SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE MEETING

Open Session

August 26, 2002
Gaithersburg Holiday Inn
Gaithersburg, MD

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE MEETING
AUGUST 26, 2002

COMMITTEE PARTICIPANTS

Maryanne Harvey, MS	Chairperson
James F. Camburn, B.S.	
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Alisa M. Gilbert	Consumer Representative
Miles G. Harrison, Jr., M.D.	
Jessica W. Henderson, Ph.D.	Consumer Representative
Debra M. Ikeda, M.D.	
Andrew Karellas, Ph.D.	
Amy F. Lee, M.D.	
Melissa C. Martin, M.S.	
Etta D. Pisano, M.D.	
Linda S. Pura, RN, MPA	Consumer Representative
Catalina R. Ramos-Hernandez, M.D.	Consumer Representative
Amy R. Rigsby, R.T. (M)	
Donald C. Young, M.D.	

FDA PARTICIPANTS

Charles Finder, M.D.	Committee Executive Secretary Associate Director Division of Mammography Quality and Radiation Programs
Roger Burkhart, Ph.D.	Accreditation and Certification Branch Division of Mammography Quality and Radiation Programs
Michael Divine, M.S.	Inspection and Compliance Branch Division of Mammography Quality and Radiation Programs
Charles Gunzburg, M.S.	Inspection and Compliance Branch Division of Mammography Quality and Radiation Programs
Kish Chakrabarti, Ph.D.	Accreditation and Certification Branch Division of Mammography Quality and Radiation Programs

CALL TO ORDER

Committee Chair Marianne Harvey, M.S., called meeting to order at 9:00 a.m. **Committee Executive Secretary Charles Finder, M.D.,** read the conflict of interest statement, announcing full waivers to all committee members and to **Daniel Kopans, M.D.,** for their professional affiliations or their financial involvement with accrediting bodies, manufacturers of mammography equipment, or mammography facilities. In addition, several members reported that they received or will receive compensation for lectures, but they affirmed that were asked to speak for their expertise and not because of their membership on the committee. Ms. Harvey then asked the committee members to introduce themselves.

ALTERNATIVE STANDARDS

Dr. Finder provided brief background information on the alternative standard requirement and stated that since the last committee meeting, the Division has approved several requests for alternative standards.

Roger Burkhart, Ph.D., Accreditation and Certification Branch, Division of Mammography Quality and Radiation Programs, described the alternative standards that had been approved since the last committee meeting. First, an alternative standard for manufacturer's software modification of the AEC was approved on September 24, 2001. Second, an alternative standard for conducting mammography equipment evaluations after a software upgrade under medical physicist oversight was approved on May 31, 2002; the standard refers to testing conditions after a modification takes place and involves a request related to specific software upgrades. A third alternative standard was approved on June 27, 2002; the standard addresses the time period for corrective actions following failure of quality control tests for full field digital

mammography (FFDM) units. Dr. Burkhart noted that the standard only applies to those General Electric (GE) units mentioned in the requested alternative standard.

OPEN PUBLIC HEARING

Kenneth Crocker, director of marketing, product planning, Fischer Imaging Corporation, stated that digital mammography is becoming more widely used and that that the delays in providing oversight for FFDM and lack of uniformity in standards are problems. Moreover, manufacturers have no incentive for standardization. FDA and accrediting bodies should develop uniform standards, seeking guidance from industry in the process, and FDA should allow accrediting bodies to accept manufacturers' manuals for accreditation on an interim basis. Accrediting bodies should simplify accreditation requirements and make them more uniform. In addition, Mr. Crocker suggested eliminating the requirement to maintain a film/screen system because it imposes an undue burden. FDA should synchronize tests that allow 30 days for corrective action and develop a uniform standard rather than wait for manufacturers to do it.

Committee members noted that facilities use FFDM and film/screen equipment differently; larger than average patients may need multiple exposures, making them more appropriate for film/screen equipment. However, from a public health viewpoint, it makes sense to not require film mammography because it limits access in rural areas; with film/screen equipment, one cannot electronically transmit images for interpretation.

Dr. Finder then read a statement from **Pamela Gormley, R.T. (R) (M), mammography supervisor, EPIC Imaging,** into the record. Ms. Gormley wrote that the requirement to maintain a film/screen system is outdated technology and a waste of resources; digital units provide better resolution with less radiation than film/screen systems.

OPEN COMMITTEE DISCUSSION

Overview of MQSA Inspection Findings and Current Inspection Follow-up Actions

Michael Divine, M.S., Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs, summarized FDA inspection and compliance data. He noted that problems have been declining over time. He listed FDA's options for inspection follow up and summarized the specific types of regulatory actions FDA has taken, which are primarily additional mammography reviews (35 actions) and patient and physician notification (11 actions).

Good Guidance Practices and Directions for Discussion of the MQSA Guidance Under the Final Regulations

Dr. Finder provided background information on FDA procedures for developing new guidance documents and gave information about the policy guidance help system.

MQSA GUIDANCE: COMMITTEE DISCUSSION

Automatic Exposure Control (AEC) Testing

Committee members discussed whether all AEC modes should be tested at the annual survey, or whether the medical physicist should perform a test onsite only if the facility is using a specific mode clinically. It seems unnecessary to test every available mode of a complex AEC system if a facility does not intend to use those modes; however, what should be done if a facility decides that it needs to begin using a particular mode that hasn't been previously tested. In that case, Committee members suggested that the medical physicist should be called in to evaluate the

AEC only when the new mode is a substantial departure from the initial test. In addition, the longer testing takes, the longer a machine is out of service for a facility and the more the testing costs.

Dr. Finder noted that the regulations are slightly different for testing at the initial evaluation and at the annual survey and asked the committee whether full testing at the initial evaluation and lesser tests at the annual survey should be acceptable.

Committee members who are medical physicists indicated that they follow ACR guidelines and test in mag mode. Some members said that if a facility does not use a mode, they do not test it; others said that each mode should be tested on some thickness to verify tracking between modes. For units with individual detectors, the full set of tests should be conducted on one of the detectors, then the results should be cross-checked with the other detectors for 4 cm. Several committee members suggested that only modes that are clinically used should be tested routinely, but all modes should be tested at installation. Some committee members suggested that it is to the medical physicist's and the facility's benefit to test all the AEC modes while some suggested that AEC problems are not a major clinical issue—problems become evident quickly, and technologists are vigilant about image quality. Some believed that this is more of a regulatory problem, than a practical clinical problem.

Committee members pointed out that technologists may inadvertently use the wrong submode, especially when many technologists use the same machine; in addition, technologists have to make judgments for patients who fall between sizes. For that reason, a range of AEC testing would be appropriate. Each submode needs to be tested at some thickness to show that it tracks. It was also brought up that when testing at 8 cm, the density control on some units may have to be adjusted to obtain optimum film density.

The committee discussed whether the manual mode could be used in the event of AEC failure. Several committee members said that if the AEC fails, their recommendation is that the unit be taken out of service; their facilities do not allow manual exposure. The problem is not common because AECs tend to drift a bit rather than totally fail.

Priscilla Butler, director, Breast Imaging Accreditation Program, American College of Radiology (ACR), asked for clarification on FDA's interpretation of AEC failure and the definition of manual mode. Dr. Finder responded that AEC failure can refer to both testing failure and when someone suspects that there are problems with the clinical images. Regarding the manual mode, the FDA is trying to deal with the fact that units have multiple AEC modes. If only 1 or 2 modes are affected, a facility could continue to use the unaffected AEC modes. In cases of complete AEC failure, the regulations allow use of the manual mode for up to 30 days.

Full Field Digital Mammography (FFDM)

Dr. Finder noted that the guidance document is available for public comment and includes a long new section on FFDM. He asked committee members whether they had any comments on the guidance. Dr. Pisano noted that a clinical trial for which she is the principal investigator has generated a fair amount of data. Once the data are made public, the FDA should be able to reduce the various quality control requirements currently applied to FFDM units. Dr. Finder noted that the regulations governing FFDM were written before any units were approved. Manufacturers were asked to establish an appropriate quality control system. FDA will revise the regulations as data become available. Because units are so different from each other, it will be hard to standardize quality control.

Dr. Karellas noted that medical physicists find it easier to work with modules from accrediting bodies, such as ACR, than manufacturers' manuals. If manufacturers cooperate, a document could be developed that parallels ACR guidelines.

Ms. Gilbert noted that the guidance document does not contain much information on mammography for breasts that have implants or have undergone reconstructive procedures. Dr. Finder noted that the regulations were written with cosmetic implants in mind. Recommending additional training for technologists who do mammography on patients who have undergone surgery was suggested.

Claude Goode, State of California, described a case in which a woman's implants ruptured during mammography and said that the FDA or another entity needs to set some standards for mammography of patients with breast implants. Dr. Finder stated that the regulations currently do have standards for patients with breast implants.

Daniel B. Kopans, M.D., F.A.C.R., Harvard Medical School and Massachusetts General Hospital, Boston, noted that the standard of care is not to do routine mammographies of women with mastectomies. Committee members concurred that the case reflects an isolated incident; they noted that mammography is not recommended for screening of women with breast reconstruction. Committee members observed that sufficient guidance about imaging of breast implants is available from professional societies for technologists and radiologists. The issue is medical, rather than regulatory.

Assessment Categories

Dr. Finder said that concerns have been raised about the BIRADS assessment categories when evaluating postoperative breasts, because the categories do not cover all situations. In addition,

the categories were not designed with the male breast in mind. Other areas of concern include appropriate categorization when waiting for comparison films and the use of category 3 (probably benign). Another issue is the use of multiple assessment categories and the FDA requirement that an overall assessment category be assigned if multiple categories are used.

The committee concurred that the currently available categories were not necessarily appropriate in all cases. Suggestions included adding BIRAD 6, "known cancer present," and clarification of category 0. Dr. Pisano noted that category 0 is intended to be used when a patient is in the process of being worked up; it is not a final category. In most settings, 0 means more tests are needed.

Dr. Finder observed that the issue of assessment categories for each breast has been raised before and asked whether the assessment categories should be for each lesion, rather than overall. Dr. Kopans said that physicians are supposed to read the full report and that such categorization would be redundant. Dr. Pisano stated that she believes that ACR's BIRADS committee would not object to the use of a two-breast assessment system. Dr. Finder noted that the regulations say to provide one overall assessment category for the study. Part of the reason for this requirement was to prevent a facility from counting a two-breast study as two separate exams for purposes of initial or continuing experience. Dr. Ikeda expressed concern about adding an assessment for the second breast because of the possibility of missing the most suspicious finding; if one must read 20,000 reports, an overall assessment is important.

Dr. Finder provided background information on the regulatory history of FFDM. When the first FFDM unit was approved in early 2000, no accreditation body existed. The MQSA requires that units and facilities be accredited and certified. The only way to handle the situation

was to link digital units to otherwise accredited film/screen units. As a result, facilities with FFDM are required to have a film/screen unit; the units need not be in the same location.

ACRIN TRIAL OF FFDM

Dr. Pisano described the American College of Radiology Imaging Network (ACRIN) trial, an NCI-funded screening trial for asymptomatic women comparing outcomes following digital and film/screen mammography. The goal is to enroll 49,500 women at 29 centers; if a woman would normally be screened at the participating site, she is eligible to participate. Exclusion criteria include dominant lump on physical exam, nipple discharge, implants, pregnancy, and inability to participate in follow up. Dr. Pisano described criteria for image acquisition and interpretation as well as the procedures for workup of lesions. Outcome measures include biopsy as well as ratings on the standard BIRADS scale, Probability of Malignancy scale, and Call Back scale. Dr. Pisano also described the follow-up protocol. The study is keeping track of downstream costs; one hypothesis is that digital mammography has a lower rate of false positives and therefore is associated with lower downstream costs. In addition, a quality-of-life assessment is being conducted through a telephone survey. Reader studies will take place in Year 3; soft- and hard-copy readings for each manufacturer will be compared. The study is also looking at image quality for different machines across sites and is examining variation over time.

Committee Questions for Dr. Pisano

Committee members asked questions concerning the participation rate of eligible women, the protocol if a suspected malignancy is found, recruitment and minority representation, exclusion

criteria, and cost. Dr. Pisano replied that the capacity of the facility, not participant willingness, poses the biggest limitation to participation. The study is collecting age and ethnicity data. To recruit patients, the study is publicized at centers that perform high daily rates of screening mammographies, and it also has generated local publicity. Recruitment has targeted minority populations; the goal is to reflect the proportion in the general population. Minority participation is good so far. When a suspected malignancy is found, it is handled by local clinicians. Each site handles workup according to its own protocol. Everything is adapted to accommodate both digital and analog images. Regarding exclusion criteria, women who have had a mastectomy and would normally get a screening mammography for the opposite breast are eligible, but women who have had lumpectomy are not eligible because they are defined as needing diagnostic, not screening, mammography. There is no specific age cutoff. The facilities charge for the film/screen mammogram, but the digital mammogram is free.

POTENTIAL NEW APPLICATIONS OF FFDM

Dr. Kopans reviewed how digital mammography works and listed its advantages. He then explained digital subtraction mammography, contrast enhanced mammography, and digital tomosynthesis, saying that these applications may turn out to be more useful than conventional digital mammography alone. Because these technologies can create perfectly registered images of the whole breast, direct correlation with whole-breast ultrasound and other imaging modalities will be possible. These will probably replace conventional digital mammography. Dr. Kopans noted that by removing the structure noise of the breast (i.e., overlapping structures), digital tomosynthesis makes tumors easier to see; he then showed many slides comparing tomosynthesis images with conventional mammograms. Compared with film/screen mammograms, digital

tomosynthesis provides greater conspicuity of lesions, more clearly defined borders of lesions, a reduced callback rate, an accurate three-dimensional location, and better differentiation of benign from malignant tumors. Some drawbacks are that the image-processing time is currently too long (2 hours) and that the radiologist must read many images, although they can be reviewed quickly at a workstation.

Committee Questions for Dr. Kopans

Committee members asked questions concerning the angle from which the images were taken and how the images are archived, whether the researchers have been able to display left and right breasts side by side, and the cost of the technology. Dr. Kopans responded that all images are in oblique projection. The images are being archived on CD and are viewed on a GE Advantage workstation. Breasts have been displayed side by side, but readers tend to read one breast image at a time. The process could add $100,000 to a digital mammography system. Dr. Kopans noted that 25 percent of recalls are for women with superimposed tissues, so the technology may improve patient management. Dr. Kopans suggested that it might take at least 2 years for digital tomosynthesis to receive FDA approval as a diagnostic device.

INSPECTION DEMONSTRATION PROJECT—UPDATE

Charles Gunzburg, M.S., Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs, provided an update on the Inspection Demonstration Project (IDP). When annual inspections began, the facility compliance rate was initially low; as facilities learned what was required, compliance increased dramatically. The 1998 reauthorization of the MQSA kept the annual inspection requirement but added a provision for the IDP, a pilot program

under which inspections of selected facilities may be conducted less frequently than annually. As required by the Act, the program could not be implemented before April 2001. Mr. Gunzburg described the IDP plan and State participation criteria, and presented the timeline for the study.

FFDM ACCREDITATION AND CERTIFICATION—UPDATE

Kish Chakrabarti, Ph.D., Accreditation and Certification Branch, Division of Mammography Quality and Radiation Programs, updated the committee on FFDM accreditation and certification. He summarized the approval process and requirements for FFDM, noting that the rules and application information are on the FDA Web site. Dr. Chakrabarti observed that some problems with medical physicist testing of FFDM units have been found. For example, with the GE Senographe 2000D, the signal-to-noise (SNR) ratio should be ? 50. If a facility does not use the raw image, the SNR will be artificially high. Some physicists are using incorrect procedures when conducting equipment tests. Some tests must be performed using the raw images, but that does not always happen. In addition, physicists are deviating from manufacturers' requirements with respect to viewing conditions, are not checking calibration properly, or are using the wrong manual. Physicists are exhibiting similar problems with Fisher units. These problems lead to delays in certification approval.

Committee Questions for Dr. Chakrabarti

Dr. Karellas asked whether FFDM facilities are required to have a printer; Dr. Chakrabarti said that FDA requires the facility to have the capability to provide the original mammogram on hard copy. The printer does not have to be onsite. The printer must be compatible with manufacturer specifications and included in the facility FFDM application.

Ms. Butler updated the committee on ACR's FFDM accreditation module. In November 2001, ACR was asked to submit a formal application for FDA approval of the module. In July 2002, ACR submitted a complete application to FDA. At the end of July, FDA advised ACR that the information provided with the alternative standard request was insufficient. In early August, ACR's digital subcommittee collected additional data to supplement the alternative standard request. Currently, the material is under internal ACR review.

Ms. Butler reviewed the proposed accreditation process for FFDM, including the evaluation process and requirements for phantom exposure and dosimetry. She noted that the requirements apply only to GE machines. After final FDA approval of the GE module, ACR will complete modules for other FDA-approved units. She added that ACR supports efforts to harmonize quality control tests among different manufacturers.

Joel Gray, Lo Rad/Hologic Corporation, asked whether the phantom image requirements for fibers, specks, and masses remain the same as for screen-film. He also asked if each accrediting body will have to individually apply to become an accreditor of FFDM units? Ms. Butler noted that for GE, the standard was 4 fibers, 3speck groups, and 3 masses. Dr. Finder stated that each accreditation body will have to individually apply to be an FFDM accreditation body. Committee members discussed the basis for the standards; Ms. Butler noted that they flow from the GE quality control manual. Committee members noted that a new phantom is being developed for digital mammography that is much more challenging. Committee members concurred on the need for a new phantom.

Jerry Thomas, Uniformed Services University of the Health Sciences, suggested that 8 hours of training with digital mammography systems might not be enough for technologists and physicists but should be sufficient for physicians. Dr. Pisano stated that in her experience,

the 8 hours of training was adequate for technologists. Ms Martin stated that 8 hours of general training for the physicist was not sufficient and recommended that training be done in conjunction with the manufacturer's service engineer.

Dr. Crocker stated that the need for a uniform accreditation process is urgent. The process seems sequential, rather than parallel.

Stephen Vastagh, industry manager, National Electrical Manufacturers Association (NEMA), said that NEMA plans to work with manufacturers to harmonize quality control requirements and that NEMA is pleased the accreditation bodies are supportive.

STATES AS CERTIFICATION AGENCIES

Dr. Burkhart reviewed the history of the States as Certification Agencies (SAC) Demonstration Project. The project provided FDA with a great deal of information that was subsequently used to develop regulations and to establish procedures and criteria for FDA's future oversight activities. The final SAC regulations became effective in May 2002. States interested in becoming SAC States should talk to FDA about their plans. One of the first steps a State will have to take will be to develop regulations equivalent to MQSA regulations. FDA currently has no active SAC applications.

REVIEW OF SUMMARY MINUTES

The Summary Minutes of the August 2001 meeting were reviewed; no changes were made.

FUTURE MEETINGS

Dr. Finder noted that Dr. Lee's term is expiring and thanked her for her efforts. The next committee meeting is planned for spring 2003; the agenda will depend on what happens with MQSA reauthorization.

ADJOURNMENT

Ms. Harvey thanked the participants and the committee and adjourned the meeting at 4:11 p.m.

I certify that I attended this session of the National Mammography Quality Assurance Advisory Committee on August 26, 2002, and that these minutes accurately reflect what transpired.

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Charles Finder, M.D.
Executive Secretary

I approve the minutes of the August 26, 2002, meeting as recorded in this summary.

Maryanne Harvey, MS
Chairperson

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