SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE MEETING

Open Session

September 28, 2006
Atrium Court Hotel
Rockville, MD

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE MEETING
September 28, 2006

COMMITTEE PARTICIPANTS

Carolyn B. Hendricks, M.D.	Chair
Jeffrey W. Byng, Ph.D.	
Scott Ferguson, M.D.	
Jacqueline S. Holland, R.N., C.R.	
Debra L. Monticciolo, M.D.	
Carol J. Mount, R.T. (R)(M)	
John M. Sandrik, Ph.D.	
Jane B. Segelken, B.S., M.A.	
Julie E. Timins, M.D.	
Margaret S. Volpe, M.B.A.	
Mark B. Williams, Ph.D.	

FDA PARTICIPANTS

Nancy Wynne	Committee Executive Secretary
Charles Finder, M.D.	Associate Director, Division of Mammography Quality and Radiation Programs
Helen Barr, M.D.	Director, Division of Mammography Quality and Radiation Programs
CDR Sean Boyd	Chief, Electronic Products Branch
Michael Divine	Chief, Inspection and Compliance Branch

CONFLICT OF INTEREST STATEMENT

Executive Secretary Nancy Wynne convened the meeting at 10:03 a.m. and read the conflict of interest statement. Full waivers had been granted to the following participants: Julie E. Timins, M.D.; Mark B. Williams, Ph.D.; and Carol J. Mount, R.T.(R)(M).

COMMITTEE BUSINESS

Committee Chair Carolyn B. Hendricks, M.D., noted that the panel members present represented a quorum. She then asked the panel members to introduce themselves.

APPROVED ALTERNATIVE STANDARDS

Charles Finder, M.D., Associate Director, Division of Mammography Quality and Radiation Programs, discussed alternative standards approved since the last panel meeting. FDA may approve an alternative to an existing quality standard under Section 900.12 when the agency has determined that the alternative would be at least as effective as the existing standard, when the proposed alternative would be too limited in scope to justify an amendment or would offer such great expected benefit that the time to amend the standard would represent an unjustifiable risk to health, and the alternative would be pursuant to 42 U.S.C. 263(b).

The agency has approved one alternative standard and modified another since the September meeting. The new one deals with allowed corrective action periods for users of the Fuji computed radiography mammography system. Current regulations require that whenever a full-field digital mammography (FFDM) system fails any quality control test, the problem must be corrected prior to returning the system to use, but for screen film systems 30 days is allowed for certain failed QC tests. The approved alternative standard allows the same period for tests

similar to those screen film tests and is consistent with previously approved alternatives for other FFDM systems.

An alternative standard granted to General Electric for software upgrades issued in 2002 permits post-upgrade testing to be performed under medical physicist oversight. It was modified to list specific software upgrades added in March and July, 2006.

RADIOLOGICAL HEALTH PROGRAM UPDATE

CDR Sean Boyd, Chief, Electronic Products Branch, said that the program had remained basically unchanged since its inception, but now focus is shifting away from product design and manufacture to product use. The program focuses on equipment and procedures which expose patients to high doses of radiation. There is a desire to place more reliance on voluntary consensus standards rather than FDA's performance standards alone. The program also promotes technology and use practices that reduce dose. The program seeks to educate both the general public as well as professionals.

CDR Boyd discussed some of the program's accomplishments from the past year. Fluoroscopy amendments to the performance standard for diagnostic x-ray systems and their major components went into effect June 10, 2006. They provide that users are continually informed of exposure rate and cumulative dose and that the measures may be recorded and included as part of the facility QA program as well as assurance that the x-ray beam is in the right location.

Efforts have been reduced in certain areas. There are reduced reporting and imports review requirements for low-risk consumer products. Monitoring focus is shifting away from examination of installed equipment in favor of full manufacturing inspections. Requirements for

MQSA inspection radiation measurements have also been reduced; measurements made annually by the medical physicist and tri-annually by the accreditation body will be accepted. In the ten years of the program, 100,000 measurements have been collected showing no problem with equipment dose.

Efforts have correspondingly been increased in other areas. Report and imports reviews will focus on high-risk electronic products and medical devices. Manufacturer inspections will be used to address equipment problems at the source.

Ongoing activities include electronic reporting, website redesign, training programs, and dose monitoring. An electronic reporting system has been developed, and software is available to allow manufacturers to submit required reports electronically. This will increase efficiency for manufacturers as well as FDA and help identify and trend data from the reports. Website redesign is intended to better educate the public and professionals. Online training programs are being developed for FDA and state inspectors for basic health physics and medical imaging equipment testing. A pilot study is being planned to capture medical imaging dose information in order to look at creating a national dose registry. FDA plans to coordinate the study with MedSun Hospitals, which currently voluntarily provides FDA with adverse event reporting information. They plan to look at dose in CT procedures alone this year.

Dr. Williams asked if there were plans to expand the dose monitoring program to include other modalities. CDR Boyd said that was the ultimate goal but currently they are just doing a pilot study as proof of concept.

OPEN PUBLIC HEARING

Ms. Wynne read a statement provided by Judith A. Wagner, R.N. Issues identified by physicians concerned with improving breast care include poor reimbursement, liability, shortages of technologists and qualified radiologists, the need for more educational opportunities in breast care, the need to make breast care a subspecialty of radiology, the need to standardize breast diagnostic procedures for all who perform them, and the need for physicians to enter fellowship programs in breast care. Ms. Wagner also hears from physicians that mandating additional requirements will decrease the numbers of those practicing in breast care and may cause the closure of some centers, thereby decreasing access.

Breast care is evolving rapidly, and requirements must evolve with it. Ms. Wagner supports mandating accreditation for all image guided needle biopsies. She commented on an article in Diagnostic Imaging on the quality of breast care in Europe. She talked about work flow issues related to digital imaging. A recent article described a Staten Island hospital which reduced wait times, improved the quality of care, and improved the patient experience for its breast center. None of the center's ten radiologists spent more than half of his or her time on breast imaging.

Ms. Wagner proposed centers of excellence which would receive images from sources such as mobile units and satellite clinics. She also advocated electronic work flow for increased efficiency.

Stephen Vastagh, Secretary, NEMA XR Section - Mammography Group, called attention to two standards recently published by NEMA to make quality control plans for displays and printers for digital mammography more uniform. They are the QC manual template

for manufacturers of hardcopy output devices and displays and work stations labeled for final interpretation of FFDM. Mr. Vastagh said the standards were available on the NEMA website.

UPDATE OF RECENTLY ISSUED GUIDANCE DOCUMENTS

Dr. Finder stated that three guidance documents had been issued since the last meeting: documents 9 and 10 of the MQSA Final Regulations Modifications and Additions to Policy Guidance Help System and the MQSA Inspection Procedures. Document 9, issued April 19, 2006, dealt with issues such as definitions of final interpretation, lossless and lossy compression, use of small FFDM receptors SFDM) , the impact of the Health Insurance Portability and Accountability Act (HIPAA), retention of records, the effect of film digitization and compression of FFDM, transferring records, clarification of continuing education requirements, and documenting MQSA requirements for foreign-trained physicians. Document 10, issued October 31, 2005, was a major update of the rest of the policy guidance help system. It simplified the system by deleting topics on inspection issues which were incorporated into a separate document (MQSA inspection procedures) which is the third guidance document published. Document 10 also addressed accreditation and certification extension for FFDM units, acceptable uses for attestation, personnel requirements, mechanisms for physicists to obtain a credentialing letter, major repairs for FFDM units, and it updated the list of inspection questions. The final guidance document issued was the MQSA inspection procedures, which contains the instructions given to inspectors.

OPEN COMMITTEE DISCUSSION

Dr. Finder explained the process for the committee discussion. Dr. Sandrik asked if the industry representatives would be voting, and Dr. Finder said yes.

Application for Approval as an Accreditation Body - 900.3; Standards for Accreditation Bodies - 900.4

The first Footnote, number 31, asked if state accreditation bodies should be required to explain how to distinguish between adverse actions taken by the state functioning as a state under more stringent state regulations from those taken by the state acting as an accreditation body. The committee voted in favor of the requirement.

Regarding Footnote 32, the committee voted in favor of there being policies and procedures for issuing accreditation extensions for reaccrediting facilities. For Footnote 33, the committee voted in favor of FDA protecting accreditation body applications from public disclosure until final approval has been granted.

Footnote 34 dealt with FDA authorization of changes to accreditation body procedures, and the committee voted in favor of rewording the requirement to clarify that the accreditation body needs to obtain FDA approval prior to implementation of changes. For Footnote 35, the committee voted in favor of adding the state certification agency to the list of who is notified about problem facilities.

Footnote 36 asked if the frequency of review requirement should be reworded to clarify that images must be obtained from each unit at a facility. Dr. Finder said the regulation already requires that but that it would be helpful to add it here as well. Dr. Timins agreed that it would help clarify the document. The committee voted in favor of rewording the requirement. Dr. Byng asked if each technologist was required to provide images, and Dr. Finder said no.

Footnote 37 asked if "image receptor" should be added to the examination identification information for FFDM units. The committee voted in favor. Dr. Sandrik suggested it could be more general by deleting cassette/screen since image receptor has been defined as basically the same thing. Ms. Volpe suggested adding image receptor to the list of definitions.

Footnote 38 asked if a system for determining when an additional mammography review (AMR) is indicated, should be added. Dr. Monticciolo asked about the current situation. Dr. Finder said the accreditation bodies were already doing it and the idea was simply to specifically state it in the regulations. Dr. Ferguson asked if there would be any change, and Dr. Finder said there might be a change on the form in terms of specifically asking about it. Dr. Timins suggested that it did not need to be addressed since it is not a problem. Dr. Finder stated that criteria would be established for when it would be appropriate. The committee's vote was split.

Footnote 39 proposed an additional requirement stipulating what percentage of a person's practice should be in mammography or breast imaging. Dr. Timins said that volume and numbers are more important than percentage of practice. Dr. Ferguson asked if the idea was to have a minimum volume one would have to read before sitting on a review panel. Dr. Finder said either volume or percentage of practice could be used. Dr. Hendricks asked about the clinical practice of radiologists currently providing the review function. Dr. Monticciolo said that people are recommended and a committee ensures they are qualified. She said she had never seen any problem with it and did not think it was a good idea to have specific requirements. Dr. Timins noted that it would be the same rate required to read mammograms. **Penny Butler, American College of Radiology,** said ACR requires clinical image reviewers to have at least 50 percent of their practice in breast imaging. The committee's vote was split with more members saying no.

Footnote 40 asked the related question whether the types of clinical images reviewed should be clarified to include mammographic modalities. Dr. Sandrik suggested not using "modalities" and "types" for consistency. He questioned whether there was enough data to support any number for general mammography and whether there was enough data to support how it would be subdivided. Dr. Ferguson said it would significantly impact the ability of small states to do reviews. The committee voted against the clarification.

Footnote 41 asked if the phantom image review requirement should be reworded to clarify that phantoms must be obtained from each unit at the facility. Dr. Finder said the clarification had already been made and this would simply put it into the regulations. The committee voted yes.

Footnote 42 asked if at least two independent reviewers should be specified for phantom image scoring. Dr. Byng asked if that was the current requirement. Dr. Finder said it was the current standard but that it does not appear in the regulations. Dr. Williams asked if ACR felt two was an appropriate number. Ms. Butler said two is adequate. The committee voted in favor.

For footnote 43, the committee voted against having an additional requirement stipulating what percentage of a phantom image reviewer's practice should be in mammography. Footnote 44 asked if types should be clarified to include mammographic modalities. Dr. Hendricks asked if ACR makes any distinction in modality related to reviewers. Ms. Butler said that reviewers must be qualified under MQSA to read digital if they read digital, but there is no percentage requirement. The committee voted against the stipulation.

Footnote 45 asked if the regulations for facility accreditation should be divided into separate scenarios for initial accreditation and reaccreditation. Dr. Timins asked how the process differed. Dr. Finder said that for initial accreditation there is a mammography equipment

evaluation but for reaccreditation there is instead an annual survey. Also, facilities undergoing initial accreditation operate under a six-month provisional certificate, and there are differences between moving from a provisional to a full three-year certificate versus going from a full certificate to another full one. Dr. Finder said it was purely a clarification of the regulations. The committee voted in favor of the revision.

Footnote 46 asked if the survey required prior to accreditation should have to have been completed since the initial application. Dr. Finder said that the change would really just correct the wording of the current regulation. Dr. Ferguson asked if the physicist report done for initial installation would suffice. Dr. Finder said the mammography equipment evaluation could be done prior to the application, but the survey includes quality assurance procedures that the facility could not have been doing since they would not have been operating. He said he did not think it would change how facilities are currently being treated but would clarify what is expected in the regulations.

Dr. Sandrik asked if it would require collecting repeat data or whether facilities could simply add to the mammography equipment evaluation. Dr. Finder said the intent was not to require another mammography equipment evaluation. The committee voted in favor of the modification.

Regarding Footnote 47, the committee voted in favor of modifying the requirement to allow surveys up to fourteen months old for reaccreditation purposes.

Footnote 48 asked if the reporting should be reduced from annual to every three years and if there should be a requirement that facilities notify the accreditation body of significant changes to personnel and equipment within a specified time period. Regarding the first part of the question, the committee's vote was split with more members saying yes.

Dr. Monticciolo asked what personnel would be considered significant. Dr. Finder said it depended. Dr. Monticciolo was concerned about facilities with temporary technologists or other help. Dr. Ferguson thought there should be more detail. Dr. Hendricks asked what happens currently when, for example, a facility's lead radiologist leaves. Dr. Finder said that ACR requires immediate notification of the departure of the lead interpreting physician.

Kaye J. Goss-Terry, R.T. (M), Mammography Accreditation Program, Texas Department of State Health Services, stated that Texas has a 30 day requirement for personnel and that accrediting bodies require facilities to notify the state before or at the time of new equipment installation. Ms. Butler said ACR requires notification of a change to the lead interpreting physician or the mammography unit. ACR receives notification of other changes during reaccreditation. Dr. Finder modified the second part of the question to require notification for lead interpreting physician and new equipment, and the committee voted in favor. Dr. Byng asked if any distinction would be made with regard to equipment. Dr. Finder said he thought they would have to break it down. Dr. Sandrik suggested it could be handled when FDA reviews accreditation plans rather than making it explicit in the regulations. Dr. Williams said the lead radiologist should oversee equipment changes.

Regarding Footnotes 49 and 50, the committee voted in favor of adding the state certification agency to the reporting requirements.

Evaluation - 900.5; Withdrawal of Approval - 900.6; Hearings - 900.7; Requirements for Certification - 900.11; Scope - 900.20; Application for Approval as a Certification Agency - 900.21; Standards for Certification Agencies - 900.22; Evaluation - 900.23; Withdrawal of Approval - 900.24; Hearings and Appeals - 900.25

Footnote 51 asked if the accreditation body does not meeting all the requirements of its own policies and procedures should that be considered a major deficiency. Dr. Finder said that certain policies had already been specified in the regulations. Dr. Timins said that only

substantive failures should be so considered. The committee voted against the expansion of major deficiencies.

Footnote 52 asked if all four types of certificates and the requirements for obtaining them should be enumerated here. Dr. Timins said the four types should be defined in the definitions section. Dr. Finder said they would discuss that along with the rest of the Definition section. The committee voted in favor with the understanding that the four types would be defined.

Regarding footnote 53, the committee voted in favor of adding state certification agency where appropriate with regard to reinstatements.

Moving to the state certification agencies, for Footnote 148 the committee voted in favor of limiting the state certification agencies to enforcing quality standards in the regulations; stricter enforcement would have to be done under the state's own authority. Footnote 149 asked if "at least as stringent" should be changed to "substantially the same." Dr. Finder said the issue was that anything more stringent could currently be enforced under MQSA, so the idea is to clarify when a state is enforcing its own regulations. Dr. Hendricks asked if there were instances where a significant number of violations would occur under state regulations as opposed to MQSA.

Helen Barr, M.D., Director, Division of Mammography Quality and Radiation Programs, said that states do things not envisioned by MQSA and not endorsed by FDA and the agency wants it to be clear when they are enforcing their own state law. The committee voted in favor of the change. Footnote 150 proposed the same change, and the committee again voted in favor of it.

Regarding Footnote 151, the committee supported having a policy and procedure for denying a certificate as opposed to suspending or revoking. Regarding Footnote 152, the

committee supported having policies and procedures for taking action against a facility that performs mammography without a certificate.

Footnote 153 asked if there should be policies and procedures for maintaining the certification status of facilities whose accreditation body's approval has been withdrawn by FDA. Dr. Timins asked if this was already dealt with in 900.13(b). Dr. Finder said that section basically only deals with what FDA will do; this question asks whether there should procedures in the certification agency's application for dealing with the situation.

Dr. Hendricks asked what currently happens when an accreditation body's approval is withdrawn. Dr. Finder said it had happened only once under MQSA; the facilities were given time to switch to a different accreditation body and their certification status was maintained. Dr. Sandrik suggested that instead of simply maintaining the certificates that there should perhaps be some review of the validity of the accreditations provided. Dr. Finder said there would likely be language dealing with FDA's ability to make decisions related to problem accreditations and shorten the amount of time certificates are valid. The committee voted in favor of Footnote 153.

Footnotes 154 and 155 dealt with the issue of changing language from "at least as stringent" to "substantially the same;" the committee approved both changes. Dr. Hendricks asked whether the state agencies would correspondingly change their own regulations. Dr. Finder said they would not have to change their regulations; the point is simply to clarify which actions are taken under state authority rather than MQSA.

Footnote 156 asked if a term of approval should be established for state certification agencies. Dr. Finder said accreditation bodies had a term of seven years. Dr. Byng asked if there was a review at some time other than reapplication. Dr. Finder said that both accreditation bodies and state certification agencies undergo annual reviews and continually update FDA on

any changes to policies and procedures. He said that reapproval may help deal with more minor problems that may not have been resolved during the annual review process. Dr. Finder stated that the one accreditation body that ceased to be did so when several issues came to a head when it was up for reapproval.

Dr. Ferguson asked for clarification of what had transpired. Dr. Finder said the accreditation body was not being required to do anything not required of all other bodies and that the final straw was really State financial issues. Dr. Ferguson asked why reapproval was necessary given that they are reviewed every year. Dr. Finder said that minor issues are not always fully resolved and said that reapproval can be an added incentive; he also stressed that major issues are dealt with right away.

Dr. Sandrik was not sure reapproval was necessary and thought the evaluation and withdrawal of approval could serve a similar purpose. Dr. Finder suggested it might be easier to deal with such issues in a formal reapproval process rather than by revoking the accreditation approval, and he reiterated that it was already required of accreditation bodies. The committee's vote was split. Dr. Finder then asked if the term of approval for accreditation bodies should be maintained, and the vote was again split.

Footnote 157 asked if there should be a regulation dealing with public disclosure of state certification agency applications. Dr. Finder said the idea was to protect the information at least until a final decision was made on the application. Dr. Sandrik asked what information would be disclosed, and Dr. Finder said the application itself. He said it would be helpful for the agency to have it spelled out in regulation so as to be able to deal with any Freedom of Information Act requests related to the evaluation process. Dr. Timins asked if the material would already appear

in the state register. Dr. Finder said part of it would but not the individual policies and procedures. The committee voted in favor of the proposal.

Regarding Footnote 158, the committee voted in favor of again changing "at least as stringent" to "substantially the same." For Footnote 159, the committee voted in favor of modifying the section to clarify that FDA retains authority over appeals regarding accreditation bodies. For 160, the committee voted in favor of allowing state certification agencies flexibility to have AMRs performed by non-accreditation body reviewers. Dr. Byng asked if the intent was to clarify that the state will have the same authority as FDA, and Dr. Finder said that was correct.

Regarding Footnote161, the committee voted against expanding the requirement that certification agencies obtain FDA authorization for changes to standards to include fees, staffing, policies, etc. For Footnote 162, the committee voted that the section should be rewritten to clarify that the changes should have been already approved by FDA prior to this review.

Footnote 163 asked if certificates issued by the state certification agency should remain in effect for some time period after withdrawal of approval. Dr. Finder said this would give the state the same authority FDA has to extend certificates. Dr. Ferguson asked what the current time period was. Dr. Finder said he thought up to one year. Dr. Timins thought it was important in order to protect facilities and patients and suggested that reimbursement may be tied to certification. Dr. Ferguson suggested a generous period of time. Dr. Sandrik suggested the rule should not explicitly state a time period and that it should be looked at on a case-by-case basis. The committee voted in favor of Footnote 163.

Footnote 164 asked if there should be regulations to deal with a reapplication by a state certification agency after FDA withdraws approval. Dr. Ferguson suggested it should be just like an initial application. Dr. Finder said it should also involve looking specifically at whatever

problems caused them to lose their status. Dr. Ferguson clarified his statement to be at a minimum. The committee voted in favor.

Ms. Butler wanted to return to Footnote 48. Part of the annual update required by ACR requests an update of pertinent information from facilities, but ACR felt it was really a duplication of work already being done annually for FDA. ACR asked FDA to consider eliminating the request of the annual survey being sent by the medical physicist. ACR still thinks the annual update is very important but thinks the annual survey is not necessary. Dr. Finder called for another vote. The committee was split but more towards yes.

Dr. Hendricks asked the members for any comments or suggestions regarding the areas already covered. Ms. Mount said that the explanations of the item may have changed her view but had no changes for any material already covered. Dr. Timins asked that the differences between certification, certifying body, accreditation, and accrediting body be stated clearly. Dr. Finder said that mammography facilities must be certified by either FDA or one of the state certification agencies in order to practice lawfully. To become certified a facility must either be accredited or be in the accreditation process. The most important part of accreditation is the clinical image review intended to ensure quality.

When a facility applies for accreditation, the accreditation body notifies the certification agency, which then issues a provisional six-month certificate allowing the facility to perform mammography. This allows the facility time to generate clinical images to be submitted to the accreditation body. The accreditation body reviews the materials submitted, and if the quality is acceptable, the certification agency will issue a three-year certificate. After three years, facilities must reapply, but there will be no provisional certificate issued for reaccreditation.

Certification responsibilities include annual inspection either by an FDA or state inspector, and facilities must correct any deficiencies and, in some cases, notify the certification agency of how they corrected those deficiencies.

Ms. Volpe asked if all the past dates would be changed, and Dr. Finder said those requirement dates would be updated or gotten rid of. Ms. Volpe asked if electronic submissions were allowed. She also talked about the importance of training in the administration of compression to someone with an implant. Dr. Finder said they would address that when they got to that section. Dr. Ferguson also inquired about electronic submission for the accreditation process. Dr. Finder said that records could be electronic but said that a more important issue was that the records had to be available at each facility at the time of inspection. Dr. Finder said another issue often raised is why FDA does not have a central database. He went on to explain the problems with FDA trying to maintain a personnel database.

Dr. Timins asked for clarification whether Footnote 32 was intended to help accreditation bodies that may be falling behind. Dr. Finder said the idea was to allow facilities to continue performing mammography when, through no fault of the facility, a decision has not been made by the accreditation body.

Ms. Volpe proposed adding a section under the consumer complaint mechanism to require a mechanism for the consumer to file a complaint directly with both the accreditation body and FDA.

Quality Standards - 900.12 a, c, f, g, h, i, and j

Footnote 54 asked if a statement should be added that facilities are responsible for verifying that all personnel meet all applicable requirements prior to allowing someone to provide mammography services. Dr. Sandrik asked what the intent was and whether it had been

an issue. Dr. Finder said while infrequent it had happened that personnel were found at the time of inspection not to have documented their initial qualifications. He also noted that it may be a year before an inspector looks at those records. Dr. Sandrik asked if the problem was more a case of failing to provide documentation rather than personnel not meeting the qualifications. Dr. Finder said to some extent but there have been cases where people who did not meet the initial qualifications were allowed to work.

Dr. Monticciolo asked what would really change. Dr. Finder said the idea was to ensure that facilities know their ongoing responsibilities with regard to personnel qualifications so that problems are not discovered during inspection. Dr. Timins said it seemed obvious that the facility would be responsible for verifying qualifications. Dr. Ferguson agreed the facility should be responsible and asked if there could be a number that qualified personnel could give to facilities rather than a lot of paperwork, particularly for those who work for multiple facilities. Dr. Finder said there were a number of problems with FDA maintaining a personnel database. FDA feels the best way is for the responsibility to lie with the responsible legal entity. Dr. Ferguson felt it would be better for the onus to be on one central party with perhaps a secure website where information could be accessed.

Dr. Finder said that inspectors look at continuing requirements but do not currently review initial qualifications that do not expire and reiterated that there were a number of problems with having a national personnel database. Dr. Barr said FDA's database system was not currently covered under the privacy act, which would require substantially more resources and which would be necessary if it were to contain personnel information. There are also issues of discoverability, and Dr. Barr suggested that the government might not be the best choice for a central repository anyway.

The committee voted in favor of Footnote 54. Regarding Footnote 55, the committee voted in favor of standardizing the format for all three personnel categories. Dr. Timins said it was reasonable but was not sure it should be mandatory.

Footnote 56 asked how the fact that newly issued Board Certificates expire, should be dealt with. Dr. Timins was opposed to requiring board recertification to qualify as a mammography interpreter. Dr. Monticciolo agreed and said that currently people can either be board certified or meet educational requirements, so it would not make sense to require people who were not certified to recertify. Dr. Finder asked for a vote whether board certification should be a permanent initial requirement. The committee said yes.

Footnote 57 asked if there should be a limit to the amount of physics that can be included in the three months of mammography training. Dr. Finder said there was guidance that no more than 90 hours could be in physics. Dr. Timins suggested a better way to put it would be to put a minimum on the amount of other training rather than limiting physics training. Dr. Monticciolo did not imagine anyone could have too much physics and thought it unlikely that people were really getting an acceptable amount. Dr. Finder said the previous committee wanted to require some physics training but did not specify a minimum or maximum amount. He said that having more than 90 hours was great but that only 90 could count towards the three months of mammography training. The committee voted in favor.

Regarding Footnote 58, the committee voted in favor of accepting fellowship training as part of the three months. Ms. Volpe wondered if the three year time period should be decreased so the training is more recent. Dr. Monticciolo said the value of having a three year period was that people could be exposed to mammography over three years of their residency training rather than crammed in at the end when people are studying for the boards.

Footnote 59 asked if the continuing requirements should be measured from a set date rather than from the inspection date. Dr. Monticciolo supported it and said it would help eliminate confusion during inspection. Dr. Finder asked if December 31st was a good date, and Dr. Ferguson thought it was a good time to remember. Dr. Finder pointed out that facilities would be cited if someone did not meet the requirements on whatever date is selected irrespective of whether they have met the requirements in between the date and when the inspector comes. Dr. Timins said radiologists in particular have problems with this if they read at multiple facilities. She said the initial phase-in might be problematic but thought a grace period would help. The committee voted in favor.

Footnote 60 asked if the mammographic modality-specific CME should be deleted. Dr. Barr said this was just for the continuing requirement and there would still be a requirement for initial training by mammographic modality. Dr. Monticciolo thought it would give physicians flexibility to meet their own personal educational goals. Dr. Timins said the Institute of Medicine (IOM) report had made the same recommendation so that other educational requirements could be pursued. The committee voted in favor of the deletion.

Regarding Footnote 61 the committee voted in favor of deleting "before resuming the independent interpretation of mammograms" and adding a grace period instead. Footnote 62 asked if a statement about requalification for a lapsed state license should be included. Dr. Finder said it would basically say that you have to get your license updated. Dr. Ferguson hoped that people who lost their license because of something technical like not paying to maintain it would not have to go through the whole process. Dr. Finder said there had been cases where the state licensing board did not issue licenses in a timely fashion. He said this deals with situations

where someone lets their license lapse for some reason. Dr. Timins wondered if the states were already handling this issue. Dr. Finder said it was simply intended to clarify regulations.

Pam Wilcox, ACR, cautioned that clarifying the regulations in this way might mean that people are cited when, for example, the board has not issued their license in a timely manner. She said there was already a good process in place to handle it. Dr. Ferguson worried that someone could be cited for a technicality and it could result in a major violation if an interpreting physician did not have a license. Dr. Finder said they were not dealing with the requirement that you must be licensed to practice medicine in the state. He said it dealt with situations where someone allowed their license to lapse and stressed that this was not a new requirement. Dr. Monticciolo worried about state boards being delinquent or someone forgetting to send in their money. Dr. Finder said that inspectors are instructed not to cite when the state is at fault but that if someone forgot to send in their application or payment then it would be a valid citation. The committee voted against Footnote 62.

Footnote 63 asked how renewing of certification should be handled. Dr. Finder said that if they are going to accept board certificates as an initial requirement that does not need to be renewed, should the technologists still be required to submit an up-to-date certificate. Dr. Monticciolo asked what was involved for a technologist to renew their certificate. Ms. Mount said that you have to show a certain number of credits in mammography and favored leaving it the way it was. The committee voted to maintain the certificate as a requirement that can expire and needs to be kept current.

Ms. Volpe asked if a technologist certification was valid across the country, and Dr. Finder said yes but noted that some states require you to be licensed specifically for their state.

Footnote 64 asked if a minimum number of hours of training in each of the areas specified should be given. Dr. Timins said it would be burdensome and unnecessary to specify in regulation. Dr. Monticciolo agreed and advocated flexibility in the training of technologists. Ms. Mount also agreed and said the technologists generally spread out their training appropriately. The committee voted against the proposal.

Footnote 65 asked if the time spent doing the 25 exams should count towards the 40 hours of training. Dr. Finder said that current guidance allows a half hour per exam to count. Dr. Monticciolo thought it was supposed to be 40 hours of education and the exam should be separate. Ms. Mount said it was appropriate to count 12.5 hours for the exams and thought it was one of the more important parts of the training. Dr. Ferguson agreed. Dr. Monticciolo agreed the exams are important but wanted to ensure that technologists get enough classroom time. The committee voted in favor of 65.

Footnotes 66 and 67 were similar to issues already discussed related to interpreting physicians. Regarding Footnote 66, the committee voted in favor of establishing a set date for measuring continuing requirements. For Footnote 67, the committee voted to replace "may not resume performing unsupervised exams" with a grace period. Dr. Finder asked what time frame would be appropriate. Dr. Timins wondered if technologist education was as readily available as physician education. Ms. Mount said it is available but usually one will have to travel to it, and for some rural communities it may be challenging. Dr. Timins suggested 60 days for technologists. Dr. Finder wondered if it should be uniform with the interpreting physicians. They agreed to a grace period of 60 days for everyone.

Regarding Footnote 68, the committee voted to modify the technologist requirements to be consistent with the suggested changes for interpreting physician. Footnote 69 asked if there

should be a time limit for performing 25 exams under direct supervision when a technologist fails to meet the continuing experience requirement of 200. Dr. Finder said physicians were limited to six months for their 240. Ms. Volpe noted that someone in a rural area or someone working part time may have difficulty doing it in a given time frame. Dr. Monticciolo thought it would be hard to enforce different time limits. Ms. Mount said six months would be generous, especially at a high volume institution. Dr. Monticciolo thought it should be shorter since the technologists have fewer mammograms to do. Ms. Mount suggested one week and pointed out that a technologist in this situation would not be able to do any without supervision until they requalified. Dr. Monticciolo suggested three months, but Ms. Mount said that if they did not do 200 in two years there may just not be very many for them to do.

Dr. Finder asked what the grace period would entail and how it would relate to the requalification requirement. Dr. Sandrik was bothered that a grace period basically means that for some period of time the regulations are unnecessary. Ms. Mount said that in her facility a technologist found not to be up-to-date at inspection is sent home without pay until their file is up-to-date. Dr. Timins suggested that for various reasons having a relatively short grace period would be good.

Dr. Finder asked about the situation where, as of December 31st a technologist had not completed the continuing experience requirement, but by the time of the inspection they have far exceeded the requirement. He asked whether the technologist would have to requalify, whether the mammograms done in the ensuing time counted, and whether the technologist would have to go under direct supervision. This scenario raised questions about using a fixed date to measure compliance with the requirement. Dr. Monticciolo asked about physicians who, because of when

they start working, only have half a year or so to meet the requirement. Dr. Finder said the requirement does not apply for the first two years.

Dr. Timins said the purpose of the regulation is to protect the public and did not think that the proposed situation would harm the public. She also suggested it would be fine for a physician to exceed the requirements some years and fall short others so long as the average works out. Dr. Finder said that was the idea behind having a two-year requirement. Dr. Sandrik suggested a transition period rather than a grace period to help people switch over to the fixed date requirement. Dr. Finder said it sounded like FDA should consider allowing people to meet the requirements either on December 31st or the date of inspection. Dr. Ferguson said that would protect the public.

Dr. Byng returned to the issue of what is done about violations that have already occurred as of the time they are discovered at inspection. Dr. Finder noted it was more of an issue for a small facility with only one technologist or radiologist but that even large facilities may face significant problems with personnel coverage in this situation. Dr. Ferguson said there should be a 30-day grace period. Dr. Hendricks asked if an inspection could indicate that a citation made had already been rectified. Dr. Finder said certain such citations are called corrected before inspection and the facility is not cited.

Footnote 70 had previously been discussed with regard to physicians and technologists. Footnote 71 asked if complete mammography equipment evaluations should be added here as well as to other sections of the regulations, meaning that it could be counted as equivalent to a survey of a unit. Dr. Finder noted that in many ways there is more testing done for the equipment evaluation. Dr. Sandrik said that an equipment evaluation for changing one component might be far less than what is done for a survey. Dr. Finder said that is why the

question says complete mammography equipment evaluation. He said that term needed to be defined but it basically refers to the initial evaluation of the mammography unit.

Dr. Byng wanted to ensure that the wording would not mean that facilities would not complete an entire survey. The committee voted in favor.

Footnote 72 asked if the limitation on which type of medical physicist can provide direct supervision for continuing experience should be eliminated. Dr. Williams asked what the two types of qualified medical physicists were. Dr. Finder said the difference was bachelor's versus master's or higher. The committee voted in favor of eliminating this distinction.

Footnote 73 asked if there should be a requirement that facilities must release personnel records to the individual if requested. Dr. Timins thought state law addressed this issue. Dr. Finder said that about once a year someone calls who cannot get their personnel records in order to move to a different facility. Dr. Byng asked what kind of enforcement there would be. Dr. Finder said that a call from FDA pointing out a regulation can be quite effective. The committee voted in favor of the requirement.

Footnote 84 asked if facility name and location should be added to the mammography report. Dr. Timins said it greatly facilitates obtaining records. Ms. Mount asked if this was in addition to having the information on the films, and Dr. Finder said yes. The committee voted in favor. Footnote 85 asked if the name of the referring physician should be added. Dr. Ferguson asked about situations where there is no referring physician and where there are multiple. Dr. Timins said that from a liability point of view the fact that a patient is self-referred should be documented in the report. She also said that for a significant abnormality transmission of the information to either the patient or referring physician should be documented. Dr. Monticciolo talked about a free clinic that they work with. Reports go to a nurse practitioner at the clinic, so

a requirement that reports go to a physician would make it difficult to treat those who come to the clinic. Dr. Timins agreed and said she meant to say healthcare provider. Dr. Monticciolo also had a problem with the report having to be sent to a single individual. Dr. Ferguson had similar experience with a clinic with rotating staff.

Dr. Finder asked who the reports are sent to when dealing with clinics. Dr. Monticciolo said they just use the name of the clinic. Dr. Finder said that what FDA was really trying to do was to ensure that whoever ordered the exam was identified on the report. Ms. Holland suggested using the term referral source, and Dr. Finder said it sounded reasonable. Dr. Byng asked for clarification whether transmission of the report was handled separately, and Dr. Finder said that was correct.

Footnote 86 asked if reporting by individual breast or individual lesion should be allowed for final assessment. An approved alternative standard allows an assessment category for each breast under certain conditions. Dr. Byng asked if there would be both an individual and overall assessment. Dr. Finder said an overall assessment was not required. Dr. Monticciolo thought it would help avoid situations where, for example, a six-month follow-up of one breast was missed by the clinician because the other breast was biopsied. Dr. Finder said the same could be the case with multiple lesions in the same breast. The committee voted in favor of allowing reporting both by individual breast but split on reporting by individual lesion.

Dr. Finder said caution was required whenever assessment categories are changed. Dr. Timins said she had never used individual assessments of lesions and that for complex patients the physician can simply read the report. Dr. Monticciolo said that doing it by lesion would be so complicated that there should be direct interaction among the practitioners. Dr. Finder said that facilities with computerized monitoring systems felt it would give them more flexibility. He

also pointed out the assessment categories used by FDA are not the same as BI-RADS. Ms. Butler said the BI-RADS guidance was to give one final assessment category based on the most worrisome finding but the report should detail the individual findings. The committee's vote was split with regard to allowing reporting by individual lesion. Dr. Ferguson stated the key was allowing, not requiring. Dr. Byng asked if it was not currently allowed. Dr. Finder said it was only allowed if you also give an overall final assessment.

Footnote 87 asked if the benign final assessment category should be clarified to avoid confusion with the negative category, which some have taken to be the same thing. The committee voted in favor of the clarification.

Footnote 88 asked if the suspicious category should be subdivided into low, intermediate, and moderate. Ms. Butler said it was a recommendation from the BI-RADS committee. Dr. Monticciolo thought it would be an unnecessary complication to require it. Dr. Timins agreed and noted that on occasion she had used the subdivided designations. Dr. Finder asked if it should be allowed. Dr. Finder said they require "suspicious" to be used but that people add on their own modifiers. Ms. Holland said that a suspicious finding required follow-up so there was no reason to break it down.

Dr. Finder said part of the idea was to differentiate lesions they really thought would turn out to be cancerous for the medical audit. Ms. Segelken agreed with the comments of Ms. Holland. Dr. Monticciolo agreed as well and thought it would be an unnecessary complication with potential bad consequences for patients. The committee voted no.

Regarding Footnote 89, the committee voted in favor of adding "known biopsy proven malignancy" as one of the assessment categories. For Footnote 90, the committee voted to add "post procedure mammogram for marker placement."

Footnote 91 asked if the word "incomplete" should be changed to inconclusive, given that the study is complete and there is simply need for further studies. Dr. Timins thought inconclusive sounded more like it applied to interpretation and suggested using "incomplete - need additional imaging evaluation." Dr. Ferguson agreed. The committee rejected the change.

Footnote 92 asked if a separate category for "need prior mammograms for comparison" should be added. Dr. Ferguson said it would be cumbersome to have it as a separate category. Dr. Finder said the idea was that the category would require that another report be issued within some period of time. He said that currently if comparison films never become available there is no requirement that the case be re-reviewed and a final assessment given based on the information available. Dr. Timins said in her practice if the previous films are not received within a certain period of time, a final report is issued. Dr. Ferguson felt a large proportion of screening mammograms would be in this category and said he uses incomplete to signify that they need additional studies, not prior films. Dr. Finder said it would force facilities which use incomplete to avoid issuing a report, or forget to issue one to issue a final assessment category. The committee voted against the addition.

Dr. Ferguson asked if there was a way to combine BI-RADS with FDA's assessment scale. Dr. Finder said the concordance between the two was well established and said that BI-RADS is indeed proprietary. Ms. Wilcox said the BI-RADS scale is shared universally. Dr. Ferguson wondered if numbers should be attached to the assessment categories. Dr. Finder said some of the categories being added do not relate to a change in the probability of malignancy and that the post procedure mammogram category is not part of BI-RADS. He said facilities have the choice whether to use a numbering system but only in addition to the words of the approved assessment categories.

Footnote 93 asked if the timeframes in this section should be modified to take into account that there is no requirement as to when the mammogram is interpreted or how to deal with the situation where the facility is waiting for prior films before issuing a report. Dr. Monticciolo said she would leave it as the 30-day limit already in the regulations. Dr. Finder said that 30 days was for average reports as opposed to suspicious or highly suggestive reports that are designated "as soon as possible." He said that the current guidance recommends three days to get the report to the referring physician and five days to the patient. Dr. Finder noted that all of these time periods are measured from the time an assessment is given to the report. Dr. Timins noted the referring physician may not be available for some time and suggested it be left as is.

Ms. Volpe said that 30 days is too long for patients to have to wait. She said the mammogram should be read within 10 days, and the patient should have to wait no more than 15 or the delay should be explained to the patient if they are waiting for prior films from another location. She also said that suspicious or abnormal findings should be communicated to the patient as soon as the mammogram is read. Dr. Barr said the problem was that there is no requirement for when a mammogram must be read and interpreted. Dr. Finder said the "as soon as possible" only comes into play once an assessment has been made. He also said that all mammograms must be read and a report issued within 30 days. Ms. Segelken thought even 30 days was too long.

Dr. Ferguson said he goes on ten day vacations, so mammograms from the first day of his vacation would not be read for at least ten days, and the alternative, hiring someone else to read the films, is not really a possibility in his area. He thought 30 days was a reasonable period. Dr. Monticciolo said having 30 days can help her avoid unnecessary biopsy by allowing her to wait

for prior films. She did not think the 30 days would change the treatment of any disease that is present. Ms. Segelken said that "as soon as possible" was too ambiguous given that not all facilities are good at communicating with patients. Ms. Holland agreed and said many poor and under-served people in her community suffer because of the lack of communication. The committee's vote was split.

Footnote 94 asked if "when mammographically indicated" should be added. Ms. Volpe suggested "when clinically or mammographically indicated." Dr. Finder asked for a vote on her suggestion, and the committee said yes. Dr. Byng suggested just using "when indicated."

Footnote 95 was basically the same as a previously discussed change. Regarding footnote 96, the committee voted in favor of having a timeframe for release of records. Dr. Ferguson asked how long it takes at larger facilities, and Ms Mount said they are usually sent out the same week. Dr. Ferguson suggested fourteen days. Dr. Monticciolo thought a timeframe would make facilities respond better but thought two weeks might be tight for some facilities. Dr. Timins agreed and talked about problems with retrieving films from storage and related to holidays. Dr. Monticciolo suggested fifteen days from when the request is received. She said the problem was out-of-state, unfamiliar facilities or when a patient does not quite know the exact name of the facility.

Ms. Segelken asked if new patients are instructed to bring in their old films. Dr. Monticciolo said they are but patients do not comply very well. The committee voted in favor of a fifteen day period.

Footnote 97 asked if specific requirements and penalties should be set with respect to record retention for facilities that are closing. Dr. Timins said it was hard to penalize a bankrupt, closed facility but thought it appropriate to require that films be made available. Dr. Sandrik

suggested that facilities would have to demonstrate they had a plan in place when they are accredited. Dr. Finder said requiring some guarantee or bond might discourage facilities from entering the field. Dr. Sandrik suggested facilities could be required to simply submit a plan. Dr. Ferguson said it was hard to cover all bases in terms of patient notification in these kinds of circumstances. The committee voted in favor of addressing the issue in the regulations.

Footnote 98 asked if there should be clarification that the section on mammographic image identification only applies to images for final interpretation and also asked what "permanent" means with regard to softcopy digital images. Dr. Finder said the issue was that identifying information can be toggled on or off for digital images. He said sometimes the information is left off or it overlies the image of the breast. Dr. Byng suggested there may be situations other than final interpretation where it would be appropriate to have identifying information. Dr. Sandrik said sometimes it is annoying to have the information present. Ms. Mount said radiologists at her facility prefer to read the image without the information and view it just to make sure they have the right patient.

Dr. Williams said it should be able to be toggled off at final interpretation but wondered if there were situations where it might be a liability to have the information appear. Dr. Sandrik said it might be important to have if one was depending on the location of the labeling. He said if the radiologist was present it might be clearly obvious but said in situations where the radiologist is in another room it may be a liability not to have the labeling. Dr. Hendricks asked about storage of digital images. Dr. Sandrik said it depended but in most cases when a hardcopy is made, the labeling is put in the appropriate place. Dr. Williams said the information would be stored in the DICOM header and would be retrievable.

Dr. Finder said the regulation does not differentiate film screen from digital and noted that if the ability to toggle the information on or off was not considered permanent, no FFDM images meet the current requirements. Dr. Monticciolo said that final images would have to have the labeling but all others could be toggled. Dr. Sandrik said they would have to address the idea of permanent digital imaging. Dr. Finder asked if the committee agreed that FFDM was a different system that had to be dealt with, and the committee said yes.

Footnote 129 asked if combining medical audits from different facilities under the same ownership should be allowed. Dr. Byng said that underperforming facilities could be lost in the data. Dr. Finder said that was part of the rationale for the original regulation but said you could also gain information from having larger numbers and better statistics. Another major concern at the time was the difficulty in combining facilities with significantly different patient populations.

Dr. Byng asked if the benefit was in simplifying the audit and reducing the costs of it. Dr. Finder said that small facilities might not have enough cases to include in the audit to make it statistically significant and also acknowledged that it might save facilities some resources. He also said that if the audits were combined, problems at one facility could cause all of them to be cited.

Dr. Monticciolo was in favor of combining and said it would be easier to assess physicians who read for multiple facilities. Dr. Finder said that currently facilities are allowed to combine but they still have to break it down by individual facility. The committee's vote was split with more in favor.

Footnote 130 asked if certain metrics should be required for the medical audit. Dr. Monticciolo thought it would increase resource expenditures without benefit and make it difficult for facilities to meet the requirement. Dr. Ferguson agreed and asked what the data would be

used for. Dr. Byng noted there were no standards associated with the metrics. Dr. Monticciolo said it would require more resources and drive people out of practice. Dr. Byng said some of the metrics were simply recalculations of numbers that facilities would already have. Dr. Williams said the IOM had recommended this with the logic that a reanalysis would provide these additional metrics.

Dr. Sandrik asked how it would really change the practice or improve quality to essentially re-crunch some numbers. Dr. Ferguson said the re-crunching should be left to those doing research. The committee voted against requiring the metrics.

Footnote 131 asked if phantom image quality should be added to this section. Dr. Monticciolo asked how it would change current practice given that the phantom is checked every week and must pass certain standards. The committee voted no.

Regarding Footnote 132, the committee voted in favor of adding state certification agencies to the requirement on AMR. For 133, the committee voted in favor of including a requirement that facilities have to reimburse the accreditation body for the cost of the AMR.

Footnote 134 asked if the notification should be limited to only those patients at risk. Dr. Ferguson said that when he was involved in reviewing such a circumstance the mammograms were read and patients without quality exams were notified. He said that notifying all the facilities would scare women. Ms. Volpe said patients would find out at their next mammogram. Dr. Monticciolo said it depended on the severity and noted that a facility producing bad films for an AMR was probably doing bad films regularly. She also said it would depend on when the facility started producing bad films.

Dr. Finder said the facility could have been in operation for decades, in which case it would not make sense to notify all of the patients. He said FDA tries to determine what time

frames, machines, or technologists, for example, are involved to focus the notification; otherwise a two-year span is looked at. Dr. Finder asked if there should be some limits along the lines discussed, and the committee said yes.

Regarding Footnote 135, the committee voted in favor of modifying the regulations to specifically state that if the facility fails to complete the notification, FDA or the state can perform the notification through any means available and require reimbursement from the facility.

Revocation of Accreditation and Revocation of Accreditation Body Approval - 900.13; Suspension or Revocation of Certificates - 900.14; Appeals of Adverse Accreditation or Reaccreditation Decisions that Preclude Certification or Recertification - 900.15; Appeals of Denials of Certification - 900.17; Alternative Requirements for Section 900.12 Quality Standards - 900.18

Having finished the day's agenda, Dr. Finder suggested the committee move on to matters scheduled for the following day and suggested that time be allowed tomorrow to recap them for those who missed today's discussion.

Footnote 136 asked if the section should be rewritten to clarify the differences when all units versus only some are denied accreditation and if the differences between initial and reaccreditation scenarios should be clarified. The committee said yes to both questions. Regarding Footnote 137, the committee voted in favor of including a statement to clarify that even expiring certificates can be extended for up to a year. Dr. Finder noted they may not be able to do it due to the language of the statute.

Footnote 138 asked if the one year period should be extended if no viable accreditation alternatives exist. Dr. Timins asked if it had happened, and Dr. Finder said only one accreditation body had ever relinquished its authority and in that instance another accreditation body was able to take over for it. Dr. Ferguson asked how long it would take to get all the facilities accredited by a new body. Dr. Monticciolo noted that ACR has a national program that

could serve as a viable alternative. Ms. Butler said ACR had taken over for California, the largest state body at the time, within a year. The committee voted in favor.

Footnote 139 asked if failure to pay inspection fees should be a listed cause for suspension. Dr. Ferguson wondered if it would help the public to close down a facility for not paying inspection fees and asked what options existed for struggling facilities. Dr. Finder said the fee depends on the number of units but for the average of 1.5 units it would be around $2,000 per year. Dr. Monticciolo worried about someone at a facility losing the check or not sending it in. Dr. Finder said the purpose of this change was to deal with situations where facilities have gotten multiple notifications and have missed their payments for multiple years.

Dr. Barr said that currently FDA could not deny a facility a certificate based solely on failure to pay inspection fees. Dr. Ferguson asked if there could be discretion when such an action would be applied. Dr. Finder said governmental entities, which include facilities that provide more than 50 percent of their mammography work to things like CDC programs and low-income groups, do not pay at all. He said the intent was to encourage facilities with the ability to pay who simply do not want to. The committee was split.

Footnote 140 asked if continued use of an unaccredited unit should be a cause for suspension. Dr. Finder said it referred to facilities that continue to use an unaccredited unit after being specifically notified not to. Dr. Ferguson hoped it would be very clear that it did not apply to scenarios where a unit is unaccredited for a short period because someone forgot to send in some paperwork. The committee voted yes.

Footnote 141 asked if facility denial, suspension, or revocation of accreditation should be a cause for suspension of the certificate without a hearing. Dr. Sandrik asked if the accreditation bodies go through a hearing process prior to revoking accreditation. Dr. Finder said yes. He

pointed out that for a provisional facility with a six-month certificate that is denied accreditation, the certificate is null and void upon denial of accreditation. But for a fully accredited and certified facility that is denied reaccreditation the certificate remains in effect until its expiration. Dr. Finder said that the agency's lawyers had said that a certificate could not be automatically suspended or dropped because of denial of accreditation. He stated that the question should have been reworded so that it only applied to suspension or revocation.

Ms. Volpe said if there was a significant health or safety issue the certificate should be suspended until after a hearing is held. Dr. Finder said a denial of accreditation simply meant the images produced did not pass the quality standards, not that there was necessarily any risk to human health. But a suspension or revocation is usually the result of a failed AMR, meaning there is risk to human health. Dr. Ferguson agreed that if there was a risk to human health the facility should be immediately prevented from doing mammography and then given a hearing. The committee voted yes with regard to suspension and revocation.

Footnote 142 asked if a regulation consistent with the statute should be included indicating that owners of a facility with a revoked certificate can not operate a mammography facility for two years. Dr. Finder said it was allowed in the statute and they merely wanted to add the language to the regulation. Dr. Ferguson asked if someone in a large hospital chain could mess up and cause the whole chain not to be able to perform mammography. Dr. Finder said that in such an organization notification would go to multiple individuals who would all have to decide not to do what was required.

Mike Divine, Chief, Inspection and Compliance Branch, said it would probably boil down to whoever was identified as being responsible for the violation and not affect the rest of the people at the facility. The committee voted in favor.

Regarding Footnote 143, the committee voted in favor of the section being rewritten to separate out appeals of adverse accreditation decisions from appeals of adverse certification decisions.

Footnote 144 asked if a separate section should be included dealing with causes for denials of certification. Dr. Ferguson said it seemed like the judgment would be based on the report of a field inspector who may not get along with people at the facility. Dr. Finder said the purpose was to establish under what circumstances a certificate would be denied. He also said there was a lot of back and forth with a facility prior to taking this kind of action. Dr. Ferguson asked if the committee would have an opportunity to see the wording. Dr. Finder said the plan was to publish a draft amendment for public comment and have another meeting during that public comment period. The committee voted in favor of Footnote 144.

Footnote 145 asked if the alternative requirements should be expanded to include alternatives to accreditation body and state certification agency regulations. Dr. Finder said the question was whether there should be the same flexibility as exists for facilities. The committee voted yes.

Footnote 146 asked if the section should be modified to place the notice on the FDA website rather than things like the Federal Register. Ms. Volpe said it would be fine to put alternative standards on the website in addition to those places already specified, and Dr. Finder said that is what they are currently doing. The vote was split. Dr. Sandrik was troubled by the idea of putting current technology into regulations.

Footnote 147 asked if the basis for approval, rather than the application itself, be made available to the public. Dr. Finder said confidential material is sometimes included in the application. The committee voted in favor of Footnote 147. Dr. Timins asked what confidential

material there might be, and Dr. Finder suggested data obtained from a manufacturer's units under certain conditions could be. Dr. Sandrik agreed and said his company had provided proprietary data to support several alternative standards they applied for. The committee voted in favor.

ADJOURNMENT

Dr. Hendricks adjourned the meeting at 5:10 p.m.

I certify that I attended this session of the National Mammography Quality Assurance Advisory Committee on September 28, 2006, and that these minutes accurately reflect what transpired.

_____

Nancy Wynne
Executive Secretary

I approve the minutes of the September 28, 2006, meeting as recorded in this summary.

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Carolyn Hendricks, M.D.
Chairperson

Summary prepared by
Eric C. Mollen
Neal R. Gross & Company
1323 Rhode Island Ave., NW
Washington, DC 20005
(202) 234-4433
eric.mollen@gmail.com