U.S. FOOD AND DRUG ADMINISTRATION

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

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THURSDAY,
SEPTEMBER 28, 2006

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The above-entitled matter convened in Remington 1&2 of the Atrium Court Hotel, 3 Research Court, Rockville, Maryland, at 10:00 a.m., Carolyn B. Hendricks, M.D., Chair, presiding.

PRESENT:

CAROLYN B. HENDRICKS, M.D.	Chair
JEFFREY W. BYNG, PH.D.	Industry Rep
SCOTT FERGUSON, M.D.	Member
JACQUELIN S. HOLLAND, R.N.,C.R.	Consumer Rep
DEBRA L. MONTICCIOLO, M.D.	Member
CAROL J. MOUNT, R.T., (R) (M)	Member
JOHN M. SANDRIK, PH.D.	Industry Rep
JANE B. SEGELKEN, B.S., M.A.	Consumer Rep
JULIE E. TIMINS, M.D.	Member
MARGARET S. VOLPE, M.B.A.	Consumer Rep
MARK B. WILLIAMS, PH.D.	Member
NANCY WYNNE,	Exec. Sec.

FDA PARTICIPANTS:

CHARLES FINDER, M.D.

CDR SEAN BOYD
Chief, Electronic Products Branch

HELEN J. BARR, M.D.
Director, Division of Mammography Quality and Radiation Programs

MIKE DIVINE
Chief, Inspection and Compliance Branch

PUBLIC SPEAKERS:
PENNY BUTLER
American College of Radiology

KAYE J. GOSS-TERRY, R.T. (M)
Mammography Accreditation Program
Texas Department of State Health Services

STEPHEN VASTAGH
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PAM WILCOX
American College of Radiology

A-G-E-N-D-A

P-R-O-C-E-E-D-I-N-G-S

10:03 a.m.

MS. WYNNE: Welcome everyone. At this point I would like to read the FDA's Conflict of Interest Statement. FDA Conflict of Interest Disclosure Statement. Particular matter of general applicability, National Mammography Quality Assurance Advisory Committee, September 28, 2006.

The Food and Drug Administration is convening today's meeting of the National Mammography Quality Assurance Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representatives, all members of the Committee are special Government employees or regular federal employees from other agencies and are subject to federal conflict of interest laws and regulations.

The following information on the status of the Committee's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found in 18 U.S.C. 208 are being provided to

participants in today's meeting and to the public.

FDA has determined that members of this Committee are in compliance with federal ethics conflict of interest laws. Under 18 U.S.C. 208 Congress has authorized FDA to grant waivers to special Government employees who have financial conflicts when it is determined that the agency's need for particular individual services outweighs his or her potential financial conflict of interest.

Member of this Committee who are special Government employees have been screened for potential financial conflict of interest of their own as well as those imputed to them including those of their employer, spouse, or minor child in areas related to the discussion of today's meeting.

These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves the review and discussion of the following general issues: 1) Amendments to the current MQSA regulations; and 2) All

guidance documents issued since the last meeting.

The Committee will also receive updates on recently approved alternative standards and the radiological health programs. Based on the agenda for today's meeting and all financial interest reported by the members of the Committee, conflict of interest waivers have been issued in accordance with 18 U.S.C. Section 208(b)(3) to Dr. Julie Timins, Dr. Mark Williams, and Ms. Carol Mount.

The waivers allow these individuals to participate fully in today's deliberations. Copies of these waivers may be obtained by visiting the agency's website www.fda.gov\ohrms\documents\default.htm, or by submitting a written request to the agency's Freedom of Information Office, Room 630 of the Parklawn Building.

A copy of this statement is also available for review at the registration table during the meeting and will be included as part of the official transcript.

Drs. John Sandrik and Jeffrey Byng are serving as the industry representatives acting on

behalf of all related industry and are employees of GE Healthcare and Eastman Kodak Company respectively.

We would like to remind members that if the discussion involves any other matters, products or firms not already on the agenda for which the FDA participant has a personal or imputed financial interest, the participant needs to exclude themselves from such involvement and their exclusion will be noted for the record.

FDA encourages all other participants to advise the Committee of any financial relationships that they may have with any firm at this time. Thank you.

DR. HENDRICKS: Good morning. My name is Carolyn Hendricks and I'm chairing the meeting and I want to announce that the members present represent a quorum for the meeting. I would like to begin with the members of the panel introducing themselves.

DR. SANDRIK: John Sandrik, GE Healthcare.

MS. VOLPE: Margaret Volpe, consumer representative.

MS. SEGELKEN: Jane Segelken, consumer

representative.

DR. MONTICCIOLO: Debbie Monticciolo. I'm a radiologist specializing in breast imaging, Texas A&M.

MS. HOLLAND: Jackie Holland, consumer representative. I'm from James Cancer Hospital at Ohio State University.

DR. TIMINS: Julie Timins. I'm a diagnostic radiologist. I practice mammography and general radiology at an intercity hospital in New Jersey.

DR. FERGUSON: I'm Scott Ferguson. I'm also a general radiologist. I practice mammography and general radiology in West Memphis, Arkansas.

DR. HENDRICKS: I'm a medical oncologist. My name is Carolyn Hendricks and I specialize in breast disease and I practice in Bethesda, Maryland.

MS. WYNNE: Nancy Wynne employed with the FDA, executive secretary.

DR. WILLIAMS: I'm Mark Williams. I'm a physicist from the University of Virginia.

MS. MOUNT: Carol Mount. I'm the manager

of the Breast Imaging and Intervention Department, Mayo Clinic, Rochester, Minnesota.

DR. BYNG: Jeff Byng, Eastman Kodak Company.

DR. HENDRICKS: The next item on the agenda is approved alternative standards by Dr. Finder.

DR. FINDER: Good morning. For those not familiar with Section 900.18 of the regulations, FDA may approve an alternative to a quality standard under Section 900.12 when the agency determines that (1) The proposed alternative standard will be at least as effective insuring quality mammography as the standard it proposes to replace; and

(2) The proposed alternative is too limited in its applicability to justify an amendment to the standard or offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to human health; and

(3) The granting of the alternative is in keeping with the purpose of the statute which is 42

U.S.C. 263(b).

Since last September's meeting the division has approved one alternative standard and modified one other. The new one deals with the allowed corrective action periods when using the Fuji computed radiography mammography system.

As the regulations are currently written, anytime a full-field digital mammography system fails any quality control test, the problem must be corrected prior to returning the system to use.

For screen film systems we allow 30 days for certain failed quality control tests. This alternative allows the same 30-day period for tests that are the same or similar to those screen film tests. The alternative also is consistent with previously approved alternative standards that were granted to other full-field digital mammography systems.

The second one deals with modifications to an alternative standard granted to General Electric for their software upgrades which was originally issued in 2002. The approved alternative permits the

post-upgrade testing to be performed under medical physicist oversight. The modification lists the specific software upgrades that were added in March and July of 2006.

These alternative standards in their entirety are available on our website in the policy guidance help system if anybody has any questions.

DR. HENDRICKS: Thank you very much. Next we'll welcome to the podium Commander Sean Boyd who is Chief of the Electronics Products Branch, Radiologic Health Program Update. Welcome.

CDR BOYD: Thank you. As said, I'm here to provide a brief update on FDA's Radiological Health Program, some new initiatives that we have undertaken over the past couple of years to revise the program to meet today's public health needs.

I'll wait for the projector. Just to give everybody a brief overview of FDA rad. health mission and goals, it has remained unchanged since the program's inception is to protect the public from hazardous or unnecessary electronic product emissions. This includes all radiation emitting products and

medical device and all types of radiation.

The program has been somewhat unchanged since its inception about 30 to 40 years ago and we are now working to refocus our efforts to address today's public health problems which we see as less related to product design and manufacture and more related to product use.

That is one of our main focuses is to shift from a sole focus on manufacture of products and to work more on the radiological health program to look at use conditions and inform professionals and the public of proper use.

Some of the initiatives within this program are to focus on equipment and procedures that expose patients to high radiation doses. In the case of nonmedical products we would focus on equipment that exposed the public to potentially high radiation or for products that are used in either national security or in law enforcement applications. We will use both regulatory and nonregulatory mechanisms to have manufacturers build equipment with radiation and safety and dose reduction in mind.

Examples include routine and targeted manufacturer inspection and testing, which is something the agency has always done. But we would also like to rely more on increased use of available voluntary consensus standards rather than our own performance standards alone for manufactured products.

We also want to promote technology and use practices that reduce dose such as automatic exposure or rate control, last image hold, dose display for medical imaging systems, and factor in facility quality control programs. This also means we are focusing our work with state radiation control programs to encourage and assist users to minimize dose and exposure.

We also want to educate the public on the risks and benefits of radiation emitting products and devices to ensure that patients and users are better informed of the products that they might be subject to. We want to continue to reinforce professional's knowledge of radiation safety and dose reduction concepts.

In the case of medical imaging we want to

ensure that professionals know the exposures and doses being delivered by the equipment, periodically monitor these doses, record patient doses, and possibly compare the information to national averages all of which will allow minimization of dose to the patient and medical personnel.

I'll cover some areas of accomplishment over the past year to include fluoroscopy amendments that we published as well as some areas where we are reducing effort and increasing effort.

Fluoroscopy amendments to the performance standard for diagnostic x-ray systems and their major components were published June 10 of 2005. They went into effect June 10 of this year and affect equipment manufacturers after June 10, 2006.

The amendments address different performance features that help users ensure they are delivering the right dose to the right place and have a record of what dose was delivered to patients. Performance requirements exist to assure the x-ray beam is in the desired location by providing tighter controls on x-ray field size.

The x-ray beam has a desired intensity and displays duration exposure rates and cumulative dose and has limited intensity in case of fluoroscopic systems which are accomplished by increased filtration and last image hold for this equipment.

These changes will continually inform the user of exposure rate and cumulative dose and allow these measures to be recorded and included as part of our facility QA program.

Some of the areas that we've focused on reducing activities for low-risk products and in areas that we haven't seen a large impact on public health protection.

The first of these areas where we have reduced reporting requirements and imports review for low-risk consumer products, laser products would include optical drives, fax machines, laser printers, television products and microwave ovens that pose little risk of personal exposure.

We are also shifting our monitoring focus away from examination of installed equipment in favor of conducting full manufacturer inspections because we

believe there is greater benefit to reviewing design and production process at the manufacturing facility than conducting a single unit test in the field.

We have also reduced requirements for MQSA inspection radiation measurements where we no longer perform a measurement during inspection, but rather accept the dose measurements made annually by the medical physicist and tri-annually by the accreditation body. Over the 10-year life of the program 100,000 measurements have been collected showing no problem with equipment dose.

These areas where we have reduced effort we have freed some resources to increase effort in the area of focusing on report review and imports review for high-risk electronic products and medical devices and, as I said before, as a result of decreasing our inspection of installed units in our field test program we can redirect our investigational resources toward looking at manufacturing facilities.

This doesn't mean we are not going to conduct any field tests in the future. We are just scaling back that effort and focusing on targeted

field tests as opposed to having routine programs.

Some of the activities we are currently working on and will continue to pursue over the coming year including electronic reporting, website redesign training programs, and dose monitoring program.

First we have developed an electronic reporting system that provides software templates to replace all paper reporting guides that currently exist for medical and nonmedical radiation safety product reports.

We made available software that can be downloaded from FDA's website and allows manufacturers to report and submit required reports electronically. Use of this software increases efficiency at the manufacturer's side of preparing the report and submitting the report to us in electronic form rather than paper and better allows us to quickly process and provide feedback to the manufacturer.

It also helps us identify information contained within the reports so that we can triage things for review, take action when a manufacturer specifically request it, and then better trend the

data that we have inside those reports to look at either industry, manufacturer, or product line trends.

A critical piece toward our education campaign will be our website redesign where we want to better educate the public and professionals with information that we provide over the web.

We are developing a new site with a different look and content that will provide all the same information, or similar information that we provide now to manufacturers on how they need to comply with our requirements but also add additional information on things that we would like consumers and professionals to know about, safe use of radiation emitting electronic products and devices.

We are also are developing online training programs for FDA and state inspectors that will cover basic health physics and medical imaging equipment testing. Essentially radiographic and fluoroscopic FDA field tests.

Last, but not least, we are planning a pilot study right now to capture medical imaging dose and formation. This is to explore the possibility of

creating a national dose registry or facilities would report doses to an organization delivered for various procedures and receive information back on how their facility compared with others in the nation, in the region, in their state or within another grouping.

We plan to coordinate our study with MedSun Hospitals who currently provide FDA voluntarily with adverse event reporting information. Working with these hospitals we would like to design a program to collect dose this year on CT procedures alone and hope to expand that program with other organizations outside of FDA toward the end of the year.

That was the overview that I wanted to provide. If you have any questions for me, I can take them now. I have also provided my e-mail address as well as Rad Health and our new initiatives webpage where you can get more information.

DR. HENDRICKS: Any questions for Commander Boyd? Yes.

DR. WILLIAMS: Are there plans to expand the dose monitoring program to include modalities like CR and DR in the near future?

CDR BOYD: The last slide where I talked about those?

DR. WILLIAMS: Yes. Correct.

CDR BOYD: Ultimately we would expand it to other modalities but right now we are doing a pilot study, just kind of a proof of concept to see whether or how facilities would be able to share the information with us and ultimately expand that to other modalities other than CT, but that is a next year and beyond project.

We are also aware that other organizations like ACR and AAPM have similar interests and are looking into it. We also want to look to DOD and VA and see what information they can share with us as well.

DR. HENDRICKS: Thank you very much. The next item on the agenda is the open public hearing and I will begin by making the following comments. Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making.

To ensure such transparency at the open

public hearing session of this Advisory Committee meeting, the FDA believes it is important to understand the context of an individual's presentation. For this reason, the FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise this Committee of any financial relationship that you may have with the sponsor, its product, and, if known, its direct competitors.

For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at this meeting.

Likewise, FDA encourages you at the beginning of your statement to advise this Committee if you do not have any such financial relationships. If you choose not to address the issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

MS. WYNNE: At this time I would like to read a statement into the record. The statement is from Judith A. Wagner, breast cancer patient advocate

and breast cancer survivor.

Statement to the National Mammography Quality Assurance Advisory Committee, September 2006.

"I spoke before this FDA Committee last year and, unfortunately, am unable to attend the second meeting. I appreciate the opportunity to have my comments read into the record.

"I continue my advocacy to inform women about how to make quality breast care decisions and recently spoke to an engineering firm for a wellness luncheon at which six of the 23 who attended were men. I continue to be asked to speak as one person tells another. Knowledge opens minds to search for quality of care and we must be able to provide it for women.

"MQSA reauthorization is scheduled for 2007. Three studies have been a part of the information that will set this reauthorization apart from any previous MQSA reauthorization: The Institute of Medicine Study, Improving Quality Breast Imaging Quality Standards; The National Mammography Quality Assurance Advisory Committee meeting; the GAO study, Mammography. The Current Nationwide Capacity is

Adequate but Access Problems may Exist in Certain Locations, July 2006.

"Senator Mikulski's committee will be reviewing the gathered information in order to make informed decisions for the reauthorization of MQSA. I continue to hear the same response from those physicians concerned with improving the delivery of breast care to women.

"Poor reimbursement; liability issues; shortages of technologists and qualified clinical breast radiologists; need for more educational opportunities in breast care; need to make breast care a subspecialty of radiology; need to standardize the breast diagnostic procedures for all physicians performing them; need for breast care to be an area of medicine that will create the desire for physicians to enter fellowship programs.

"On the other hand, I hear the following: That to mandate more requirements will decrease the number of physicians reading mammography and performing diagnostic breast procedures. Increasing the standards of care may cause the closure of some

breast centers and, thus, decrease access to breast care for women.

"Breast care and interventional procedures are evolving at a very rapid pace. Senator Barbara Mikulski introduced MQSA in 1992. I am sure these requirements initially set the medical community in a tailspin. Yet, they rose to the challenge and breast cancer detection has improved. For example, diagnosis of DCIS increased by 25 percent due to improved screening. But as with anything, as breast care evolves, so must the requirements.

"I advocate mandating accreditation for all image guided needle breast biopsies. I realize that until MQSA has had a name change to Breast Imaging Quality Standards Act, the FDA will not be able include ultrasound or MRI guided breast biopsies, only stereotactic breast biopsies.

"With new imaging modalities on the horizon such as tomosynthesis and the increasing use of digital mammography, standards need to be put in place to ensure that the patient is receiving breast care delivered by those who are most qualified and

performing these procedures with the highest standards possible.

"As I listened to commentaries about the evolution of the Betamax to the VCR tape, and now to CDs and beyond, it is evident that if we do not require standards for breast care delivery, then it will quickly become an overwhelming task if it isn't already.

"A most recent article in Diagnostic Imaging, `Screening Mammography. Practitioners Consider Europe in the Quest for Better Quality,' gives a clear picture of the obstacles involved with the U.S. breast care model.

"In Europe breast care is performed by dedicated clinical breast radiologists who have standards under which they must practice with continued job training and performance testing.

"Work flow issues. Work flow issues are also of a great significance. Digital imaging technology has opened the way for a more streamlined method to send mammograms and other imaging modalities from one place to another, which certainly could

influence issues of access and radiology shortages in the lower populated areas.

"The article by Jerry Kolb, `Going Filmless. Lessons From a Swedish Breast Care Center.' We need to look at the European example of efficiency with a more receptive attitude.

"A recent article, January/February 2006, Breast Care Services, titled, `Improving Access and Quality for Breast Health Services,' describes a hospital in Staten Island, New York, that wanted to develop a breast center approach for the provision of breast health services.

"The hospital had a three-fold objective which it did accomplish. (1) To ensure wait times for the complete spectrum of breast imaging services, reducing them; (2) to improve the quality of care; (3) to improve the patient's overall experience.

"The hospital had a group of 10 radiologists providing services, each with different levels of training. No radiologists spent more than 50 percent of his or her time doing breast imaging which was identified as a key area for improvement.

The evolution of this breast center and the key role of the dedicated breast radiologists are explained in detail in this article, `An Evolution for Quality.'

"In our very global society we need to look forward and towards centers of excellence that will receive mammography from outlying sources such as mobile units and satellite clinics, one centralized place where the best and most up-to-date equipment will be located, and the breast radiologist is the key coordinator.

"Lastly, regarding electronic work flow. Electronic management takes any paper flow pattern and ascertains the most efficient means of increasing productivity of the organization utilizing electronics. This would increase productivity and revenues as well as reduce unnecessary work for the breast care team leaving more productive time to actually perform and interpret mammography.

"You have to take the final outcome and break it down into individual steps on how to get the desired result. This methodology needs to be streamlined and refined for ultimate efficiency in the

breast center. Data programs to gather statistical information, standards of performance related to outcomes will be extremely important.

"Time cannot be recaptured, and what is done in this fleeting time will have significance for the future of breast care. Those radiologists who had been the pioneers of breast care will need to be replaced by new pioneers who will have the same passion and determination to save lives by diagnosing and treating breast cancer at an early, curable stage. Their challenges will be even greater as the diagnostic equipment reaches far beyond the early methods of sciagraphy and then mammography.

"This is a world of change where you can e-mail someone in Europe and have a response in minutes. So it is with breast care. Digital mammography has opened the breast care communication network and now we have to put standards in place to ensure women will receive the best care as time quickly slips away.

"Thank you for this opportunity to speak. Judith A. Wagner."

DR. HENDRICKS: At this time I would like to invite any other open public hearing speakers to the podium beginning with Stephen Vastagh.

MR. VASTAGH: Good morning, Madam Chairman, and members of the Committee. My name is Stephen Vastagh and I am the Secretary of the NEMA X-Ray Section Mammography Group which includes mammography equipment manufacturers. NEMA is a vendor who supports the trade association and I have a small financial relationship to the vendors this way. I keep telling my boss he should increase my financial relationship.

NEMA is pleased to participate in the process of developing standards and QC plans for digital mammography. We are also pleased to be able to participate directly in the work of this Committee through the two industry representatives that sit with you on this Committee today for the first time.

I wanted to call your attention to two standards that NEMA published recently, specifically for the digital mammography community. These two standards will bring greater uniformity to the quality

control plans for displays and printers that are approved for digital mammography.

They are the quality control manual template for manufacturers of hardcopy output devices and displays and work stations labeled for final interpretation of full-field digital mammography. These standards -- I have a few copies with me. If you are interested I will be happy to share one with you. They are only also uniquely available from the NEMA website for free downloading and in the handout which is available at the desk outside I have identified the links from which you can download these standards free of charge.

This may be of interest to physicists particularly and we have provided this information to APM at their annual meeting. Thank you very much, Madam Chair.

DR. HENDRICKS: Are there any other open public hearing speakers to approach the podium? If not, then we will move to the next item on the agenda which is by Dr. Charles Finder involving an update of recently issued guidance documents.

DR. FINDER: Since the last meeting, FDA has issued three guidance documents. They are the Mammography Quality Standards Act Final Regulations, Modifications and Additions to Policy Guidance Help System No. 9 and No. 10, and also the MQSA Inspection Procedures. Document No. 9 was issued on April 19, 2006. That document dealt mainly with the following issues.

It included some definitions of final interpretation in lossless and lossy digital compression; use of small field digital mammography image receptors; the impact of the health insurance portability and accountability act requirements on certain MQSA activities; retention of medical outcomes audit records; steps for facilities to take when patients do not wish to receive their summaries; combining medical reports; the effect of film digitization and compression of full-field digital mammography; digital data on retention; transferring interpretation of mammographic images; clarification of continuing education requirements; U.S. and foreign trained physicians; and similar type issues.

Document No. 10, which was issued on October 31, 2005, was basically a major updating of the rest of the policy guidance help system. It included a simplification of the policy guidance help system by deleting a number of topics dealing with inspection issues and incorporating them into a separate inspection procedures document which is the third guidance document that was issued.

It also had information regarding accreditation and certification extension for full-field digital mammography units. It included tables indicating the acceptable uses for attestation, for personnel requirements, mechanisms for physicists to obtain a physicist credentialing letter from FDA. Talked about major repairs for FFDM units and these were added to existing tables for film screen. And the list of inspection questions were updated.

The third document was the detailed inspection procedures document. This document contained the actual instructions given to our inspectors on how they are supposed to inspect the mammography facility. This way facilities would be

given the information to know exactly what to expect during an inspection.

All these guidance documents have been incorporated into the policy guidance help system which can be found on our website. Does anybody have any questions? Okay.

DR. HENDRICKS: The next item on the agenda are some directions for the ongoing discussion, again by Dr. Finder.

DR. FINDER: The main purpose of the meeting today and tomorrow is to discuss possible changes to the final regulations. Prior to the meeting the Committee members were given a copy of the regulations along with certain sections highlighted for possible revision based on our experience implementing the regulations, as well as questions and comments we have received over the years.

They were also instructed to make their own suggestions to any portion of the regulations. We will be projecting the document that they were given on the screen as we proceed through the regulations and have made the document available to the audience

also as a hardcopy handout. It is also available on our website.

Once we get into this you'll see that there is a lot of material to cover so I am going to suggest that we go through each item in turn asking for a show of hands for either a yes or no opinion.

In cases where there is a significant disagreement among the Committee, Dr. Hendricks will ask for brief comments from the Committee and then we will go for another show of hands. We are not asking for detailed wordsmithing but rather a consensus on whether or not to make a change and in which direction to move.

After the meeting the FDA will take the Committee's ideas, develop detailed amendments to the regulations, and then issue them for public comment. Does anybody have any questions before we begin?

DR. SANDRIK: Are the industry representatives voting in this matter?

DR. FINDER: Yes, they can raise their hands during this matter. Any other questions? Okay.

We are going to try to go through these in

the order in which they are listed in the agenda. The first one that we're going to be talking about, Application for Approval as an Accreditation Body which is 900.3, the requirements, and Standards for Accreditation Bodies, 900.4.

In your handouts it begins on page 9 and will go through page 21, footnotes No. 31 through 50. The first one starts on page 10 actually and what we are talking about here there is a listing of the procedures and policies that an accreditation body must submit for initial approval.

The question that we're asking is should state accreditation bodies be required to provide explanations of how adverse actions taken by the state functioning as a state under more stringent state requirements will be distinguished from those taken by the state functioning as an accreditation body. We will be asking for a show of hands who believe that we should go ahead and require that or not. Yes? Okay. No? Okay.

Next one. Should there be policies and procedures for issuing accreditation extensions for

reaccrediting facilities? Yes? No? Okay. It's going quickly, faster than I thought.

Next one is on page 12, footnote No. 33. Should FDA protect the accreditation body applications from disclosure until final approval has been given? Yes? No? Not a lot of disagreement so far.

Next page is No. 34. It deals with the requirement about the accreditation body obtaining authorization from FDA for any changes it may make in its procedures. The question really here is should this requirement be reworded to clarify that the accreditation body needs to obtain FDA approval prior to implementing any changes. Yes? No? Okay.

Moving right along. Comment 35 deals with who should be notified when an accreditation body deals with a problem facility. The question here is should the State Certification Agency be added to the notification list of who the accreditation body needs to notify. That would be important in those cases in which a facility is actually certified by a State Certification Agency rather than FDA. Yes on that or no? Yes? Okay. I'm glad we worded these questions

so well.

Next one is requirement regarding the frequency for review. Should the requirement be reworded to clarify that the images must be obtained from each mammography unit at the facility? I do want to clarify that the regulation itself requires that but it is not written in this space so it is somewhat a little confusing. It's not the fact the facility cannot or could get away without having their units accredited and the films reviewed for each unit.

DR. TIMINS: I think that is further dealt with on page 15, lines 33 and 34 but I think, indeed, it would clarify to have it stated here as well.

DR. HENDRICKS: Do we need a show of hands on that line item?

DR. BYNG: Dr. Finder, just a clarification. Did the technologist -- is each technologist required to provide images?

DR. FINDER: No. The accreditation process reviews images from each mammography unit but not necessarily from each technologists.

Page 15, footnote No. 37. We are asking

here in terms of examination identification there is a requirement that the cassette and screen be identified. We are asking should image receptor be added basically for full-field digital units. Yes? No? Okay.

DR. SANDRIK: Comment?

DR. FINDER: Yes.

DR. SANDRIK: I just would lightly suggest that you try to more generalize the situation, even to delete cassette screening and make it image receptor by itself. Basically they mean the same thing and, in fact, image receptor is defined in the performance standards so I don't think there would necessarily be ambiguity there.

MS. VOLPE: May I make a comment? I would suggest you add image receptor to the list of definitions.

DR. FINDER: Okay. Next, footnote No. 38. Should a system for determining when an additional mammography review when it's indicated be added in here? Should there be a specific requirement that when images are being reviewed during any clinical

image review by the accreditation body that there be an assessment of whether additional review needs to be done?

This would be a case where the images are of such poor quality that the concept of a problem that is significant enough to require an additional mammography review, should that be indicated. Should we put it specifically in the regulations? Yes?

DR. MONTICCIOLO: I have a question. How does that change from what the situation is as it is now?

DR. FINDER: In effect, the accreditation bodies are doing that. It is just a question of putting it into the regulations and specifically stating it. There is good feedback from the accreditation bodies. We haven't had a true problem with it. Again, it's more clarification in terms of placing it directly in the regulations.

DR. FERGUSON: There would be no change in the way things are done today?

DR. FINDER: There might be some change in the form with a specific box for this type of thing

but most of the accreditation bodies have already taken care of that.

DR. TIMINS: I would just argue that if it's not a problem, it doesn't need to be addressed.

DR. WILLIAMS: Would the intent be to suggest some circumstances under which that was appropriate but not necessarily make it bounded?

DR. FINDER: Yes. Part of the issue there is to set up some type of criteria as part of the evaluation process so that it is written. They would have to include that in the policies. Again, they have pretty much done that. It is more a matter of clarifying it in the regulations. If we can have another show of hands whether we should or shouldn't. Yes, we should? No, we shouldn't? Okay.

Next is on page 16. Yes?

DR. TIMINS: I'm just responding preemptively to No. 39. Please, define the question.

DR. FINDER: Number 39. Should there be an additional requirement stipulating what percentage of a person's practice be a mammography or breast imaging? This is dealing with the review physicians

that look at the clinical images for the accreditation bodies. Yes?

DR. TIMINS: I would argue against that because I think volume and numbers is more important than percentage of practice.

DR. FINDER: Okay. Would you then be -- let's take the original question. Should there be an additional requirement based on percentage. Yes? No? All right. How about yes? No? Okay. What about requiring certain volume numbers? Yes? Yes for volume? No for volume? Okay.

DR. FERGUSON: I would like a little more clarification on that. When you say volume, you are asking for the reviewers for mammography, like I said on the review panel, review films. You are saying there should be a minimum volume that I would read before I would sit on the review panel. Is that correct?

DR. FINDER: Either a minimum volume or a percentage of your practice would have to be in mammography, or we could even be talking about, for example, if you reviewed full-field digital

mammography what percentage or volume of your practice would have to be in that mammographic modality versus a different mammographic modality.

DR. FERGUSON: Your record of the sense of the committee was?

DR. FINDER: Split vote.

DR. HENDRICKS: Can I have a clarification on currently what the -- where do we stand right now in terms of the radiologists that are providing this review function? Where do they stand in terms of their clinical practice in terms of either percentage or volume to kind of see where the benchmark is set right now, Dr. Timins or Dr. Monticciolo.

DR. MONTICCIOLO: Well, currently people are recommended for that function and the committee that is involved with that reviews to make sure they are qualified to read mammograms, so they have to meet the qualifications of the accreditation body and then their involvement in breast is reviewed. I have never seen that as a problem.

That's why I'm opposed to that. I can't imagine you would want to count numbers. There could

be somebody who is very, very skilled who might have retired and is willing to work or is qualified but is in a smaller community. I don't see how that would benefit.

DR. HENDRICKS: Dr. Timins.

DR. TIMINS: That effectively puts it at the 960 mammograms per two years which is the basic for reading mammography. It puts it at the same rate as other mammographers.

DR. HENDRICKS: Can we invite input from ACR? Just for clarification. Please introduce yourself.

MS. BUTLER: Yes. My name is Penny Butler, Senior Director for Breast Imaging Accreditation Programs at the ACR. Currently the requirements for clinical image reviewers at the ACR is that they must have at least 50 percent of their practice in breast imaging.

DR. HENDRICKS: Thank you very much.

Dr. Finder, just to clarify, do we invite members from the audience to also come to the podium to clarify with questions?

MR. VASTAGH: Can Dr. Finder state the results of the votes because they will not be reflected on the record.

DR. FINDER: I will do that. It's a good idea.

DR. HENDRICKS: So the clarification has been made now that the ACR standard is that 50 percent of the practice must be in breast imaging. Do you want to revote then with the additional discussion?

DR. FINDER: Sure. Yes, we go with the percentage or some type of volume? Yes? No? Okay. I would say it was split with the greater number no. As a corollary to that, should the types of clinical images that are to be reviewed be clarified to include specifically the term mammographic modalities?

This, again, goes to one of the earlier points of should these reviewers have certain percentages or volumes in the exact mammographic modality in which they are actually reviewing. If they are going to be reviewing full-field digital, should they have certain specifications there. Again, I would ask for a yes or no. Yes?

DR. SANDRIK: Just a point of clarification here. In a sense you have two questions. One is, I think a matter of making consistency in the language of the regulation and not having both modalities and types as a way of describing something about mammography. I think that is one aspect of the question.

Now you have introduced another aspect of actually subdividing the requirement in terms of fractions along each type.

I think one is just do you even have enough data to support a number for general mammography. I wonder even further if there is enough data to support how you would subdivide that if you would even consider that.

DR. FERGUSON: I would like to comment. If I understand it correctly, that you are talking about requiring a volume or percentage of your practice say in digital mammography in order to review digital mammography. I would like to say from the state accreditations, a small state like Arkansas, Iowa, whoever else reviews, we may have three digital

units in the whole state and we may have eight or nine radiologists on our review panel. You are going to significantly impact our ability to do reviews if you limit it.

DR. FINDER: Okay. So with that discussion, after that discussion, do we have hands for yes? Should we include this? No? I would say that the majority says no on that.

Forty-one is actually a repeat. Well, I take it back. This one deals with the same issue we had before except for phantom image. Should there be a phantom image required specifically at this point from each of the units? Again, this is just a clarification in wording because it is clarified in other areas. Should we make the clarification also here in the regulations? Yes? No? The yeses have it.

Page 17, No. 42. For phantom image scoring, this is phantom image scoring, should at least two independent reviewers be specified in the regulations? Yes or no? Yes?

DR. BYNG: Is that the current

requirement?

DR. FINDER: It's the current standard. It is not the requirement because it doesn't appear in the regulation. I can tell you that early on in the program we did have an accreditation body that no longer is an accreditation body that had only one reviewer for each of these so the standard now is two. But, again, it's not in the regulations. The question is whether to put it in there.

DR. WILLIAMS: Has there been any experience on the part of the ACR as to whether or not two is an appropriate number, whether it should be fewer or greater?

MS. BUTLER: Penny Butler, ACR. Yes, we think two is adequate. Occasionally we'll need three but definitely not less than two.

DR. FINDER: Any other comments? Okay. So, yes? No? Okay. I would say the majority are yeses. Again, this is now referring for the phantom image reviewers. Should there be an additional requirement stipulating what percentage of the person's practice be in mammography. This is for the

medical physicist or the person reviewing. I shouldn't say medical physicist but the person reviewing the phantom images. Yes? No? I would say the nos.

Should types again here be clarified to include demographic modalities? Yes?

DR. HENDRICKS: Dr. Finder, if I could just get clarification. Currently in terms of ACR is there a distinction in terms of mammographic modalities that is in current practice related to the reviewers?

MS. BUTLER: Penny Butler, ACR. With regards to both clinical and phantom image reviewers, we require that they be qualified under MQSA to read digital if they review digital. As far as percentages, we do not have a requirement there for digital.

DR. HENDRICKS: Thank you.

DR. FINDER: So, yes?

DR. SANDRIK: I've got one clarification again. The question of is it a matter of changing the wording just for consistency in the regulations or

also then adding to the percentage of practice.

DR. FINDER: The question would be both. In terms of should we be including specific requirements for each mammographic modality type? Yes? No? The majority I would say is no.

No. 45 which is at the bottom of the page. This deals with accreditation and reaccreditation. This is a major question in terms of rewriting the regulations to clarify the differences. There are some subtle differences between a facility that is undergoing accreditation initially versus reaccreditation. There have been in the past some confusion between what are the requirements for a facility in those different types. Should we undertake a revision of the regulations to basically split these into two separate areas so that the requirements for each is specifically stated?

DR. TIMINS: A question. What is the difference between accreditation and reaccreditation in the process?

DR. FINDER: There are a number of differences that are involved. For example, a

facility that is undergone initial accreditation has to have mammography equipment evaluation done on their equipment prior to becoming accredited.

Once they are already accredited, the reaccreditation process does not require a mammography equipment evaluation. It requires an annual survey, the results of the annual survey, and those two things are somewhat different.

In addition, a facility that is in the process of undergoing accreditation is actually going from a nonaccreditation status to a fully accredited status. In those six months where they are applying, they are not officially given "accreditation." That is something else we need to clarify, I think, in the other areas of the regulations.

But until they actually finish the process and are granted accreditation by an accreditation body, they are operating under a provisional six-month certificate rather than a full three-year certificate and the changes from going from a six-month to a three-year certificate is different than from a facility going from a full three-year to another full

three-year.

So we would be looking in this area to kind of break these two different pathways out and spell it out in the regulations so that I think it would be clearer for facilities what they are expected. Again, I must say this is, from my standpoint, purely a clarification in the regulations.

The accreditation body has already handled these things. It's if we are going to be rewriting the regulations should we kind of specify it. Again, unless somebody has any other questions, should we go ahead and split these up or no? Yes? No? I'll take that as a yes.

Next page is No. 46. This deals, again, with these differences between initial accreditation and full accreditation. It says, "Prior to accreditation a survey that was performed no earlier than six months before the date of application for accreditation."

Should this be modified to state that the survey must have been completed since the initial application? I think the wording actually here in the

regulations was somewhat confusing. What we are looking for is a survey that is done after the facility is actually applied to the accreditation body.

A facility couldn't have done a survey six months before it applied. It wouldn't have been doing any cases. It wouldn't have been doing any QC. This is an attempt to kind of correct miswording in the regulation here.

DR. FERGUSON: I have a question about this.

DR. FINDER: Yes.

DR. FERGUSON: It says "be modified since the initial application." Would it be possible that somebody bought a unit and wanted to apply and had their -- you know, when you equipment is installed you have a physicist come out and do whatever they do prior to turning it over to you. Would there be like a technicality that this physicist report was done on initial installation and then they made application? I haven't done that in a while so I don't know if you can discard that.

DR. FINDER: This is one of those issues again that deals with the differences between the mammography equipment evaluation, which actually is in the paragraph right above this, which I think would address your issue about evaluating the equipment. That would be allowed before the actual application would be acceptable.

The survey, however, also includes quality assurance procedures that the facility would have done and they couldn't have been doing quality assurance procedures because they wouldn't have been operating before they had been granted at least the approval of the application. Again, I don't think it's going to make any difference to the way facilities are being treated but I do think it kind of clarifies in the regulation what is expected and resolves an issue that we have been dealing with.

DR. SANDRIK: One question is does this mean repeating data that may have already been acquired as part of the mammography equipment evaluation or just adding in those parts that were necessary once the facility started doing clinical

exams?

DR. FINDER: As far as I'm concerned, and the way we would have to write it to make sure that is the case, is that it would just include the new aspects of it, not require another mammography equipment evaluation. Certainly not that.

DR. FERGUSON: And I appreciate his comment because that is exactly what happened to me one time. I had to have the physicist come out and completely redo everything that had been done within six weeks because of a technicality. If it can be just the stuff that wasn't covered, that would be very good in my mind.

DR. FINDER: Okay. So we have a yes vote here? Yes? No? I would say the yeses have it.

Okay. Now going down to the next one, No. 47. This deals with the facility that is undergoing, in effect, reaccreditation. Should we modify this requirement to allow that the survey be up to 14 months old for accreditation or reaccreditation purposes?

This is, again, to get at the issue of not

having a facility repeat a survey just because it is older than six months and now they are coming up for accreditation to allow the accreditation body to use a survey that had been done as far back as 14 months which is the standard that we allow for the annual inspection when we go in.

Here it is a question of revising the regulations to allow facilities that leeway so that they don't have to have a survey repeated because they are undergoing reaccreditation. Yes? No? Again, yes carries the day there.

Next is a reporting requirement for the accreditation body to us. Should this reporting be reduced from annual to every three years? Should there also be a requirement that facilities notify the accreditation body of significant changes to personnel and equipment within a specified time frame?

Let's take the first one. Should the reporting to FDA be reduced from annual to every three years? Yes? No? Okay, it's split. Should there be a requirement that facilities notify the accreditation body of significant changes within a specified time

period?

DR. MONTICCIOLO: What is meant by significant personnel?

DR. FINDER: That's a good question. We would basically be talking about or could be talking about lead interpreting physician or individual physicians. Could be technologists. It depends on what we would be dealing with and it could go anywhere from anyone of the three personnel categories to just lead interpreting physician.

Certainly if there were equipment changes we would like the accreditation body notified of that. Again, it would be the renew unit or processor, those types of things. We could have a little discussion on what you think is appropriate and what kind of detail to go down into.

DR. MONTICCIOLO: My concern is for a facility that has a temporary technologist or some help. Every time they do that are they going to have to go through a lot of paperwork? It seems like that would be counterproductive.

DR. FERGUSON: I would like to see some

more detail. A lot of times when you have guidelines and it gets down to the people in the field, well, there are rules and it might be subject to, "Well, I think this is a significant change." It might be what one of us might consider a minor change. I think we ought to have some more detail in it.

DR. HENDRICKS: Just from a practical standpoint, what happens right now, for example, when the lead radiologist leaves a facility? Just in a practical sense what happens from the standpoint of the accreditation body?

DR. FINDER: I believe that the facility is supposed to notify the accreditation body, but I think it's in the annual update. Or do they have to notify you right away? All right. For the lead interpreting physician, at least for the American College of Radiology, they are supposed to notify right away.

Do you have a time frame? No time frame established. For individual physicians and other personnel, I believe that you get notified during the annual update. Three-year accreditation. Okay.

MS. GOSS-TERRY: Kaye Goss-Terry with the State of Texas. Sometimes we get forgotten, us and Iowa and Arkansas. The State of Texas has a 30-day rule for personnel so they have to submit their information within 30 days except for locals we don't require that.

We require the facility to check the credentials. Also the equipment part on here. The accrediting bodies require them to notify us of new equipment before they are installed or at the time. So I think that part needs to be taken out.

MS. BUTLER: The ACR's requirements are a little bit different. We require notification of lead interpreting physician change and mammography unit change. Processor and other personnel, we get notified of those changes when they go through reaccreditation.

And part of the rationale behind this is lead interpreting physician is the individual responsible for the quality that is being performed at that so we put the responsibility on the professional at the facility.

DR. FERGUSON: And how would that differentiate between the state accrediting bodies? You say it's a little different. What is the difference?

MS. BUTLER: Penny Butler, ACR. The difference from what Kaye just mentioned is we do not require facilities to tell us if they have hired a new tech or hired a new physician, for example, within the 30-day period. That's one of the differences. We also don't require them to tell us if they have installed a new unit. Way ahead of time they are supposed to notify us that they have installed a new unit and send us all the required material before they start using it.

DR. HENDRICKS: I wonder then if it makes sense to clarify that for either lead interpreting physician and new equipment.

DR. FINDER: If we are only talking about notifying the accreditation bodies for lead interpreting physicians and for new equipment. Would people say yes or no? Yes? No? Okay. It looks like a yes for the lead interpreting physician. All right.

DR. BYNG: Dr. Finder, is there a distinction on equipment much in the same way you are making a distinction on personnel?

DR. FINDER: I think we are actually going to be talking about that a little bit more because I do think we need to break down what equipment truly is. And it becomes even more complicated when we start dealing with digital units because the way they are separated out. Basically, you are talking about for film screen the processor and the unit itself.

With digital, are we talking about each new monitor or each new printer? I think if we are going to require something like this, I think we would have to stay at a fairly high level in terms of major component, major piece of equipment.

DR. SANDRIK: I think this issue will come up in many of the regulations where you try to put a regulation listing things that something applies to and then trying to decide whether it is something that should be added or subtracted from the list later on.

I think in many cases this may well be sort of a detail that is handled when the FDA reviews

an accreditation body's accreditation plan and decides whether they are going to accept it or not. It need not necessarily be explicitly part of the regulation.

DR. WILLIAMS: The other thing is I think it would be consistent with the philosophy that it needs to be articulated with the ACR which is that the responsibility be on the lead radiologist to oversee all of the quality assurance that goes on and the equipment change, therefore, would fall under that.

DR. FINDER: Moving right along, page 20, footnote No. 49. Again, in terms of these reporting requirements, should the State Certification Agency be added for these reporting requirements. That's the same for 49 and 50.

Again, that would only apply to those specific situations where there is a State Certification Agency and it would be limited to the facilities in those states and for the accreditation body also.

Let's take both of them together, I think. Yes on that? No? So both of those are yes.

That concludes the first section. Moving

right along. We are way ahead of schedule. I guess we can all take a two-hour break. Okay.

The next section -- do we want to move ahead or take a break?

DR. HENDRICKS: I think we should move ahead.

DR. FINDER: The next section deals with evaluation which is 900.5. Also withdrawal of approval, 900.6, hearings 900.7. Then we'll move to another section dealing with the requirements for 900.11, requirements for certification.

Then all the SAC requirements which are 900.20 through 900.25. We'll take them in sections. The first group is included in pages 21 through 25 and consist of footnotes 51 through 53. Let's do those first. Okay.

Basically we are asking the question here about major deficiencies. Should one of these deficiencies be -- if the accreditation body does not fulfill all its requirements under its own policies and procedures should that be considered a major deficiency. Yes or no?

DR. FERGUSON: I would like to know what we are trying to get at with this. This is a change and probably a significant change I would think.

DR. FINDER: It's basically a question of at what point do you consider problems sufficient where an accreditation body isn't following its own procedures to declare them having a significant deficiency and take action. Is it any policy and procedure or is it just the ones that have already been listed?

DR. FERGUSON: I guess, again, I would want to know -- we have listed minor things and major things. What will we be trying to drill down to?

DR. FINDER: If we included language of this type, any accreditation body that failed to follow any of its procedures could theoretically end up as a major deficiency.

Right. Yes.

DR. TIMINS: I feel that is unnecessarily harsh. Jots and tittles get missed all the time and I think it should be substantive.

DR. FINDER: Okay. So let's just take a

show of hands. Yes for this? No for this? I would say it's a no.

DR. HENDRICKS: Just to clarify, so then the major deficiencies still stand?

DR. FINDER: As currently written. I believe that is the consensus of the group.

Next is on page 23, footnote No. 52. Should all four types of certificates and the requirements for obtaining certificates be enumerated here? This would just be a clarification. Yes?

DR. TIMINS: When I first saw this question I had to search through the document to find the definition. I would like to see the definitions of all four types of certificates in the definitions to begin with so that you start off at a full run.

DR. FINDER: I believe that is question No. -- no (laughing.) We actually do have that and we'll get to that issue in the definition section when we get there. Okay. That's a good point. With that understanding that there would be definitions for what the four types of certificates are, should we place in this area the requirements for obtaining those

certificates. Yes? No? I would say that's a yes.

On page 24 this deals with reinstatements and the interaction between FDA and the accreditation body should the State Certification Agency be added where appropriate to this section. Again, this would apply to just those facilities that are certified by the State Certification Agency. Yes? No? That would be a yes.

The next group of questions, continually moving on, starts on page 54. We begin with footnote No. 148. Let's take a minute to get the projector to the right group, 148. These are the regulations dealing with the State Certification Agencies.

Page 54, footnote No. 148. Everybody found it? Okay. The question that we're asking here, "Should the State Certification Agency be limited to enforcing the quality standards set forth in the regulations? Any stricter enforcement would have to be under the state's own authority." Yes? Show of hands. No? Okay. I'll take that as a yes.

As a corollary to that, under footnote 149, "Should the statement `at least as stringent' be

changed to `substantially the same?'" Again, the concept behind this is to ensure that the State Certification Agency enforces the MQSA regulations and if they have more stringent state regulations that they wish to enforce, they can do that but they would have to make it clear that they are operating under their own state requirements rather than under an MQSA umbrella. Yes on that? No? The nos again? Two nos so that would be a split.

DR. BYNG: Dr. Finder, can you add further clarification to "substantially the same" versus "at least as stringent?"

DR. FINDER: The concept here is that if it says, "at least as stringent" there is the issue about that they can basically enforce under MQSA anything that is more stringent.

If somebody wanted to say that -- if a state wanted to say, for example, and had this in their own regulations that only, let's say, board certified radiologists could read mammography, whereas we allow board certified or physicians with a certain amount of training.

The question comes up would they enforce that as an MQSA violation or as a state violation? What we are trying to clarify here is they can go ahead and enforce their own regulations but it would be under the state auspices. They wouldn't claim this was an MQSA violation because, again, that is not our requirement per se.

This is a similar type issue with the accreditation bodies but there it has been clarified before where accreditation bodies basically enforce the MQSA regulations. If they are going to enforce something more stringent, they do it under their state authority.

DR. FERGUSON: And you're just saying that to make that clear?

DR. FINDER: The idea here would be that it would be to make that issue clear under whose authority they would be taking certain actions.

DR. HENDRICKS: Just from a practical standpoint, are there instances where there is a significant number of violations that would occur under these state agencies as opposed to the MSQA? Is

that a significant problem where there is a big difference in the violations, for example?

DR. FINDER: Dr. Barr wants to speak.

DR. BARR: Hi and welcome. Helen Barr, Director of the Division of Mammography Quality and Radiation Programs. I think this is one of these circumstances where Dr. Finder is being a little too PC. The bottom line is that states can go out there and do some things that are really outside of the spirit of MQSA and by this language we are trying to prevent that.

They do some things that were really not envisioned by MQA which we don't endorse or believe in and we want to ensure that when they do these things, which they have the right to do under their state law, that it is clear that it's not part of MQSA, that they are enforcing these types of actions under the state, and that this is not the spirit of MQSA. That is really what we are trying to accomplish here if that makes it any easier. Thank you.

DR. FERGUSON: I appreciate that. It brought to my mind one question. You said state

agencies. Does ACR have anything outside of what --

DR. BARR: No. I'm talking about states as governmental entities themselves. No, this doesn't have to do with the accreditation bodies.

DR. FINDER: Okay. So we want to take that vote again now that we've had all this discussion? Why don't we take votes. Well, the first one we already got a yes. I assume that there was no change for 148? All right. 149, yes? No? Okay. So it's just a yes.

150 is the same issue about "at least as stringent" versus "substantially the same." Yes? No? That was a yes. 151. This deals with policies and procedures. Should there be a policy and procedure for denying a certificate versus just suspending or revoking? This is another one of the actions or situations that can occur. It is not specifically stated in the policies and procedures that are required. Should we add one that talks about denying a certificate? Yes? No? Yes has it.

Should there be policies and procedures for taking action against the facility that performs

mammography without a certificate? Yes? No? Okay. Should there be policies and procedures for maintaining the certification status of facilities whose accreditation body has been withdrawn by FDA?

Yes, do you have a question?

DR. TIMINS: I was wondering if this particular item was already dealt with on page 48, Section 900.13(b)?

DR. FINDER: Let's go back. You said 48. What line would that be on?

DR. TIMINS: 900 --

DR. FINDER: No, line number on the page. It should be over on the left-hand side page numbers and line numbers.

DR. TIMINS: It would be 11.

DR. FINDER: Okay. Right. That would be another area where this could be dealt with in terms of specifically stating that the State Certification Agency what it will do if FDA withdraws the accreditation body's ability to accredit facilities in that state. But here we are talking about should they have procedures in their application for dealing with

this situation. This section that you're talking about basically deals with just what FDA will do.

DR. HENDRICKS: I just have a question to clarify that also. What occurs right now, for example, when an accreditation body's approval is withdrawn? What currently happens to the facilities that are overseen by that body?

DR. FINDER: That has happened only once in the history of the MQSA. And what basically happened was that the facilities were given time to switch over to a different accreditation body and the certification status was maintained. The situation, however, was that FDA held all those certificates.

It was not a situation where the state was the certifying agency. Again, this is more for clarification. We had our procedures in place to deal with that situation. We just want to make sure the State Certification Agencies have that same type of procedure in place.

Going back to 153. Yes? No?

DR. SANDRIK: Just one comment. It's somewhat maybe the wording part of it but you talk

about maintaining. I think maybe there needs to be some consideration, say, for reviewing the accreditation because if, in fact, you find that the accreditation body has not been performing properly, possibly the accreditations that they have provided aren't really valid and maybe some method of actually going back and seeing the validity of those at the facilities in question should be part of this.

DR. FINDER: I think that we would be talking about them including some type of language similar to what we have in the regulations dealing specifically with FDA when they encounter this type of situation.

It deals with the fact that FDA can make those decisions and can shorten the amount of time that the remaining certificate is valid in cases such as that where we believe there has been such a big problem that the question of all those accredited facilities might be in question. So, again, we are not wordsmithing here.

We are talking about the concept of just requiring that they have policies and procedures in

place, how we would actually -- what we would actually be looking for from the State Certification Agencies at that time would obviously go along with that type of reasoning. Again, on this question 153, yes? No? The yeses have it.

Again, for 154 we are back in that same issue about at least as stringent versus substantially the same. Should we modify it to be consistent with the other sections we've already talked about? Yes? No? Same for 155. Yes? No?

DR. HENDRICKS: I just have a quick question related to the last items that we approved. Do we see then that if we made this modification to substantially the same for these various line items that the state agencies would then have to go back and do a fair bit of revision of their regulations?

DR. FINDER: No, the states wouldn't have to change their regulations at all. It then comes down to only a question of whatever action they would take just to clarify that they are taking that action under their state authority, not under MQSA, but they don't have to change their regulations at all.

Okay, 156. Should there be an approval term established for the State Certification Agencies? We have one for the accreditation bodies. They have to reapply every seven years. There is no such requirement in the state certification requirements.

DR. BYNG: Is there a review at some period besides the reapplication?

DR. FINDER: Both the accreditation bodies and the State Certification Agencies undergo an annual review, and they are also updating us continually on any changes to their procedures and their policies. For whatever reason the State Certification Agency does not have a reapplication date, whereas the accreditation bodies do.

The question is why is there that difference? Should they be the same? I will say that the fact that they actually come up for reapproval sometimes makes it a little easier to deal with various bodies.

Not in terms of major problems but just clearing up some minor things that have taken, or may have taken awhile to deal with. I will bring out one

point. The one accreditation body -- accreditation, not certification, but the one accreditation body that stopped being an accreditation body did so at the time it was up for reapproval. That is when several issues came to a head and they decided to drop out of that process.

DR. FERGUSON: I'm curious because that's my fear in this. Tell me why did they drop out? Did FDA say, "Okay, we don't like the way you've been doing things up to this point. If you don't change it, we're not going to reapprove it." They decided that what you wanted was so onerous that they decided not to do it. Is that how it transpired?

DR. FINDER: I can't give an estimate of what they thought but we were not requiring them to do anything else that anybody else wasn't doing. I think the final issue that brought it to a head really had nothing to do with the requirements. It had to do with financial issues within the state.

DR. FERGUSON: You did say that they are reviewed every year and if you find a problem, I'm sure you bring that out every year. Why would you if

you review them every year then also want to have a redo in, say, seven years?

DR. FINDER: As I say, there are times when you encounter minor issues with these various agencies or bodies. You bring it up and it really doesn't get 100 percent changed the way you would like it and this goes on for a while.

The concept here being that when they come up for reapproval you have an added kind of incentive for people to make the changes you've been asking for. Again, this is not -- if it's a major issue, it is dealt with right away but sometimes you have these minor things that kind of drag on for a while.

DR. SANDRIK: I mean, you do have two upcoming sessions, one on both the evaluation we talked about and a subsequent one on withdrawal of approval. It seems like you do have the mechanisms in place to do this without necessarily adding an additional layer of bureaucracy to the process.

DR. FINDER: I believe that is true. Again, it is a question of degree. Do you want to go through the process of denying somebody or revoking

versus kind of dealing with this at a formal reapproval process. As I say, the main issue why this comes up is because we already require it for the accreditation bodies. They undergo that. You could recommend, if you wanted to, to suggest that we get rid of the other requirement.

DR. FERGUSON: I think that's the nod of approval if you're looking at them every year.

DR. FINDER: Okay. So let's go back to this issue. Should we set a term of approval for the State Certification Agency? Yes? No? I would say that's split.

While we're at it, we might as well ask the same question for the accreditation bodies. Should they -- they currently do have a reapproval term of seven years. Should we maintain that? Yes?

SANDRIK: Do you have the same authorities as pointed out here of both the annual review and authority for withdrawal?

DR. FINDER: Yes. Again, let's take the vote for the accreditation bodies. Yes, keep it the way it is? And no? Again, split for the

accreditation bodies.

Okay. Next page, No. 158, same question again. I missed one? Oh, I'm sorry, yes, 157. Should there be a regulation dealing with public disclosure of State Certification Agency applications? On this, we would basically be talking about protecting information submitted from the state at least until there has been a final decision made on that application process. Right now it is moot on that point. Should we include language dealing with that? Yes?

DR. SANDRIK: Could you identify them? What would be disclosed? Is it just a matter of saying this facility got an accreditation or something?

DR. FINDER: No.

DR. SANDRIK: Or the personnel qualifications and things?

DR. FINDER: No. What we would be talking about here is the actual application that was submitted to FDA from the state in terms of their policies and procedures, those types of things.

Obviously the regulations would be known to the public anyhow through the state process but their internal policies and procedure that they would be submitting.

DR. FERGUSON: Again, what are we trying to get to with this and is this a burden or an expense? I mean, if it's necessary and there's a good reason, I'm for it.

DR. FINDER: It comes down to an issue about what we as FDA should be releasing during the evaluation process. It would make it easier for us, I believe, if it was spelled out under what conditions what materials would be released and when they would be released so that if somebody applied to us under Freedom of Information Act, let's say, to see what had been submitted to us, what we would be releasing and when.

Yes.

DR. TIMINS: Would this be material that already appears in the state register?

DR. FINDER: No. Part of it would be because we would be talking about the regulations. Those obviously would be public knowledge because it

would be made that way by the state. However, the individual procedures and policies that would be submitted to us would not be generally made known to the public. Certainly not while they were applying. states don't have to and we wouldn't want to probably announce that somebody has applied and made an application until the final decision had been made on whether we would approve them or not. Those are the types of issues. It's basically a nondiscoverability issue until at least the decision would be made one way or the other on the status of the applicant.

So 157, yes or no? Yes? Okay. No? I'll take that as a yes. I will thank the audience member for picking that up.

158, again we get back to at least the stringent versus the substantially the same. The question there is yes, should we make that change, and no. And the yeses have it.

159, appeals. Should this section be modified to clarify that FDA retains authority over appeals regarding accreditation bodies? In the beginning we had some question about if somebody

appealed and in an accreditation body decision, would it go to the State Certification Agency or would it come to FDA?

The regulations actually give FDA that authority. It's just a matter, again, of clearing it up and clarifying that if somebody appeals an accreditation body decision, it comes to us as FDA is the oversight agency of the accreditation body.

Yes.

DR. SANDRIK: One comment on that. Some states can be both accreditation bodies and certifying bodies so I think maybe having like a third party that is looking at that in case there is an accreditation body problem that is not being reviewed by the same people basically the problem might be posed against.

DR. FINDER: Again, what we would be talking about is not accreditation body appeals going to the certification agency. They would come directly to FDA no matter who was the certification agency because only FDA has oversight authority over the AV, not a State Certification Agency so it would come to us. That is the purpose of hopefully the

clarification language. Yes on that? No? That would be a yes.

160 is should state certification agencies have the flexibility to have reviews performed by nonaccreditation body reviewers? The review that we're talking about here are additional mammography reviews. We have on occasion used reviewers who were not from that accreditation body, from the facilities accreditation body, to perform additional mammography reviews.

It occurs very occasionally specific circumstances but it has occurred in the past. The question here is should the State Certification Agencies have that same flexibility? The answer is yes? No? That's a yes.

DR. BYNG: Just a clarification here. You are clarifying in the regulation that the state will have the same authority as you? Did I hear you correctly on that?

DR. FINDER: Yes, that would be the intent.

Next, 161 where we are talking about

changes to standards. Should we expand this to specifically state fees, staffing policies, et cetera? They have to obtain an authorization from us when they are making changes. Do we want to include those types of specifics? Yes? No? I'll take that as a no.

Okay. Next, page 58, footnote No. 162. Should this section be rewritten to clarify that the changes should already have been approved by FDA prior to this review? If you look at this section, it kind of gives you the impression that we would be reviewing changes that we didn't know about beforehand and that shouldn't be happening.

All changes to their policies and procedures should have been authorized by us prior to them actually making the change so we would be talking about revising this language to be consistent with the fact that they would be getting approval before instituting any of these changes. That's what we're talking about here. Yes on that? No? That's a yes.

Last is on page 59 where we are dealing with footnote 163. Should certificates issued by the

State Certification Agency remain in effect for some time period after withdrawal of approval? Here we are talking about approval of an accreditation body so this would be a situation where FDA withdrew the approval of an accreditation body.

What would the State Certification Certificates do? What would those facilities do? Again, we would be talking about giving the state the same authority that we have in order to extend those certificates out for some time period and the language presumably would be similar to the authorities that we give ourselves to deal with these situations.

Yes.

DR. FERGUSON: If you weren't to do this, I suppose, and your state body was decertified, then every facility in the state would be effectively out of business. Right? What is the current time period that you have, six months?

DR. FINDER: I believe it's up to one year in order to carry those certificates over. This is a little bit different situation than with the accreditation body if they go out because

theoretically we could just take over for some time but it would require a process for us to issue new certificates.

I don't believe that if a State Certification Agency actually went out of business that it would take a full year for us to deal with that situation. The other certification agency would take over fairly quickly but, again, we have no regulatory language in here to deal with that situation. We would like to put something in about it.

Yes.

DR. TIMINS: I think it's very important that there be this protective period put in the regulation to protect the consumer and the facility. Reimbursement could be tied to this. Insurance plans could require that a patient go to a facility with such certification.

DR. FINDER: That's a very good point because the certification status is tied to billing and reimbursement so any even short-term lapse of that could result in significant problems.

DR. FERGUSON: I would suggest a generous period of time because I think it can get more complicated than a few months.

DR. SANDRIK: Yes, I guess I would actually suggest writing the rule that a period of time is not explicitly part of it. It would be looked at on a case-by-case basis how many accreditation bodies are affected or how many facilities or affected, what the nature of the problems were and that sort of thing. That should help determine how long it's going to take to solve the problems.

DR. FINDER: A show of hands yes for this? No? I think that is a yes.

Should we have regulations dealing with a reapplication by a State Certification Agency after FDA withdraws approval. Yes? No? Okay.

DR. FERGUSON: I was going to say I would assume it would be just like an initial application.

DR. FINDER: Again, we haven't written anything. I would assume that it would actually involve more than that in the sense we would certainly be looking at whatever problems got them to lose their

certification status to make sure those have been corrected. But I'm sure it would involve an entire review of the entire system but, yes.

DR. FERGUSON: I should have said at a minimum an initial application.

DR. FINDER: Yes on that? Show of hands? No? That was a yes. Okay. We've gone through those sections pretty quickly. Do we want to go and continue on or do we want to break for lunch now?

DR. HENDRICKS: I propose that we break for lunch. In that instance --

DR. FINDER: Before you do that --

DR. HENDRICKS: Yes.

DR. FINDER: -- I think we need to check and make sure that lunch is ready before we break for it.

DR. HENDRICKS: If we do break for lunch, after we confirm that lunch is ready, we want the committee to return by 1:00. Apparently right next door is an inclusive brunch for $15 for the panel members.

We request that we exit this room as

expeditiously as possible when we break for lunch because it will be secured by the FDA staff during this break. You are advised to take any personal belongings that you want with you during the break because you will not be allowed to enter into this room until we reconvene the meeting.

DR. FINDER: Let me check on that because the last I heard we were going to be allowed to eat lunch in here but let me check on that. Nancy is actually going to check on that.

DR. HENDRICKS: Okay. The lunch really isn't ready. It's not ready until noon. Do you want to clarify whether we can eat in here or whether we'll be able to reenter the room?

Penny? I'm sorry. I didn't hear the question. Yes, we certainly have time remaining before lunch.

MS. BUTLER: Thank you. Penny Butler, ACR. I wanted to revisit or just bring up item 47 or is it 48? Yes, I'm sorry, 48. Footnote 48 on page 18. Thank you, Charlie. This is the regulation that requires accrediting bodies to ask their facilities to

submit the results of such surveys and any other information that the body may require to the body at least annually.

If I recall correctly, this was a split vote. Should the reporting be reduced from annual to every three years? I wanted to bring up a clarification from the ACR because this was actually an issue that we had presented to the ACR.

During the ACR's annual update that we request of all facilities we asked them for an update on pertinent information related to the facility like address, phone numbers, interpreting physician, that kind of thing. We also asked them for a copy of their medical physicist report that we are required to review.

We felt that this was a duplication of effort for the facility and it's a lot of extra work that really is not necessary because these facilities are already going extremely detailed annual inspection by their FDA inspector. We had requested FDA to consider eliminating the request of the annual survey being sent to the medical physicist.

We still think it's very important to have an annual update to get this pertinent information but it was just the annual survey that we thought wasn't necessary because of the complete review it was already going through every single year. Thank you.

DR. FINDER: Okay. With those comments we can actually look again and see a show of hands. Does anybody want to change that aspect of it? Yes? From one to three years, yes. To go from one to three years. No? Okay. It's more toward the yes than the split. Okay.

DR. HENDRICKS: Right now we'll break for lunch and then we'll reconvene at 1:00.

(Whereupon, at 11:59 a.m. recessed for lunch to reconvene at 1:00 p.m.)

DR. HENDRICKS: Let's take our seats in preparation for resuming the meeting. I would like to welcome everyone back to the afternoon session. We are going to begin this afternoon's session by petitioning the members of the panel as to whether they have any comments on the items that were previously covered or whether they had any writing

items or items that they wanted to be brought for discussion specifically on the topics that we have already covered to get input from members of the panel. Yes.

MS. MOUNT: I would just say that having the clarification and having Dr. Finder kind of explain where the question is coming from may have changed my view from what I sent in previously but I think everything we have covered I better understand now and I have no change.

DR. HENDRICKS: Yes.

DR. TIMINS: Actually, this was something that I had written in to Dr. Finder when we answered these questions. I would like to have the differences between certification and accreditation and also certification or certifying body and accreditation or accrediting body stated clearly both in definitions and in the body of the report, and also perhaps clarified here.

DR. HENDRICKS: Do you want to take a minute to clarify?

DR. FINDER: Okay. I think many of the

questions that we have in here are an attempt to try and clarify those exact differences between accreditation, initial accreditation, reaccreditation, certification. I can go over just a little bit in terms of what general accreditation is, what certification is.

In order for mammography facilities to perform lawfully, it has to be certified by either the FDA or one of the State Certification Agencies. These are agencies that we have approved to do that.

In order to become certified you have to either be accredited or in the accreditation process. What that process entails, amongst other things, and there are a number of things here, but I think the most important of the accreditation body functions is the review of the clinical images to ensure that the quality is there.

What a facility needs to do if it wants to become accredited and certified, it must go out, set up a facility, must have equipment. That equipment has to be not inspected but have an equipment evaluation performed by a medical physicist showing

that it meets all of our qualifications.

Then the facility applies to the accreditation body, sends in an application saying that it wants to become accredited. It submits certain information at that time. The accreditation body notifies the certification agency that issues a certificate allowing that facility to perform mammography legally.

That certificate the first time around is what is called a provisional certificate or a six-month certificate. That allows the facility to operate and to generate the clinical images that can be submitted as part of the accreditation process amongst other things that have to be submitted.

Once that material is submitted to the accreditation body, the accreditation body reviews it and makes a decision on whether the quality is there at that facility. If it is, it transmits that information to the certification body which then issues a three-year certificate which allows that facility to perform mammography services legally.

Then at the end of that three-year process

it begins again. They reapply. But, again, here's the difference. In the initial accreditation there is that six month provisional status. When you go from an accreditation status to a reaccreditation there is no provisional.

You just get a three-year certificate if you go through the process successfully. That is in a nutshell what's involved. As part of the certification responsibilities, the facilities are inspected by either an FDA or a state inspector annually and they review the quality control procedures.

They check personnel qualifications and there is a report generated from those annual inspections. If there are any deficiencies found during those inspections, it's the responsibility of the facility to correct those things and in certain cases to notify the certification agency of how they have corrected those problems.

In a nutshell, does that answer your question or do you have any other specific questions about the process? No? Okay. But I agree that I

think we do need to do a better job in the definition section and in the procedures themselves about differentiating some of these factors.

DR. HENDRICKS: Any other comments from the panels?

MS. VOLPE: I have several comments. I am assuming that you will be going through and cleaning up the dates that are way past and using only dates that are in the future. The current documents use 1999, 2002, and things of that sort.

DR. FINDER: Yes. Those dates are the dates when the final regulations went into effect and when certain requirements, mainly equipment requirements, went into effect. Those are basically the 2002 dates. Yes, the idea would be to update or get rid of those requirement dates because now they are required of all facilities in all equipment.

MS. VOLPE: I have several other comments. I am assuming you will allow for electronic submission to the FDA instead of having to mail in all of the stuff that the different bodies have to do when they apply for accreditation and so forth.

Then I have other definitions that I believe should be added which we can talk about later. On the area I believe we did page 46, where it's talking about on line 38 the artiste training and breast implants, I believe the artiste should also be trained as to the proper method of administering compression to someone with an implant.

I have an implant and as a breast cancer survivor I have never had to have a mammogram on that breast but I have never seen a question on any form I filled out asking if I had implants when I go in to have the mammogram.

DR. FINDER: Okay. We haven't gotten to that section yet but we certainly can address that at that time.

DR. FERGUSON: Will you be addressing the electronic submission that she mentioned because that is something we talked quite a bit about last time about physicians who read for multiple clinics and the people in the field being able to access that without having to submit for multiple sites.

DR. FINDER: I think there are two or

maybe even more issues. Are you talking about electronic submission for the accreditation process, the approval?

MS. VOLPE: Yes, I was.

DR. FINDER: In terms of applying to FDA for, let's say, an accreditation body wants to become an accreditation body approved by us, we will accept electronic transfers of documents. That's not a problem. The issue about facilities, let's say, keeping their records which is the one I think you're addressing, again, it can be electronic.

We don't necessarily need to have them on paper. Probably a deeper issue there is does it have to be available at each facility at the time of the inspection. That is something certainly that we can discuss about this.

I think part of the issues are what we require and if we change some of the regulations, it may not be as onerous as it was in the past. I think when we get to that section, we certainly can address that type of issue.

DR. FERGUSON: As I recall, it had to do

with warehousing the information where the guy in the field could access it immediately and you didn't have to run around getting all your documentation to each side.

DR. FINDER: Right. And, again, I guess it's a question that has always been brought up to us, why doesn't FDA keep a central database of this information also? That was one of the other suggestions to us. There are multiple problems with us trying to maintain that information, get that information, and release that information to only to the right people at the right time.

Up until the time we have required that it is the facility's responsibility to have that information available at the time of the inspections. Again, those are issues we can certainly address as we go into those sections if you want to.

DR. TIMINS: On one of the questions that we covered was No. 32 on page 10. Should there be policies and procedures for issuing accreditation extensions for reaccrediting facilities? Is this to assist the accreditation body that is late in getting

through this or falling behind in the renewal process?

DR. FINDER: This section deals with the situation where, for lack of a better term, through no fault of the facility the decision hasn't yet been made by the accreditation body. This allows a process so that they don't have to stop performing mammography. They can be issued this extension.

It actually was, I believe, a change in the last reauthorization that allows this type of process to go in and that is why we want the procedures in the regulations in the policies of the accreditation bodies to address this new aspect of the accreditation process.

DR. TIMINS: The vote on that was affirmative?

DR. FINDER: Yes.

MS. VOLPE: I have another comment. On page 20 under the consumer complaint mechanism, I think it would be worthwhile to add a section to require a mechanism for a consumer to file a complaint directly with both the accreditation body and the FDA and that will give the consumer more confidence that