SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE MEETING

Open Session

September 29, 2006
Atrium Court Hotel
Rockville, MD

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COMMITTEE PARTICIPANTS

Carolyn B. Hendricks, M.D.	Chair
Jeffrey W. Byng, Ph.D.	
Scott Ferguson, M.D.	
Jacqueline S. Holland, R.N., C.R.	
Philip Z. Israel, M.D.	
Debra L. Monticciolo, M.D.	
Carol J. Mount, R.T. (R)(M)	
John M. Sandrik, Ph.D.	
Jane B. Segelken, B.S., M.A.	
Julie E. Timins, M.D.	
Margaret S. Volpe, M.B.A.	
Mark B. Williams, Ph.D.	

FDA PARTICIPANTS

Nancy Wynne	Committee Executive Secretary
Charles Finder, M.D.	Associate Director, Division of Mammography Quality and Radiation Programs (DMQRP)
Kish Chakrabarti, Ph.D.	Office of Device Evaluation
Michael Divine	Chief, Inspection and Compliance Branch, DMQRP
Walid Mourad, Ph.D.	Information Management Branch, DMQRP

CALL TO ORDER

Committee Chair Carolyn B. Hendricks, M.D., called the meeting to order at 8:05 a.m. **Executive Secretary Nancy M. Wynne** read the conflict of interest statement. Waivers were granted to Philip Z. Israel, M.D.; Julie E. Timins, M.D.; Mark Williams, Ph.D.; and Carol J. Mount, R.T.(R)(M).

COMMITTEE BUSINESS

Dr. Hendricks welcomed Dr. Israel to the panel and asked him to introduce himself. She then noted that standards related to revocation, accreditation, and accreditation body approval had been reviewed the previous day.

OPEN PUBLIC HEARING

D. David Dershaw, M.D., FACR, American College of Radiology and the Society of Breast Imaging, said that the two organizations he represents support regulation of stereotactic breast biopsy under MQSA and propose use of the voluntary ACR accreditation program for that purpose. It was modeled after the ACR mammography accreditation program which served as the basis for the FDA regulatory program. It assesses personnel, equipment, and clinical performance and includes a quality control program.

The personnel qualifications establish a minimum level of training and experience, both initially and on a continuing basis. The clinical image evaluation looks at the relationship of the biopsy probe to the targeted lesion. This may be determined at least partially by the equipment used, and the program does not mandate particular equipment. The assessment of phantom images and dose criteria is similar to that in the mammography program. The program requires

facilities to perform quality control testing at specific intervals as laid out in its quality control manual.

Reviewers of images and phantoms must be ABR certified as well as ACR members. There is a formal training program and a quality control program for reviewers. All are in clinical or physics practice in the U.S., and they are not permitted to review facilities within their own states.

Over the past five years there has been gradual improvement in the number of facilities and units accredited and in the percentages that pass renewal. Approximately two thirds of failures are due to suboptimal clinical imaging. A paper published by Levin, et al. based on CMS data shows that most of the increase in breast biopsies, imaging-guided and otherwise, can be attributed to an increase in procedures performed by radiologists. Seventy-two percent of imaging-guided biopsies are currently performed by radiologists, who are responsible for 79 percent of the increase in biopsy performance from 1999 to 2004. In 2004, 86 percent of all biopsies performed were imaging-guided.

The available data does not clearly indicate how many of the image-guided biopsies are stereotactic, but it is estimated that stereotactic procedures account for slightly less than half, or around 50,000 procedures in 2004.

Dr. Byng asked about the total number of units and facilities that do biopsies, and Dr. Dershaw said it was nearly impossible to get such information because of the diverse nature of the health care system.

Dr. Israel asked if Dr. Dershaw supported the National Approvals Program for Breast Centers being developed by ACR and ACS. Dr. Dershaw stated that if a mandatory program

was to be put in place, the program he outlined should be a part of it and that other programs should not compromise accreditation programs already in place.

OPEN COMMITTEE DISCUSSION

Definitions - 900.2

Charles Finder, M.D., Associate Director, Division of Mammography Quality and Radiation Programs, led the discussion. Regarding the first footnote, the committee felt there should be definitions added for unit and facility accreditation and reaccreditation. Under Footnote two, the committee also felt a definition should be added for audit interpreting physician. Similarly for Footnote three the committee supported a definition of automatic exposure control. Noting that it was already defined in manufacturer performance standards, Dr. Sandrik hoped the definitions would be the same. Dr. Finder thought that would probably be the plan.

For Footnote four the committee felt a definition should also be added for automatic exposure control mode. Footnote five asked whether residency and fellowship training should be specifically mentioned with regard to category I training for interpreting physicians; the committee's consensus was yes. With regard to Footnote six, the committee felt that the definition of certificate should be expanded to describe the four kinds, full, provisional, temporary renewal, and limited provisional. Dr. Byng asked whether this would just move the definitions from 900.11 forward. Dr. Finder said that was true except that two new types of certificates were added by a change in the statute.

Footnote seven asked whether a definition should be added for corrective actions required following failed quality control tests, and the committee again answered in the affirmative.

Footnote eight asked whether final interpretation should be defined. Dr. Timins argued that the term is self-explanatory. Dr. Byng thought there might be a connection with digital soft copy images, and Ms. Volpe pointed out that consumers and members of the public would not necessarily understand the term. The vote was split. Dr. Finder said the issue had to do with the transfer of images and what constituted an image of final interpretation quality particularly for digital ones.

Regarding Footnote nine, whether hard copy image should be defined, the committee said yes. Dr. Sandrik suggested that the concept should be spelled out rather than simply defining it in terms of existing technology. Dr. Finder said they had, in previously issued guidance, attempted to do just that for both hard copy image and final interpretation and asked Dr. Sandrik to look at them and make any suggestions for improvement.

For Footnote ten, the committee felt that definitions for lossy and lossless compression should be included. Footnote eleven addresses whether the definition of mammogram should be expanded to address digital mammography, digitization of screen film mammograms, and the algorithms used in manipulation and compression of digital images. Dr. Finder highlighted two issues: whether manipulated images become copies or degraded portions of mammograms and whether digitized film screen mammograms can be retained and the originals destroyed. Dr. Sandrik proposed the concept of a primary and secondary mammogram where the primary can be linked to the original data and the original acquisition process. The committee felt the definition should be expanded.

Footnote 11 asked whether mammographic examination should be defined. Dr. Finder said it concerned the issue of counting images for the initial or continuing experience requirements. The current guidance is that a screening and diagnostic procedure for a single

patient on one day can be counted as two separate exams and that a single view of a single image counts as an exam. The consensus was that it should be defined.

The next issue was whether the term mammographic modality should be modified to include full field digital, tomosynthesis, or breast CT and to exclude xeromammography. Dr. Timins was hesitant to include tomosynthesis and breast CT given that they do not represent the current standard of care. Dr. Finder noted that the question was related to another, concerning whether these procedures should be regulated under MQSA at all. He said the issue was if it was decided to regulate these modalities, would the same eight hours of training be required of those who perform the procedures.

Dr. Timins said there are not guidelines for the performance and interpretation of tomosynthesis or breast CT and so she would not recommend including them in the regulation. Dr. Sandrik said that first the term modality must be defined. The committee said the definition should not be modified. Dr. Hendricks wondered whether digital but not tomosynthesis or breast CT should be included. Dr. Williams suggested they could replace xeromammography with small field of view digital. Dr. Finder rephrased the question and asked whether xeromammography should be removed from the definition, and the committee said yes. He then asked whether full field digital should be included, and the committee said yes.

Footnote 14 asked whether the exclusion for interventional should be deleted from the definition for mammography, which would mean that interventional mammography would be regulated under MQSA. The vote was somewhat split with the majority not in favor of deleting the exclusion. Dr. Timins expressed a desire to regulate stereotactic biopsy, and Dr. Finder said they would ask about that in a separate question. Dr. Israel discussed his efforts over the past fifteen years to incorporate stereotactic breast biopsy into standard practice. He said the

technique has kept women out of the operating room by allowing diagnosis through minimally invasive surgery. He said there should be accreditation and quality assurance but thought it should be left to the professional medical organizations rather than be regulated by FDA.

Ms. Volpe asked whether wire-guided procedures should be included. Dr. Finder said needle localization is included in interventional and would be excluded based on the committee's preliminary vote and that there is no established accreditation program for needle localization. Dr. Williams thought some needle localizations were done with stereotactic guidance, and Dr. Finder agreed. Dr. Israel mentioned newer technologies on the horizon and suggested it might be hard to draw a line. Dr. Timins argues that stereotactic is different from needle localization in that there is a much greater need for quality control of the imaging with stereotactic.

Dr. Monticciolo agreed and said that those performing needle localization and the equipment used were already fully regulated by FDA. Dr. Finder noted that FDA does not regulate mammographic units used strictly for needle localization. Dr. Monticciolo imagined that would not be a very common situation. Dr. Finder said they did not have any data but knew anecdotally that there were unregulated units devoted to interventional mammography. Dr. Timins noted that for obvious lesions the same image quality would not be necessary so older units might be used.

Dr. Hendricks expressed concern that the pass rate for the ACR stereotactic accreditation program was only 60 percent for best image. Dr. Finder said that issue had been raised before and noted that even though the images may have failed the ACR stereotactic accreditation program review, the actual biopsy probably did yield positive pathology results. Unfortunately, the ACR process does not collect that type of data. He said another consideration was whether the focus should be more outcomes-based if FDA goes ahead with regulation of interventional or

stereotactic. Dr. Timins said quality review for breast biopsy should include concordance of findings.

Dr. Hendricks asked whether the ACR data looked at accuracy of clip placement in a targeted lesion. **Penny Butler, American College of Radiology,** said the images were assessed with regard to needle placement. Most failures had to do with the needle not really being close to the lesion. Dr. Ferguson asked what category the first attempt deficiencies were in. Ms. Butler said that about a third were technical failures and the rest were clinical problems. Dr. Ferguson asked how many failures involved submitted images showing the needle in the wrong place. Ms. Butler said it does happen but on repeat testing they pass.

Dr. Monticciolo asked what percentage of facilities fail, and Ms. Butler said just under 35 percent. Dr. Hendricks stated that the failures at best effort where the lesion was not targeted will have a clinical impact. Dr. Timins said that the quality of mammography had improved dramatically since MQSA and suggested that similar improvements could be achieved for stereotactic biopsy with regulation.

Dr. Byng asked about the scope of the quality problem. Dr. Israel said that one universal measurement of quality is litigation and that the litigation rate for stereotactic biopsy is exceedingly low compared with mammographic interpretation. Dr. Finder said that the rate of missing lesions at biopsy, whether surgical or stereotactic is probably around two percent. Dr. Israel thought that was probably correct. Dr. Timins noted that stereotactic and needle procedures can also be used to confirm a highly suspected malignancy just prior to surgery. She also noted that there are many factors which affect clip placement and so it is not as crucial to a determination of quality.

Dr. Finder asked if the exclusion for interventional should be deleted. The vote was split with more toward no. He then asked if stereotactic biopsy should be regulated. The vote was again split but most members said yes.

The next issue dealt with mammography system components. For film screen, an equipment evaluation must be performed on new units and new processors. For FFDM, the question is whether all the various components must be evaluated by a medical physicist or whether a new category of equipment should be established that would be tested under medical physicist oversight.

Dr. Sandrik supported bringing the concept of medical physicist oversight from guidance into regulation but thought it was unnecessary and complex to subdivide systems into components. Dr. Finder said the guidance basically deals with at what level of repair of a system requires equipment evaluation. He also said that medical physicists were asking why they have to travel to run tests that could just as easily have been performed by someone else.

Dr. Williams said it was very well intentioned but would be quite difficult to specify. Dr. Sandrik said that the regulation requires mammography equipment evaluation for major repairs, and guidance defines what is and is not a major repair. Dr. Finder agreed but said the issue was new pieces of equipment, all of which currently require evaluation by a physicist. Dr. Mourad said the issue was whether unambiguous data could be provided to a physicist who is not there.

Dr. Timins supported the idea of medical physicist oversight and said the physicists were in the best position to determine if it is adequate for a technologist to perform a given test. Dr. Ferguson agreed and pointed out that the physicist is going to examine the equipment once a year anyway. Dr. Mourad also supported leaving the decision up to the physicist.

Regarding Footnote 16, Dr. Finder asked if the definition should be modified to specifically allow for medical physicist oversight, and the vote was in favor. For Footnote 17, should a definition be added for mammography system components, the vote was split but basically in favor. Regarding the addition of a definition for medical physicist oversight, the committee voted in favor of the addition.

Dr. Finder said that Footnote 18 addresses a clarification of the definition such that mean optical density be measured during the automatic exposure control (AEC) test in a given equipment configuration. The committee voted in favor of the clarification.

Regarding whether the definition of positive mammogram should be modified to include cases where biopsy is recommended, Dr. Finder said the issue had to with reporting requirements, which mandate that positive mammogram reports have to go out as soon as possible as opposed to the 30-day requirement for other than positive findings. Also, positive mammograms must be included in the medical outcomes audit.

Dr. Timins asked for clarification of the BIRADS. Dr. Hendricks noted that many reports say the decision to biopsy should be based on clinical grounds only and wondered if all those mammograms would be included as well. Dr. Finder said that some reports say that you can biopsy if you feel like it or not. Dr. Timins said she was hesitant to include anything other than BIRADS 4 or 5, suspicious or highly suspicious. The vote was split with more saying no.

The next footnote asked if the definition of qualified instructor should be modified to mandate additional instructor requirements for facilities undergoing corrective action. Dr. Sandrik asked if the there was indication that facilities get into trouble because of the inadequacy of the original instructors, but Dr. Finder said that would be extremely difficult to evaluate because the original instruction could have been ten or twenty years prior. Dr. Timins said the

idea was fraught with difficulties and opposed it. Dr. Ferguson was concerned about timely availability of qualified instructors. The committee was not in favor of the modification.

The next two questions asked if definitions should be added for repeat rate and reject rate. Ms. Volpe was in favor of adding them for the benefit of consumers or others who might read the document. The committee voted in the affirmative for Footnote 22 and 23.

Footnote 24 asked about adding a definition for requalification so as to clarify the fact that it does not negate the responsibility to meet continuing requirements. The committee voted in favor. Regarding the addition of a definition for small-field digital mammography, the vote was somewhat split but basically yes.

Footnote 26 asked about adding a definition for soft copy image. Dr. Byng was concerned that the definition should encompass future technology, and Dr. Finder said that was their goal. The committee voted in favor of the addition. Footnote 27 proposed adding a definition for starting date, and the committee was in favor.

Footnote 28 asked if the definition of medical physicist's survey should be expanded to differentiate between unit and facility surveys. Dr. Sandrik wondered if it was necessary given that the regulation on surveys only identifies facility surveys. Dr. Finder said that unit surveys, while not defined, were referred to in the regulation. The committee voted in favor.

Footnote 29 proposed including a definition for technique factors, and the committee voted in favor of the addition. Dr. Sandrik noted that it already existed in federal performance standards and asked that it be the same. The next footnote asked if a definition should be added for "time frequencies for quality control testing, and Dr. Finder said the issue was whether the definition in the guidance should be put into the regulation. The committee again voted in favor.

Dr. Finder asked if anyone had any additional proposals for definitions to add. Ms. Volpe suggested a definition for image receptor under Footnote 37. She also suggested adding definitions of craniolcaudal and mediolateral oblique, SID, and collimators.

Dr. Finder brought up a question from the audience about including a definition for CR systems, and he asked whether DR, the more standard FFDM unit, should also be defined. Dr. Williams spoke in favor of clarifying what CR and DR really refer to. Dr. Finder said that currently CR and DR systems are part of the modality of FFDM. The committee voted in favor.

Quality Standards - 900.12 b and e

Footnote 74 asked if it should be required that all digital components be approved or cleared specifically for mammographic use. Dr. Mourad suggested that some components but not others should require approval. Dr. Sandrik said it would not assure that the components would be compatible and provide the quality expected to meet standards. He said it also would not result in all components having a quality control plan included with them. Dr. Timins thought that requiring all components to be cleared was not a good idea. Dr. Monticciolo agreed as well.

Dr. Finder suggested that receptors, monitors, and printers would require approval and asked about digitizers, assuming digitization is allowed. Ms. Mount said they should be at least to the extent of requiring a certain resolution. Dr. Byng said it depended on the intent of the digitization, and Dr. Finder agreed that it was only important insofar as it impacts interpretation or patient care.

Dr. Finder asked if image receptors should require approval, and the committee said yes. Dr. Ferguson asked how specific an approval was intended. Dr. Finder said it could either be

approval by the Office of Device Evaluation or through setting standards that the components would have to meet. He said that they did not want a requirement that would preclude the use of different equipment that was cheaper and more beneficial. He also noted there was always the possibility of an alternative standard.

Noting that displays used to be part of FFDM systems but increasingly come from third-parties, **Kish Chakrabarti, Ph.D., Office of Device Evaluation**, said it was important for displays to be subjected to some level of scrutiny. Dr. Finder said the only requirement under MQSA for monitors and printers is that they meet the quality control standards of the image receptor manufacturer. Dr. Chakrabarti said that monitors and printers must have the same specifications and performance as the manufacturer's original component.

Dr. Finder asked if they should include a requirement for monitors, and the committee said yes. Dr. Byng asked for additional clarification, and Dr. Finder said that manufacturers currently have to get their units and components approved by ODE, but there is no requirement in MQSA that only approved components must be used. Dr. Sandrik asked if it would be limited to ODE approval, and Dr. Finder said it would probably be either ODE approval or meeting some list of specifications. He also acknowledged the ongoing compatibility issues.

The committee voted in favor of requiring approval or clearance of printers. With regard to digitizers, the vote was split. For PACS, the committee was not in favor of requiring clearance or approval.

Footnote 75 asked if a unit converted from one modality to another should be considered a new unit for purposes of mammographic equipment evaluation and accreditation. Dr. Williams said tests of aspects of the unit pertaining to the tube and unit assembly would be redundant. He also thought an up-to-date physics inspection should stand. However, Dr. Williams said the

individual plates, scanner, reader, etc. should be evaluated, but he did not think it would be considered a new unit. Dr. Sandrik suggested the conversion could be considered a major repair based in image receptor replacement. Dr. Finder said working out the details would be problematic. He pointed out that a survey is not the same as an equipment evaluation and suggested that a equipment evaluation done ten years prior should perhaps be repeated.

Ms. Mount asked if a dual use unit would be accredited as two separate units, and Dr. Finder said that was correct. FDA suspects that dual use will not last very long as facilities tend to move to CR exclusively. Dr. Ferguson wondered if considering it to be a major repair would help facilities avoid fees. Dr. Finder said fees would be due anyway since the general consensus is that a mammography equipment evaluation would be needed.

Dr. Timins was concerned the additional cost of reaccreditation would discourage facilities from updating image receptors. Dr. Williams said reaccreditation was probably appropriate due to the impact of the image receptor on the overall image quality.

The committee voted in favor of considering converted units as new units. Dr. Williams said no with regard to equipment evaluation but yes with regard to reaccreditation.

Footnote 76 asked if a light should be required on all mammography systems. Ms. Mount said a light is very important and noted that the shadow of the breast on the receptor can determine prior to exposure whether or not one is missing any tissue. Dr. Byng asked if it had to be a light or merely have identification capability. Dr. Sandrik thought there could be a device that would serve the same purpose, perhaps by indicating the boundary, but not be a light in the conventional sense. Ms. Mount did not think a boundary would be as efficient at helping the technologist as a whole field. The committee voted in favor of the requirement. Dr. Finder

asked how many units would not meet the requirement, and Dr. Williams said he had not seen any.

With regard to Footnote77, the committee favored deleting the effective date. For Footnote 78, the committee voted in favor of clarifying technique factors. Dr. Sandrik said the technique factors were already stated in the rule and wondered if it needed to be repeated. Ms. Volpe was concerned about someone having to flip back and forth within the document.

Footnote 79 asked if configuration should be redefined to be contact, magnification and different sizes and exclude target filter combinations. Dr. Sandrik commented that it might be better to come up with what is meant by configuration rather than simply providing a list. Dr. Williams agreed but said some manufacturers have AEC for some target filter combinations but not others and thought perhaps there should be AEC for all combinations possible on a particular unit. Dr. Finder called for a vote; few voted, but those who did, did so in the affirmative.

The second part of the question asked if the range should be limited to 2-6 centimeters. Dr. Sandrik said that eight centimeters of acrylic is considerably denser than an eight centimeter compressed breast. Most studies evaluating composition versus thickness indicate such a breast is around 20 percent glandular and 80 percent fatty while the average breast is probably closer to 35 percent glandular. Dr. Williams said the ACR recommends going up to 8 centimeters and wondered if there were data available. Dr. Sandrik said a publication in *Medical Physics* by Kruger and Schueler, discussed the percentile ranges and average composition of the breast. According to the paper, eight centimeters of the BR-12 corresponds to the 99.8 percentile while eight centimeters of acrylic corresponds to more than the 99.9 percentile. They recommended that a more realistic recommendation would be to use the 90^{th} percentile, around 6.2 centimeters of BR-12 or 5.7 centimeters of acrylic.

Dr. Byng suggested referencing section 900.12 (e)(5). Dr. Finder said that section (b) deals with mammography equipment evaluation, which requires AEC testing under various configurations, whereas (e) deals with the annual survey which only uses one configuration. The committee voted in favor of limiting the range to 2-6 centimeters.

Footnote 80 asked if kilovoltage peak reducibility should be added. Ms. Volpe wanted it to be added to the definitions section as well. Dr. Sandrik asked if adding it here also implied deleting it from the QC test, and Dr. Finder said that was correct. The committee voted yes.

Footnote 81 asked if a similar requirement should be added for film used for hardcopy interpretations. Dr. Sandrik wondered if there was any way to verify it given that there is no clearance required for mammographic film. Dr. Finder said the same wording was already in place for x-ray film and presumed that it had served its purpose. Dr. Sandrik suggested that compatibility between printers and the film used was more of an issue. Dr. Byng did not think the proposed requirement would present any particular hardship but was not sure what it would accomplish. The committee voted against the proposed requirement. Dr. Finder then asked if something should instead be done to address compatibility between film and printer. The committee voted yes.

Footnote 82 asked if view box and room lighting conditions should be specified. Dr. Finder said it was more of an issue with digital than film and noted there had been debate around the issue when it was originally discussed relative only to film. Ms. Mount asked if the ACR had recommendations in place. Ms. Butler said the 1999 QC manual specified 3,000 candelas per meter squared for the view box and no more than 50 lux for ambient lighting conditions, but 10 lux has since been proposed. Dr. Byng noted that the current requirements had been in effect for some time and thought there were potential significant ramifications to implement a new

standard for viewing conditions. Dr. Williams said there was some literature indicating that users could adjust to a wide variety of viewing conditions and suggested a performance based requirement. Dr. Finder agreed there was not enough data to specify exactly what the numbers should be but thought the prevalence of mixed reading rooms made it important to do something. The committee's vote was split but mainly yes.

With regard to Footnote 83, the committee was split but overall supported requiring masking devices where hardcopy images are interpreted or compared.

Moving to section 900.12(e), Footnote 99 proposed adding a section setting specific requirements for FFDM and asked what tests should be included. Dr. Finder said that currently the required QC testing is determined by the manufacturer and that that system has worked fairly well. But as more FFDM units are introduced, it becomes harder to know exactly what testing needs to be done, so there has been a hope to create a universal set of QC procedures. He noted that people had thus far not been able to develop a universal QC manual, that it took 20-25 years for a universal QC manual for screen film mammography, and that there are four or five different technologies used in FFDM. The committee was split but basically in favor.

Dr. Hendricks asked if the ACR recommendations that were distributed were similar to what would be proposed. Dr. Finder said they had not yet reviewed them and noted that others were working on the issue as well. Dr. Timins asked how many different types of FFDM systems Dr. Williams had worked with. He said there were four or five approved by FDA and said there were sizeable distinctions in the way they operate. Dr. Williams also said there were some fairly universal tests that could be applied to all of them. He noted that there would probably be some digital tests that are not being done with screen film and that there may be tests that can only be done practically using software which does not exist on current FFDM systems.

Dr. Timins asked if FDA had any problems with writing QC regulations for new evolving equipment. Dr. Finder said it would have to be well thought out in order to craft something that would not have to be rewritten for at least a significant period of time. He suggested that at the very least they could set up a framework establishing a certain name for a certain test as well as frequency of testing.

With regard to Footnote 100, the committee voted in favor of adding the approved alternative standard for when the sensitometer is not available. For Footnote 101, the general consensus of the committee was that criteria for establishing new processor operating levels should not be added but left in guidance.

Footnote 102 asked if a phantom image should be required for each unit and processor combination. Dr. Monticciolo asked if there would be any gain given that processor quality control is done everyday. Dr. Williams said the phantom test looks at the entire process right to the final product and that one way to avoid testing all combinations would be to make sure that each unit passed with at least one processor and each processor passed with at least one unit. Dr. Finder said the current guidance limits the number of films run through each processor if processors are matched.

The committee voted against requiring phantoms for each combination. Dr. Finder asked if the current guidance should be put into regulation, and the committee voted no.

Footnote 103 asked if the minimum optical density of the phantom should be raised. The consensus of the committee was more in favor of raising it. Dr. Sandrik said raising it was perhaps reasonable but said it could depend a lot on viewing conditions and suggested that a performance based approach might be more appropriate and is better coherent with future technology. Dr. Williams agreed but said that since 1.2 is not generally acceptable to

radiologists that the number should be raised if it is kept. Ms. Mount suggested that the minimum should be 1.4 or perhaps even higher. Dr. Sandrik said the density obtained from operating in the AEC mode normally used for the standard breast should suffice if it allows you to pass the test and said that specifying a number was micromanaging.

Dr. Byng pointed out that the test is done at standard imaging conditions as part of the weekly QC test and wondered if any facilities were actually performing the test at a density of 1.2. Dr. Williams said not in his institution and said 1.2 was outdated. Dr. Monticciolo agreed with the comment that if there is going to be a number specified then it should be higher. Ms. Butler said that ACR still gets phantom images at very low densities that result in failures.

Footnote 104 asked if the position and composition of the added test object be further defined. Dr. Finder said the idea was to standardize so that someone couldn't just use whatever test object would give the desired result. Dr. Byng suggested there could be a range specified with the understanding that users would use the same one on an ongoing basis. The committee voted in favor.

For Footnote 105, the committee was split regarding the addition of criteria for establishing new phantom image and optical density operating levels. Dr. Finder asked if it should be left in guidance, and the committee voted yes.

Footnote 106 asked if the repeat analysis should be limited to either the repeat or reject rates but not both. The current wording is unclear and facilities are unsure whether both tests are required. Dr. Finder said repeat rate was meant to get at additional exposure to the patient rather than how many test films have to be run. Ms. Mount felt both should be done because there is no additional burden involved with doing both. Dr. Williams asked if there was any value in the reject rate. Dr. Byng thought quality would be assured by the repeat rate. Dr. Finder noted that

the ACR QC manual includes films related to biopsy, which is outside of the scope of MQSA, in reject rate as well as discarded QC films. Dr. Byng asked what the definition of total was, and Dr. Finder said it would depend on whether one was referring to rejects or repeats. Dr. Sandrik thought the focus of MQSA should be extra dose and that rejects were more of an issue of facility efficiency. The committee voted in favor of keeping and defining repeat rather than reject rate.

The related question asked what would constitute acceptable corrective action. Ms. Mount said that when the rate is exceeded at her facility they simply repeat the analysis weekly until a cause can be established. Dr. Finder noted that the current action limit was a two percent change over 90 days and said the rate could bounce around a lot on a weekly basis. Dr. Williams liked the fact that Ms. Mount's approach differentiates between the time it takes to correct the underlying issue and the time it takes to evaluate whether the correction worked. Dr. Byng asked if there had ever been consideration of an absolute criteria rather than just looking at the change. Dr. Finder said there had been but the problem was that facilities do not necessarily all conduct the analyses in the same way and said it was consistent with other QC standards to let facilities set their own baseline within certain limits and monitor any deviation from it.

Footnote 107 asked if the dark room fog test requirement should be expanded to include all areas where films are stored, handled, or processed. Dr. Byng asked about the definition of handled and pointed to the difficulties involved with automatic film handling devices and wondered if off-site storage facilities had to be checked as well. Dr. Finder said that guidance had addressed such devices and that it was only intended to look at where films are stored at the facility level. Dr. Sandrik wondered whether the test could be done just once assuming the radiation and light levels were not of significance rather than doing it semiannually. Dr.

Williams did not think every six months was an undue burden given the possibility that things could change. Ms. Mount asked whether radiation monitoring was really included, and Dr. Byng said there was not a radiation fog test. Dr. Finder said this was one of the most frequent citations during inspections and gave the example of door seals peeling off or deteriorating. He said it was more of an issue in terms of handling rather than films stored in boxes.

Dr. Monticciolo thought it would add a lot of burden for those who handle films in mobile units. Dr. Finder agreed if they go to that level and said that currently every dark room is evaluated at some point. Dr. Timins felt it was sufficient to limit it to dark rooms. Dr. Ferguson agreed. The committee voted no.

Regarding Footnote 108, the committee voted in favor of making the screen film contact test annual rather than semiannual. For Footnote 109, the committee voted in favor of deleting the effective date.

For Footnote 110, Dr. Finder asked if they should get rid of the date and combine sections A and B. The committee said yes. Dr. Finder then asked if it should be specified that it be done in the contact configuration with at least one image size using the appropriate technique factors. Dr. Williams suggested that all modes used clinically could be evaluated. Dr. Finder said that would create more testing. Dr. Williams said in some cases it might but in others only a single mode is used anyway. Dr. Finder said the purpose was to concentrate the testing in the mammography equipment evaluation so it is only required once and then simply test a single configuration. He said the idea was to clarify the regulation to agree with current guidance. Dr. Mourad said there had been very positive feedback from physicists regarding the guidance. The committee voted in favor of moving the guidance into regulation.

The final part of the question asked if all AEC detectors and modes should be tested. Dr. Sandrik proposed testing the most commonly used detector over the full range of thicknesses and the rest at just one thickness. Dr. Finder said the current guidance was basically that. Dr. Williams asked if this was different than the situation discussed regarding clinically used modes. Dr. Finder said the attempt was to reduce the amount of testing while ensuring that all detectors work consistent with the spirit of the regulation. Dr. Byng asked if unused detectors would have to be tested. Dr. Finder said that the guidance only addressed items used clinically. He said that units that are limited in some manner are supposed to have a notification saying it should not be used in whatever configuration it was not tested in. Dr. Williams asked if the logic was that since the same lookup table would be used, testing one over the range would mean you did not need to test the others, and Dr. Finder agreed. The committee voted in favor of testing all detectors used clinically with reduced testing for more than one detector.

Regarding Footnote 111, the committee voted in favor of deleting focal spot dimensions. For Footnote 112, the committee voted in favor of the section on system resolution specifically mentioning that the test should be performed in the contact configuration.

Number 113 asked if resolution should also be tested in the magnification configuration, and the committee's vote was split. Dr. Sandrik referred to a number of papers. One by Gary Barnes and Don Fry said the main benefit of magnification mammography is signal-to-noise ratio, not limiting resolution. Kunio Doi found the same benefit as well as a secondary benefit of improvement of contrast by the error gap; the benefit was not proportional to that you get by limiting resolution. J. Law found that image quality for realistic objects improved as focal spot size decreased and said that for clinical image quality, limiting resolution by bar patterns is misleading and the numbers in MQSA are far off from the clinically relevant. Dr. Sandrik said

the problem with current regulation is it provides no limit on the magnification value for testing magnifications.

Dr. Timins said she was against resolution testing on magnification after hearing about the studies cited by Dr. Sandrik. Dr. Sandrik said there was value in magnification mammography but that its value cannot be evaluated by eliminating bar pattern resolution measurement. Dr. Timins clarified that there are things other than resolution that make a lesion more conspicuous, and the value of magnification is not necessarily to be found in fine resolution. Dr. Byng agreed.

Dr. Mourad agreed but said that the small focal spot may be unacceptably large for doing magnification views. He said there could be an argument for a more global assessment of image quality. Dr. Sandrik liked that idea but suggested as a fall back they could limit magnification to 1.5, which, while irrelevant, would do no harm.

Ms. Butler said it seems that facilities are currently meeting magnification standards. Dr. Sandrik said that as long as physicists agree to limit magnification to 1.5 there will be essentially no failures.

Regarding Footnote 114, the committee voted in favor of deleting focal spot dimension. For Footnote 115, the committee voted in favor of the collimation assessment test being performed for all combinations of collimators, image receptor sizes, targets and focal spots used for full field imaging in the contact configuration. Dr. Hendricks said the question was a bit technical for non-physics members, and Dr. Finder said not everyone has to vote. Dr. Byng asked if it was just for all configurations used clinically, and Dr. Finder said yes.

For Footnote 116, the committee voted in favor of allowing medical physicist oversight for the performance of the uniformity of screen speed test. For Footnote 117, the committee

voted in favor of allowing separate averages for different speed cassettes. Dr. Sandrik asked whether they meant averages, and Dr. Finder said it was ranges.

Footnote 118 asked if the medical physicist should have the final say as to whether the system artifact test passes or not. Dr. Byng asked if currently the radiologist had oversight as lead interpreting physician, and Dr. Finder said that was right. Dr. Williams thought it would be hard to get the radiologist in to evaluate specific artifacts and that physicists might have to use their best judgment and get the radiologist for anything ambiguous.

Ms. Butler noted that currently the artifact test is part of the medical physicist report, but the QC manual encourages communication with the radiologist on some issues, for example tolerance of artifacts.

Dr. Finder called for a vote, and the committee voted yes, but Dr. Williams, a medical physicist, voted no. Dr. Monticciolo said she wanted to change her vote. Another vote was called, and the committee voted against giving the medical physicist the final say.

Footnote 119 asked if medical physicist oversight should be allowed for the system artifact test at mobile facilities using remote processors. Dr. Byng asked if this would allow the test to be done remotely, and Dr. Finder said yes. He said the test would be done and the film sent to the physicist for review. The committee voted in favor.

Footnote 120 asked if the regulation should be simplified to require 21 milliGray within a 3-second period. Dr. Byng asked about the overall intent of the measurement. Dr. Finder said the point was to ensure that units can image a large breast in a period of time sufficiently short to reduce motion artifacts. Dr. Byng wondered if it was the right measurement and thought it might relate to the non-Moly/Moly configuration. The committee voted in favor of the change.

The second part of the question asked what should be required for non-Moly/Moly systems. Dr. Sandrik said the main concern was really exposure time. Dr. Williams thought that made sense and noted that most if not all units exceed the current standard. Dr. Finder asked how Dr. Sandrik's suggestion would affect digital units, and Dr. Sandrik said the exposure time limit could be obtained using the reference of a properly exposed image of the detector under some conditions. Dr. Byng said there was some value in the screen film context in isolating the equipment component.

Regarding Footnote 121, the committee voted in favor of renaming decompression compression release. For Footnote 122, the committee voted in favor of adding the approved alternative standard allowing units that are always in automatic mode. For 123, the committee voted in favor of moving the film screen contact test into the annual test. Regarding 124, the committee voted in favor of the test being done under medical physicist oversight for new cassettes as they are put into service.

Dr. Finder said the committee had already addressed Footnotes 125 regarding the addition of requirements for viewbox and room viewing conditions and Footnote 126 regarding the 90-day period for the repeat analysis corrective action.

Footnote 127 asked if the section should be limited to units and a new section be created for components that can be evaluated under medical physicist oversight, and the committee voted in favor. Dr. Finder said that Footnote 128 dealing with universal quality control testing for full field digital units had already been covered.

Dr. Finder raised the issue of what a final interpretation quality mammogram is with FFDM. He asked whether printers used infrequently to print a patient's digital films have up-to-date QC testing and whether films produced from printers that do not should be considered final

interpretation quality images. Ms. Mount said her facility does it everyday but noted the printer was in the department rather than in some records area. Dr. Williams said that technically speaking, such images would not be viable for final interpretation and proposed that facilities should have responsibility for QC.

Dr. Finder asked if most facilities were doing it or whether enforcement was needed. He said they had seen such images that were uninterpretable because identifying information was covering the image of the breast. Dr. Hendricks asked if that triggered some type of facility evaluation, and Dr. Finder said no. Dr. Byng asked what QC test would address the problem he raised. Dr. Finder said none and that he was simply suggesting that if images are released in that condition, the appropriate QC is probably not being done. Dr. Timins said she had not run into that problem. Ms. Mount said that vendors tell facilities to do the QC.

Dr. Finder asked if there were any other issues in this section. Dr. Sandrik said that a reference plane should be identified for the measurements in the x-ray field/light field testing. Ms. Butler asked about considerations to remove the Kvp measurement from annual tests.

Dr. Ferguson returned to the issue of release of medical records and suggested that the fifteen day time period should be for sending the films or sending notification that they are not available. Ms. Segelken suggested five or seven days would be more appropriate for notification that the films were not available. Dr. Monticciolo said that if facilities are not given sufficient time to look for the films, they may not even try. Dr. Finder noted that films are supposed to be available for ten years and suggested that FDA should be notified if they are not. Dr. Monticciolo noted that films can be signed out and not returned. Dr. Finder agreed and said the problem was films that cannot be located.

Mike Divine, Chief, Inspection and Compliance Branch, said that some facilities with fluctuating processors or phantoms outside of limits, rather than fixing the problem, simply change their operating levels. However, there are situations where it is appropriate for facilities to change operating levels. He suggested the regulations could limit such changes to appropriate situations such as major changes to the processing system or changes in equipment.

REVIEW OF SUMMARY MINUTES AND FUTURE MEETINGS

Ms. Wynne said the summary minutes from the September 2005 meeting were available. She said the next meeting was planned for the spring of 2007. She thanked John Sandrik and Carolyn Hendricks, whose terms are expiring.

ADJOURNMENT

Dr. Hendricks adjourned the meeting at 12:11 p.m.

I certify that I attended this session of the National Mammography Quality Assurance Advisory Committee on September 29, 2006, and that these minutes accurately reflect what transpired.

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Nancy M. Wynne
Executive Secretary

I approve the minutes of the September 29, 2006, meeting as recorded in this summary.

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Carolyn Hendricks, M.D.
Chairperson

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