

**SUMMARY MINUTES**

**OF THE**

**NATIONAL MAMMOGRAPHY QUALITY ASSURANCE**

**ADVISORY COMMITTEE**

**August 22, 2001**

**Gaithersburg Holiday Inn  
Two Montgomery Village Avenue  
Gaithersburg, MD 20877**

**National Mammography Quality Assurance Advisory Committee  
August 22, 2001**

**Attendees**

**Committee Chair**

Maryanne Harvey, M.S.

**Executive Secretary**

Charles Finder, M.D.

**Attendees**

Carolyn Brown-Davis, B.A.

James F. Camburn, B.S.

Kambiz Dowlatshahi, M.D.

Nancy J. Ellingson, R.T.

Jessica W. Henderson, Ph.D.

Andrew Karellas, Ph.D.

Amy F. Lee, M.D.

Etta D. Pisano, M.D.

Catalina R. Ramos-Hernandez, M.D.

Amy R. Rigsby, R.T. (M)

Debra M. Ikeda, M.D.

Donald C. Young, M.D.

## **OPEN COMMITTEE DISCUSSION—August 22, 2001**

**Maryanne Harvey, M.S., Chair of the National Mammography Quality**

**Assurance Advisory Committee**, opened the meeting at 9:05 a.m. **Executive Secretary**

**Charles Finder** welcomed participants and read the conflict of interest statement, announcing full waivers for a number of the Committee members because of their financial involvement with accrediting bodies, manufacturers, mammography facilities, and professional societies. **Ms.**

**Harvey** asked the Committee members to introduce themselves.

### **COMMITTEE BUSINESS**

**Dr. Finder** asked all panel members, agency liaisons, and organization representatives to give him their mailing addresses and email addresses.

### **ALTERNATIVE STANDARDS REQUESTS**

**Dr. Finder** gave a brief background on the alternative standard requirement and stated that the FDA had not approved any requests for alternative standards since the last meeting.

### **OPEN PUBLIC HEARING**

**Dr. Finder** noted that one speaker had requested time to address the Committee but had later cancelled.

### **OPEN COMMITTEE DISCUSSION**

#### **Overview of MQSA Inspection Findings**

**Walid G. Mourad, Ph.D., of the Inspection Support Branch of the Division of Mammography Quality and Radiation Programs** gave an overview of inspection findings under the Mammography Quality Standards Act (MQSA) and Reauthorization Act (MQRSA). He provided regulatory background on the Acts and their implications for the inspection

program. After outlining the scope of an inspection, he summarized the various finding levels and presented a history of inspection findings by level from FY95 to FY01. Dr. Mourad provided perspective on the impact of the final regulations, noting that FDA had added new requirements that led to new findings at all levels and had reclassified other findings, leading to increases in some level one and two findings and decreases in level three findings. He predicted a future trend of decreasing percentages of facilities with citations at all levels. Dr. Mourad added that MQSA also provided for a demonstration inspection program scheduled to start in May 2002 in which selected eligible facilities will be inspected once in two years. MQSA also covers the new modality of full field digital mammography (FFDM), which is in use at a small number of facilities. The only possible FFDM related citations to date have been in the area of training requirements.

#### **Appropriateness of Current Inspection Follow-up Actions (Committee Discussion)**

**Dr. Finder** asked the Committee to comment on an FDA proposal to change the way it handles the majority of Level 1 citations. Currently, FDA issues Warning Letters to facilities with Level 1 findings. Under the proposal, the facility would have 15 days to respond to the citation and a Warning Letter would be issued only if the response wasn't effective or timely.

**Dr. Pisano** voiced concern that the facility should receive some official, legal written notification on the spot that it is in violation and what action is needed to respond. The Committee found the proposal reasonable as long as MQSA inspectors and facilities remain clear about the proper response to the citation.

#### **Good Guidance Practices and Directions for Discussion of the MQSA Guidance under the Final Regulations**

**Dr. Finder** presented questions and answers that are being proposed as additions or modifications to currently approved guidance. The proposed changes address questions received from facilities and patients since the last guidance document was issued. He noted that the panel was to limit its discussion to the guidance, not the regulations, and distinguished between regulatory and guidance language.

Members of the Committee had no questions or comments on the majority of questions. On page three, question 1, regarding charges to patients for hardcopies of FFDM exams, there was extensive discussion of the cost to facilities to maintain printers that can produce readable hard copies of FFDM results versus the right of a consumer to obtain films in hard copy. While it was noted that consumers can be given electronic or CD copies, other Committee members stated that many facilities cannot read or compare such versions at present. There was no objection to the question as written, but the Committee noted this issue would have to be revisited in the future.

On page 3, question 4, regarding negative mammograms with positive clinical findings, there was general agreement that the answer was reasonable as stated, but it was noted that such circumstances should not be described as “rare.” On page 5, question 3, it was noted that mammography records will fall under the Health Insurance Portability and Accountability Act regulations. These regulations, which are currently under discussion, will have an impact on mammography record retention as well also the storage, confidentiality, and transmission of FFDM data.

On page 8, line 42, the committee recommended a change to state that the MQSA certificate should be displayed until the facility actually ceases operations. There was

considerable discussion about enforceability of these provisions and about the problem of seeing that facilities are closed responsibly, with records kept available to consumers. It was suggested that wording about responsible transfer of medical records and consumer notification be added. There were no further changes suggested.

### **Facility Satisfaction Survey**

**Nancy Wynne, Chief of the Outreach and Compliance Branch**, reviewed the history of the survey, which was first performed in 1997. That survey obtained a good response rate and showed a high level of satisfaction with the inspection process. A follow-up survey was begun in the Fall of 2000. It was done by an outside contractor that surveyed a geographically representative sample of 10% of currently existing facilities. Review of preliminary data shows generally high levels of satisfaction with the overall inspection. Most facilities were pleased with the inspection timeframe, saying it took an average of 10 hours for preparation and six hours for the inspection to be completed. The inspection impacted on patient care in that an average of 9 patients had to be rescheduled to accommodate the inspection. Ms. Wynne added that the survey showed that hardcopy materials sent to the facility by FDA were more widely used than information put out by the FDA on its website. This suggests that the FDA should focus on encouraging facilities to use the website more.

Next steps include analyzing the data in depth, comparing this information with previous survey results and then using this information to make improvements in the inspections. Ms. Wynne said that the results of the survey would be posted on the website after the first of the year.

## **Mammography Access Issues**

**Helen Barr, M.D., Deputy Director of the Division of Mammography Quality and Radiation Programs**, informed the Committee that the Division is contracting with an outside firm to look at the issue of long waiting times to obtain mammography appointments and decreased access to mammography facilities in particular regions of the country. She noted that data from the facility satisfaction survey indicates that facilities are now averaging 21 mammograms per day, compared to 16 in 1997. Dr. Barr reported a 2% decline in fully certified mammography facilities since 1996. The Division is also collecting information on where and why closures of facilities are occurring.

**Priscilla (Penny) Butler, Director of the Breast Imaging Accreditation program of the American College of Radiology (ACR)**, discussed mammography facility closures, noting that the ACR occasionally learns of closures after the fact or indirectly. She outlined ACR's facility closure procedures and noted that since April 2001 the ACR has started manually tracking the reasons for closures. Opening of new facilities is not keeping pace with closures, at the rate of 83 new and 252 closed facilities, with the primary known reason for closure apparently being financial. One impact of these closures on patients is that patients are having difficulty accessing old films for comparisons from these closed sites, even though the ACR is working with the FDA to notify facilities of their obligations after closure. Ms. Butler concluded that the ACR would continue to collect these data and monitor the trends over time, sharing the information with FDA.

**Mr. Camburn** suggested that the number of mammography units also be tracked over time because some states have lost facilities but their total number of mammography units has

increased. **Dr. Lee** suggested that the data be analyzed to see if closure is a regional phenomenon or a national one. **Dr. Pisano** applauded the tracking effort, and expressed concern about the shortage of radiologists nationwide and the lack of incentives for newcomers to enter the field of breast imaging. Other members of the Committee mentioned both litigation and financial disincentives as deterrents to workforce development. Both **Dr. Ramos-Hernandez** and **Ms. Brown-Davis** expressed concern over the gap between those women who can get services and those who are in rural and underserved populations.

Observing that many of the trends mentioned are not unique to radiology or mammography but apply to medicine in general, **Dr. Finder** asked the Committee for suggestions that the FDA could implement. Suggestions included making the inspection less burdensome by paring some regulations at each step and carefully considering any new regulations or fees. The analysis of the facility satisfaction survey was lauded as a good step, as was the demonstration project of inspecting facilities every other year. Greater use of automation and use of less people-intensive functions were suggested to make quality assurance less burdensome. Shorter inspections and consolidated, centralized personnel information were also mentioned. It was noted, however, that quality should not be sacrificed and that this is an evolutionary process to get the greatest return on money and time spent to ensure quality mammography for all.

### **Inspection Demonstration Project Update**

**Dr. Helen Barr, Deputy Director of the Division of Mammography Quality and Radiation Programs**, explained the background of the inspection demonstration project, which was authorized under MQSRA in October 1998. She outlined the goals and

requirements of the program, which seeks to reduce MQSA inspection frequency for high performance facilities while maintaining quality. She explained the program's consultative approach and outlined state and facility criteria for participation. All 50 states were asked to participate, and some 14 agreed, although participation is limited to no more than 10% of a state's facilities. One limitation of the project is the voluntary and limited nature of facility participation, which means that the sample is not truly random or statistically valid. Because of this, the program must see what the significance of the descriptive statistics will be and what the applicability of results will be nationwide. Dr. Barr described the timelines through May of 2002, when the demonstration program will be implemented.

Committee discussion focused on cost and outcome measures of the program. The idea of shorter inspections occurring more frequently was suggested, although analysis of the cost savings proved to be not as significant as with the proposed plan.

### **Full-Field Digital Mammography (FFDM) Accreditation**

**Ruth Fischer, MHSA, Chief of the Accreditation and Certification Branch of the Division of Mammography Quality and Radiation Programs**, presented background on full-field digital mammography (FFDM), noting that the first such device was approved on January 28, 2000. Under the MQSA, a facility must be accredited before it can be certified, but there is no accreditation program for this new mammographic modality. Until an accreditation program is available, FFDM can only be used in previously accredited and certified film-screen facilities, which must document certain training and equipment standards.

**Penny Butler of the ACR** discussed the FFDM accreditation module, noting that the draft accreditation testing protocols and forms were devised by the ACR's Subcommittee on

FFDM. A pilot test of the module was done in Spring 2001, and Ms. Butler described its goals. She explained the need for a different protocol for each manufacturer's unit because, for example, the exposure control mechanism is different for each manufacturer's FFDM system and the instructions for phantom exposure must be unit-specific. Ms. Butler listed the tests for technologists and medical physicists for the current unit, saying that some are the same as those in the ACR's film-screen quality control (QC) manual, although many are specific to the FFDM unit. The pilot test looked at 10 GE units. Facilities found the application and testing instructions generally easy to follow, although some revisions to the forms are needed. ACR must now develop separate accreditation packages for each manufacturer as the new models become available, are granted FDA approval, and are pilot tested. Ms. Butler stated that the accreditation module has been approved by the ACR's Committee on Mammography Accreditation and is now undergoing review by ACR's Council Steering Committee. This could happen by the end of September. At that time the package will be sent to FDA for review. The final approval comes with ACR's Executive Committee of the Board of Chancellors. When it has been approved, the ACR will work with the FDA to advise facilities of the appropriate process for accreditation.

#### **States as Certification Agencies—Update**

**Kaye Chesemore, M.B.A., of the Accreditation and Certification Branch of the Division of Mammography Quality and Radiation Programs**, updated the Committee on the States as Certification Agencies Demonstration Project, which is in its third year. Both Iowa and Illinois are serving as demonstration project certification agencies. FDA retains oversight authority to ensure nationwide consistency. The FDA also provides feedback to states through

quarterly and annual summaries and annual site visits. FDA evaluates key indicators such as the state's technical staffing and training, the state's information system's capability and application, the inspection and compliance activity, and the percent of certificates promptly issued. The FDA is currently revising its performance evaluation instrument and looks forward to other states joining the project. In answer to a Committee question, Ms. Chesemore clarified that participation is not voluntary for facilities in the two participating states.

### **Future Direction of the MQSA Program**

**Dr. Finder** asked the Committee for guidance on future directions. **Ms. Harvey** suggested briefer inspections in which the inspectors look at a sample of completed images. **Mr. Camburn** stated that contrary to some States, Michigan inspectors were not radiologic technologists and did not have training in review of clinical images. **Dr. Young** suggested focusing on continuous quality improvement rather than reviews of paperwork. **Dr. Karellas** suggested an emphasis on increasing efficiency rather than increasing amount of work. The Committee strongly recommended looking at the issue of access to mammography for women throughout the country. **Ms. Ellingson** also suggested looking at quality control technology.

### **REVIEW OF SUMMARY MINUTES**

The Summary Minutes of the September 2000 meeting were reviewed. It was noted that radiology technologists should not be referred to as technicians. **Dr. Finder** set no specific future meeting dates but asked the panel for preferred days of the week. Any day but Friday was acceptable. **Dr. Finder** also thanked Committee members **Kambiz Dowlatshahi, M.D.**, and **Carolyn Brown-Davis, B.A.**, whose terms will end in January 2002, for their years of service to the Committee.

**Ms. Harvey** thanked the Committee and the audience, and the meeting was adjourned at 3:30 p.m.

I certify that I attended the Open Session of the National Mammography Quality Assurance Advisory Committee Meeting on August 22, 2001 and that this summary accurately reflects what transpired.

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Charles Finder, M.D.  
Committee Executive Secretary

I approve the minutes of this meeting as recorded in this summary.

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Maryanne Harvey, M.S.  
Committee Chair

Summary minutes prepared by  
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