MOURAD: So the only thing we ask the
22 inspectors to look at is did the physicist do the

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1 survey on it, did the physicist do the equipment
2 evaluations on it, did the facility do the QC on it?
3 That's all.

4 MS. MARTIN: No. I'm asking for the
5 question that is the resolution test under the
6 physicist equipment evaluation, it says that we have
7 to do it with film-screen.

8 DR. MOURAD: Gotcha. Okay. Now we also
9 have a regulation that says for digital units, you do
10 the tests that are recommended by the modality
11 manufacturer, and that falls into there. So you look
12 at the manufacturer of the modality and whatever test
13 they ask you to do for the resolution, you do that.
14 It doesn't follow the 11 and 13 line pairs.

15 Now if I may make two comments since I'm
16 here.

17 CHAIRPERSON HARVEY: Sure.

18 DR. MOURAD: The uniformity of screen-
19 speed is an annual test by the regulations, it's part
20 of the survey test, so that's something we cannot
21 change immediately. Be aware of that. The other one
22 is the screen-film contact is also a semi-annual in

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1 the regulations, so if we have to change that, again
2 we have to amend the regs. Just be aware of that.
3 Thanks.

4 DR. CHAKRABARTI: Kish Chakrabarti with
5 FDA. What Melissa asked is in actual physicist test
6 during equipment evaluation, as well as for annual
7 test, there are some tests which require film
8 processing and film. In a complete digital system why
9 would you want to have an additional burden on the
10 facility to have a processor - and I have discussed
11 with all the manufacturers that I know that those are
12 the tests somehow to be removed. And I think all
13 manufacturers are currently thinking that ultimately -
14 - but as it stands now, that there are two or three
15 tests which requires films and stays there, but I
16 think we should be all discussing in future, and I'm
17 talking with the manufacturers, all of them that why
18 in a complete digital system there would be tests
19 which requires film. Did I answer you, Melissa?

20 MS. MARTIN: Yes. I just want to know
21 when.

22 DR. CHAKRABARTI: One thing that I

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1 suggested that you -- is he a Christian, the chair of
2 that committee. I mean that as -- IEC where I
3 suggested and everybody took it, the Europeans are
4 working on it. One way to look at that extra field is
5 Phosphor, bringing that Phosphor out. And I'm talking
6 with manufacturers on that, and there are
7 manufacturers who will be coming with the idea of a
8 Phosphor which can look at the x-ray film. There can
9 be some type density given, and that's one area I know
10 IEC is accepting that, and Christian, if he wants to
11 talk - say something about that. This is a very
12 important test, where the x-ray field must be traced.
13 And the Phosphor would be one where there would be no
14 film required. But when, I cannot answer.

15 CHAIRPERSON HARVEY: Would the direct
16 print paper work?

17 DR. CHAKRABARTI: Good point, and I raised
18 that issue and I'm told that that direct print paper
19 is not at the level that much.

20 MS. MARTIN: That is the challenge, is the
21 field alignment test and the resolution tests are
22 still two film tests. And the Phosphor would work

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1 fine if that's going to be acceptable. I'm just
2 bringing up two issues that the physicists are having
3 a real problem with in the way we're currently told to
4 do this.

5 One of the other items that is providing
6 us a challenge, and Dr. Karellas may know more than
7 I'm aware - the Fisher system currently requires an
8 invasive method to measure the kVp. And so, that is
9 the other challenge that physicists are currently
10 faced with on annual basis to meet the requirements.
11 And Fisher says there's supposed to be one model of
12 equipment that will be out and available that will
13 measure their kVP. So I'm just bringing it that we
14 are faced with certain challenges that we're told to
15 measure that are not necessarily easily accommodated.

16 DR. KARELLAS: Andrew Karellas. Just one
17 brief comment on the uniformity. No matter who does
18 it, I don't know who's going to save any time. It's
19 just a matter of option, but I agree with you in
20 general. Whoever does it, it does not really matter
21 that much, as long as it is done. And most
22 importantly, that a physicist has reviewed it. And we

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1 all know that there are some facilities that the
2 technologists can do it, and there are many facilities
3 that the technologists would not be able to do it
4 properly.

5 On the digital, there is at least one
6 manufacturer that recommends the use of film as a part
7 of the QA. It is difficult to recommend a specific
8 alternative right now but, of course, using a Phosphor
9 that you can observe and measure is very tricky. It's
10 sort of a nice idea, but you don't really have -- you
11 cannot put a ruler very easily, and you cannot have a
12 quantitative measurement.

13 The use of Phosphors has been around for
14 a very long time, and service engineers have been
15 using them for aligning collimators. The use of
16 storage Phosphorus, CR-type of technology, is
17 potentially an alternative in institutions that they
18 do have it. But a small facility, or relatively
19 small, maybe just breast imaging or mammography, so
20 they may not have anything at all. So I think the
21 challenge at this stage would be out there to the
22 world and the manufacturers to see what they have to

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1 recommend. It's very difficult to recommend
2 technologies from our point of view that we have not
3 tested, and we don't know if they work.

4 MS. MARTIN: Agreed. As far as quality
5 control, I think the one point I'd really like to make
6 is I'd really like to keep the requirement in that the
7 physicist must review and approve the quality control
8 for the facility. I think that's really important and
9 requires the physicist to actually be on site. I
10 really don't want to go away from the idea that the
11 physicist that's responsible for that facility would
12 be allowed to do an off-site review in any way. And
13 I just would like to make that recommendation, that we
14 keep that requirement in the regulations.

15 DR. TIMINS: Julie Timins. Now one of the
16 questions that had been posed was when a new processor
17 came on line, when it's installed or there's been a
18 major repair, I believe that the physicist at this
19 point has to do the QC and approve before any patients
20 are done. This can be burdensome, and one suggestion
21 was perhaps to have the physicist supervising maybe
22 remotely the initial QC, and then have let's say 10

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1 business days to actually come down and finalize the
2 approval, but allow patients to be studied after the
3 QC has been done, maybe by a technologist and reviewed
4 off-site. So give 10 working days for the physicist
5 to come down while allowing the facility to function.

6 MS. MARTIN: I thought the physicist
7 already had the option to do it. It's under
8 supervision. It's not -- is it direct on-site?

9 DR. FINDER: Yes. The regulations require
10 that when a mammography equipment evaluation for
11 either the unit or a processor, if it's a newly
12 installed processor, that the physicist has to come
13 on-site and do the testing of that processor before
14 any patient films are run through there. I guess the
15 question is, is it possible to accomplish the same
16 quality, the same safety by having physicist oversight
17 and not requiring the physicist to physically be out
18 there at that time, again in order to make the switch
19 to a new processor a lot smoother, less burdensome, et
20 cetera. So what do people think?

21 MS. MARTIN: Assuming the physicist is
22 comfortable with it, I would leave it up to physicist

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1 oversight. I don't have a problem with that, as long
2 as it's physicist oversight. If the facility sends in
3 the QC to you, you've got all the data right there,
4 whether the QC, the strip is right, the phantom is
5 right, the images are right. I wouldn't have a
6 problem going with the physicist oversight. What's
7 your opinion?

8 MS. RIGSBY: This is Amy Rigsby. I think
9 I would feel comfortable with that being a facility,
10 as long as the physicist gave the go-ahead before we
11 started patients.

12 MS. MARTIN: Right.

13 MS. RIGSBY: I would want that. I mean,
14 have them have the data in their hands and say okay.
15 But if it weren't that, I wouldn't want it to be the
16 responsibility of the technologist or anybody else to
17 decide that it was okay.

18 MS. MARTIN: Yes. I would like to make
19 that point. I don't -- I would think the physicist
20 has to approve it before any patients are done on it.
21 I don't want 10 days of patients, and then you tell me
22 you put a new processor in.

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1 DR. TIMINS: It's just a matter of
2 physical presence.

3 MS. MARTIN: Right. But if the physicist
4 has signed off on it, they're going to know whether
5 they're comfortable with that facility's QC
6 technologist or not. And if the physicist says
7 they're comfortable with that facility's QC
8 technologist and they have all the data, and can check
9 the image quality and dose calculations and signs off
10 on it, that's really physicist oversight.

11 CHAIRPERSON HARVEY: Andrew.

12 DR. KARELLAS: The physicist should
13 exercise the oversight. However, it is extremely
14 critical that it is communicated properly. Very
15 frequently, somebody may say well, I called the
16 physicist. The physicist should be notified, has a
17 chance to review the data, and the approval has to be
18 done in writing with date. Approval without a
19 signature and a date and a comment stating what you
20 observed and why you're allowing it, isn't worth very
21 much, so I think the physicist will find out that some
22 of the time may have to go to the facility. Although

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1 much of the time, if they do everything correctly, the
2 physicist may not have to visit the facility, but they
3 should have a chance to review the data, go over with
4 the technologist, see what the problem, how the
5 processor was installed. Initially, there are likely
6 to be problems, the first day of operation and how
7 they were resolved, and then he can sign off.

8 DR. RAMOS: Yes. This is Catalina Ramos.
9 I totally agree. I think that if that is going to
10 change, the way that it's written and the way that
11 it's communicated needs to be very clear. Things
12 happen down the line, and sometimes language change.
13 And as a patient, I will not feel comfortable if I
14 come in that period, and for some reason there is no
15 one responsible. There is not extreme quality
16 assurance that those films are going to be accurate.

17 CHAIRPERSON HARVEY: Great. Carol.

18 MS. MOUNT: Carol Mount. I have one more
19 comment about one of the tests that we're doing, the
20 phantom image. And I think it's excellent. However,
21 we have it set up as a 1.2 density in the regs, and I
22 just feel that we are setting people up for failure if

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1 they really think a 1.2 is going to cut it. I don't
2 know. I guess I would like feedback from people,
3 physicists especially, or technologists what your
4 feeling is on this. But also, if we were to increase
5 our mid-density, I also think with the high contrast
6 films out there, we should also increase the allowable
7 contrast fluctuation, because the high contrast films,
8 the higher you go, and if we're going to allow a .2
9 mid-density range difference, we actually then need to
10 increase that contrast just a little bit for those
11 high contrast films. I'd like your feelings on that.

12 MS. MARTIN: Actually, that was my last
13 topic, was the great phantom image. I would like to
14 make a proposal, and Carol brought in one point of it.
15 I think the parameters we've used as the initial MQSA
16 parameters are set to make people fail their clinical
17 image reviews if they only meet those minimum
18 standards. I would really love to see data, and I
19 doubt if it's available. I would love to see
20 correlation of anyone that has passed a clinical
21 review that had a phantom image that was a 4-3-3 score
22 with a phantom background of 1.2. And I think that's

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1 a great falsehood that we are telling people that they
2 can pass with those images.

3 I think we need to set probably 1.6 as the
4 aim, and 1.4 as the minimum. And I would really like
5 to see the standard image quality set at 5-4-3-1/2 or
6 5-4-4 score, or 5-3-1/2-4 score because that's really
7 what it takes for that phantom image to make a
8 clinical image that will pass today's requirements.
9 If you can't see five fibers, I don't see how you
10 would ever get a clinical image that would pass.

11 DR. KARELLAS: I agree with the 1.2
12 density. It is too low. The question is whether we
13 want to have a regulation for that or not. I review
14 a lot of phantoms, and it is true that from time to
15 time some of them may be low. And recommending a 1.4
16 is, perhaps, reasonable for the phantom, and 1.6 might
17 be a little too restrictive, 1.4 might be reasonable,
18 I believe, in all situations. I do not see that as a
19 huge problem, but I see that in a significant number
20 of phantoms that they come, that they look okay, but
21 the density is clearly too low.

22 On the issue of specs on the phantom, it

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1 is very difficult to fail a phantom on specs. Unless
2 you really feel like you want to penalize that
3 facility because they have all kinds of other things,
4 interfering speck-like features and you subtract quite
5 aggressively. But truly, if you read the rules very
6 carefully about how to score the phantom, it is
7 difficult to fail them by applying these rules.

8 However, it is not all that difficult to
9 give a low score on the masses. The masses are pretty
10 tough, even for good facilities sometimes. Increasing
11 the threshold for specks is a very tough call. We
12 have to be extremely careful as to whether that's a
13 reasonable thing to do. We do not know where we are
14 going as far as any new phantoms, or any new ways of
15 testing mammographic facilities, but it is true that
16 we have to think of the significance if we are to
17 recommend changing the recommendations.

18 Interestingly, one manufacturer has a
19 higher standard for specks than what we use for film,
20 or what we use for other facilities. So other
21 manufacturers of -- and that is for digital
22 mammography. Other manufacturers have stayed at the

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1 current level of three groups.

2 CHAIRPERSON HARVEY: Maryanne Harvey. Are
3 there any of these tests that we might consider
4 eliminating from either QC or physics? Everything is
5 -- the recommendation should be to stay --

6 MS. MARTIN: I don't have any
7 recommendations for eliminating any of them.

8 CHAIRPERSON HARVEY: Jim.

9 MR. CAMBURN: Yes. Jim Camburn. From the
10 state regulatory perspective, we would strongly
11 support keeping these tests as part of the annual
12 exams.

13 CHAIRPERSON HARVEY: One of the questions
14 that came up had to do with measuring dose, because
15 there were zero numbers of violations.

16 MS. MARTIN: I don't see why -- I guess my
17 response to that would be the physicists are doing it,
18 and there's been absolutely no reason. I think it's a
19 choice of where the FDA chooses to spend its money.
20 And if this is a mandated -- I think it's a
21 requirement under the current regulations that the
22 inspectors actually measure this. If it's not, I

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1 don't see any reason really that you're spending all
2 the money for the inspectors to go in and remeasure
3 the dose that the physicist has already measured. I
4 think it's an absolute waste.

5 DR. FINDER: Well, this is Dr. Finder.
6 There is no regulatory requirement that it be done by
7 the inspector. There is a requirement that the dose
8 be measured, and that it be within a certain level,
9 but it doesn't specifically state who does it. And I
10 guess one of the questions is, is who should be doing
11 the dose?

12 Right now we have three different groups
13 doing it. We have the inspector doing it annually.
14 We have the physicist doing it annually, and we have
15 the accreditation body doing it every three years.
16 The question really is should we keep it that way,
17 should we look at the inspection and say it's not
18 cost-effective to continue to do that, just let the
19 physicist and the ABs do it, or some other combination
20 thereof.

21 DR. TIMINS: Julie Timins. In speaking to
22 the inspectors in my State of New Jersey, the fine

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1 State of New Jersey, they all felt very strongly that
2 they would like to continue doing an annual dose
3 check; that they felt that it was such an important
4 issue and not difficult to do, that it should be
5 continued.

6 MS. MARTIN: I'm not arguing the
7 difficulty of it. I think it was a question of where
8 do you spend your limited resources. And I think it
9 is a measurement that the physicists are making every
10 year. And so if you had to look at what equipment
11 that would be eliminated that is an expensive set of
12 equipment, that is probably a test that the physicists
13 are adequately covering. And that's where I'm coming
14 from. If we're looking for where do you spend your
15 dollars, that is one expensive set of equipment that
16 has to be sent out, maintained and calibrated every
17 single year, that I'm really not -- according to this,
18 we've not had any problems with. And that's what I
19 was going with, was correlating the findings with what
20 we're actually measuring.

21 DR. TIMINS: Well, we have a number of QC
22 programs in New Jersey well beyond mammography, and so

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1 we've got the equipment. We're using it in
2 practitioners' offices all the time, chiropractors,
3 podiatrists, internists, so keeping the equipment
4 functional and calibrated is not an issue.

5 DR. FINDER: Dr. Finder. Actually, it is
6 an issue because we supply the equipment. We supply
7 the calibration for the units that are supposedly only
8 being used for mammography in the fine State of New
9 Jersey. They may be using this equipment for other
10 reasons, but -- no, I still think you can back to New
11 Jersey, but the cost of the equipment and the
12 calibration of the equipment for mammography purposes
13 is part of the program. And whether they are using
14 this for other state activities, or whether they have
15 their own equipment for the other state tests that
16 they do, that is separate. I just wanted to clarify
17 that.

18 CHAIRPERSON HARVEY: Dr. Karellas.

19 DR. KARELLAS: Andrew Karellas. I don't
20 believe that the inspectors going through all these
21 tests is necessary. I think it's a duplication. I
22 think they should be free to conduct tests if they

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1 felt there is a need for, and I don't think inspectors
2 should be restricted from conducting any of these
3 tests. But routinely measuring dose is a duplication
4 of effort, and I don't believe is a good use of their
5 time.

6 The physicists provide very comprehensive
7 reports, and if somebody does not believe that report,
8 then I think we have a huge problem. But the
9 statistics show that these reports are very accurate,
10 because there is nobody contests that. And so if we
11 go on and we continue doing something that the
12 statistics are telling us that there is very little
13 value in doing it, then what are we going to
14 eliminate?

15 CHAIRPERSON HARVEY: Jim.

16 MR. CAMBURN: Jim Camburn again. When we
17 measure dose during mammography tests, really it's not
18 a very lengthy procedure. We check half-value layer,
19 we check exposure at skin entrance, and from that dose
20 is calculated. And probably like other states, we do
21 this not just with diagnostic mammography equipment,
22 but we do this with stereotactic mammography, as well,

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1 which does not even come under the MQSA umbrella. And
2 it seems to be such an integral, important test to
3 ensure the population that radiation doses are really
4 being maintained and the doses that are linked to
5 image quality are what they should be. So it's not
6 just a matter of checking the phantom image or the
7 dose separately, the two are linked.

8 And there's also a position that I'm sure
9 most of the members are aware of, of the Conference of
10 Radiation Control Program Directors. This is a
11 conference that represents all of the states'
12 radiation control programs. And they have come up
13 with a list of items that they think are essential,
14 that should be essential parts of all annual
15 mammography inspections. And the first three on their
16 list are all related to this, measure exposure at skin
17 entrance, measure half-value layer, and calculate
18 average mean glandular dose as part of state
19 inspections. I really don't think we should be
20 tampering with that, and trying to cut back in that
21 area.

22 In terms of what the doses find, I guess

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1 I agree with Andrew that most of the time there is
2 very good correlation there, but there isn't always.
3 We had a case just last month where the physicist who
4 went in to do the exam we're thinking he probably did
5 not get a chance to really talk one-on-one with the
6 mammography technologist who uses a particular
7 machine, and he used some machine settings and some
8 factors to calculate dose that when we went in there
9 later, the operator of the machine said no, we don't
10 use the machine that way. And we got some
11 significantly different dose results than what the
12 physicist got. Now maybe the operator told us wrong.
13 You know, there could be communication problems there,
14 but it seems like this is a very good double-check too
15 that should continue.

16 CHAIRPERSON HARVEY: We have a member of
17 the audience.

18 MS. BUTLER: Penny Butler from ACR. I did
19 want to comment regarding the medical physicist test
20 that the ACR has data from the Atkins study that
21 perhaps kVp checked on an annual basis is not really
22 necessary. It might be useful to check it during

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1 equipment evaluation, but it's not something that
2 fails. And the calibration, particularly with the
3 requirement of the new units, and over the past 10
4 years units where the high frequency generators have
5 really stabilized, so that may not be necessary.

6 I was also going to comment about the dose
7 issue. And with regard to dose, the accreditation
8 body does check it, the physicist does check it once
9 a year. Looking at the data that Mike Divine
10 presented, it looks like it's not something that
11 fails. And so if it doesn't fail, why do we need
12 three tests? Those are my only comments.

13 MS. MARTIN: The other question I'd like
14 to bring up is if this is the topic of what -- is
15 there any plans to incorporate stereotactic units and
16 QC programs for those units? Are we still ignoring
17 the fact that they're out there?

18 DR. FINDER: This is Dr. Finder. We don't
19 ignore anything, although Dr. Barr is coming up to the
20 microphone.

21 DR. BARR: Just so we won't ignore -- this
22 is Helen Barr, FDA. Our position, Melissa, is and

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1 continues to be that until we have a public health
2 risk demonstrated to us that stereotactic is out there
3 causing, and that public health risk is demonstrated
4 to us that federal regulation is the way to fix that
5 demonstrated public health risk, that we're not
6 including it under MQSA at this time. If you can
7 convince us otherwise, we're more than happy to
8 listen. Thank you.

9 MS. MARTIN: Just thought it was a topic
10 that needed to be brought up. I have no further
11 topics, if somebody else does.

12 DR. FERGUSON: Being new to the committee
13 and not certain of how things function, we had a lot
14 of discussion about doing the test three times, and it
15 seemed to me that it was pretty -- we need to do the
16 test one time, and somebody doesn't need to be doing
17 it. How do we resolve that? Do we vote? Do we tell
18 them - we nod our heads, or where do we go with this?

19 DR. FINDER: Well, this is Dr. Finder. I
20 think we've heard both sides. We've heard people who
21 have made arguments, good arguments for why the test
22 is valuable and probably should be kept, and we've

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1 heard other ones that say that it's redundancy and for
2 cost issues might be one of the tests that could be
3 dropped.

4 We've heard the committee. We're going to
5 look at the issues and the costs, and all the details,
6 and try and come up with a decision whether this test
7 or any of the other suggestions that have been brought
8 up should be implemented. Obviously, these types of
9 things will be brought back to the committee. They'll
10 be informed about which way we're going and things
11 like that, but I don't think it really has to be a
12 vote in the sense of if only two people or three
13 people said that it's a good idea one way or the
14 other, and other people - and there were four people
15 that said it wasn't - that that would be the defining
16 factor in this. We're not taking votes like that. We
17 want to get the opinions of the committee, and then
18 we're going to have look long and hard at the details
19 of it before any decisions are made. So I don't
20 really think we need to get a vote, we need to get a
21 sense of what the committee is thinking though, and I
22 think we've got that.

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1 DR. KARELLAS: Andrew Karellas. One issue
2 with image quality is often associated with artifacts,
3 and it is more difficult to set standards with the
4 tools that we have. Often you may see everything that
5 you need to see in the phantom, but you have
6 horrendous artifacts, and it is easier for the medical
7 physicist to make a comment or a very strong comment
8 that you need something to do about that. I would
9 imagine that from the regulator's point of view, the
10 inspectors would be a little more difficult, because
11 everything shows up there but there are clear
12 artifacts. And you can, of course, say it's
13 unacceptable. It becomes somewhat subjective, but we
14 all know that if you gave it to five reviewers or ten
15 reviewers, every one of them would agree that there
16 are very severe and unacceptable artifacts, most often
17 from dust-like artifacts or worn out screens, or
18 sometimes anti-scatter grid line artifact.

19 CHAIRPERSON HARVEY: Any more comments
20 regarding equipment or quality control? Thank you.
21 So settle down, we're going to start the next
22 mechanism to reduce the regulatory and inspection

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1 burden. And it has to do with medical records and the
2 audit. And we started talking about this already.
3 This conversation began earlier this morning, and it's
4 an important one because medical records take a lot of
5 time and effort on the part of the facilities that
6 have to do the work regarding the medical records.
7 And also, the audit is a major activity in every
8 facility that's under MQSA. So let's -- shall we
9 start with the medical audit, since that's the one
10 that we began earlier today. Dr. Reicher had raised
11 the issue of a standardized form that would include
12 the different ingredients or the different pieces of
13 information that we would like to see on the audit.

14 The importance of the audit, of course, is
15 to help the facility essentially to understand its own
16 processes, and to improve internally. The thing that
17 I hear back from a lot of our inspectors is it's a
18 burden on the Rad Techs, and the doctors don't spend
19 as much time working on it as they ought to. So the
20 Rad Techs are running around trying to gather the
21 data, but the doctors don't necessarily use it for the
22 purpose for which it was intended. So I would hope

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1 that we could look at this medical audit with the hope
2 of some renewal of spirit to it, and some -- because
3 it's one of the most important - do we find cancers?
4 The goal here is to have quality image that leads us
5 to find cancers, that lead to other further studies
6 and treatment on women as part of a process. What are
7 our experiences with medical audits? Quiet group
8 suddenly. Do we have some positive points on medical
9 audits? No, don't like them at all? Out the door?

10 MS. MARTIN: I mean, from the physicist,
11 I only have the complaints, so I can't contribute
12 anything that's positive, because all I do is listen
13 to the people at the facilities complain about them.
14 I know that --

15 CHAIRPERSON HARVEY: The collecting of the
16 data?

17 MS. MARTIN: Yes.

18 CHAIRPERSON HARVEY: How difficult it is.

19 MS. MARTIN: How difficult the data is to
20 collect. And they call asking us, what do we do? We
21 can't get the data. I said it's not the physicist
22 doing the audit, but we do have a problem out there.

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1 It's very difficult to actually collect the data
2 apparently the way it's supposed to be collected. And
3 I think it's very different whether you're talking
4 about a large facility with a good tumor board where
5 most of the procedures are handled there, versus the
6 small facility who is sending their patients away for
7 most of their surgeries. And those are the ones that
8 seem to have the real problems, is the ones without
9 the computer, without the tumor board, without that
10 database to work with. They have a very, very
11 difficult time.

12 CHAIRPERSON HARVEY: Okay. Do you feel
13 that too?

14 MS. RIGSBY: We are not a large, large
15 facility but we have an information system, PenRad,
16 that collects our information. And then we have a
17 person who that's her job, is to get the further
18 results from the surgeries, pathology, all of that
19 kind of thing. And then the computer prints the
20 report after she inputs the information, but I could
21 see where a small facility who didn't have the
22 personnel or the computer to do that, that it would be

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1 a problem.

2 CHAIRPERSON HARVEY: Yes, Ms. Mount.

3 MS. MOUNT: Carol Mount. I would have to
4 agree with Amy that we also have a system in place
5 where we have a person that that's their job, they
6 enter data. They follow-up on biopsies, do pathology
7 reports. And without that, it would be extremely
8 difficult, but because we have that in place, it works
9 very well for us.

10 CHAIRPERSON HARVEY: We have a guest from
11 the audience.

12 MS. DESTONET: Judy Destonet from
13 Baltimore. We have a group of people who do nothing
14 but collect our medical audit data, and it's very
15 expensive, time consuming, but indeed it is very
16 useful. It allows us to assess our practice, to
17 determine who's doing a good job and who needs CME or
18 who needs further feedback on what they're doing. But
19 the committee needs to understand that when you look
20 at audit data, we don't just look at the number of
21 cancers that are found per thousand, because there are
22 very many variables that go into that data. What your

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1 patient population is like, are you doing asymptomatic
2 women, are you doing symptomatic patients, are you
3 doing patients who have prevalence, or many who have
4 never had mammograms before? So there are very, very
5 many variables, and it's not just a number per
6 thousand that you can look at and assess the quality
7 of a facility, so we have to be very careful when we
8 analyze the data that we don't over-estimate how good
9 a facility is, or under-estimate what a facility is
10 doing.

11 The committee also should recognize that
12 this is an unreimbursed mandate on the facilities, and
13 in my practice it, indeed, is costly, but something
14 that we continue to do.

15 CHAIRPERSON HARVEY: Dr. Karellas.

16 DR. KARELLAS: Andrew Karellas. That was
17 very well said. This is exactly why I cautioned
18 earlier. It's okay to collect certain data, but it is
19 very easy to be wrong on the analysis of the data.
20 And there are some toprnotch investigators around the
21 country that have made that their life, and they try
22 very hard, and that's all they do. And they are right

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1 much of the time, but they may not be correct in every
2 analysis they do. And they recognize that, so we just
3 have to be extremely careful as to how the data is
4 collected, and how it is analyzed in view of what that
5 facility is all about.

6 And there is no question that some
7 institutions do a very good job in these audits
8 because they are automated, computerized, they have
9 good tumor boards. But the small facilities, it is a
10 very difficult thing to do, and it is not reimbursed
11 by anybody, so that adds another burden.

12 A final thought that I would like on that
13 issue is that now you can see if somebody who is
14 finishing residency and was sitting right here, and we
15 told them well, look, you have the option of reading
16 musculoskeletal MRI all day and deal with these
17 issues, or you may come here to do mammography, and we
18 will analyze you every year, and we will measure you
19 every year. And if you were a young resident and you
20 wanted to go into a new field, and pay your school
21 debts, you tell me where you would want to go. Of
22 course, I'm sure that a certain number of them will

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1 still feel the call and the dedication and they will
2 do it, and some do. But we are having a hard time to
3 attract the best and the brightest. We attract many
4 best and brightest but not enough into the field, so
5 that is a problem.

6 CHAIRPERSON HARVEY: Yes. Ms. Pura.

7 MS. PURA: Linda Pura. I do realize that
8 it is difficult getting those pathology reports, or
9 any kind of report back, especially from surgeons -
10 Dr. Harrison excepted - because I deal with a great
11 many providers, and they also have medical providers,
12 clinical providers, primary care providers, they have
13 a difficulty getting pathology reports or any type of
14 report back, so that I understand and I certainly
15 empathize with that.

16 However, being a consumer and being a
17 consumer representative, I have to say that this is a
18 section I would not like to see reduced in strength,
19 or taken out at all.

20 CHAIRPERSON HARVEY: Yes, Ms. Martin.

21 MS. MARTIN: One of the questions we get
22 asked routinely and that I have carefully avoided

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1 answering, but I think it's still a valid question;
2 what is the -- is the number that is attached to Dr.
3 X versus Dr. Z - and we heard data presented this
4 morning, even within a group reading the same
5 population, you had numbers that came from four in a
6 thousand to thirteen in a thousand, depending on the
7 physician.

8 What is the purpose of this data? Is it
9 to set a standard, if the doctor doesn't read a 6 out
10 of a thousand? In other words, that's a question.
11 Are they going to get told that they are not adequate
12 if they don't find at least six per thousand? You
13 know, we're collecting a lot of data. What are we
14 doing with it?

15 DR. FINDER: This is Dr. Finder. When you
16 say we're collecting a lot of data, you have to be
17 careful about who is "we". The federal government is
18 not collecting this data. This data is for the
19 purposes of the facility. It stays at the facility.
20 All the inspector does when they check for this, is to
21 make sure that it was done. They don't collect it and
22 send it to us, so we don't have any national data.

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1 The purpose of the audit as originally
2 envisioned for the regulations was as a tool to help
3 the facility analyze their own facility to see how
4 they're doing, and what we actually created was a
5 review audit physician who was supposed to look at
6 this data and make the judgment for that facility, for
7 those physicians, does the data show that something
8 needs to be done? If so, they can decide. But we
9 were never trying to set a standard saying that if you
10 read six per thousand or whatever, that there's some
11 magic number, because of all the variables that go
12 into it. Even in the same facility you may have
13 people doing screenings only versus diagnostic only,
14 or you'll have somebody who is doing a much smaller
15 number of films, and the statistical variability will
16 change the numbers significantly. So this was
17 supposed to be, and the way we look at it right now is
18 an internal learning tool for the facility. They're
19 supposed to decide what actions, if any, need to be
20 taken.

21 If some people have advocated trying to
22 turn this into a mechanism that can be used for

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1 regulatory action to say that if somebody doesn't meet
2 a certain standard, that we should take some action,
3 we should cite the facility, we should stop them from
4 doing it. And part of the problem is the variability
5 in these numbers.

6 We have had -- I've been at meetings where
7 somebody - nationally known mammographers have stood
8 up and said well, it depends, if you looked at my
9 numbers from my diagnostic center, I would look so-
10 and-so. If you looked at my numbers from my screening
11 center, I'd look like this - I'd look like two
12 different people, even though I read the exact same
13 way. These are the types of problems that we have,
14 depending on how you want to use it. But I think as
15 it stands right now, the audit is supposed to be used
16 as an internal teaching tool.

17 CHAIRPERSON HARVEY: Dr. Reicher.

18 DR. REICHER: At the risk of being
19 reiteratively redundant, I mentioned earlier that we
20 should try to encourage some sort of standardized data
21 collection, and I agree with all the comments that we
22 need to tread lightly. I'm observing that we tread

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1 pretty heavily when it comes to physics, and we tread
2 very lightly when it comes to interfering with medical
3 practice. That may be appropriate, but it's an
4 observation anyway, particularly in this case where
5 the medical practice is reasonably easily
6 quantifiable.

7 And one of the requirements in the data
8 collection is not to separate data collection out
9 between screening and diagnostic mammography. And at
10 the risk of increasing the data collection burden,
11 that would be one of the first things - that would be
12 the first thing I would suggest, if there is a
13 standardized set of data that one could propose that
14 each institution collect. It would make it easier for
15 the inspectors, and it would put us in a position a
16 year or two from now where it would be easier to reach
17 agreement, because reaching agreement is highly
18 dependent on everybody evaluating the same
19 information. So extending that thought of a
20 standardized form, I would strongly urge that sites be
21 asked to separate their diagnostic and screening data,
22 because then the data would, in fact, be comparable.

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1 The other thing is on the topic of
2 reducing regulatory burden on facilities and
3 inspectors. The question was raised before as to what
4 do you do when there is no film? As a provider, I
5 would ask that question, as well. It looks, as I
6 read, and re-read, and re-read the regulations, it's
7 very unclear to me whether I have to be able to
8 provide film, or whether I can provide data on a CD to
9 them.

10 DR. FINDER: That question actually has
11 been specifically answered in our policy guidance help
12 system, and what we've said there is for the time
13 being, facilities have to maintain the ability for
14 FFDM system, for Full Field Digital Systems, the
15 ability to produce hard copy for two reasons. One is,
16 the accreditation bodies at the present time only
17 handle hard copy, they don't handle electronic data.
18 So in order to become accredited they need that
19 capability.

20 Two, they need to be able to produce a
21 hard copy for a patient, because at the present time,
22 most facilities, most referring physicians don't have

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1 the capability to take a CD and look at it in any
2 meaningful way, so they have to have that capability.

3 We have, however, said that in those cases
4 where you're transferring let's say from one facility
5 to another that has FFDM, as long as they're
6 compatible and both sides agree to it, then you can
7 transmit the data electronically in those kind of
8 cases.

9 DR. REICHER: Okay. So as I understand
10 what you just said, everyone who has digital mammo,
11 has to have a printer.

12 DR. FINDER: Yes.

13 DR. REICHER: Currently.

14 DR. FINDER: Yes.

15 DR. REICHER: And so since this is an
16 advisory committee, I'm asking you to begin to
17 envision the circumstances under which that will
18 change. I mean, how many CD-ROMs have to exist on
19 computers in the United States? I guess, at the
20 moment I would contend that CD-ROM is more available
21 than a viewbox. In fact, a quality CD-ROM is my
22 referring physician's office I think is more likely

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1 than a clean viewbox in his office. But again, we're
2 operating from different data sets there. If you
3 agree with me, we would no longer have a printer
4 requirement. I would ask you to begin to envision
5 under what circumstances that rule will change,
6 because once you establish the criteria, you can go
7 out and measure things and see has that criteria been
8 met.

9 And then the last thing is the record
10 requirement. Right now a facility is required to keep
11 it's like five years if you've got prior mammograms
12 containers, and another thing that the FDA could do is
13 consider reducing the record requirement to something
14 like the previous three mammograms, or the previous
15 two mammograms, or some number that is not based in
16 time but is based on a legitimate prior record. And
17 I think that potentially could tremendously reduce the
18 data burden on facilities.

19 DR. FINDER: That's a good point. I just
20 want to mention that while most of the things we've
21 been talking about today would require, at most,
22 either a change in guidance or a change in regulation.

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1 Changing the record retention requirement would need
2 a change in the law, because that is specifically
3 included in the act itself, so that would have to go
4 through Congress. That's not something we could do at
5 this -- well, I couldn't do it. I just want to
6 mention that. It is possible, but I want to --

7 DR. TIMINS: Julie Timins. As somebody
8 who reads mammography, I really don't want to get rid
9 of any previous mammograms because you always have an
10 area that was covered in 1998 that wasn't covered
11 since, or subtle changes or differences in technique
12 and positioning. And I find those previous mammograms
13 so indispensable in increasing my accuracy and my
14 certainty.

15 CHAIRPERSON HARVEY: Ms. Martin.

16 MS. MARTIN: One of the other questions
17 that has come up is for those facilities that have the
18 CAD systems where you take a film, and then you read
19 the film. You basically digitize a film. Is it
20 acceptable if they only maintain the digitized data
21 and not the original film?

22 CHAIRPERSON HARVEY: As I understand it,

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1 we will discuss that later.

2 MS. MARTIN: Oh. Excuse me.

3 DR. FINDER: Yes. We have a whole section
4 on that.

5 MS. MARTIN: That's right, so save your
6 questions. Well, we didn't look at medical records,
7 or do we have -- anyone want -- so we're comfortable
8 with the way that medical records are kept, and we
9 don't have any questions or changes that we see that
10 we would like to make? No. All right. One, two,
11 three, closing this section. So we're ready to move
12 on to other issues.

13 Some of the other issues that have come up
14 had to do with the future for stereotactic inspection
15 processes. I know that this group doesn't have any
16 regulatory authority over ultrasound, but I would like
17 to make the pitch to the government to see that
18 ultrasound is also a very important aspect, need a
19 localization, all the stereotactic, the digital that
20 we have regulation on film-screen, and digital coming.
21 But these other areas also need to be incorporated, so
22 those are some of my other issues that I think are

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1 important that we remember.

2 What other issues are we dealing with out
3 there in the everyday world that need to be discussed?
4 Yes.

5 DR. HENDRICKS: Carol Hendricks again. I
6 just have a question. Have the sites ever been
7 surveyed as to where they perceive the burdens to be
8 in these four categories in terms of records
9 outweighing the physical examination of the site,
10 versus just which -- you know, we're supposed to be
11 addressing the burdens, and so how do the sites bring
12 these burdens, or are they all -- I know they all need
13 to be reduced, but is there one of these areas that's
14 a bigger oppressing concern for the facilities right
15 now for us to try to address?

16 CHAIRPERSON HARVEY: Right. I don't
17 believe we've -- have you done any surveys that looked
18 at this particular issue?

19 DR. FINDER: We did two facility surveys
20 over the last several years and addressed some of
21 these issues in terms of -- did we actually have data
22 on specific areas that they wanted to decrease? Wait.

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1 Hang on, Nancy. They won't hear you until you get up
2 to the mic.

3 MS. WYNNE: Nancy Wynne with FDA. There
4 were not specific areas, targeted areas that they said
5 were the most burdensome. In aggregate, the time in
6 the facility, the down-time was the issue. I think we
7 can go back and look at those two particular surveys
8 and try to glean and cull anything from them, but when
9 we did the synopsis on the survey, there was not any
10 that I can recall that were specific.

11 DR. FINDER: This is Dr. Finder. I'd also
12 add that the comments that we heard here today are the
13 comments that we hear from facilities, and when we go
14 to meetings, it's the paperwork burden, it's the cost
15 of the audit, it's the cost of these types of things.
16 But usually, not a specific one test or one issue.
17 It's the entire overall viewpoint of what it's costing
18 facilities.

19 CHAIRPERSON HARVEY: Ms. Martin.

20 MS. MARTIN: I would just bring up the
21 topic again, that if you have a facility with multiple
22 machines and the inspector on-site reviews say two of

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1 the machines, and they exactly correlate with what the
2 physicist has provided in their report, I mean within
3 some reasonable number, I would reiterate, I don't
4 think it's necessary that they inspect all the
5 machines in that facility. And I think that would be
6 a way to reduce the down-time. And that's the comment
7 I get all the time, is the amount of down-time
8 associated with the inspections, because they take the
9 machine down for the physicist, and they have to turn
10 around and take the machine down again for the
11 inspector. And so if it's a duplication of effort,
12 the inspector's got no reason to think there's a
13 problem, if we can do anything to incorporate the
14 physicist's numbers into the report for the facility,
15 I'd really like to see that reduced. Anything we can
16 do to reduce down-time in the facility would help.

17 CHAIRPERSON HARVEY: Yes. Dr. Henderson.

18 DR. HENDERSON: I would agree with you. I
19 just want to reiterate that since I'm representing the
20 public, I'm agreeing with Dr. Camburn's comment that
21 dose would probably be the most important test to the
22 public. And I would not support eliminating that,

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1 even though it could be redundant. I would not
2 support eliminating that because I think the public's
3 perception is that's the most important test that
4 there could be ever be. And three tests may not even
5 be enough for them.

6 CHAIRPERSON HARVEY: Dr. Karellas.

7 DR. KARELLAS: Well, this is why we went
8 to school and studied science. If you see the
9 numbers, and I understand the sensitivity. I
10 perfectly understand the sensitivity, and sometimes
11 you have to check two and three times because if it
12 fails, it will be a very bad outcome and very
13 embarrassing, so I understand Mr. Camburn's and Dr.
14 Henderson's concern about that. So I don't want to
15 minimize the importance. And I think their aim is
16 very noble, and I understand they want to protect the
17 public. At some point we may have to look very
18 carefully, but the statistics say something, and they
19 say it again, and again, and again. And we really
20 have to back off a little bit and think, and say well,
21 we don't have the detector with us, and we always
22 exercise our option to measure anything at any time,

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1 and that's fair.

2 There are indirect ways of calculating the
3 dose. Machines now have the mAs, and the kVp, and you
4 can very easily calculate the entrance exposure by
5 looking at mAs and kVp. You can have a plot or a
6 graph. In fact, I think that many of us could do it
7 quite easily, not very, very accurately, but certainly
8 to know whether something looks like it's really too
9 much. And if you have an average breast, or when you
10 do the phantom, for example, you take a phantom and
11 you place it there, you take a very quick image. You
12 know what the mAs and kVp is, you know you're very
13 well within it. So there are indirect ways that the
14 inspectors do monitor the dose indirectly. They may
15 not have to use a detector, but it's a shortcut that
16 they can perform. There are many ways of doing that.

17 CHAIRPERSON HARVEY: Okay. Yes, please
18 come to the speaker.

19 MS. CORYELL: Hello. My name is Tammy
20 Coryell, and I'm a mammography tech from Missouri.
21 And I formerly worked for the Missouri Department of
22 Health as a state inspector, not a mammography - or

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1 not an MQSA inspector, but I have just a couple of
2 quick questions that I wanted to pose to you. And one
3 is, on the density difference on the phantom, that
4 seems to be a big issue with a lot of facilities, that
5 they're going out of control on the density difference
6 because the window is so tight. And more contrast is
7 a really good thing. Can there be like a lower limit
8 set that you can't go below a certain number, but a
9 little bit more than a plus 5 increase on the density
10 difference?

11 And then another question that I had was
12 on viewboxes. I feel like the inspection process does
13 not really include anything to do with viewing
14 conditions, particularly the technologist's viewing
15 conditions. And a lot of times they're very, very
16 poor. The ACR and probably all of the other
17 accrediting bodies state that the technologist should
18 have the same viewing conditions available to them as
19 the radiologist, but nobody is really checking that.
20 And I've gone into facilities that were using
21 something that was so poor it should not even have
22 been used for general diagnostic radiology, let alone

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1 mammography.

2 Another question that I have is on the
3 inspector's phantom, their phantom is different than
4 the facility phantom. And a lot of times what I see
5 is the facility may be getting an average or a back-
6 grab density of around 1.75, 1.8. The inspector
7 phantom, because it's a little bit different, it does
8 not have the disk on top, therefore, they get a little
9 bit different compression thickness than what the
10 facility gets, a lot of times their background density
11 may come out at 2.0 upwards to 2.2. And I feel like
12 that maybe it will be a good idea for the inspector to
13 also shoot a phantom using the facility's phantom, and
14 check that against their charts to make sure that they
15 are, indeed, in control.

16 One other item, or I guess I have two
17 others and they've very quick, is the way that the
18 deficiencies are currently done, there are some things
19 that you get cited for; for instance, fixer retention.
20 If you go four months on fixer retention, you are
21 going to get a deficiency for that. There are other
22 things -- which is a good thing. I'm not saying that

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1 it shouldn't be cited, but there are other things that
2 a lot of the general public does not know, but if you
3 miss doing processor QC for a day, and it's only one
4 day out of a month or 30 days of processor QC, you're
5 not going to get a deficiency for that. And I feel
6 that sends a message to the public that the QC is
7 really not that important, if we're going to allow
8 acceptable losses. Don't worry about those patients
9 that were done on those days that the QC was not done,
10 because it was only a small percentage out of your
11 overall QC.

12 I feel like processor QC is very, very
13 important. It should be important every day for every
14 patient. We should not have any acceptable losses.
15 And if you can get a deficiency for one month late, or
16 even one day late on your fixer retention, then we
17 should be a little bit more stringent with how our
18 regular processor and phantom QC is done.

19 And the last thing is just a comment. The
20 State of Missouri has done a film review during the
21 inspection not done by the MQSA inspectors, it's done
22 by a registered technologist for the last five years

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1 in conjunction with their inspection, and it has
2 turned -- and we've talked about this today. That's
3 why I wanted to bring this up. It's turned up a lot
4 of really interesting things.

5 Facilities that have done very, very well
6 on MQSA year after year, that we anticipated were
7 going to have very good films, they've never had a
8 problem with ACR, or any accreditation, has had some
9 of the poorest films that we've seen in our state. And
10 other facilities that maybe had problematic
11 inspections because they couldn't dot the Is an cross
12 the Ts, have had excellent films. And it didn't seem
13 to matter a whole lot about the type of facility, or
14 the size of it. It was more of a how many exams are
15 they doing?

16 We looked only at technical quality.
17 We're technologists. We only looked at what the
18 technologist should be looking for. It had nothing to
19 do with the reading, but it was really interesting.
20 We just pulled films at random, and checked them, and
21 then did an educational time with the technologist,
22 but I just thought that you guys might be interested

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1 in knowing. And if you'd like to know more about
2 that, feel free to contact the Missouri Department of
3 Health and they can give you more information on that.
4 So thank you for your time.

5 CHAIRPERSON HARVEY: Thank you. Very
6 interesting. Yes.

7 MR. LIPPERT: My name is Richard Lippert.
8 I'm with Mammologix. We provide a back-office
9 solution for mammography facilities, and produce
10 somewhere between 1,500 and 1,700 medical audits each
11 year for facilities. And I amazed as I listen to the
12 redundancy in some features of measurement, such as
13 dosage, and how we can measure it two and three times.
14 I would encourage this committee to keep in the
15 thought, especially from patient advocacy, that the
16 goal of mammography quality assurance and the program
17 is to be able to measure a performance. And if you
18 keep in mind your recommendations to the Institute of
19 Medicine, I would encourage you to continue to
20 remember that if we do not do an audit, or if we
21 reduce that, irregardless of the burden that it places
22 on a facility, we have nothing to measure against.

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1 And we certainly have heard a number of
2 comments, and commentary on continuing the improvement
3 and the interpretive skills of the physician. If we
4 don't have something to measure, what are we going to
5 measure against?

6 CHAIRPERSON HARVEY: Another comment.

7 DR. THOMAS: I'd like to make a comment
8 and come back to Melissa's area real quickly. As
9 we're moving into the area of digital imaging,
10 currently the way the regulations are being
11 implemented is follow the manufacturers' quality
12 assurance programs. We have three specifically
13 separate and distinct programs with little
14 commonality, which is going to increase the QC burden
15 on facilities, not reduce QC burden, as well as has
16 already been mentioned in completely filmless
17 facilities. So I think there are solutions to that if
18 those are required. A couple of those tests, one of
19 those tests, specifically focal spots are meaningless
20 in digital today.

21 If we look at three areas specifically, if
22 we look at the quality assurance in viewing

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1 conditions, and specifically the work station, they
2 are substantially different between the approach with
3 a lot of commonality. It went just from being
4 completely automated to substantial manual testing.

5 If we look at film printers that are used
6 in digital imaging, the manufacturers say well, we'll
7 follow the film printers manufacturers' QC program.
8 Some of those are poor to non-existent. My experience
9 with film printers, laser printers are that they're
10 very, very stable overall. I've had some
11 parenthetical answers recently that have shown me that
12 I might not be in possession of the full data set
13 there. But as we move away from screen-film imaging
14 and to digital imaging, the burden of the facilities
15 are going to be substantially different than the
16 current mindset of screen-film imaging. And more
17 specifically, if a facility decides to have a digital
18 unit from Vendor A, and digital unit from Vendor B,
19 now they have two distinct QC programs that must be
20 implemented and maintained. And the interpretation of
21 the data between some of the vendors is substantially
22 different to create levels of confusion that are also

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1 going to result in levels of misinterpretation of that
2 QC data. So those are additional things that as we
3 migrate from the 500 facilities that are digital now
4 to what probably will be several thousand in a few
5 years, that's going to be an additional burden on the
6 facility that needs to be looked at critically.

7 CHAIRPERSON HARVEY: Okay. Ms. Butler.

8 MS. BUTLER: Penny Butler. Either I have
9 to get taller or move. I just wanted to respond to
10 that question, and actually, it's been raised a couple
11 of other times during this day. The ACR is currently
12 working on a quality control manual for digital to
13 address this very problem. It's in its very early
14 stages right now. We intend on, after a certain level
15 gets put together, sharing this with the manufacturers
16 and getting their comments on this also. But I just
17 wanted to let you know that that is in progress. I
18 think once we get to its final end, we'll have to work
19 closely with the FDA to see about alternative
20 standards and how we can handle this regulatorily.

21 CHAIRPERSON HARVEY: Is that the best way?
22 Yes. Dr. Karellas.

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