SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE MEETING

Open Session

September 27, 2005
Gaithersburg Holiday Inn
Gaithersburg, MD

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COMMITTEE PARTICIPANTS

Carolyn B. Hendricks, MD	Chair
Scott Ferguson, M.D.	
Alisa M. Gilbert	
Miles G. Harrison, Jr., M.D.	
Jacqueline S. Holland, R.N., C.R.	
Melissa C. Martin, M.S.	
Debra L. Monticciolo, M.D.	
Carol J. Mount, R.T. (R)(M)	
William A. Passetti, B.S., A.A.	
Linda S. Pura, R.N., M.P.A.	
Diane I. Rinella, R.T. (R)(M)	
Jane B. Segelken, B.S., M.A.	
Mark B. Williams, Ph.D.	

FDA PARTICIPANTS

Charles Finder, M.D.	Committee Executive Secretary
Helen Barr, M.D.	Director, Division of Mammography Quality and Radiation Programs

CALL TO ORDER AND COMMITTEE BUSINESS

Committee Chair Carolyn B. Hendricks, M.D., called the meeting to order at 9:03 a.m. Dr. Hendricks noted that the committee members present represented a quorum. **Executive Secretary Charles Finder, MD**, 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 are 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.

Dr. Hendricks asked the committee members to introduce themselves.

OPEN PUBLIC HEARING

Dr. Hendricks read the FDA's statement on disclosure with respect to the open public speaker process.

Judith A. Wagner, R.N., spoke about her experiences with a surgeon who used stereotactic biopsy and could not localize and biopsy the lesion found on her yearly screening mammogram. After going to an accredited breast center, a diagnostic radiologist localized her calcifications without difficulty, and Ms. Wagner was diagnosed with ductal carcinoma in situ (DCIS). She then began gathering information about the standards necessary to perform image-guided breast biopsies and advocating quality breast care.

Ms. Wagner stated that early diagnosis of breast cancer when it is less than 15 mm is critical for improving morbidity and mortality in breast cancer and that quality standards must be

mandated. In September 2004 she told the Institute of Medicine's (IOM) Improving Mammography Quality Standards Committee that all image-guided breast biopsies, stereotactic, ultrasound, and MRI should be required to have accreditation standards.

The quality of breast care may be affected by the quality of the procedure at any stage in the process. Ms. Wagner held that the diagnostic radiologist should be a sub specialist dedicating all of his or her time to breast imaging. The majority of radiology groups do not have a radiologist focused entirely on breast imaging because they have to spend some time on call and weekends and because they do not make enough money on mammography. Ms. Wagner recognized that recommendations could not be put into place until there were increases in reimbursement for mammography and biopsy procedures. She also raised the issue of the inability to fill breast fellowship positions.

In a recent article in *Diagnostic Imaging,* Dr. Daniel Kopans noted that there had been a 25 percent drop in the breast cancer death rate since screening was implemented and that most of that decrease could be attributed to screening. Ms. Wagner urged the committee to ensure that the recommendations of the IOM study be adopted by FDA and Congress. She also requested that the committee and Congress look at the costs of implementing the recommendations so as to avoid losing physicians and centers.

Richard O. Wagner, M.D., talked about his experience as a general radiologist in the Milwaukee area. He was removed from his sites of practice because he raised issues of quality of practice after a non-radiologist performed a poor interventional breast procedure on his wife, Judith Wagner. He found that poorly performed biopsies were not uncommon, poor concordance led to delayed diagnoses, and patients were not informed of their biopsy options,

resulting in greater than 50 percent of biopsies performed by his practice group being open surgical procedures.

Dr. Wagner brought these issues before his Quality Assurance Committee, but there was no substantive action taken to address them. He began counseling patients on alternatives to open biopsies. He was verbally harassed and finally economic pressure was applied to his group so that he would be removed from his sites of practice. The group's clinic contract was recently renewed after Dr. Wagner and two other partners were removed for speaking to patients and raising concerns about quality of care. Dr. Wagner has since resigned from his group to spend the rest of his career as a dedicated breast radiologist.

Implementing mandated accreditation standards would ensure all physicians performing these procedures met the highest standards. The Breast Imaging Quality Standards Act (BIQSA) should replace the Mammography Quality Standards Act (MQSA) so that all image-guided breast biopsies would be regulated. There are currently multitudes of credentialing bodies, each with its own standards. Patients are unaware of this. A uniform standard would help deal with the turf issues experienced by Dr. Wagner and others.

Voluntary standards have not worked. Dr. Wagner felt that higher standards as well as treating breast care as a sub specialty would get more physicians interested in the field.

He maintained that any shortage of breast care providers resulting from mandated accreditation standards would be short-term at worst and would discourage physicians not truly interested in providing breast care. This elimination of low quality providers could also lead to lower incidence of malpractice claims. New physicians need to be recruited into breast care and protected from turf issues, low reimbursement, and malpractice.

Screening mammography is intended to decrease the morbidity and mortality of breast cancer. When cancers are found early, before they have metastasized, they are curable and much less costly to treat than more advanced cancers. The purpose of screening is to find small cancers, not larger ones. To achieve the goal of early detection, there is a need for highly trained and dedicated breast imaging specialists with high quality screening skills capable of performing image-guided minimally invasive biopsies.

Dr. Finder read into the record written comments submitted by **Dr. Murray Reicher, Chairman, DR Systems, Inc**., on full field digital mammography (FFDM) guidance. With regard to question five on page 15 of the draft guidance document, FFDM manufacturers deal with the labeling of laterality and view in different ways. Dr. Reicher suggested that they embed the label in the image pixel to avoid the possibility of mislabeling. He next addressed page 26, question two. Dr. Reicher felt that image readers should be able to pick the monitor they want provided they are encouraged to display every pixel so that subsampled viewing of pixels would not be routinely performed inadvertently. Current soft copy viewing systems make it easy for this to happen. With all non-mammography imaging, the responsibility of the Picture Archival and Communications System (PACS) vendor is to provide labeling, but readers can choose to do primary readings with lossy data compression. This has become common, and the literature supports it. There is a clear difference between lossy and perceptible visually destructive data compression.

The Office of Device Evaluation (ODE) has a different standard for mammography. Manufacturers are required to label as “Not for Primary Reading” any lossy compressed image as far as DR Systems understands. Dr. Reicher wondered, if this was coming from ODE and not

MQSA, whether MQSA policy would change de facto if ODE approved a device that used lossy compression for primary reading images.

The research of DR Systems suggests that GE FFDM images can be compressed to three or four hundred kilobytes and Lorad/Fischer images to less than one megabyte with no visually detectable change, and perhaps more before the ROC curve would be altered. This could be very beneficial in terms of a provider with multiple sites being able to centralize reading to an expert mammographer.

He also discussed guidance on digitization of all film screen mammograms with discard of the original. Current guidance allows for digitization of prior films for comparison. With the belief that it might lower cost and enhance safe storage in electronic clinical access, Dr. Reicher wanted to go the next step by allowing facilities with proper quality controls to digitize the prior film and discard or transfer to the patient the original.

Dr. Reicher's main question was how to properly demonstrate that a non-identical (as a result of compression) original was functionally identical to the original to the point that it could replace the original.

OPEN COMMITTEE DISCUSSION

LCDR Sean M. Boyd, U.S. Public Health Service, Chief, Electronic Products Branch, gave an update on FDA's radiological health program. He stated that many of the public health issues that led to the Radiation Control for Health and Safety Act of 1968 had changed. One thing that changed is product environment. Markets are global, manufacturing processes have advanced, and more effective international voluntary standards are in place.

Another change since 1968 is public health needs. Product use is much more of an issue now than product or manufacturing problems. The third change is with CDRH resources being focused more on medical devices and less on radiological expertise. Those resources need to be used to address high priority problems such as dose-intensive equipment and real public health risk.

The CDRH program mission remains to protect the public from hazardous or unnecessary electronic emissions. The Radiological Health Plan for the Future contains five program elements. Three of them are standards, monitoring, and education. Under standards, the goal is to use performance standards that are enforceable and appropriate while increasing use and dependence on national or international voluntary consensus standards. CDRH wants to increase stakeholder participation in the development of these voluntary standards, pursue legislation that would allow adoption and enforcement of these voluntary standards, and to lower risk by basing enforcement actions within the standards.

Under monitoring, CDRH wants to maintain awareness of radiation-emitting products and their manufacturers, to be able to assess product emissions and conditions of use, and to understand the risk of exposure to emissions. One of the activities under monitoring is to provide some relief in reporting requirements for low-risk products and require only essential reporting. Another activity is to move from routine field and lab testing to for-cause testing. The final activity under monitoring is to emphasize assessment of use and exposure by harvesting data collected by other organizations rather than by direct measurement.

With regard to the element of education, CDRH wants the public to have the ability to make informed choices about their own exposure, users to be able to minimize exposure to themselves and those they are exposing, manufacturers who understand their responsibilities and

are sensitive to risks, and FDA and state regulators who help users to minimize exposure and risk. Activities under monitoring include creating a coordinated education program and investing in the Internet as an educational tool by revising the radiological health part of the CDRH web page.

CDRH expects several benefits: to align efforts with current and evolving public health needs; to expand the focus on patient and consumer experience, while maintaining oversight of manufacturers; targeting regulations towards dose-intensive equipment and real public health risks; increased information dissemination; and improved coordination within the radiological health community.

Dr. Hendricks asked for clarification of what would be defined as a higher risk device, and LCDR Boyd said that medical equipment with ionizing radiation, such as CT scanners and radiation therapy equipment, were higher risk and things like televisions and microwave ovens were low risk.

Priscilla F. Butler, M.S., Senior Director, Breast Imaging Accreditation Programs, American College of Radiology, discussed the Stereotactic Breast Biopsy Accreditation Program. It began in 1996 and was modeled after ACR's Mammography Accreditation Program. The program only evaluates stereotactic breast biopsy procedures and not needle localization or ductography. Specifically the program evaluates personnel qualifications, clinical image quality, phantom image quality and dose, and the facility's quality control program.

With regard to personnel, initial qualifications and continuing education and experience are evaluated for physicians, medical physicists, and technologists. Because physicians other than radiologists perform stereotactic breast biopsies, ACR and the American College of Surgeons (ACS) jointly developed qualifications, and they defined collaborative and independent

settings in which the procedures would be performed. In a collaborative setting, radiologists and other physicians work together, perhaps focusing on different aspects, and in an independent setting, the radiologist or other physician works independent from the other specialty.

Under clinical image quality, facilities must submit good examples of mass biopsy and calcification biopsy for evaluation. Needle, vacuum suction, and other FDA-approved core biopsy devices are evaluated. The basic criterion for clinical image quality is accurate needle positioning of targeted lesions.

For phantom image quality and dose, the dose must be less than 300 millirads, and the quality criteria will vary depending on the phantom used. Fibers, specks, and masses are looked at for the standard Mammography Accreditation Phantom (MAP) or a mini phantom. Facilities are required to perform quality control tests outlined in the 1999 Stereotactic Breast Biopsy Quality Control Manual.

With regard to the reviewers, they must be ABR certified and ACR members. There is a required formal training program, and reviewers must have a minimum of five years experience in a clinical or physics practice in the U.S. Potential conflict of interest is also addressed. ACR performs quality control with regard to the reviewers themselves.

There are currently 436 stereotactic units accredited at 428 facilities. Facilities have three attempts at accreditation. In 2000, the initial pass rate was 60 percent, and in 2004 the rate was nearly 70 percent, but there was a slight drop in 2005. Ms. Butler pointed out that under MQSA, 90 percent of mammography units pass on the initial attempt compared to the 70 percent that passed when the program was voluntary.

For renewal accreditation, there was significant improvement in 2003 and 2004, but, again, a slight drop was seen in 2005. Ms. Butler explained how as the mammography program

was instituted, facilities replaced older units, and the new units led to increases in the initial pass rate, but renewal rates dropped because the units being renewed were older.

In terms of the reasons why facilities are failing initial accreditation, the majority, 63 percent, fail due to clinical failures, and another ten percent fail because of a combination of clinical and phantom.

Dr. Hendricks asked for clarification of what had to be submitted for the clinical review. Ms. Butler said that the mammograms where the targeted lesions were identified, as well as pre and post biopsy images and, for calcifications, the specimen radiography exams are submitted. She said that post procedure mammograms were not submitted. Dr. Hendricks asked if the critical question was whether calcifications were present in the core specimens. Ms. Butler said that calcifications had to be seen on the original mammograms, show good placement of the needle on pre and post fire biopsy images, and then show the calcifications on the specimen radiography exams.

Dr. Hendricks then asked how many examples would be submitted by a facility. Ms. Butler responded that they submit two cases, one showing accurate targeting of a mass and one for calcifications, and if they do fine needle aspiration cytology (FNAC), the facility is asked to submit those cases, too. She said that if a facility failed on one, they would fail accreditation. Dr. Hendricks then asked if she was surprised at the failure rates given that facilities were able to submit their best work, and Ms. Butler agreed that she was surprised.

Ms. Butler said that there was a similar program to evaluate breast ultrasound imaging as well as ultrasound biopsy procedures. Dr. Hendricks asked about the total number of stereotactic units in the U.S., and Ms. Butler estimated there were around 3,000 units. Dr. Hendricks then

asked about the mix of academic and individual radiology groups who agreed to participate. Ms. Butler said it was primarily radiologists in a variety of practice settings.

Ms. Wagner asked whether mandating qualifications improved quality compared with a voluntary program. Ms. Butler agreed that it did. In mammography accreditation, pass rates increased steadily after MQSA went into effect. Dr. Monticciolo asked whether there was any information on non-radiologists in stereotactic. Ms. Butler said that several surgeon practices had applied for accreditation and said the next speaker would talk about the ACS program.

Dr. Barr asked if ACR followed the submitted cases to look at diagnosis and whether there was any correlation between failures and diagnosis of a lesion. Ms. Butler said it was not something they were tracking. Dr. Hendricks asked about the burden on the facility to participate in the program. Ms. Butler said the fees were $1,200 for the first unit and somewhat less for the second. As far as time, many of the personnel requirements that need to be documented parallel what MQSA requires, and the same is true of many of the tests required for quality control.

Dr. Monticciolo felt that most of the requirements were reasonable, but she had a problem with the fact that almost all masses are easier to see with ultrasound, and she did not want to have to stereotactically biopsy a mass simply for the purpose of accreditation. Ms. Butler said a meeting was being convened to look at that issue and acknowledged the evolving nature of the practice of medicine.

Dr. Hendricks asked how participants were selected to participate in the voluntary program. Ms. Butler said they self-identified themselves. Dr. Williams and Ms. Martin said that the time required for the annual physics survey for stereotactic was less than for a normal mammography unit. To show that the quality control procedures were not burdensome, Ms.

Martin explained that some sites had bought the ACR quality control manual and adopted the program rather than paying to get accredited.

Mr. Passetti asked how many of the approximately 3,000 facilities performing stereotactic biopsy were also MQSA accredited. Ms. Butler had no data on that question but felt from anecdotal experience that most stereo units were associated with MQSA accredited facilities. Ms. Mount said that from the standpoint of the technologist the quality control was also not burdensome.

Ms. Wagner pointed out that ACR's website had an option to search for facilities by type and location.

Kambiz Dowlatshahi, M.D. FACS, American College of Surgeons (ACS), presented the views of the ACS on stereotactic programs. He first discussed the history of mammography.

Screening mammography started in the 1960s and became widely used in the late '80s and early '90s. Radiologists wire localized the suspicious lesions detected by mammography, and surgeons removed them for diagnosis. Seventy-five to eighty percent of all biopsies at that time were benign, so Dr. Dowlatshahi introduced the stereotactic needle biopsy in the U.S.

The technique was developed in Sweden and the first unit in the U.S. was at the University of Chicago. It was tested against open biopsy, and radiologists and later surgeons adopted the procedure. Another diagnostic step for intervention was breast ultrasound, popularized by Dr. Staren. In 1997, Dr. Dowlatshahi and Dr. Staren began teaching stereotactic and ultrasound courses at the annual meeting of the ACS.

The practice of surgery is becoming ever more image-dependent. The safety of the patient and accuracy of the procedure through correct diagnosis is critical. Image-guided treatment of breast cancer is on the horizon with minimally invasive techniques such as laser

treatment, radio frequency, and cryosurgery. Surgeons are also placing radiation devices for partial treatment of breast tumors.

Dr. Dowlatshahi felt that the stereotactic biopsy program was adequate for practicing surgeons and served the goals of patient safety and diagnosis of cancer, but it is not popular among surgeons and radiologists. For surgeons working with radiologists, submission of the application is easier because the mechanism is already in place. It is more difficult for independent surgical practitioners, which is one reason why more surgeons don't participate in the voluntary stereotactic program. Dr. Dowlatshahi supported the Residency Review Committee making image-guided breast biopsy and therapy part of the resident training program.

Dr. Williams asked about the major differences between the ACR and ACS programs. Dr. Dowlatshahi replied that there wasn't much difference. Ms. Butler stated that the requirements of the programs were the same and that the only real difference was administrative, that the review portion of the ACS program was done by ACR.

Dr. Hendricks asked whether any facilities had been accredited as independent rather than collaborative settings. Ms. Butler said that most applications to the ACR program were independent radiologists. Dr. Hendricks then asked about differences in quality assurance and whether some data was being generated for the current accreditation process for physicians on the independent track. Ms. Butler said they were requesting audit data but it was not required.

Dr. Hendricks asked how surgeons in the collaborative track documented their reading of 480 mammograms. Dr. Dowlatshahi said that even surgeons whose practice is only 50 percent breast patients would easily read 480 mammograms. Ms. Butler said that ACR requires an attestation that personnel have met the qualifications, and during site visits they look for a log.

Ms. Mount asked about facilities with an accredited biopsy table, accredited radiologist team, and a non-accredited surgeon who wants to use the table. Dr. Dowlatshahi thought the surgeon would likely have taken a training course offered by an accredited organization and simply not sought accreditation. Ms. Mount then asked, assuming the process was mandated, whether that surgeon could legally use the table. Dr. Dowlatshahi said the answer was probably yes but that given that it was a voluntary program it would be the surgeon's responsibility to have taken the course and passed the test. Ms. Butler hoped that under ACR's program the collaborative setting could cover that and that the surgeon would be working with a radiologist and would have documentation to show that he or she was qualified. Part of ACR's agreement with the participants in the voluntary program was that all personnel must be qualified and the lead interpreting physician would be responsible for ensuring that everyone was qualified.

Dr. Ferguson asked whether ACS felt accreditation should be required. Dr. Dowlatshahi proposed that the college supported keeping the program voluntary so long as it worked. Dr. Ferguson then asked for Dr. Dowlatshahi's personal views, and he said that it was a skill that a surgeon should have if he or she was going to treat patients. Ms. Segelken raised the issue of rural areas where only around 20 people were diagnosed with breast cancer every year. Dr. Dowlatshahi thought it might be unfair to require surgeons and radiologists in such a community to become skilled at such a procedure and suggested that people in the community might be better off going to a larger center somewhere else.

Ms. Martin asked how many of the approximately 475 accredited units were accredited through the ACS program and how many were standalone surgical centers through the ACR program. Ms. Butler said that ACR's records indicated about 12 facilities had been accredited through ACS and that not many independent surgical practices had been accredited by ACR.

Dr. Hendricks asked what steps could be taken to increase participation in the voluntary programs. Ms. Butler said ACR had done some marketing in an effort to raise the visibility of the program and had tried to work through third party payers, but she didn't think their efforts had had much of an impact.

Pam Wilcox, American College of Radiology, said that ACR had been heavily marketing the program to third party payers as a way to improve quality but that the payers did not seem that interested given that stereotactic biopsy and breast ultrasound are not high ticket procedures.

Ms. Rinella asked whether an ACS-accredited facility did not need a radiologist onsite, and Dr. Dowlatshahi said that was correct. **Susan Sprinkle-Vincent, Advanced Health Education Center, Houston, Texas**, added that a stereotactic program that was not accredited did not need to have a qualified mammographer doing the procedure with the surgeon or radiologist. She felt that a technologist assisting in a stereotactic procedure should be a qualified mammographer.

Donald A. Flater, Chief, Bureau of Radiological Health, Iowa Department of Public Health, discussed Iowa's mandatory interventional mammography program. He first gave some statistics on the state of Iowa. Of the state's 138 hospitals, 96 have fewer than 50 beds. There are 24 stereotactic units in the state, including two mobile and three upright. There are 85 radiologists in 22 facilities and 24 non-radiologist physicians in six facilities, only two of which are facilities where only surgeons use the stereotactic units.

Mr. Flater then discussed noncompliance issues found, including an individual jeopardizing public health and safety by fraudulently manufacturing phantom images. The state sought revocation of the individual's certificate to practice mammography.

He also talked about the issue of radiologist assistants not doing interpretations. Some rural facilities have their radiologist at another facility, and the radiologist assistants do sometimes do interpretation. He also said that Iowa mandates the ACR quality control.

Dr. Williams asked why he didn't include assessment of the collimation. Mr. Flater didn't realize it was an issue and said he would look into it. He said that physicists are used in Iowa and must be board certified or board eligible, and that that issue had never come up. He noted that the first compliance problem listed was not following the recommendation of the physicist, which they are forced to do, and that collimation would be addressed by the physicist and corrected.

Dr. Hendricks asked whether the Iowa program had the same clinical component as ACR. Mr. Flater said that the program does require images to be provided which go to the clinical image review group, who must meet the stereotactic requirements. Dr. Hendricks then asked about the criteria for pass/fail, and Mr. Flater could not provide any information.

Helen J. Barr, M.D., Director, Division of Mammography Quality and Radiation Programs, asked if Mr. Flater had any evidence that quality had been improved by putting the mandatory program into effect, and Mr. Flater said that they did not track that.

Dr. Ferguson asked about access problems in rural areas of Iowa and how far people had to travel to get a stereotactic biopsy. Mr. Flater said that the mammography program had grown ever since it started and that the farming communities liked to have the mammography facilities easily accessible and were willing to pay for them. He said the mammography facilities were spread throughout the state. Dr. Ferguson asked if Iowa had any kind of program to help women without the means to travel. Mr. Flater said the health department's breast cancer detection

centers would pay for individuals who needed exams, but he wasn't sure about stereotactic specifically.

Dr. Hendricks asked whether there were many facilities in Iowa with no violations or whether the violations were scattered across facilities. Mr. Flater stated that the violations were sporadic and not lumped together and that there weren't repeats, which can lead to civil penalties. Dr. Hendricks then asked whether adding the stereotactic inspection procedures had increased the burden on facilities and personnel. Mr. Flater did not think so and agreed with the reasons given by Ms. Butler. Dr. Hendricks asked what would happen if there were surgeons who wanted to participate who did not meet the criteria. Mr. Flater said they would not be allowed to do so.

Dr. Barr discussed the IOM recommendations regarding interventional mammography. She first returned to a recommendation she neglected to discuss the previous day, to change MQSA to BIQSA to include all breast imaging procedures. She pointed out that since ultrasound and MRI are not defined as x-ray of the breast, this recommendation would require a statutory change rather than a regulatory one.

One of IOM's recommendations on interventional mammography was to remove the exemption for stereotactic breast biopsy procedures and develop regulations. The rationales were that stereotactic breast biopsy uses mammographic x-ray imaging, FDA had indicated its intent to regulate, and the profession now had more experience with stereotactic procedures.

The report also included comments on interventional regulations. It noted that while there was a voluntary accreditation program, fewer than 500 of the 4,000 to 5,000 interventional mammography units had been accredited. The IOM committee intended to include all stereotactic biopsy procedures and equipment used, including needle localization, but Dr. Barr

was not sure that wording to that effect had actually been made a part of the recommendation, and she noted that there was no accreditation for needle localization at the time. The committee felt that mandatory accreditation of interventional equipment rather than procedures would be sufficient and that FDA inspectors needed to be trained to conduct inspections of stereotactic breast biopsy procedures and interventional equipment.

Dr. Barr wondered whether there was really a genuine public health risk requiring mandated accreditation as there was with mammography when MQSA went into effect. She also emphasized the lack of evidence that mandatory programs improved quality. The Office of Surveillance and Biometrics searched its database and found six reports related to interventional procedures in the past two and a half years.

Ms. Martin reminded Dr. Barr of the data presented by Ms. Butler that a third of facilities were not passing the initial or repeat accreditation. Dr. Barr said the same thing occurred with mammography when they started but in the case of Stereotactic biopsy the failures probably weren't related to lesions not being captured.

Dr. Williams thought the data would be difficult to obtain in that it would require tracking of cases that ultimately turned out to be false negatives or missed biopsies. He also talked about wire localization and said the re-excision rate for positive margins was about 50 percent. Dr. Barr agreed.

Ms. Mount discussed her experience in rural areas where surgeons attempt to position patients without a technologist and the importance of specific dose and positioning training for physicians who will not have a technologist with them. Dr. Hendricks said that the preliminary data from the ACR voluntary accreditation program highlighted significant technical problems related to the skill of those performing the procedure.

Dr. Dowlatshahi asked about the number of stereotactic units in the U.S. Dr. Barr said she didn't have hard data on the number of units but the estimates range from 2,000 to 5,000. Dr. Finder asked if the review of calcifications and mass was one per facility, and Ms. Butler said that it was one per unit. Dr. Barr returned to a point made earlier by Lt. Commander Boyd that proper use of equipment was more of an issue than the equipment itself.

Ms. Martin talked about equipment wearing out and said facilities would continue to use old equipment unless there was some requirement that it be replaced, and Dr. Barr said that there were equipment requirements in MQSA. Dr. Monticciolo didn't think wire localization was a significant issue and said it was a basic, straightforward procedure. She said that they did have some problems with surgeons not believing a specimen x-ray was necessary to confirm that the lesion had been removed. Dr. Barr said that in her practice they use the stereotactic unit to localize lesions for open biopsy. Dr. Monticciolo said the stereotactic unit was useful for lesions only seen in one projection. She said that didn't happen much.

Dr. Monticciolo felt that wire localization equipment should be accredited. Dr. Dowlatshahi agreed that it was an issue between radiologists and surgeons. He said that wire localization with stereotactic was more problematic since the wire may move after decompression.

Dr. Williams agreed that wire localization was a cooperative venture between the radiologist and surgeon and worried about people not working together well. He also said that surgeons were very good at taking the two views with the wire and triangulating and correcting for misplacement of the wire. He also thought the computations would become more difficult as cancers were detected earlier and there were larger numbers of non-palpable lesions.

Dr. Monticciolo said she thought the data on miss rates for stereo was similar to that of surgical miss rates, which is often quoted as being less than two percent. She also pointed out that data on misses and complications was requested but not required for accreditation. Ms. Butler said that most facilities did provide that information but that it could not be analyzed yet as it had not been put into a database. Dr. Barr asked when they might be able to analyze the data, but Ms. Butler did not know.

Dr. Hendricks said that in her community the breast surgeons were shifting most of their procedures to the radiologist. She hoped that the collaborative and independent tracks could be compared to determine which approach was best. Dr. Barr asked whether she would rather wait for that type of data before creating a regulatory program. Dr. Hendricks said that a different standard would be needed for stereotactic as opposed to mammography. She felt the survey data was very important, and she said it was interesting to look at the audit data correlated with the pathology of the breast disease being diagnosed.

Dr. Monticciolo said there was a large body of evidence showing that stereotactic guided biopsy can be performed accurately, and Dr. Hendricks agreed. Dr. Ferguson agreed with Dr. Monticciolo that the equipment for wire localization should be accredited and supported mandatory accreditation for stereotactic. With regard to the evidence discussed by Dr. Monticciolo, Dr. Ferguson felt it came from accredited facilities doing high quality work. Dr. Monticciolo had never seen wire localization be an issue if the surgeons and radiologists work well together.

Dr. Barr asked Dr. Finder what it would mean to remove the exemption for equipment used only for wire localization. Dr. Finder asked for clarification on what was meant by that since accreditation normally requires the submission of clinical images. Ms. Mount asked if the

post films used to show the wire was in place could be used. Dr. Finder said that now one must submit a bilateral mammogram of a normal examination and that that would require a change to the accreditation process.

Dr. Monticciolo emphasized the difficulty of getting the same positioning to use films from a unit only used for wire localization. Ms. Butler thought some of the units were also used for diagnostic films. Dr. Monticciolo's facility does localizations only on accredited equipment. Ms. Butler thought it might be possible if diagnostic images rather than just screens were done. Dr. Barr stated that if the localizations had to be done on an accredited mammography unit then the accreditation procedure would not change.

Ms. Martin said there were at least three centers that had mammography units used solely for localization. She also suggested annual evaluation of these units by the physicist rather than having to evaluate films. Dr. Finder clarified that accreditation was defined in statute and regulation as involving review of clinical images.

Ms. Mount said that in accrediting stereo units, one positions the needle to biopsy the area of interest. Dr. Barr said that an accreditation program for localizations would have to be developed to go that route. Dr. Monticciolo recommended that the equipment pass the physicist's quality assurance and quality control. She also said that the images submitted for stereotactic accreditation were not assessed for patient positioning and were not assessed the same way a clinical review was done. Dr. Williams pointed out that many of the machines had a small field of view and could not visualize the entire breast. Dr. Monticciolo said that copies of mammograms were submitted with accreditation but they were not judged the same way as clinical images for accreditation.

Dr. Barr asked Dr. Finder if there was a way to incorporate a physicist survey into the inspection procedure without an accreditation program. Dr. Finder said the agency would have to talk to its lawyers but he was doubtful they could certify something without accrediting it.

Dr. Ferguson thought they should hold stereo to the same standards as MQSA. Dr. Monticciolo agreed and thought the program developed in collaboration between ACS and ACR was a good one. Ms. Martin agreed.

Dr. Finder said there were similarities and differences between mammography and stereotactic biopsy. One main difference is that while the audits for mammography allow us to obtain outcomes data, obtaining results from every patient can be problematic. However, that should not be a problem with patients undergoing biopsy. He asked whether outcomes should be looked at to a greater degree with stereotactic if it were regulated.

Dr. Monticciolo did not think there was evidence the additional audit recommended for mammography would improve quality. She agreed that for stereotactic biopsy outcomes could be obtained. She said the data requested by ACR's accreditation program, such as re-biopsy rates, discordance, and hematoma formation, would be a good audit, and she supported making collection of such data mandatory. Stating that the data was readily available and should be checked, Dr. Ferguson agreed. He said that it would be collected by whoever performed the biopsy.

Dr. Barr asked what the inspection process, if any, for stereo would look like. Dr. Monticciolo thought it would be nice if the inspections were minimally disruptive. Dr. Finder asked whether they had clearly defined problems associated with interventional stereotactic and whether they were focused or diffuse. Ms. Rinella asked ACR for information on why facilities failed accreditation. Ms. Butler said that it was broken down by clinical, phantom, and dose but

not as to calcifications and mass. Ms. Rinella then asked about personnel requirements, and Ms. Butler said that was not included because facilities don't proceed without having met the requirements.

Dr. Hendricks asked about the weighting of clinical and technical failures in the accreditation process. Ms. Butler said there was no weighting and that all aspects must be passed for accreditation. Dr. Finder asked if personnel had to submit documentation of their qualifications or merely an attestation that they met them. Ms. Butler said they submitted an attestation but they had to be able to produce documentation during site visits.

Ms. Wilcox said that the personnel requirements, while not a pass/fail criterion, do have an impact in terms of eligibility to apply. Ms. Martin said there was a range of problems with stereotactic. She felt the biggest problem was facilities not having a mammography technologist to work with surgeons. Dr. Barr said there were similar problems with interventional fluoroscopy procedures. Dr. Monticciolo supported the standards to ensure that everyone doing the procedures could meet a certain standard, and she agreed that a mammography technologist should be involved.

Dr. Finder asked whether technologists doing a lot of stereotactic would have problems maintaining their mammography qualifications. Ms. Butler said that issue had come up before ACR's committee and they felt it was important for technologists to maintain their MQSA requirements. Dr. Monticciolo agreed that the minimum number of films was not particularly onerous for technologists. She also thought that being able to do standard imaging helped technologists do better with stereotactic. Ms. Rinella agreed and said that technologists needed to know how to manipulate the breast. Ms. Mount also agreed. Mr. Flater said that it had not been difficult for Iowa technologists to maintain the requirements for mammography.

Dr. Barr raised the issue of a technologist hired by a surgeon having to find time to perform mammograms. She asked how becoming part of the federal regulatory process would affect the practice of breast surgeons. Dr. Harrison thought surgeons would comply with the regulations and welcome them.

Dr. Barr wondered whether pathologists and oncologists should be regulated as well. Dr. Ferguson did not think those specialties would fall into the committee's purview in light of Dr. Finder's comment that the committee deals strictly with imaging of the breast. Dr. Finder agreed and asked about the potential consequences of regulating stereotactic when there is no regulation of ultrasound or MRI biopsy and less comprehensive regulation of needle localization. Dr. Monticciolo said it was hard to tell what the unintended consequences might be but did not think there would be much movement from stereotactic to ultrasound or MRI guided biopsies since calcifications are not readily seen in those modalities. However, she did think there was potential for surgeons, but not radiologists, to move from stereotactic back to open biopsy. Dr. Hendricks did not think that was an issue given that the advent of the stereotactic biopsy had not decreased the rate of open biopsy procedures. She thought regulation might have a beneficial impact on patient selection for stereotactic procedures.

Ms. Martin said that if ultrasound procedures also had to be accredited as recommended in the report that there would be no concern about pushing patients from one to the other. Dr. Finder said the difference was that a statutory change was needed to allow regulation of ultrasound.

Dr. Dowlatshahi said the committee should give other professional societies time to provide input. He also talked about the fact that the needles used are larger and sometimes require incision, so there is not a well-defined difference between using a needle and using a

knife. Dr. Mourad asked Dr. Monticciolo what she meant when she said not to make the inspections onerous and laborious. Dr. Monticciolo said her facility's satellites sometimes had to shut down for an entire day for inspection and that inspections could be particularly disruptive with an inexperienced inspector.

Dr. Barr thought it was interesting that the committee was discussing additional regulatory burdens given the number of comments about not increasing the burden on facilities and personnel. Ms. Mount said that while none of them wanted to have to do additional work, they were all more concerned about the quality of patient care. Dr. Monticciolo emphasized that the difference between the burden of accreditation and inspection is that for accreditation facilities have time to gather information and spread the work out over time.

Ms. Wilcox emphasized the more significant implications of having to cancel a patient scheduled for stereotactic biopsy as opposed to a mammogram when the inspector has to access the unit. Ms. Martin said that mammography inspections were moving towards inspection of the physicist report and minimal time with the unit itself. She said the only thing an inspector should have to do with a stereotactic unit would be taking a phantom image, and she suggested that could be done by the technologist the morning the inspector was supposed to come.

Mr. Passetti said FDA was already moving in the right direction on inspections in terms of focusing on high-risk areas. Dr. Williams agreed with the comments of Ms. Martin and thought that looking at the physicist's report could eliminate the need for most of the inspector's tests. Mr. Flater urged caution in terms of the legal aspects of having physicists essentially acting as inspectors. Dr. Hendricks asked how Iowa deals with the down time required for inspection of stereo units. Mr. Flater said they call the facilities in advance and adjust their schedule if necessary and, for really busy facilities, they do inspections at night.

Dr. Barr asked whether there should be a statutory change to include all breast imaging. Dr. Hendricks said that based on the information the committee had received it would be premature to regulate MRI procedures. Dr. Barr asked whether regulation breast ultrasound should include interventional, and Ms. Butler said that it could be both. Ms. Rinella felt that ultrasound should be accredited given the variability in the procedures. Mr. Passetti raised the issue of whether states would have authority to do inspections for ultrasound. Dr. Barr said that if there were a program like MQSA in place the states would have that authority. Mr. Passetti said that he was unsure states would have the expertise and willingness to move into that area.

Ms. Pura said that if quality was the goal then we should move from MQSA to breast imaging mammography regulations, including for ultrasound. Mr. Flater said Iowa would need new legislation to inspect ultrasound because they could cross the line between non-ionizing and ionizing. Dr. Hendricks asked about ACR's accreditation of ultrasound procedures. Ms. Butler said they had accredited 300 to 400 facilities but that contrary to mammography, individual ultrasound units were not accredited. She did not have information on the number accredited for interventional or on pass rates. Dr. Hendricks felt the committee did not have adequate information on ultrasound.

Ms. Butler asked if the committee intended to make a recommendation to Congress regarding BIQSA. Dr. Barr said FDA probably didn't have enough information to make a recommendation on ultrasound. Dr. Ferguson said they should move towards ultrasound accreditation but didn't feel they had enough information, and he did not want the committee to get distracted from the stereotactic issue. Dr. Monticciolo agreed that there was significant variability in the practice of breast ultrasound. She was somewhat concerned about the potential burden but thought they were moving towards accreditation. Ms. Mount agreed that ultrasound

should be accredited but that they weren't ready to mandate accreditation yet. She raised the concern of facilities using substandard ultrasound units if only one unit, presumably the best, is looked at. Dr. Monticciolo thought people failed more because of operator problems and wasn't sure how much of an issue multiple units in a facility would be.

Dr. Barr asked if the committee would support regulation if a large percentage of stereotactic units were applying for and passing accreditation. Dr. Monticciolo thought regulation likely would not be needed in that situation. She returned to the issue of facilities using the quality control materials but not applying for accreditation because they don't want to pay. Ms. Wilcox said she didn't know how may had bought the stereotactic manual and not applied for accreditation. She stated that around nine years earlier the committee had stated that if 90 percent of stereotactic sites applied for accreditation under a voluntary program then regulation would not be necessary, but she did not think that was likely.

Mr. Flater said that the real question was whether those providing bad services should be allowed to continue doing so. Ms. Wagner asked about patients being driven into ultrasound if stereotactic accreditation is mandated and encouraged adoption of BIQSA to avoid that scenario.

Dr. Monticciolo said that ultrasound is preferable to stereotactic because it is more comfortable for patients and you can see the needle moving in real time. She was concerned with people doing open rather than stereotactic biopsy.

Dr. Barr asked about potential impact of regulation on access to stereotactic biopsy if some people stopped doing stereo. Dr. Monticciolo felt there were more stereotactic tables than were needed given that her table was not completely booked, and she couldn't imagine there were many being fully utilized.

DISCUSSION OF RECENTLY ISSUED GUIDANCE DOCUMENTS

Dr. Finder said one of the initial requirements for interpreting physicians is that they be board certified or have two or three months of training. However, some of the boards have started issuing time-limited certificates, and Dr. Finder asked whether they should start checking expiration dates or simply accept the certificate as permanent. Dr. Hendricks thought re-certification and documentation of such should be required.

Dr. Finder raised the issue of the longer it has been since an individual was in residency the harder it will be to show proof of their three months of training if their certificate expires. Dr. Mourad said that checking on expired certificates would treat people who were certified differently than those who qualified based on training. Dr. Monticciolo agreed that it wouldn't be fair to check up on the certificate of someone who had met the higher standard of board certification. She also said that those who were board certified likely had the three months of training. Dr. Finder said the issue would come up the following year when the Canadian board certifications expired. Dr. Ferguson felt that someone who had initially qualified shouldn't be disqualified from doing something they've been doing well simply because they do not renew their certification.

Dr. Finder mentioned that some states did not let people with expired certificates practice. Dr. Monticciolo asked for clarification whether those states were not recognizing the three months training. Dr. Finder replied that some states required board certification. Ms. Martin wondered why it would be acceptable for someone to continue to practice mammography if they did not renew their certificate given that they would not be allowed to do other imaging modalities, but Dr. Monticciolo said that one did not have to be certified to read other modalities.

She talked about the possibility of a very good reader whose certificate expired and who was planning to retire soon and did not want to go to the trouble of re-certification.

Ms. Martin said that technologists had to have current certification and wondered why the same shouldn't hold true for radiologists. Dr. Finder said that was true and mentioned that the American Board of Radiology was doing the same thing for medical physicists. Dr. Monticciolo agreed with Dr. Ferguson that they should not set a different standard for those who were board certified. Dr. Hendricks favored requiring continuous board certification for new interpreting physicians. Dr. Barr asked if that would create more barriers to people entering and remaining in the field. Dr. Mourad said that board certification for technologists had always had time limitations.

Dr. Monticciolo returned to the idea that requiring re-certification would essentially penalize those who met the higher standard and said they could simply fall back on the three month training requirement. Ms. Wilcox pointed out that a technologist's certificate is renewed as long as he or she has their CEUs, whereas radiologists and physicists are actually reexamined. Dr. Hendricks asked for ACR's position on the matter. Ms. Wilcox said they had not taken a position but that board certification was a requirement for ACR membership.

Dr. Finder returned to Dr. Murray Reicher's comments on Guidance Document No. 9 and asked about copying original mammograms and just keeping the digitized image. Before FFDM came along, statute and regulation prohibited the use of film copies because facilities were being sent sub-optimal copies. With FFDM there are now questions of what exactly is the original mammogram and how should it be displayed, transported, and retained. Now there is a question whether a film screen mammogram can be digitized and the original film discarded to make storage, retrieval, and transportation easier. Dr. Monticciolo said she had never seen a digitized

film screen as good as the original image and did not think destroying the original was a good idea. Dr. Williams agreed and said that most research studies didn't use digitized or copied films. Dr. Ferguson also agreed.

Dr. Finder then asked what evidence could convince the committee that digitizing films was acceptable. Dr. Williams said a large reader study would do. Dr. Finder asked whether such a study would look at comparison of films or merely at the end results. Dr. Williams thought it should compare films. Dr. Monticciolo said that if you knew there was something there lesions would stand out regardless of image quality. She asked whether the modulation transfer function (MTF) was known for the devices. Dr. Williams said MTF could be characterized but didn't think the data was well known or studied.

Dr. Monticciolo said they would have to do a rather large users' study to convince her that original films should be discarded. Ms. Holland agreed and wondered about the legal issues involved with discarding the original.

The next issue Dr. Finder raised based on Dr. Reicher's comments was using lossy compression on FFDM that to create a visually lossless image, one in which there would be no loss of data perceptible to the eye. Ms. Holland said there would need to be a study done for her to accept that. Dr. Monticciolo said this was a somewhat different issue since images can have more information than is detectable by the eye and said she would support it if it could be proven that there was no detectable loss. Dr. Williams raised the issue that different compression algorithms produce different results.

Dr. Williams talked about sitting on a committee that was looking at image quality and asserted that there were no longer strong arguments for data compression from the perspective of

the expense of data storage. He said the only arguments for compression were related to transmission.

Dr. Finder moved on to the issue of there being more data than can be shown on the monitor with FFDM. Dr. Reicher inquired in his submitted comments why information that couldn't even be displayed would have to be stored. Dr. Williams said that radiologists could use that information by zooming in. Dr. Reicher also asked why he couldn't use monitors with resolution less than five megapixels and simply zoom in. Dr. Williams thought the downside would be the greater time and difficulty required for image manipulation. Dr. Ferguson didn't think the additional image manipulation would actually be done.

Dr. Finder said that one of Dr. Reicher's arguments was that being able to use lower resolution monitors already present in facilities would lessen the burden associated with adoption of FFDM and that any loss of efficiency would be balanced by the lower start-up costs. Dr. Finder stated that at present end users could use lower resolution monitors as long as they met the quality control procedures of the manufacturer, but manufacturers could not advertise or sell lower resolution monitors for FFDM uses. Dr. Williams pointed out that there was only one FFDM unit where the image could be viewed at full resolution on a five megapixel monitor. Dr. Williams also said that radiologists liked to be able to see the full mammogram at an acceptable level for comparison purposes.

Ms. Martin agreed with Dr. Williams and said that while digital acquisition was faster for technologists, FFDM interpretation was slower for radiologists. She thought it was likely they would simply read the image at a lower resolution rather than spend more time zooming in. Dr. Monticciolo agreed with Dr. Williams that they don't know what affect using a four rather than five-megapixel monitor would have on image quality, but she also agreed with Dr. Finder about

the cost of monitors being a barrier to moving to FFDM. She stated that she would like to use the highest resolution possible if not for the expense.

Ms. Martin talked about radiologists having to go down the hall to look at an image on a monitor with better resolution than those used for acquisition and thought someone might request requiring five megapixel monitors for the acquisition station if it was to be used for biopsy procedures. She said acquisition monitors were typically one or two megapixels and that there was a significant difference in image quality between the acquisition and review monitors. Dr. Monticciolo said there wasn't enough information to know how much of a difference there would be between a four and five megapixel monitor.

Dr. Finder next asked about the use of cushion pads that could be put on the bucky or on the compression paddle to minimize discomfort from compression. He asked for information on the use of these pads causing a certain type of artifact. Ms. Martin said she hadn't found any artifacts when she was testing the pads. Dr. Finder said it apparently shows up during clinical examinations of patients with fatty breasts when high speed film cassette combinations or FFDM machines are used.

Ms. Rinella said that the pad went against her training in that you always want the breast to be as close as possible to the image receptor. She also said that using the top pad on the compression plate would obscure the breast. She tested it on herself and, rather than additional comfort, the pad merely provided extra warmth. She also said there was a slight increase in dose. Ms. Rinella had heard about artifacts from technologists using digital equipment.

Dr. Monticciolo asked whether the company had provided data that the pad didn't interfere with the image when it was approved for use. Ms. Martin said that it had been tested on a standard film screen system, not an ultra fast one, no artifact showed up, and the increase in

dose was less than one percent. Ms. Mount agreed that only the bottom pad could be used and said her facility used it for very apprehensive patients. She said they only see an artifact with film when the pad is misaligned and not at all on their digital unit.

Dr. Finder discussed Guidance Document Eleven, which deals with the fact that FDA will not be enforcing the continuing education requirement for each specific mammographic modality.

Dr. Finder thanked Alisa Gilbert, Melissa Martin, Linda Pura, and Miles Harrison for serving on the committee and announced that their terms would expire on January 31, 2006.

ADJOURNMENT

Dr. Hendricks thanked the participants and adjourned the meeting at 3:08 p.m.

I certify that I attended this session of the National Mammography Quality Assurance Advisory Committee on September 27, 2005, and that these minutes accurately reflect what transpired.

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Charles Finder, MD
Executive Secretary

I approve the minutes of the September 27, 2005, meeting as recorded in this summary.

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Carolyn Hendricks, M.D.
Chairperson

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