

SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE

January 31, 2000

**Gaithersburg Hilton
Two Montgomery Village Avenue
Gaithersburg, MD 20877**

**National Mammography Quality Assurance Advisory Committee
January 31, 2000**

Attendees

Committee Chair

Barbara Monsees, M.D.

Executive Secretary

Charles Finder, M.D.

Attendees

Kambiz Dowlath, M.D.

Kendra J. McCarthy, M.A.

Laura Moore-Farrell, M.D.

Robert J. Pizzutiello, Jr., M.S.E.E.

Edward A. Sickles, M.D.

Patricia Wilson, R.T., RDMS

JANUARY 31, 2000--OPEN COMMITTEE DISCUSSION

Committee Chair Dr. Barbara Monsees, opened the meeting at 9:25 a.m. Executive Secretary Dr. Charles Finder, welcomed participants and read the conflict of interest statement, announcing full waivers for 15 of the 17 Committee members because of their financial involvement with accrediting bodies, manufacturers, and professional societies. Some of these participants had received lecture compensation in their areas of specialization, but these were general fees for professional expertise only. He also noted that Drs. Sickles and Dowlat and Mr. Pizzutiello would not vote on specific equipment questions to prevent any possible conflict of interest. Dr. Finder announced that if there was any discussion of States as Certifying Bodies, it would be a general discussion only with no vote, and all state representatives could participate. Dr. Monsees asked the Committee members to introduce themselves.

APPROVAL OF ALTERNATIVE STANDARDS REQUESTS

Dr. Finder stated that since the last meeting in July, the Division had received several requests for alternative standards procedures that equal or exceed those set by the FDA and that one had been approved. The alternative described a procedure for performing daily processor QC when the facility did not have the use of a sensitometer for a short period of time. Notice of this approval had appeared in *Mammography Matters* and on the FDA web site as well.

OPEN PUBLIC HEARING

A letter from **Dr. Benjamin M. Galkin of the Institute for Mammography Research, Inc.** was read, in which Dr. Galkin reminded the Committee of a potential problem with the poor sensitivity of the current phantom-disc image quality test. He notified the

committee that he was performing a study to determine the extent to which changes in imaging parameters and patient dose go undetected by use of the current test.

OPEN COMMITTEE DISCUSSION

Inspection Demonstration Project

Mr. John McCrohan, Director of the Division of Mammographic Quality and Radiation Programs, discussed plans for an inspection demonstration project required by the Mammography Quality Standards Reauthorization Act (MQSRA). He summarized the regulatory background of the Mammography Quality Standards Act (MQSA) and of the MQSRA, which added, among other items, a requirement that the Agency look at amending the frequency of inspections. A number of groups had testified during the MQSRA hearings that annual inspections were overly burdensome. The MQSRA called for a demonstration project, limited to high quality facilities to determine the efficacy of performing less than annual inspections.

As data supporting the inspection demonstration project, Mr. McCrohan summarized MQSA inspection findings, showing that there a number of facilities without inspection findings over multiple years. He outlined the goals of the demonstration program, which sought to comply with MQSRA in evaluating whether the frequency of inspections can be reduced while still maintaining quality. The demonstration project will be designed to be consistent with state, regional, and federal regulations and to survey a few hundred facilities nationwide using biennial inspections for a study group and annual inspections for the control. Mr. McCrohan outlined the demonstration project's proposed timeline, from initiation of the program design in 1999 to

submission of the preliminary report to Congress in 2005. He also requested committee input regarding a series of questions about the proposed program set-up. These included the adequacy of the selection criteria, whether the program should be nationwide or limited, program duration, and the period of time (12 or 24 months) the facility should be inspected against.

Panel comments ranged from Mr. Pizzutiello's suggestion that the inspection period be two years, with spot checks using a normal inspection protocol to see if the facility has been consistently in compliance over a two-year period, to Dr. Sickles's suggestion that the program be set up as a template for the final program, with a one-year inspection. Dr. Monsees asked about systems for tracking and analyzing personnel data and whether there was a financial incentive for states not to participate, which would create the possibility of introducing bias in the study. There was panel consensus that the inclusion and exclusion criteria were appropriate. It was recommended that the control group should be a subset of the total eligible facilities and that the inspectors should not know whether a facility was in the control group. Dr. Sickles recommended that the demonstration project duration be as long as possible, even for two cycles, as this length would be even more attractive to facilities. Mr. McCrohan reminded the panel that some new personnel requirements will be implemented in 2001 and that in the past, each time a new requirement is implemented, there has been an increase in the number of facilities failing to meet these new requirements. This will have to be factored into the demonstration project.

Discussion of the Proposed MQSA Guidance under the Final Regulations

Dr. Finder gave an introduction to the proposed MQSA guidance, noting that the FDA is following established regulatory procedures for gathering general input on FDA guidance. He noted that the panel was to discuss the guidance, not the regulations, and distinguished between regulatory and guidance language.

Mr. Pizzutiello asked if the requirement described on page 6 of Compliance Guidance - The Mammography Quality Standards Act Final Regulations Quality Assurance Documentation, namely that logs or charts on infection control be kept when blood or infectious material is involved is new. Dr. Finder replied that it is not new; the regulation says the facility must not only comply with the procedure but also document the procedure when blood or other infectious agents are involved. Regular cleanings between each patient do not have to be logged. Mr. Pizzutiello recommended that this clarification be publicized in *Mammography Matters*, and the panel agreed.

Ms. Wilson asked why a separate protocol is required for blood contact when the standard operating procedure is to clean and disinfect the equipment after each use in any case. She and Dr. Monsees found this illogical and burdensome. Dr. Sickles thought it not burdensome in cases of blood contact, but potentially burdensome in cases of non-intact skin. Dr. Finder said he would investigate this issue.

In Compliance Guidance Document #3, the December 8, 1999 draft, Mr. Pizzutiello recommended that the Committee on Accreditation of Medical Physicists Education Program (CAMPEP) be mentioned in the discussion of certifying bodies that can approve non-U.S. institutions for medical physicists. This is not an FDA-approved certifying body but was created

by three professional bodies or groups of physicists. Dr. Finder agreed to look into adding it to the proposed guidance.

On page 11, Mr. Pizzutiello noted that tapping the foot pedal is not a fine adjustment, however, others on the committee believed that this did constitute fine adjustment. On page 12, Dr. Monsees recommended moving the word “not” so that the question being asked would read as “What documentation should facilities have to show that their mammography compression paddles were designed to not be flat and parallel.” On page 22, Mr. Pizzutiello and Ms. Wilson recommended changing the word “can” to the word “may” in the phrase facilities “can/may adjust their typical clinical technique factors.”

Dr. Finder noted that public comment period is still open, and that *Mammography Matters* has publicized the document and its comment period.

On the NMQAAC Discussion Questions and Answers of January 31, 2000, a document not previously discussed, Dr. Finder noted that these questions will be available for additional public comment before they become final guidance.

In line 15 of page 1, Dr. Sickles suggested that the wording be changed to “an” abnormal physical exam to make the context more generic. On page 2, lines 7-15, it was recommended that what constitutes a major repair should be specified, with a citation to the guidance and regulation reference.

A comment from Penny Butler of the American College of Radiology recommended that language about removing the disk should be removed because accreditation bodies no longer recommend removing the disk. She will submit language to the FDA.

On page 4, line 7, Mr. Pizzutiello noted that establishment of new processor operating levels is a common problem often handled inappropriately. He recommended that line 18 state the facility should only reset the values after consultation with a medical physicist. He also recommended that the consultation be noted in the facility's records. Ms. Butler noted that this guidance is in conflict with the ACR quality control manual, and the list in that manual should be used. Mr. Pizzutiello suggested a reference to that manual and other sources of good information. The FDA agreed that the establishment of new operating procedures can be problematic and will consider adding the proposed suggestions to the guidance.

On page 5, line 1, it was recommended that it be noted that having a written preliminary equipment evaluation report is adequate for this reporting requirement. On line 7, Dr. Sickles and Dr. Monsees thought it reasonable to use the category "negative" for post-lumpectomy patients whose mammograms are otherwise negative. On p. 5, line 20, Dr. Sickles recommended inserting a statement that ultimately the facility, not the interpreting physician, has the responsibility to see the whole process described in the regulations is instituted.

Concerning page 6, lines 21-25, there was considerable discussion on testing at various thicknesses, and it was suggested by Ms. Butler that this guidance should be consistent with ACR quality control manuals.

Regarding page 7, Mr. Pizzutiello stated that because replacing the Bucky assembly is a major and rather infrequent repair, he recommended that the medical physicist should evaluate it. He also recommended explaining, in the guidance document, what is an AART (M) certificate.

Regarding the table on page 8, the panel suggested fine-tuning the wording regarding units designed for special situations or for special views and noting that this equipment still has to go through accreditation tests. It was suggested that the clinically relevant combinations of screen film and screen speed should be tested.

Concerning the table on page 9, Mr. Pizzutiello commented in general that anything with a significant impact on image quality needs more medical physicist involvement. He and Dr. Sickles agreed that the AEC adjustment categories should be left to the professional judgment of the medical physicist, although Dr. Finder noted that, by regulation, a major repair means that a medical physicist must be present. Mr. Pizzutiello and Ms. Butler of the ACR recommended creating a new category in which medical physicists are consulted when these repairs are not considered major. Ms. Butler noted that, in the past, ACR developed, in conjunction with FDA, a table describing those items considered to be major repairs. Mr. Pizzutiello offered to help revise FDA's proposed guidance in the area of medical physicist involvement following equipment repairs. Dr. Monsees and Dr. Sickles suggested that the FDA develop a more extensive list identifying those repairs considered major (requiring verification by an on-site medical physicist) and those which are not major repairs but require some form of oversight by a medical physicist.

Dr. Finder presented plaques and letters of appreciation to outgoing panel members; Dr. Moore-Farrell, Ms. Wilson, and Dr. Sickles.

Update on Full Field Digital Mammography Certification

Dr. Helen Barr, Deputy Director of the Division of Mammography Quality and Radiation Programs at FDA, noted that the General Electric (GE) Senograph 2000 full field

digital mammography (FFDM) system had recently been cleared for marketing by FDA's Office of Device evaluation, after five years of work. She reviewed the regulatory history of FFDM. At the present time, no accreditation bodies exist to accredit FFDM. Under these conditions, the FDA is requiring that FFDM units only be used in certified screen film facilities as an interim method of assuring that qualified personnel and adequate quality control procedures are used. GE was told that until accreditation bodies develop an accreditation process, FFDM can only be used in FDA certified screen film facilities. Dr. Barr listed the information FDA is requiring of facilities to extend their screen film certification to include their new FFDM units.

American College of Radiology (ACR) Accreditation Activities

Priscilla Butler noted that it will take time to develop accreditation standards for FFDM. ACR's digital subcommittee of the Mammography Accreditation program is now designing a pilot program and is currently developing and testing administrative and technical tools, as well as FFDM clinical tests for the pilot. She estimated that results of the pilot accreditation program would be ready in 18 to 24 months. Dr. Sickles stated that the real utility of FFDM will be with soft-copy views, so he thought that ultimately using hard copy is not the most effective means of accreditation.

Update on States as Certifiers

Ruth Fischer, M.H.S.A., Chief of the FDA Mammography Standards Branch, gave an update on States as Certifiers, noting that Texas is expected to join the program sometime this year. She added that adequate staffing is critical, and some changes in the final regulatory program may be made based on the demonstration project. The proposed regulation

is at the Office of Management and Budget and should be published in the Federal Register for public comment in April.

Update on Voluntary Stereotactic Accreditation Programs

Priscilla Butler of the American College of Radiology discussed progress made on the joint accreditation program of the American College of Surgeons and the American College of Radiology. Some 473 facilities have applied for accreditation through the ACR, and 365 have been accredited. She stated there had not been a tremendous influx of applications.

Dr. Finder read a **letter from Dr. Winchester from the American College of Surgeons** in which he listed the accomplishments during 1998-99. Three facilities were accredited out of 200 applications, although it was noted that some surgeons were accredited through the ACR's program. Dr. Dowlat and Mr. Pizzutiello commented that some surgeons and medical physicists are reluctant to go through a burdensome administrative process and there is not a great incentive to self-regulate. There was some discussion of FDA intentions regarding federal regulation. Dr. Moore-Farrell brought up the point that in some cases, the fact that the whole facility has to be accredited as one entity can be an impediment to accreditation because failure of any one individual to comply with accreditation requirements means that the facility cannot be accredited.

Mr. Don Flater of the Iowa Department of Health described the accreditation program his department developed in Iowa. Currently, all Iowa stereotactic units are now in the accreditation program.

Final Regulations—Early Inspection Findings

Dr. Walid Mourad of the **FDA's Inspector Support Branch** described the background of the Interim and Final Regulations. He reported on the frequency of finding levels and the breakdown of individual inspection findings under the final regulations. He said that there has been an increase in the total number of findings, which are believed to be a result of changes in requirements due to the final regulations. Dr. Mourad reviewed the most serious findings, noting that the increase in numbers is due to the FDA's tightening of the standards. He briefly reviewed some issues involving inspection software and inspector guidance, average inspection times, and FDA action in identifying and correcting erroneous inspection findings. He also advised the committee about future inspection issues including a look at repeat findings scheduled for July 2000, a review of the demonstration project on inspection frequency, and possible expansion of the questions on FFDM from what currently exists in the inspection software.

Both Dr. Monsees and Mr. Pizzutiello commended FDA on the development of the policy guidance search engine, but recommended that the guidance be updated more frequently. Mr. McCrohan addressed the issue of timeliness of release of guidance by briefly reviewing the process guidance must go through before it can be incorporated into the search engine.

REVIEW OF SUMMARY MINUTES

The Summary Minutes of the July 1999 meeting were reviewed. No comments or changes were made.

Possible future meeting dates were discussed. Due to problems inclement caused with attendance at this meeting, it was suggested that future meetings not be scheduled during the

Winter months. The next meeting would probably be held in the Fall of 2000. Committee members were asked to send issues for the next meeting to Committee Chair Barbara Monsees or Executive Secretary Charles Finder.

Dr. Monsees thanked the Committee and the audience. The meeting was adjourned for the day at 3:00 p.m.

I certify that I attended the Open Session of the National Mammography Quality Assurance Advisory Committee Meeting on January 31, 2000 and that this summary accurately reflects what transpired.

Charles Finder, M.D.
Committee Executive Secretary

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

Barbara Monsees, M.D.
Committee Chair

Summary minutes prepared by
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