

SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE MEETING

Open Session

September 26, 2005
Gaithersburg Holiday Inn
Gaithersburg, MD

CALL TO ORDER

Committee Chair Carolyn B. Hendricks, M.D., called the meeting to order at 9:04 a.m. **Executive Secretary Charles Finder, M.D.**, read the conflict of interest statement. Full waivers had been granted to the following participants because of their financial involvement with facilities that would be subject to FDA's regulation on mammography quality standards: Diane I. Rinella, R.T. (R)(M); Jacquelin S. Holland, R.N.; Debra L. Monticciolo, M.D.; William A. Passetti, B.S., A.A.; Mark B. Williams, Ph.D.; and Jane B. Segelken, B.S., M.A. Waivers were currently on file for Carolyn B. Hendricks, M.D.; Scott Ferguson, M.D.; Carol J. Mount, R.T.(R)(M); Alisa Gilbert; Miles G. Harrison, Jr., M.D.; Linda S. Pura, R.N., M.P.A.; and Melissa C. Martin, M.S.

COMMITTEE BUSINESS

Dr. Hendricks noted that the committee members present represented a quorum and asked the committee members to introduce themselves. She then read the FDA's statement on disclosure with respect to the open public speaker process.

APPROVED ALTERNATIVE STANDARDS

Dr. Finder discussed alternative standards approved since the last committee 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 and 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 Statute 42, USB 263(b).

The agency has approved two alternative standards since the April committee meeting. The first allows a specially trained quality controlled technologist to make system artifact films and phantom images at remote processing sites used by mobile mammography facilities and submit them to the facility medical physicist for evaluation so that the medical physicist does not need to visit each remote processing site as part of the annual survey. The second approved alternative permits system artifact tests to be performed without testing all target filter combinations during the annual physics survey.

OPEN PUBLIC HEARING

Dr. Carol H. Lee, American College of Radiology (ACR), spoke about the organization's commitment to quality and history of accreditation for breast imaging. She stated that the recent Institute of Medicine (IOM) report (entitled Improving Breast Imaging Quality Standards) did not specify what problems existed in breast imaging practice.

With regard to mammographic interpretation, the recall rate in the U.S. was shown to be twice that of the United Kingdom. The same study also found that more cancers were detected in the U.S. and that most of the additional cancers found were small invasive cancers and DCIS. Studies have also shown that the size of tumors within stages has decreased since the advent of modern mammography. Breast cancer mortality in the U.S. has decreased by 25 percent in the past ten years, and the decrease in tumor size within stage in the past 30 years accounts for most of the observed improvement in survival in localized breast cancer.

Dr. Lee discussed the shortage of manpower in breast imaging in the U.S. A recent study of Massachusetts radiology residents found that only three percent would like to spend a significant amount of time on mammography, only eight percent would like to do mammography

at all, and only one of the 63 senior residents surveyed planned to pursue a breast imaging fellowship. When asked why they did not want to do mammography, the majority reported they were afraid of lawsuits.

Dr. Lee then discussed specific recommendations from the IOM report. One suggested a requirement for separate tracking of screening and diagnostic mammography so that results could be compared to established benchmarks. However, the difference between screening and diagnostic varies among practices and facilities, making comparison difficult. Dr. Lee questioned the applicability of benchmarks to individual practices. After leaving her academic practice at Yale and setting up a private practice in Hawaii, Dr. Lee's performance did not change, but her benchmarks did due to the different patient population. Now her recall rate is higher and her positive predictive value is lower.

Another recommendation from the IOM report was for mandatory tracking of all cases with BI-RADS 0 assessment. This is difficult with commercially available tracking software and requires additional time, effort, and expense, and the report itself states that there has been no benefit provided by this additional tracking. A third recommendation was for inclusion of interventional mammographic procedures, particularly stereotactic biopsy, in the Mammography Quality Standards Act (MQSA). ACR believes this will lead to improvement in the quality of these procedures. Similarly, the recommendation for regulation of breast ultrasound and magnetic resonance imaging (MRI) would likely result in improvements in quality. However, the breast MRI accreditation program had not yet been established, and hardware and software for the procedure was still being developed.

Increased regulation, if unfunded, risks limiting access to care through decreases in manpower and facilities.

Lawrence Bassett, M.D., Society for Breast Imaging (SBI), discussed concerns of the organization regarding the IOM report. The four categories of recommendations within the report are improving mammography interpretation; revising MQSA regulations, inspection, and enforcement; ensuring adequate work force; and improving breast imaging quality beyond mammography.

The recommendations to improve mammography interpretation involve revising and standardizing the medical audit component of MQSA and facilitating voluntary advanced medical audit with feedback. Though increased regulations are designed to improve care, work force problems and low reimbursement may negatively impact patient care. SBI feels that there should be incentives to support improved care before additional regulations are imposed. The new audit recommendations would require more time and paper work. Dr. Bassett's facility hired a QA coordinator to perform the audit functions since the radiologists were already under staffed, but small rural facilities may not have the resources to carry out additional audit requirements.

Another recommendation was the establishment of breast imaging centers of excellence and the undertaking of projects and studies within those centers to look at the effects of CME, reader volume, et cetera. SBI supports the recommended centers of excellence but feels there is a lack of evidence that variables such as reader volume affect interpretation quality. Furthermore, a requirement for reading a greater volume would impose further cuts in the breast imaging work force.

SBI also supports streamlining the process by modifying regulations to clarify their intent and by determining which requirements are effective in improving mammography quality. SBI wants to look at how to reduce the burden on current breast imagers. However, the use of

radiologist assistants in interpreting breast images has not been proven effective and does not reduce the medical or legal responsibility of the interpreting physician. SBI wants to increase output without sacrificing quality.

SBI also supports mandated accreditation for breast imaging methods other than mammography but feels that accreditation for breast MRI must come later once appropriate standards have been developed.

Dr. Finder then read a comment submitted anonymously for the record by a registered nurse and patient advocate from a women's diagnostic center. According to the author of the letter, studies have shown that in order to remain proficient, doctors must read a minimum of 2,500 films per year, yet the government requires only 480 and does not monitor compliance. Radiology groups are unlikely to go to the effort to go back and identify false negatives.

The author discovered 18 false negatives in the last two years at her center. A fellowship-trained mammographer joined the center and identified two physicians who should not read mammography at all. Furthermore, the cancers being missed were not small and hard to see. This mammographer left the center, and the radiology group has delayed finding a qualified replacement because the position will not generate the same revenue as other physicians in the group.

The author suggested that since most radiologists would rather not do mammography and other women's imaging, radiology groups should subsidize salaries for those who are willing and not expect them to do general radiology as well. The author confronted the radiologists at her center with data on their own performance, but they responded that they should not be held to the same standards since they don't read as many films per year as mammography experts.

The author made several specific recommendations. Minimal reading and CME standards should be improved. Reimbursement for breast imaging must be increased. Radiology groups must recruit breast imagers and be willing to subsidize their salaries. Regulatory agencies must find a way to monitor physician accuracy. MQSA must be more comprehensive and expanded to become the Breast Imaging Quality Standards Act (BIQSA). For stereotaxis, only registered mammography technologists should set up the equipment and position the patient.

The ACR will begin labeling false negatives as sentinel events, which will have a significant impact on hospital accreditation. Perhaps they will begin to demand higher quality breast imaging readers.

Dr. Finder next read into the record comments submitted by **Richard L. Ellis, M.D., Co-Director, Norma J. Vinger Center for Breast Care, Gundersen Lutheran Medical Center.** Early detection and diagnosis has resulted in the greatest reduction in mortality from breast cancer, but there is a need for higher quality interpretation. Therefore, there is need for a performance audit of screening mammography interpretation to look at the mean and median size of the detected carcinoma, total screening volume per year, recall rate, and positive predictive value for BI-RADS 4 and 5. Although mammography and breast imaging CME programs are important, many do not provide for direct improvement in interpretation of screening mammography.

Another issue is that access to care may be lost in many communities if there are physician performance standards, but this has been addressed in other countries. Were inappropriately low standards to be set to maintain access, mortality rates would not be reduced and the cost of care would increase. Also, communities and medical institutions should look at

creating interdisciplinary breast care teams to provide for improved overall care, efficient use of resources, and substantially reduced costs.

A third issue is the establishment of one universal accreditation standard for breast ultrasound. Similarly, standards should be developed for breast MRI and imaging-guided breast tumor ablation. The final issue addressed by Dr. Ellis was the shrinking number of radiologists and training residents who want to do breast imaging. Low reimbursement and exposure to malpractice need to be addressed, and there should be incentives to keep radiologists in breast imaging. Creative solutions, such as graduated reimbursement rates based on physician performance, a national medical malpractice arbitration committee, and tort reform, are necessary.

OPEN COMMITTEE DISCUSSION

Michael P. Divine, M.S., Acting Chief, Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs (DMQRP), discussed inspection observations and follow-up actions. There are three levels of inspection findings, level one, serious; level two, moderate; and level three, minor. With regard to facility performance over time, violations at all three levels have been decreasing, there are very few level 1 violations, and about 70 percent of facilities have no violations.

Level one violations of interpreting physician initial qualifications (certification, training or licensing) are rare with twenty facilities cited in 2004. This number has been decreasing over the last several years. The problems with physician licensing can be attributed to failure to renew a license or to have the proper documentation on hand at the time of the inspection. There

are almost no initial qualification issues with medical physicists anymore, and the number of violations related to technologists has been decreasing.

There are some problems with level one quality control violations, but the number is not that significant when compared to the total number of facilities. With the exception of high fog density, which occurred in approximately one percent of facilities, there were very few level two problems relating to phantom score and processing conditions. There were some level two violations dealing with the annual survey, particularly facilities having more than 14 months between annual surveys or having incomplete surveys.

With regard to the testing done by inspectors, inspectors have not recorded a dose exceeding 300 millirads since 1997, and the most common violation detected during inspector testing was with alignment, occurring in approximately two percent of facilities. Level two problems with interpreting physician qualifications mainly dealt with continuing experience and continuing education, but the numbers have been decreasing. The same was true for technologist and medical physicist continuing qualifications.

As for medical records, a small number of facilities had problems with sending out patient letters or mammography reports within 30 days, a level one violation. There are still problems with assessment categories, but this can be attributed in large part to the wording. A small number of facilities still have problems with procedures for customer complaints and infection control, but the numbers are dropping.

Level two problems with the medical outcomes audit system were highest in the areas of no annual analysis, failure to break down the analyses by physician, and no analysis of the entire facility. The highest numbers of problems overall were seen in the category of failure to

maintain personnel documents, a level three violation. This violation was detected in approximately five percent of facilities

Follow-up actions are taken for facilities with ongoing problems. The types of action FDA can take are follow-up inspections; additional mammography review; patient and physician notification if the additional mammography review showed a serious risk to human health; a directed plan of correction; civil money penalties; suspension or revocation of a facility's certificate; and obtaining an injunction from a federal court if the facility's mammography is a serious risk to human health or if the facility was performing mammograms without a certificate.

Follow-up inspections check on corrective actions taken for serious problems and are performed on facilities with a level one or repeat level two violations in addition to other problems in the past. They are usually limited to certain specific problems. Additional mammography review is usually done by the accreditation body, and if a serious risk to human health is found, there is a requirement that the facility notify patients and their physicians of the problems and possible follow-up actions the patients may should take. Directed plans of correction impose additional requirements, allow for monitoring of the quality assurance program, and could include additional inspections. Suspension is reserved for facilities with serious violations, and a hearing is required to allow the facility to contest the suspension unless a serious health hazard is identified. In that case, FDA shuts down the facility immediately.

Since MQSA was enacted in 1994, there have been 64 additional mammography reviews, 17 patient/physician notifications, four directed plans of correction, three civil money penalties, six certificate suspensions, and no certificate revocations or injunctions. In many cases in which the additional mammography review finds a serious risk to human health that resulted in accreditation being revoked, the certificate was removed almost immediately.

Dr. Hendricks asked which parts of the inspection routine could be eliminated without impacting the quality of the inspections. Mr. Divine suggested that the dose testing, as well as the reproducibility test that is done in conjunction with it, and the beam quality test could perhaps be eliminated since the agency does not find many problems with those tests.

Mr. Passetti asked about the average dose across facilities, and Mr. Divine responded that it was around 1.7 milligray. He stated that the doses had been on the rise but that the increases could be attributed to a preference for darker films and had not resulted in any noncompliances.

Dr. Hendricks asked whether the possible changes Mr. Divine had mentioned would reduce the time or expense required for inspections. Mr. Divine suggested that the elimination of the dose testing could reduce the time by half an hour per unit but did not know how the costs would be affected. Dr. Williams suggested that the agency look at the distribution of doses around the average to see if it might be useful to consider a different upper limit. Mr. Divine replied that that data had already been collected and was probably still available online. Dr. Finder added that if the agency wasn't measuring dose every year, the medical physicists would still continue to measure dose every year and the accreditation body would every three years.

Dr. Hendricks asked for clarification whether 70 percent of facilities had no findings at all during their inspection, and Mr. Divine confirmed this. She then asked whether those facilities might benefit from less frequent inspections while maintaining their quality of care. Mr. Divine said it was a possibility but mentioned a study that showed an increase in problems when facilities skipped an inspection. Dr. Finder added that Congress had asked the agency to look at this issue in the last reauthorization and the preliminary results did not support having inspections every other year.

Helen J. Barr, M.D., Director, DMQRP, CDRH, discussed recommendations made by IOM. Clarifying earlier remarks, she stated that they were already collecting dose data supplied by the medical physicists to compare to the data collected by the inspectors and that the inspection demonstration program was in the first reauthorization of MQSA, not the last one.

The IOM report was intended to address concerns about the quality of mammography image interpretation. Congress commissioned the study as preparation for the next reauthorization of MQSA. The report, entitled *Improving Breast Imaging Quality Standards*, was done by the Committee on Improving Mammography Quality Standards of the National Cancer Policy Board at IOM. The four main areas of recommendations were improving mammography interpretations; revising MQSA regulations, inspections, and enforcement; ensuring adequate work force for screening and diagnosis; and improving breast imaging quality beyond mammography.

The first recommendation under improving interpretation was to revise and standardize medical outcomes audit. The first specific recommendation in this area was that the medical audit should include the calculation of three measures: PPV_2 (the proportion of all women recommended for biopsy after mammography (Category 4 or 5) that are diagnosed with breast cancer); the cancer detection rate per 1,000 women; and the abnormal interpretation rate, where the interpretation leads to additional imaging or biopsy. The rationale for this change was that MQSA does not currently require calculation of specific performance measures and that these three measures would give facilities a good idea of how they were performing. PPV_2 was felt to be more useful than PPV_3 (the proportion of women biopsied due to the interpreting physician's recommendation who are diagnosed with cancer at the time of biopsy) and would be easier to calculate than PPV_1 , the proportion of all women with positive examinations (Category 0, 4, 5)

diagnosed with breast cancer. Dr. Ferguson voiced the opinion that the additional calculations would be a burden and wondered how they would improve quality.

The next recommendation in this area was that performance measures should be stratified by screening and diagnostic mammography. The rationale was that it was difficult to interpret and compare performance with current literature or established databases.

Dr. Monticciolo said that it would be difficult to discriminate between the two given the differences between practices and thought the recommendation represented a burden without much gain. Ms. Mount agreed and said that even satellite facilities within her facility had different definitions for screening and diagnostic. Dr. Hendricks felt this was an important point in spite of differences among practices. She suggested that if definitions were established the overwhelming burden of women seeking diagnostic imaging who are more appropriate for screening could be lessened. Dr. Hendricks defined screening mammogram as the screening of a woman 40 or older with no breast symptoms at the time of examination. Dr. Monticciolo agreed that a standard would be nice but was concerned about the implications of imposing such a standard, particularly for patients with implants.

Ms. Pura suggested the use of simple terms such as symptomatic and asymptomatic could help. Dr. Hendricks reminded the committee of their charge to decrease the burden on the system and suggested that a standard could lessen the burden by cutting down on the high proportion of women seeking mammography more than once a year by identifying which women would benefit from more frequent imaging. In her practice in Bethesda, women will schedule an appointment slot on a day they know a particular physician will be reading and want to meet with the mammographer after their imaging, and this decreases the number of high quality images that can be read and interpreted. The public needs to be educated about who would

benefit from more frequent imaging and who needs a screening rather than diagnostic approach. Dr. Monticciolo agreed that education is important but was not convinced that separating out audit data would be helpful.

IOM recommendation C under “revise and standardize medical outcomes audit” was that facilities should have the option of combining audit measures for physicians at multiple facilities. The rationale is that the data would be more meaningful when greater numbers of exams per physician are analyzed. Dr. Finder discussed the current requirement that each facility do its own audit broken down by facility and by individual physician. The agency’s authority is with regard to facilities, not individuals, and keeping the audit at the facility level allowed physicians to compare themselves to one another since they would all be dealing with basically the same population. An alternative standard was already approved allowing mobile units, each of which is individually certified and is considered a separate facility but which share physicians, to combine their data into one audit.

The agency was concerned how to combine data from different fixed facilities into a cogent analysis. For practice groups that practice at multiple facilities, the agency has recommended that they do their own second analysis of the combined data. Dr. Monticciolo stated that physician performance was the important measure, so for those who read at multiple facilities it would make sense. Also, the greater the numbers, the more information you will have about a specific individual. Dr. Hendricks supported combined data for multiple satellite offices of one large clinical practice. Dr. Ferguson asked whether the recommendation was for mandated combination of data or simply allowing for combination, and Dr. Finder said that it could be done either way depending on the advice given.

Recommendation D under “revise and standardize medical outcomes audit” was that audit data collection and analyses be verified at inspection but not collected. The rationale was that no change in the current procedure was warranted because regulators are not able to verify the accuracy of the data. Dr. Ferguson inquired whether the purpose of the data was for the physicians to judge their own performance. Dr. Finder confirmed this and said the information remained at the facility. As the data was intended for the physicians, Dr. Ferguson supported allowing this rather than mandating it. Dr. Finder raised the issue of some physicians reading at multiple facilities and others not having data. Dr. Ferguson brought up that there could be a physician who read primarily diagnostic exams at one facility and read primarily screening exams at another facility. The audit data would be significantly different if looked at separately or combined.

Recommendation E under “revise and standardize medical audit” was to increase reimbursement rates to cover new audit procedures. The rationales are the costs are already significant, the new procedures will add to the expense, costs were not factored in past reimbursements, and the health care payers should cover costs. Dr. Ferguson strongly supported this recommendation. Dr. Hendricks wondered what metrics could be used to look at quality of care if the three specific performance measures from recommendation A could not be accepted.

The next recommendation under improving mammography interpretation was for a voluntary advanced medical audit with feedback., The audit should include collection of patient characteristics and tumor staging from pathology reports and establishing a data and statistical coordinating center. Ms. Pura stated that getting pathology reports from surgeons was difficult as her facility already did this as a requirement for a state program and was not sure how valuable the information would be. Dr. Lee disagreed and declared that knowing cancer stage

was important given that only detecting large cancers did not do much good and was not the intent of mammography. She agreed that the data would be difficult to collect. As far as useful metrics, Dr. Lee suggested that cancer detection rate and false negatives were useful pieces of information. Ms. Pura agreed that tumor size was important but was concerned about the difficulty in collecting that information and the potential impact on access to care.

Dr. Barr asked whether FDA should look at what was actually done for the audit rather than just at whether it was done, whether the data from the audit should remain at the facility, and whether there should be citations for those who do not do an audit. Dr. Hendricks raised the issue of report cards for hospitals and asked what information would be on a report card for a mammography facility without creating onerous regulations that would cause facilities to close. Dr. Monticciolo questioned the evidence that physicians' interpretive abilities or ultimate patient outcomes would be affected by these additional burdens. She was opposed to adding requirements with no demonstrated ability to improve interpretive abilities.

Ms. Holland asked why the FDA verified but did not collect audit data. Dr. Finder replied that the information was to be used by the facility to improve quality of care. The IOM recommendation was aimed at specifying what should be done for the audit, not at collecting the information for a national database. Originally FDA did not ask for specific information to be collected because the statistical data would be dependent on a number of factors and because of differences between screening and diagnostic patient groups. Dr. Barr clarified that a facility could be cited for not doing the audit at all and that FDA was asking about specific elements that the inspector should make sure are included.

Dr. Ferguson agreed that this recommendation represented an unnecessary burden that would not improve interpretive skills. He explained how the audit had helped him improve his

own performance, but he was not sure whether the audit should go any further than that. Ms. Pura asked whether there were any benchmarks that had been offered in terms of categories of staging. Dr. Finder stated that there were benchmarks but that they did not take variation within a facility into account.

Recommendation three under the category of improving mammography interpretation was to designate specialized breast imaging centers of excellence. These centers would participate in basic and advanced medical audits and test approaches to improve quality and effectiveness. The rationale was that several other countries have integrated and centralized breast cancer screening programs; the centers could provide multidisciplinary training and work environments and increase job satisfaction, retention of practitioners, and productivity and quality of breast care team; and high quality facilities could attract high quality personnel.

The next recommendation was that the incentives for becoming a center of excellence could be higher reimbursement rates and the ability to recruit patients and referrals, with the rationale that supportive elements and incentives are critical to encourage personnel and facilities to strive for higher quality. Element C of this recommendation was that the centers should serve as training centers for breast imaging and regional mammogram readers. The centers would have the expertise to develop and host training programs, and interpretation at these centralized facilities could help alleviate access in low volume areas. Element D of the recommendation was that the centers should be linked with facilities that provide comprehensive and multidisciplinary breast care since imaging-based centers need continuity with facilities providing non-imaging breast care treatment and follow-up.

Dr. Hendricks asked about centers already meeting the criteria for a center of excellence. Dr. Barr said that various states had tried to market facilities as “very high quality” but had found

problems doing so. She stated that 70 percent of mammography facilities practice quality mammography as defined in MQSA. Ms. Martin felt there were vast differences in quality and supported the development of breast care centers of excellence. She pointed out the difference in capability between high quality centers and local stand-alone units doing only screening. Dr. Barr asked Ms. Martin whether information on a center's quality should be made public and what patients without access to a high quality facility should do. Ms. Martin responded that they should be encouraged to get access to that type of facility.

Dr. Hendricks asked, given how burdensome the audits are claimed to be, how many facilities would want to undergo the steps necessary to attain the designation. Dr. Barr suggested it would depend a lot on whether, for example, reimbursements were higher for centers of excellence. She expressed concern about how patients without access to such a facility would feel about the center they were going to.

Dr. Williams addressed the issue of funding for the establishment of a center of excellence and said that many centers of excellence for other specialties had been underwritten by grants from the National Institutes of Health. He also suggested that there could be funding written into the budgets of these centers to help provide access for women who are not close to one of the centers. Dr. Barr pointed out that the screening modality would make these centers somewhat different than other kinds of centers of excellence.

Dr. Ferguson agreed that the designation might cause problems in rural areas and that incentives were a good idea. He thought that giving this designation but paying everyone the same amount would be detrimental to access. Dr. Hendricks stated that big insurance carriers, while trying to lower reimbursements for some services, were interested in increasing reimbursement for high quality care but that there would need to be some metric with which a

center could demonstrate that it was providing that level of care. Ms. Pura said that multi-specialty facilities where many procedures are offered could ease some of the issues of access. She also said that the centers of excellence should take Medicaid patients but was unsure what impact the committee had on Medicaid reimbursements.

Dr. Barr stated that these centers would also be the ones to test different ideas at improving quality. **Thomas Shope, Ph.D., Deputy Director, Division of Imaging and Applied Mathematics**, clarified that the IOM report was intended to give Congress advice on improving mammography and not a directive to FDA. He also emphasized that the advanced medical audit recommended was voluntary. Similarly, the report was not intended to mandate the designation of breast care centers of excellence but, rather, was looking at how Congress could foster the establishment of such centers as research facilities. Dr. Barr agreed with the comments of Dr. Shope but said that Congress would be looking to the FDA for regulations.

The final recommendation under improving mammography interpretation was to study the effectiveness of CME, reader volume, double reading, and computer-aided detection (CAD). The rationale for the first aspect of this recommendation, to demonstrate the value of CME for improving interpretive skills, was that it would enable interpreting physicians to identify weaknesses and take steps to improve and would continue to develop innovative teaching interventions to improve interpretive skills.

Dr. Monticciolo acknowledged that ACR and the American Board of Radiology would address the issue as a requirement to maintain a radiology license or board certification.

The rationale for the second aspect, to determine the effects of reader volume on interpretive accuracy, was that there was insufficient evidence to recommend an increase in

minimum interpretive volume and that there was no basis for specifying a higher volume. Dr. Ferguson felt the current requirement was sufficient to maintain access.

The final aspect of this recommendation was to look at the impact of double reading and CAD in interpretive performance over time, in different practice settings, and at different levels of experience. The rationale for this was that a second look by another reader or a computer had not been verified by prospective clinical trials, the effects on specificity were not fully understood, CAD programs were being refined, and studies were needed to confirm if consensus double reading may be most effective.

Pam Wilcox, ACR, asked whether FDA had looked into any funding opportunities for these studies. Dr. Barr said that Congress would likely address where the funding would come from and that FDA was looking into what might impact interpretive skills. Ms. Mount stated that her facility had found, in its own study of a CAD program, that it did increase the early detection rate. Dr. Finder pointed out that some of these things had been brought before the committee before for possible implementation as regulations and that the IOM did not feel there was enough evidence to recommend that FDA implement them. He asked the committee members what type of study would provide evidence that could be used to make a determination in the future.

Dr. Williams stated that a number of groups felt that CAD was something that needed to be looked at. He suggested a fairly large multi-center trial to evaluate the effectiveness of CAD across a variety of institutions. He also mentioned the American College of Radiology Imaging Network (ACRIN) evaluating the early efficacy of diagnostic tools and the digital mammography imaging screening trial (DMIST).

Susanne Myers, Senior Vice President, Mammologics, said that looking at asymptomatic versus symptomatic was important for understanding audit data. She also said that there were facilities that wanted to improve but lacked information, and she felt that guidelines such as the auditing requirements would help them. She also said that some of Mammologics clients used the audit data in an ongoing basis as part of a quality improvement program. Ms. Martin said there was frustration on the part of the facilities because of the lack of any specificity on the audit and suggested there should be minimum requirements for the audit.

The next category of recommendations in the IOM report dealt with revising MQSA regulations, inspections, and enforcement. The first recommendation in this category is to modify regulations to clarify intent and address current technology. The first part of this recommendation was to remove the exemption for stereotactic breast biopsy procedures and develop regulations, but discussion on this point was put off until the following day. The second part of this recommendation was to develop regulations for digital mammography. A uniform set of quality control test and test criteria should be developed, but this should not preclude additional test recommended by the equipment manufacturer.

According to Dr. Finder, the current regulations were developed before any full field digital mammography (FFDM) units were approved, so the regulations specified that facilities would follow the manufacturer's quality control procedures. The IOM recommendation is to develop and implement a uniform set of quality control procedures. Dr. Finder pointed out the difficulties stemming from the differences among the technologies used. Dr. Williams agreed with this point and discussed the disparity in the tests required by the various manufacturers.

Priscilla Butler, ACR, talked about the work of Martin Yaffe in Toronto developing a quality control manual for FFDM and about the DMIST research study. Martin Yaffe is working

on a system that will be applicable to centers other than research sites. Dr. Barr asked whether FDA should wait for this to be developed or go ahead with crafting regulations. She also pointed out that equipment is not the main source of problems with mammography. Dr. Williams said that they should wait at least until the clinical evaluation of the protocol discussed by Ms. Butler. The protocols are being culled from a set that included all the various procedures suggested by the manufacturers to identify the minimum useful set.

Ms. Mount urged the FDA to take into consideration the considerable down time required to perform quality control on a digital unit. Ms. Martin urged the FDA to wait for ACR's recommendations. Dr. Williams hoped that much of the quality control could be computerized and incorporated into the digital units and that this would decrease down time. Ms. Martin asked how long it would take for FDA to adopt the ACR program after it was released. Dr. Finder said that it could be submitted as an alternative standard, which would take a matter of weeks or months. To make it a regulation would take 12 to 18 months.

Dr. Barr asked whether different alternative standards or new regulations would be needed to accommodate the evolving nature of the technology. Ms. Martin and Dr. Williams both hoped that the technology would be stable enough that the standards could be adapted. Ms. Butler said that the tests were intended to be general enough for the technologies currently available but that different specific procedures would be necessary to accommodate each manufacturer's piece of equipment. She suggested that some allowance for changing technology be written into the regulations.

John Sandrik, Ph.D., GE Healthcare, disagreed that the technology would remain stable and said that at least two developments in GE's equipment under PMA submission would affect quality control. He pointed out that there was much more experience with film before

regulations were set for quality control. He agreed that there was some level of consensus on what tests to do and not to do, but he said that setting the limits of acceptability would be the problem.

Bob Uzenoff, Fujifilm Medical Systems, praised MQSA for allowing for innovative technology. He agreed that there was some agreement on what tests should be done but thought a uniform set of quality tests would be somewhat strict. He supported Dr. Finder's idea of alternative standards to address innovations in the technology. Ms. Martin reiterated that the quality program being developed by ACR would be pilot tested before implementation.

The third part of this recommendation was to update the assessment categories to reflect BI-RADS, which deals with Section 900.12(c)(1)(iv). Category B should be "Benign Finding(s);" C should be "Probably Benign Finding – Initial Short-term Follow-up Suggested;" D should be changed to read "Suspicious Abnormality – Biopsy Should be Considered;" and E should read "Highly Suggestive of Malignancy – Biopsy Should be Considered." There was also a recommendation to add a section F to read "'Known Biopsy – Proven Malignancy – Appropriate Action Should be Taken:' Reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy." Under section 900.12(c)(1)(v), the category will be "Incomplete: Need Additional Imaging Evaluation and/or Prior Mammogram for Comparison," and "For cases rated 0 because of need for prior examinations, reassessment must be performed within 30 days to assign category."

Ms. Pura asked why they did not use the BI-RADS instead of the categories that are medically reported. Dr. Finder replied that the wording for the categories was taken from the BI-RADS rather than simply using the numbers because the committee felt that could lead to confusion as to what the numbers actually meant. Some facilities were using slight variations of

the wording from the regulations, so an equivalence list was created, but the lists were getting large. Adding to the confusion, the latest BI-RADS further broke down the categories and efforts to make the assessment categories more flexible may have led to even more confusion.

Dr. Finder said that one difference between the BI-RADS and FDA's assessment categories was that FDA does not tie assessment categories to specific recommendations, but the regulatory change proposed would tie some of the categories to specific recommendations. Another difference was that IOM did not address one of the approved alternative standard assessment categories dealing with marker placement during an interventional procedure. Dr. Finder also said there had been complaints that the categories don't fit the paradigm of male breast mammograms. He explained that changing the categories at this point would lead to big changes in practice at mammography facilities as well as for the software companies.

Ms. Myers pointed out that there would be the additional challenge of making sure patients got the correct letter since patient notification letters were tied in to the categories. Ms. Butler noticed that category E from the modified version of the regulation was not the same as BI-RADS Category 5. Dr. Barr wondered whether IOM had changed the wording from that which had appeared in their draft version of the document. Dr. Bassett said that BI-RADS was not only a national but also an international standard and that to change the regulations would be a mistake. He also felt that the text recommended to be added to category E should be "appropriate action should be taken," rather than "biopsy should be considered." He said that many facilities had tied their auditing in with the numbers and that these changes would represent an additional burden in the audit.

Dr. Barr asked Dr. Bassett what he thought about the wording of "additional imaging and/or prior mammograms," and he said that it needed to be clear that meant more imaging or

looking at old films. She also asked him about the recommendation for cases rated zero, and he said that it was appropriate if the patient could be found and brought back in and that there should be justification if it can't be done. Dr. Monticciolo agreed that the 30 day period was a good goal but felt that it should not be mandated due to the difficulty of getting patients to come back in that soon, particularly when they go away on vacation.

Dr. Finder clarified that only cases requiring comparison to prior mammograms would need to be reassessed in 30 days. Dr. Monticciolo said that waiting for prior films from another facility was even more difficult, especially when the facility was outside the general area of her own. Dr. Finder said that it was an attempt to require that a final assessment be made by some point in time and that if the comparison films were not received in time that the reassessment would be based on whatever the facility did have. Dr. Ferguson asked whether there wasn't already a 30-day requirement, and Dr. Finder agreed that there was but only for the initial assessment. Dr. Finder stated that there was currently no time requirement for the final report after the comparison films were obtained. Dr. Ferguson stated that the wording should be left alone because it is standard.

Dr. Lee agreed with comments made by Ms. Pura and stated that it would be confusing for clinicians to have to stop using the BI-RADS numbers. She also emphasized the work of ACR's BI-RADS committee on the development of the wording and urged that it be left unchanged. Dr. Monticciolo asked her about patients with a palpable abnormality but no mammographic findings, and Dr. Lee said that it was terribly confusing to clinicians. Dr. Monticciolo stated that the BI-RADS committee was addressing that issue as well as patients with implants who have findings other than suspicious for malignancy. Dr. Bassett raised the issue of the standardization between mammography, ultrasound, and MRI. He said that it would

be a mistake to change something which took so long to develop and which had gotten national approval and that BI-RADS was flexible and could be changed.

Dr. Hendricks asked whether there was any perceived problem with recognizing the two groups of patients falling in Category zero. Dr. Bassett said the committee was looking for input from other societies and trying to reach consensus. According to Dr. Barr, the rationale for this proposed change was that they were more consistent with the 2003 BI-RADS to minimize confusion among clinicians and that FDA had already approved category F as an alternative standard.

The next part of recommendation five was to establish luminance standards for viewing mammograms. The proposed wording of section 900.12(e)(5)(xii) establishes that “Viewboxes used for interpreting mammograms and clinical image quality review by the technologist should be capable of producing a luminance of at least 3,000 candela per square meter. The illumination levels must be less than or equal to 20 lux.” The IOM committee recommended against evaluating viewboxes during inspection. The rationale was that viewing conditions are critical to the detection of subtle contrast differences and that the *1999 ACR Quality Control Manual* had suggested standards. Dr. Barr pointed out that if the Viewboxes weren’t evaluated during the inspection the requirement would be difficult to enforce.

Ms. Martin pointed out that the physicist did evaluate luminance but thought there should be an inspection component to enforce the proposed regulation. **Wally Mourad, FDA**, stated that in a way it was being inspected given that facilities have to fix it if the physicist’s report says that it needs to be. Ms. Martin said that while it was true that ACR checks the reports of its accredited facilities it could not require the facility to fix problems that weren’t addressed in the regulations. Ms. Butler said that if this standard was made a regulation, the facility would not be

accredited in such a situation until the facility notified ACR that the problem had been corrected, and she agreed that the viewboxes did not need to be evaluated during the MQSA inspection.

Dr. Monticciolo thought the issue was the additional time required during inspection. Dr. Barr stated that accreditation takes place every three years. Ms. Martin clarified that she did not think it should be part of the MQSA inspection but, rather, that FDA adopt as a standard that the physicist needed to look at the viewboxes.

Dr. Finder stated that in the past the committee had recommended that hot lights be available which could produce that luminance without having more expensive viewboxes. He also discussed viewing conditions and how visualization can be worse if one doesn't mask appropriately because of all the additional light. He asked whether the committee should look at viewing conditions in general. Dr. Williams asked whether there weren't already recommendations in ACR guidelines for illuminance and the luminance of the monitors and proposed that masking might not be as much of an issue for soft copy viewing.

Ms. Martin asked whether Dr. Finder was asking if the committee wanted to recommend adoption of the standards on viewing conditions from the ACR manual. Dr. Finder agreed that he wanted to know if FDA should place further regulations on viewing conditions. Dr. Barr wondered how such regulations would be enforced, and Dr. Finder asked if anyone knew how many viewboxes would not meet the conditions. Ms. Rinella stated that in her travels across the country, technologists don't know whether they're using the same luminance as the radiologists. The technologists don't have access to hot lights or masking, and the overhead lights are left on when the technologists are looking at the studies. She also said that although no one was going to stand there and make sure that it was done properly, mandated standards would at least make people more aware of the importance of viewing conditions.

Dr. Hendricks asked the accrediting bodies how often poor viewing conditions result in failure to accredit a facility. Ms. Butler said that ACR would not fail a facility for poor viewing conditions because it was not a regulatory requirement. Ms. Martin stated that around 20 percent of the facilities she consults for would have to replace their viewboxes. She also said that the local MQSA inspector was paying attention to viewing conditions but not taking any measurements. Dr. Mourad said that FDA tells inspectors not to specifically look at viewing conditions but they should bring it to the facility's attention if there were something totally abnormal.

Dr. Barr asked whether the numbers in the recommendation were sensible. Ms. Martin thought the numbers were fine and said that a normal, good radiology facility would be nowhere near violating them.

Susan Sprinkle-Vincent, Advanced Health Education Center, Houston, Texas, agreed with Ms. Rinella that most technologists at the facilities she visits do not have appropriate viewing conditions. **Donald A. Flater, Chief, Bureau of Radiological Health, Iowa Department of Public Health,** said that Iowa has aggressive inspectors and that proper viewing conditions were required in Iowa.

The next part of recommendation five was to eliminate the modality-specific CME requirement from Section 900.12(a)(1)(ii)(B). Dr. Barr stated that FDA had not been enforcing that requirement and fully supported removing it from the regulation.

In 900.4, there was a recommendation that those reviewing films for accreditation should have at least as much, if not more, experience in the modalities under review as the personnel at the facility being reviewed. Ms. Butler stated that a reviewer had to meet MQSA requirements for whatever modality he or she was reviewing. Mr. Flater agreed.

In 900.4(e)(1)(i) there was a recommendation to add the words “the results of.” Dr. Barr asked if anyone had a problem with that. Dr. Finder stated that the next slides dealt with changes to the regulations dealing with accreditation bodies and did not want to spend too much time on them since many of the changes had already been accomplished through changes in procedures.

There was also a recommendation to add “annual” before “survey” and change six to fourteen months in section 900.4(e)(1)(ii). Dr. Finder said this would make the time frame for inspections and reaccreditations the same so facilities would not have to do two surveys in the same year. He mentioned that care would have to be taken with the wording to ensure that new facilities could not do things fourteen months before starting to practice.

Another recommendation was to delete a section specifying how facilities submit their information to the accreditation body, as yearly submission is redundant. Other recommendations to section 900.11(b)(1) would ensure that facilities have all units accredited and clarified that facilities need to notify the accrediting body of any new units. Another recommendation changed the reinstatement policy so that it would not give the impression that reinstatement means that you become a new facility.

Another recommendation was to change section 900.12(a)(1)(ii)(A) to “continuing experience.” Dr. Finder said that the continuing experience and education requirements for the three personnel categories speak of measuring back 24 or 36 months from the date of the inspection. At the beginning of the program, some inspectors were trying to ensure that people met this requirement on every single calendar day, so FDA, in order to avoid this, told them in guidance to either measure back from the inspection date or from the end of the previous calendar quarter or any day in between, depending on how the facility wanted it to be done. There have been many requests to use a calendar date rather than the inspection date to simplify

the record keeping, but that had to be balanced against the idea that everyone should meet the requirements all the time. The compromise in the regulations and guidance allowed facilities some flexibility to get by with ensuring personnel met the requirements as of the last quarter, but this change would make it easier if they moved to a calendar date. The other aspect of this change is that continuing experience acquired outside the U.S. would be acceptable.

Dr. Ferguson thought it would be simpler for facilities to calculate and for inspectors to check on if it was done using a calendar date. Ms. Mount agreed. Dr. Finder said that it was originally done by inspection date because that is when the inspector is there and can see what's going on. If it were based on calendar date, the inspector would likely not be there on that date so someone could wait until the inspector was coming to become qualified. Dr. Barr asked about just using 24 months from the inspection date rather than allowing for choice. Dr. Finder said the choice was intended to make the bookkeeping easier on the facility because they could get their records set as of the previous calendar quarter rather than having to wait to hear exactly when the inspector was coming. The current requirement would present problems for people who work at multiple facilities, but since the idea is that everyone should be qualified every single day, the committee in the past did not consider that to be a problem.

Ms. Martin reiterated the comments of Ms. Mount and raised the issue of having to gather the information twice if the inspection had to be postponed into a different quarter. Dr. Monticciolo agreed and said that had happened at her facility. They provide their physicians with audit data on a year-to-year basis, so this change would match that. She also did not think allowing use of the calendar year would negatively impact quality since she wouldn't expect physicians to forget everything. Also, it would be easier to remember to do it if it was based on

the calendar year. Dr. Mourad wanted the committee to understand that this would impact when someone who just qualified initially would be eligible to meet the continuing requirements.

Dr. Monticciolo thought it would be hard to assess the quality of foreign facilities, but she did not feel the initial qualifications were so onerous as to exclude people from other countries. Dr. Barr said she was not sure there was any pressing need to allow foreign experience.

Another recommendation would eliminate the requirement that medical physicists survey at least two facilities. Ms. Butler said that physicists were forced to provide services at another facility, perhaps in violation of their contract. Dr. Finder said that surveying the same facility twice in two years satisfied the current requirement and that the same was true for multiple surveys of the same unit. Ms. Butler was pleased to hear that interpretation and didn't think the change was necessary. Dr. Williams asked, in light of that interpretation, why the word "facility" couldn't be taken out entirely, and Dr. Finder responded that there were different aspects to facility and unit surveys. He also read the part of the section that says only one survey of a specific facility in a ten-month period and only one of a specific unit during a 60-day period could count towards this requirement.

Another recommendation would require that the lead interpreting physician provide regular feedback to the technologists on the quality of images. Dr. Finder said there was already a requirement that all interpreting physicians provide feedback, and Dr. Ferguson asked if it had to be documented. Dr. Barr did not think so and wondered if that might be the intent of the change.

The next recommendation would change the optical density of the film at the center of an image of a standard FDA accepted phantom from 1.2 to 1.4 when exposed under typical clinical conditions. Ms. Martin felt 1.4 was too low and that it should be at least 1.5.

The next recommendation would make testing of cassettes used for screen-film contact occur annually rather than semi-annually. The test would also be conducted on all new cassettes being put into service and any time reduced image sharpness was suspected.

The next recommendation would change to kilovoltage peak (kVp) accuracy and reproducibility by adding “older three-phase” before screen-film systems; remove “and reproducibility;” change (A)(2) to “kVp that is obtained when the accrediting body phantom is imaged with the mammography X-ray unit set to the most commonly used clinical AEC mode;” and change (B) to “newer units with medium- and high-frequency generators will not require this test.” Ms. Martin had no problem with this recommendation except to the extent that FDA tried to enforce kVp given that it fluctuates on some models.

The next recommendation, for the system artifact test, would replace “and target-filter combinations,” with “targets, and filters.” The rationale is that only one test of focal spot size, filter, and target is necessary to assess image quality. An alternative standard allowing this change had already been approved.

The next change, to the mammography medical outcomes audit, would add, “Facilities with the same interpreting physician should combine medical audit data,” and recommend that people not be cited for failing to do aggregate data. In the general requirements section there was a recommendation to remove “individually and collectively for all interpreting physicians at the facility,” and to add (i) and (ii) to section 900.12(f)(1) to define screening and diagnostic exams. Dr. Finder said that it sounded like a diagnostic examination read as incomplete would

not have to be included in the audit. He also mentioned that having to track incomplete screening exams would increase workload. Dr. Monticciolo did feel tracking incompletes all the way to an outcome would be quite onerous for a screening site.

The next change was a wording change already agreed to by FDA regarding agency action following revocation of accreditation.

IOM's sixth recommendation was to modify inspections and strengthen enforcement. Part A of this recommendation was that several onsite inspection tests, such as dose, were redundant and had few failures. Dr. Barr returned to the fact that there had not been a dose violation since 1997. She mentioned that some might think eliminating the requirement for the dose test would not save much time, but the agency also has to buy and maintain equipment to perform such tests.

The second part of this recommendation was FDA should have authority to require facilities to stop performing mammography following two consecutive unsuccessful attempts at reaccreditation. However, the opinion of the legal staff at FDA is that they cannot require a facility to cease mammography if their MQSA certificate has not expired unless the facility represents a risk to human health. Dr. Finder said this usually happens when a facility is coming close to the expiration of its certificate anyway, so it is really only an issue for a period of a few weeks. He also was not sure that FDA could enact such a regulation that would essentially negate the entire appeal process.

The final part of recommendation six was that closed facilities and those with revoked certificates must notify patients and referring physicians, and closed facilities must retain films. If a facility is unable to, FDA should notify patients and physicians. Dr. Finder discussed FDA's guidance on this issue, which tells facilities that they should make arrangement for retention of

and patient access to records and that they should notify their accrediting body and FDA so that patients who call either one can be told what they need to do to locate their records. Bankrupt facilities pose additional difficulties in that films may be placed in the custody of the bankruptcy court, and facilities that have simply disappeared are even more problematic.

Ms. Martin asked about physicians and radiologists closing a facility and opening a new one. Dr. Finder said that type of situation was not usually problematic in that the records would simply be moved to the new facility. Dr. Barr mentioned that some states require facilities to put up a bond that can be used to sort out such issues, but she wasn't sure something similar could be done on the federal level. Dr. Ferguson asked about FDA's guidance, and Dr. Finder said that the facility should inform the state, FDA's facility hot line, and the accrediting body; make arrangements for films to be available, either at another facility or storage location; and, finally, notify patients of what arrangements had been made.

Ms. Rinella asked how often closing facilities make the proper notifications versus simply closing down. Dr. Finder said that it was a relatively small number of facilities but that even with a small facility thousands of patients might be affected. Ms. Pura asked whether any states had instituted the bond requirement mentioned by Dr. Barr. Dr. Barr thought that some states had done so, but Dr. Finder was not sure. He emphasized that the bond would represent another disincentive to the practice of mammography, especially given that most facilities adequately address these issues when they close. Dr. Finder also raised the issue of facilities with unique filing systems that make matching the exams to the patients difficult and mentioned that recently a state required a facility to reopen and distribute its films.

The next category of recommendations from the IOM report was adequate workforce for screening and diagnosis. The first recommendation in this category dealt with data on the

mammography workforce and service capacity, and the first part of it was to collect volume information during annual inspection and that Health Resources and Services Administration (HRSA) reports on volume by region, state, and type of service should include the number of facilities, number of units per 10,000 women, and number of FTE physicians reading mammograms per 10,000 women stratified by type of service where appropriate. The other parts of this recommendation were to provide unique identifiers for interpreting physicians, technologists, and medical physicists to get volume information by individual; to collect data by facility on waiting times for screening and diagnostic appointments; and for Congress to provide funding to HRSA to model future workforce supply and demand on a regular basis.

Dr. Barr said that there had always been a question as to how accurate volume information was. Ms. Pura asked whether the information would be helpful in increasing reimbursements, but Dr. Barr was not sure. Dr. Ferguson asked if ACR already had this information. Ms. Butler said they had information on numbers of patients examined and breakdowns of screening versus diagnostic but no good information on some of the other information sought.

Dr. Barr thought the unique identifier was the larger issue, especially given that the database would have to meet Privacy Act requirements if it had information based on the individual rather than just by facility. Mr. Passetti said the Florida legislature was looking at requiring volume information but thought it would be better to have nationwide data. Ms. Martin suggested that with the unique personnel identifiers, qualifications paperwork for personnel working at multiple facilities would only need to be submitted once. Dr. Ferguson agreed.

Ms. Wilcox suggested that even looking at screening and diagnostic volumes would not fully address system capacity since there would still be those doing biopsies and those who weren't. She said there were many variables that would make the volume information more complex than it would seem. Dr. Mourad said that the only things continuously checked on during inspections were the continuing experience requirements, but he said there was not a database for that information.

Dr. Finder said that the agency currently supplies medical physicists with a letter saying they meet all their initial qualifications since the physicists have more complex requirements and tend to go to many different facilities. He also emphasized the issue of giving out individuals' information to facilities as well as what to do if someone doesn't submit their information.

Mr. Flater said that Iowa already collected all that information for every facility within the state as well as for physicists who come in from other states. He also mentioned the system being set up by the Nuclear Regulatory Commission to track sources.

The next recommendations under adequate workforce dealt with strategies to recruit and retain highly skilled professionals. The specific recommendations were to encourage federal and state agencies and health care payers to develop incentives to recruit and retain skilled breast imagers, loan repayment awards through the National Health Service Corps (NHSC) and for J-1 visa waivers for physicians working in underserved areas, and HRSA should identify and designate shortage areas for breast imaging.

The rationales were that the existing supply of physicians who read mammograms at a high level is a valuable resource, it's unproductive to invest in efforts to increase the number of entrants without addressing early departure factors, retaining highly skilled practitioners could be

a cost effective way to maintain high quality breast imaging services, and the NHSC program and the J-1 waivers have been used to bolster the workforce in shortage areas.

The next adequate workforce recommendation was for effective use of breast imaging specialists, and the first aspect was to support radiologist assistant (RA) training programs and new roles for RAs in breast imaging, the rationale being that this career option for skilled technologists could be an incentive for new entrants and improve quality and efficiency. Ms. Rinella was not sure that any of the programs had a breast imaging specialty and thought that might be necessary. Ms. Mount agreed.

Dr. Monticciolo thought RAs might need to accept some of the medical-legal burden for radiologists to be willing to hire them. She also said that an RA who she worked with, while excellent, was probably over-utilized by some of the radiologists without appropriate oversight. Ms. Wilcox said that the American Registry of Radiologic Technologists, the certifying body; the American Society of Radiologic Technologists; and ACR had agreed on the responsibilities of RAs and that they would not do any interpretation.

Mr. Flater said that Iowa would have to change its rules to use RAs because interpreting physicians must be radiologists in Iowa. He also mentioned an RA currently training who wants to be allowed to do stereotactic. Ms. Pura compared these issues to what physician assistants and nurse practitioners had to go through and wondered whether RAs would be able to do the secondary readings.

The next aspect of recommendation nine was to support demonstration projects to evaluate the potential for double reading by non-physicians because double reading has the potential to improve the accuracy of interpretation. The final aspect of this recommendation was to evaluate the roles of ancillary personnel in mammography because productivity would be

maximized if technologists focused on performing mammograms, interpreting physicians focused on interpretation, and ancillary personnel took on non-technical responsibilities.

The final category of recommendations was improving breast imaging quality beyond mammography. The specific recommendation was for accreditation for non-mammography breast imaging modalities such as ultrasound and MRI. This would lead to standardization and improve the quality of breast cancer detection and diagnosis. Accreditation already exists for breast ultrasound and general MRI.

Ms. Rinella supported standardization and accreditation for breast ultrasound based on the varied standards of care she had seen in the field.

ADJOURNMENT

Dr. Hendricks thanked the participants and adjourned the meeting at 4:18 p.m.

I certify that I attended this session of the National Mammography Quality Assurance Advisory Committee on September 26, 2005, and that these minutes accurately reflect what transpired.

Charles Finder, MD
Executive Secretary

I approve the minutes of the September 26, 2005, meeting as recorded in this summary.

Carolyn Hendricks, M.D.
Chairperson

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