

SUMMARY MINUTES

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY
COMMITTEE**

January 25, 2010

**Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, Maryland**

Attendees:**Chairperson**

Eric L. Rosen, M.D.
Seattle Radiologists
Seattle, Washington

Voting Members

James P. Borgstede, M.D.
Fellow in Magnet Resonance Imaging
University of California at San Diego
San Diego, California

Catherine L. Parsons, R.T. (R)(M)
Administrative Director
Cumberland Medical Center
Crossville, Tennessee

Thomas G. Ruckdeschel, M.S.
President
Alliance Medical Physics
Alpharetta, Georgia

James A. Seibert, Ph.D.
Professor of Radiology
Department of Radiology
University of California-Davis
School of Medicine
Sacramento, California

Temporary Voting Member

David P. Winchester, M.D.
Professor of Surgery
Northwestern University
Feinberg School of Medicine
Evanston Northwestern Healthcare
Evanston, Illinois

Consumer Representatives

Nancy A. Finken, M.A.
McLean, Virginia

Deborah R. Laxague, R.N.
Obstetrics Staff Registered Nurse
Mount Shasta, California

Margaret S. Volpe
Clifton, Virginia

Natalie Compagni Portis, Psy.D., MFT
Clinical Psychologist
Oakland, California

Industry Representatives

Robert A. Uzenoff
Executive Assistant to the President
Image Quality Group, Corporate Development
Fujifilm Medical Systems, USA, Inc.
Stamford, Connecticut

Kathleen M. Willison, R.T. (R)(M)
Product Manager, Clinical Research
Hologic, Inc.
Bedford, Massachusetts

Executive Secretary

Normica Facey
Food and Drug Administration
Silver Spring, Maryland

CALL TO ORDER

Chairman Eric L. Rosen, M.D., called the meeting to order at 9:00 a.m. He noted the presence of a quorum as required by 21 C.F.R. Part 14 and asked Committee members to introduce themselves.

FDA INTRODUCTORY REMARKS

Executive Secretary Normica Facey read into the record the Conflict of Interest Disclosure Statement and advised that no conflict of interest waivers had been issued.

She advised that Robert Uzenoff was serving as an industry representative, acting on behalf of all related industry and employed by Fuji Medical Systems, USA, Inc.

She advised that Kathleen Willison was also serving as an industry representative, acting on behalf of all industry and employed by Hologic, Inc.

She read into the record the Appointment to Temporary Voting Status Statement, appointing Dr. David Winchester as a voting member of the National Mammography Quality Assurance Advisory Committee.

Helen J. Barr, M.D., Director, Division of Mammography Quality and Radiation Programs, gave a brief welcome in which she thanked Committee members for their attendance and dedication and introduced Dr. Rosen as the new Chair and Ms. Facey as the new Executive Secretary. She then introduced Charles Finder as the "brains behind the operation" and concluded with some general remarks.

APPROVED ALTERNATIVE STANDARDS

Charles A. Finder, M.D., Associate Director, Division of Mammography Quality and Radiation Programs, discussed recently approved alternative standards to the MQSA. He summarized conditions under which FDA could approve an alternative to a quality standard under Section 900.12.

He gave a short history, noting that since the November 2007 meeting; the Division had approved one new alternative standard and 17 modifications to a previously approved alternative standard.

He stated that the new alternative standard allowed multiple stationary facilities to combine their medical outcomes audit rather than breaking it out by individual facility. Dr. Finder also listed the requirements that facilities had to meet under the new alternative standard. He also discussed briefly the 17 modifications to a previously approved alternative standard, post-upgrade testing after a software upgrade, including that they had now generalized the alternative to allow it to be used by all manufacturers.

OPEN PUBLIC HEARING

Chairman Rosen noted that Committee had not received any oral presentation requests for the Open Public Hearing. He inquired whether anyone present would like to address the Committee, and there was no reply. He recognized that the Committee received one written statement from Ms. Judith Wagner, R.N., breast cancer patient advocate, which was made available to the Committee and would also be made available online with all of the day's meeting materials.

GUEST PRESENTATIONS

Sara J. Fredrickson, M.D., FACS, representing the American Society of Breast Surgeons, gave updates on Interventional Mammography and Accreditation Programs. She provided a brief description and history of the Society and its purpose.

She then discussed four programs the ASBS offered for certification and accreditation: stereotactic breast procedure certification, a stereotactic facility accreditation, breast certification, and breast ultrasound facility accreditation.

She described the certification process, noting that the goal was to provide a process for surgeons that were attainable, meaningful, and recognizable by any interested party and to certify surgeons when they have met the stringent criteria for certification.

She next defined certification as a program that attested to the accomplishments of an individual. Conversely, accreditation was defined as a program that evaluated the technology in a facility and attested to the safety and proper functioning of the technology used in the facility.

She discussed stereotactic certification, highlighting its development, goals, and principles. She then discussed the stereotactic facility accreditation program and the criteria for stereotactic certification. She also described the three components of the application for stereotactic breast procedure certification: a written examination, clinical application, and practical examination, which could only be taken after an applicant successfully passed both the clinical application and the written exam.

The current status of the stereotactic program and information regarding a recent membership survey were then discussed.

She described a stereotactic database developed at the request of the FDA to address the question of whether relevant negative outcomes among surgeons performing stereotactic biopsies in the community-based practices were comparable to outcomes reflected in the published radiologic and surgical literature. Results were then discussed.

She briefly covered the issue of discordance with the stereotactic database, noting that the society did not feel it was a useful or clinically relevant outcome to measure and difficult to assess because of multiple

definitions in the literature.

She noted that false negatives or number of missed cancers were 0% in the database. She noted that such data demonstrated that community-based surgeons were incorporating stereotaxis into their practices with results equal to or better than the results published in the surgical and radiologic literature.

She concluded with a summary, stating that properly trained surgeons were offering the stereotactic technology to their patients in place of an open surgical diagnostic biopsy with excellent results and little complications.

During a brief Q & A session, Committee members questioned Dr. Fredrickson and commented on the presentation.

Chairman Rosen strongly disagreed that discordance was not an important outcome measure, and he noted that it was very important in not only assessing whether the specimen had been adequately sampled, but also whether the diagnosis was concordant with the appearance. **Dr. Fredrickson** replied that she did not mean to imply it was not, but she thought that the most important thing about discordance was whether that discordance led to a missed cancer.

Chairman Rosen stated that most studies had shown that missed cancer at a biopsy site was not picked up on initial six-month follow-up but possibly later. **James P. Borgstede, M.D.**, shared this concern. **Dr. Fredrickson** reminded them that while the minimum follow-up was six months, the average was 12.

Natalie Portis, M.D., wondered if the 12-month data was the same as the six-month. **Dr. Fredrickson** replied that she thought that it was, but she would have to look into it.

Priscilla F. Butler, M.S., FAAPM, FACR, from the American College of Radiology, gave an update on ACR's stereotactic breast biopsy accreditation program. She first listed a number of past of ACR breast imaging accreditation programs and then gave a brief description of the Breast Imaging Centers of Excellence, initiated in October of 2006.

She then discussed the stereotactic program, which was modeled after accreditation under the Mammography Quality Standards Act. She described the personnel qualifications and continuing education for physicians both in a collaborative and independent setting. She then covered qualifications and continuing education for the radiologic technologists and medical physicists.

She summarized other aspects of the program, including quality control, equipment, quality assurance and outcome data, exam identification and labeling, clinical performance, phantom image quality, and radiation dose.

She described briefly ACR accreditation changes that came with evolution of practice and technology, and she also discussed protocol occurring when a facility does not pass the first time. Reasons for failures and pass rates were also discussed.

She ended by pointing out a website where patients and physicians

could find accredited facilities.

During a brief Q & A session, Committee members questioned Ms. Butler and commented on the presentation.

Dr. Portis asked how patients knew to access the website information, and she also wondered why a number of states had no accredited facilities and if there was a plan regarding that. She asked then if all accreditation was voluntary. **Ms. Butler** first stated that while it was not an easy job, ACR tried to ensure that when there was an article or story about it, a link would be provided to where patients could find out if a facility was accredited or not. She then noted that most states had accredited facilities, but not all had Breast Centers of Excellence. For the third question, she stated that mammography accreditation was not voluntary, but all others were.

David P. Winchester, M.D., inquired about the penetration of the Breast Centers of Excellence program. He also asked if there was data on how many of the Centers of Excellence breast imaging radiologists actually performing procedures were certified beyond basic training. **Ms. Butler** first explained that because a center would typically consist of multiple facilities, they had not been able to "ferret out" what the center distribution actually was. Addressing the second question, she explained that it was very rare that all the radiologists would have all the credentials and would be doing the procedures. Ms. Butler also stated that the ACR does not have certification however; it has accreditation for the facilities.

Dr. Borgstede wondered if someone besides a surgeon or a radiologist, for example, an OB/GYN, could be accredited with ACR or ASBS. **Ms. Butler** explained that while they could be considered if they qualified under the ACR criteria, ACR did not currently have any OB/GYNs with that accreditation. **Dr. Fredrickson** explained that for ASBS, if a gynecologist took a breast surgery fellowship program and would meet all the other requirements, then they could apply for certification.

Robert A. Uzenoff asked about the difference between 12 stereotactic breast biopsy procedures and three hands-on stereotactic breast biopsy procedures. **Ms. Butler** replied that the three hands-on would be under supervision.

Catherine L. Parsons, R.T. (R)(M), had a question regarding the technologist qualifications and the 24 continuing education credits in two years, wondering if there was going a specific number required in the modality that the accreditation was being applied for. **Ms. Butler** replied that there was not because they wanted to allow the technologist to make decisions based on their own personal experience and where they needed to focus their continuing education credits.

James A. Seibert, Ph.D., wanted to know if the accreditation requirements were the same for both the ACR and ASBS programs with respect to the physics issues. **Ms. Butler** stated they had not done a comparison. **Ms. Fredrickson** added that with ASBS, individual surgeons

must submit evidence of medical physicist evaluations of the table at the facility that they are using. If a surgeon owns a table and is applying for a facility accreditation, they must do the same. If a surgeon does not own the table, it is required by the facility that owns the table. She added that all of their requirements are based on ACR's requirements.

FDA PRESENTATIONS

Michael P. Divine, M.S., with the Diagnostic Devices Branch in the Division of Mammography Quality and Radiation Programs, gave a presentation on MQSA inspection observations. He explained that he would cover the results from the last three fiscal years, 2007 through 2009, and he then discussed three inspection observation levels, Level 1 being the most serious, Level 2 being moderately severe, and Level 3 being minor.

He next provided a representation of the inspection observations over the past ten years, noting that the number of facilities with no inspection observations increased every year, approaching 80%, and all other observations decreased over time.

He then discussed Level 1 initial qualifications and described the qualifications for the Level 2 physicians, medical physicists, and radiological technologists.

He covered quality assurance and quality control testing next. Phantom image testing, inspection testing, simple failures, over-processing/step tests, and fog failures were explained in detail. Also covered were the differences between inspections for facilities with screen film units versus inspections for digital units, issues surrounding the annual survey and equipment evaluation, medical records issues, and the medical outcomes audit that the facilities were required to maintain.

During a brief Q & A session, Committee members questioned Mr. Divine and commented on the presentation.

Chairman Rosen inquired what had been done towards standardization of the QC for full field digital mammography. **Mr. Divine** explained that while he knew there were efforts to try to standardize that, he was not the best person to speak with on the issue. However, if an organization decided to come up with a set of tests as an alternative standard, they could apply to the FDA.

Dr. Winchester asked Mr. Divine to provide him with a "takeaway message" with respect to inspections. **Mr. Divine** briefly stated that "things [were] getting better."

Ms. Butler addressed Chairman Rosen's standardization question, noting that the ACR continued to work on a quality control manual for digital and hope to have it complete in calendar year 2010. She stated that they would apply for an alternative standard once it was completed.

Dr. Barr addressed Dr. Winchester's question, stating that the

takeaway message was that the mammography industry was very compliant, given that over 75% of mammography facilities had no violations whatsoever and less than 2% of violations were in the serious category.

Dr. Seibert asked who trained the inspectors, and **Dr. Barr** replied FDA trained the MQSA inspectors.

Dr. Winchester asked if FDA had an evaluation program for performance of inspectors. **Dr. Barr** replied that they did have an audit program for inspectors.

During another Q & A session, the FDA questioned the guest speakers.

Dr. Barr asked Dr. Fredrickson if they would continue to grow and follow up on their database with more cases. **Dr. Fredrickson** stated that they could do that if it would be helpful, and **Dr. Barr** noted that it would be useful to have a longer follow-up period and more cases.

Dr. Barr asked Ms. Butler how the facilities' current pass/fail rate compared to previous years. **Ms. Butler** stated it had been improving since the inception of the program and that the current pass rate was 90% on first attempt.

Dr. Barr also had a question about clinical failures due to targeting issues and whether any thought was given in reevaluating it as a relevant measure. **Ms. Butler** stated that ACR had plans to look at outcome more closely, but she emphasized that they would have to collect data first before deciding whether it would be integrated into the pass/fail criteria. She then addressed a couple of follow-up questions regarding the Breast Imaging Centers of Excellence.

Chairman Rosen inquired about the status of including stereotactic biopsy under the MQSA. **Dr. Finder** then provided a brief update on the status of including stereotactic biopsy under MQSA. He stated that FDA was in the process of developing amendments for the regulations and was evaluating several options outside regulatory means as well.

Dr. Barr requested that Dr. Fredrickson and Ms. Butler specifically address efforts to increase voluntary participation in their programs. **Ms. Butler** noted that the development of the Breast Imaging Centers of Excellence was one of the things they had been doing to encourage voluntary accreditation in stereotactic breast biopsy. **Dr. Frederickson** noted that they had great interest in certification in both their stereotactic and ultrasound certification programs, and she further discussed their efforts to increase voluntary participation which included revisions to its website.

CDR Sean M. Boyd, MPH, USPHS, continued the FDA presentation, giving an overview on FDA's radiological health program. He stated the mission of the program - to protect the public from hazardous or unnecessary electronic product emissions - and then discussed several ways in which they accomplished that mission, including establishing performance standards,

requiring certification to standards based on quality control testing programs, requiring submission of reports, and conducting product testing and inspection.

He then covered when and why FDA would get involved in the business of regulating electronic product manufacturers and ensuring electronic product safety. He also discussed several radiation emitting devices and electronic radiation control.

He described initiatives relative to medical imaging equipment, including electronic reporting with eSubmitter and medical imaging dose reduction, where FDA had pursued efforts to reduce medical imaging exposure.

He summarized the NCRP report on ionizing radiation exposure of the U.S. population and discussed several CT perfusion events. He also covered the FDA's medical imaging initiative going forward.

During a brief Q & A session, Committee members questioned CDR Boyd and commented on the presentation.

Chairman Rosen asked for comment on dose related to mammography or trends or any movement towards relooking at the dose requirements from mammography since full-field digital might actually allow for lowering the dose of mammography. **CDR Boyd** answered that FDA did not have specific plans for mammography alone, and he then asked Dr. Finder to comment.

Dr. Finder explained that the trend was towards lower doses as more facilities switched over to digital imaging however, if the 300 millirad maximum dosage were to change, it would be involved in the amendments to the regulations, and the amendments can not be discussed at this time.

Dr. Winchester inquired about FDA's role in informing the public about radiation exposure and the relationship to cancer versus the benefit of CT scanning. **CDR Boyd** stated that FDA was partnering with several organizations to inform the public on risk that radiation exposure posed along with the benefits that CT scanning conferred.

Dr. Barr then described for the Committee the many issues that the federal regulatory business encounters, and a few follow-up comments were made regarding radiation exposure and reference doses in mammography.

DIRECTIONS FOR DISCUSSION

Dr. Finder briefly explained the procedures that FDA was following as it developed new guidance. He then gave directions for discussion of the draft guidance document, emphasizing that they would discuss the proposed guidance, not the underlying regulations, that the regulations had already gone through their own extensive approval process and that they were in the process of developing amendments to the regulations. He then stated the purpose of the day's meeting, which was to address the proposed guidance, and he asked for preliminary comments from the Committee on the document.

Mr. Uzenoff asked when the guidance document would be final, and **Dr. Finder** responded that it was a process, which he then described in further detail. He noted that if that there were no major changes, it should not take a great amount of time. His hope was that it would be out by the summer.

DISCUSSION OF DRAFT GUIDANCE DOCUMENT

Dr. Finder began going through the guidance document. After briefly covering address updates, he highlighted page 7, noting that they had updated which FFDM units were accredited by which accreditation bodies.

Margaret S. Volpe asked what FDA's mechanism for updating this was if a new unit came on the market. **Dr. Finder** explained that it would be a guidance process, where the Policy Guidance Help System would have to be updated.

Dr. Finder then moved to page 8, where the issue was further addressed, to a question about what a facility had to do when moving its mammography unit. He explained that they would put a link to a webpage outside of the Policy Guidance Help System that would describe what the accreditation bodies and certifying agencies asked for. This would allow FDA to be able to update that on a much easier basis than going through the official Policy Guidance Help System process.

He then discussed what a facility should do if it decided to close or no longer provide mammography services. He explained that they had received one comment about adding wording about digital image files, and several Committee members concurred with the suggestion.

He next highlighted page 11, which discussed guidance on the additional mammography review (AMR). He first gave an overview of the AMR process and explained that one comment FDA had received was to add into the guidance words that included the accreditation bodies and the other certifying agencies. He stated that the purpose of the guidance was to discuss the FDA's processes and to make it more comprehensive; they added additional examples of when FDA would require an AMR.

Dr. Borgstede felt that including the suggested verbiage, "the accrediting body or certifying body," would be more comprehensive.

Dr. Winchester had a question on the magnitude of AMRs, historically. **Dr. Finder** noted they only did about a dozen a year because generally mammography facilities were fairly compliant.

He then went on to page 13, describing various processes that were used with respect to AMRs. He discussed the two basic types: (1) the standard, where if a facility had a problem, the accreditation body performed the AMR for FDA; and (2) situations where the facility was allowed to have an AMR without getting the accreditation body involved, using an expert acceptable to FDA. He explained that in the second instance, the FDA works with the facility to identify an expert that is acceptable to the FDA.

Chairman Rosen commented that while he saw the utility in the approach, he felt there was a conflict of interest when the person under review chooses who was going to supervise the AMR process. He recommended that the FDA come up with a list of acceptable people. Several Committee members agreed.

Dr. Finder addressed further questions from Committee members, covering how FDA determined the acceptability or unacceptability of an outside expert and who at FDA was involved in the process of determining who would be acceptable. Concern over who determined how the outside expert was paid and the advantage of an outside reviewer was also addressed.

He went to page 14 next and discussed approval of the alternative standards. He also discussed having the alternative standards removed from the Policy Guidance Help System and on its own webpage. No objections were made from the Committee.

He then covered the use of specific laser film when dealing with digital images, noting that the recommendation would be to use the laser film compatible with the printer that the facility was using and with the caveat that whatever they produce has to be of "final interpretation quality." There were brief comments on this.

Dr. Seibert asked if there were any comments on the reverse situation, film digitization. **Dr. Finder** replied that there were not, but there was guidance that allowed facilities to do what it choose however, it still has to maintain the original film screen mammograms. **Chairman Rosen** added that it was important to maintain a standard of retaining the original image since there were cases when the originals would be required.

Dr. Finder next discussed Question 2 on page 15 regarding information that FDA wanted to put out for facilities that were having trouble getting reimbursed from Medicare and therefore, have the contacts for the Centers for Medicare and Medicaid Services listed in the document. **Chairman Rosen** agreed.

For pages 16 through 19, which dealt with medical reports and lay summaries, he discussed a couple issues, including the adding of a phrase that dealt with the date of interpretation when it was interpreted as suspicious. He noted there was a comment concerning the delays in reporting suspicious findings because people were waiting for comparison films, and he asked for the Committee's comments. **Ms. Volpe** felt there should be some way to let the referring physician know that there would be a delay.

Chairman Rosen reminded Committee members that even though the recommendation was for three to five business days from the date of interpretation, they were still also required to contact or provide the lay letter to the patient by 30 days. Several other Committee members agreed it would be better to keep the flexibility that they had in the guidance.

Dr. Finder continued with the bottom of page 15, discussing how FDA would try and regulate whether or not facilities notified patients of their results in a timely fashion. He explained that FDA was attempting to change

the way that they did the inspections by holding the facilities that have the computerized systems to a higher standard, where they would query their systems to check and see when such issues arose. He then asked for input on this change. **Ms. Parsons** wondered how often the facility would do the queries, and **Chairman Rosen** stated he thought that all facilities, whether they had computerized reporting systems or not, needed to be held to the same standard. **Dr. Portis** concurred. **Nancy A. Finken, M.A.**, was concerned about the word "verbal" as there were many ways in which a verbal contact could be intercepted and not really communicated. **Dr. Finder** clarified this for her, ultimately reassuring her that a written report was required as well.

He pointed Committee members to page 19 and discussed that FDA had received a comment that, with regard to the regulation and the cassette screen identification, it should not apply to single receptor FFDM systems once it did not have receptors that could be removed.

He then went to Question 6 on page 19, which dealt with where the markers could be placed for digital images. He noted that FDA would no longer look only for the marker to be placed in that axillary region, that they could be placed in other locations to accommodate the FFDM systems. **Chairman Rosen** did not like that recommendation, given that where the marker was placed aided the interpreter in figuring out how to orient the film properly and inverted images can make a big difference in interpretation. **Dr. Borgstede** agreed, and the industry representatives also gave their input.

Dr. Finder next discussed page 20, dealing with personnel requirements. He first asked the Committee to comment on how far FDA should go in trying to obtain proof of specific training in each mammographic modality, digital and film, before use by personnel. **Dr. Seibert** felt that while digital was the "brave new world," they still needed to keep up with the regulatory characteristics of both modalities. **Ms. Parsons** suggested there should be a cutoff year, stating that from a certain day forward, one would need to provide proof of training in film screen if doing film screen.

Chairman Rosen felt that, given the standard already in place, the issue was already addressed and that he would be "reluctant" to recommend that the FDA go back and require every training program to document specifically numbers of images interpreted with each modality. **Dr. Finder** gave an example of a newly graduated resident that was only trained in digital but worked in a film screen facility and whether FDA should request more specific documentation, question further, or accept an attestation. **Dr. Borgstede** agreed with Chairman Rosen for the physicians, but he hesitated to comment on the technologists or the physicists. Further comments followed, and it was agreed that a simple attestation as proof of training was reasonable.

Dr. Finder moved to page 22 to discuss FDA's clarification on what was meant by the six-month exemption for individuals who failed to meet continuing personnel requirements. There were no comments on this from Committee members.

He moved to page 25, where he pointed out a comment from the public where it was suggested that FDA switch back to calendar year for measuring personnel continuing requirements. He discussed some history on this, and **Chairman Rosen** commented that he did not feel that the standard needed to be changed.

Dr. Finder discussed page 29, which dealt with the issue of whether the air kerma instrument had to be calibrated to all possible target filter combinations and how that calibration would affect the kVp in dose measurements. He asked for comments from the physicists.

Thomas G. Ruckdeschel, M.S., and **Dr. Seibert** gave their input and ultimately agreed that kVp only needed to be measured in one mode.

Dr. Finder next discussed page 32, which talked about cassette replacement and the table for a screen speed cassette. He explained that FDA was advocating changing it from involvement by the medical physicist being optional to oversight, and he asked Committee members if they had any concerns about this potential change. There was no reply.

Dr. Seibert brought up some issues concerning the measurement of half-value layer, and he made some suggestions to **Dr. Finder** regarding this. He suggested that if solid state detectors with the ability to measure the half-value layer instantly are not calibrated for a specific target and filter combination, the physicist should be instructed to conduct the half-value layer using the old method, with aluminum.

Dr. Finder went on to page 33, Questions 2 and 18. He discussed FDA recommendations regarding single-use cushion pads with FFDM devices, where FDA recommended that if using the pads routinely, phantom testing should be performed with the pads in place. He emphasized that FDA could not require this but could only recommend because only the manufacturer could dictate requirements for FFDM units.

Chairman Rosen argued that the bigger issue that needed to be addressed was that it was up to the manufacturer to state the quality control standards for their devices. **Dr. Finder** agreed, noting that the goal was to establish a series of tests just like what was done for film screen. He felt that the manufacturers would be happy with that as long as tests were reasonable.

He went on to say that with regard to QC testing with cushion pads in place being the most appropriate when performing the phantom and dose tests, there was a comment that FDA should also include AEC testing and artifact testing there. He then gave background information on why FDA did not include this, and he asked the Committee for comments. **Mr. Ruckdeschel** felt that the AEC testing and the artifact testing with the pads in place were important tests to consider.

Dr. Finder then discussed testing the initial power drive, explaining that FDA guidance stated it was okay to press more than once on the pedal to get the appropriate compression value. Committee members had no questions or comments on the issue.

He next described the guidance for the medical physicists regarding

equipment evaluations for laser printers. He stated that when doing equipment evaluations, they must follow what the manufacturer says and that a phantom test alone was not sufficient. He also stated that Question 6 addressed what tests to do when there is equipment from different manufacturers. He then noted that for Question 7, the idea was to reduce the burden on the facility while still maintaining the quality by allowing them to just test the combinations that need to be tested. He then asked for comments from the physicists. **Mr. Ruckdeschel** felt that a published alternative standard was needed to establish consensus on consistent QC for physicists and technologists, especially given that manufacturers were putting a lot of the tests all over the map and the number of remote reading stations with different monitor manufacturers. **Dr. Finder** then noted that facilities could apply for alternative standards. He pointed out that there were more and more problems of remote reading sites, where the only person present is the interpreting physician. He emphasized that just because they were out there by themselves did not mean that they did not have to meet the requirements.

He then briefly discussed page 37, Question No. 9, where FDA was putting information about what the FFDM manufacturers required for a mammography equipment evaluation on an outside website so that it is clearcut and changeable when the manufacturers changed their manuals.

He went on to Question 10 briefly, laser printers and monitors approved for mammography, and then asked for comments on Question 11, which dealt with whether or not it was necessary to include artifact testing as part of the whole imaging chain. **Mr. Ruckdeschel** felt that it was necessary given that in his personal experience, he always saw artifacts and that the number one reason why detectors and monitors had to be replaced was because of artifacts.

Dr. Finder then briefly discussed questions dealing with adding units or components to various certified facilities and what kinds of testing would be required. He explained that if the test had been recently done and was not part of the whole imaging chain, the result could be used and the test need not be repeated.

For Question 15, he stated the guidance was that facilities could use the results of a previous MEE as long as it had been performed within the previous six months. He explained that there was one suggestion to change the timeframe from 6 months to 14 months. He asked for comments from the Committee. **Dr. Borgstede** agreed that it should be 14 months. **Mr. Ruckdeschel** felt it should be six months due to the fact there are a lot of changes when you change the technology. **Dr. Borgstede** agreed with **Dr. Finder's** previous comment that they ought to have some dialogue with the accreditation bodies before making the decision. **Chairman Rosen** also thought that was a good idea.

Dr. Finder thanked the Committee for their thoughts and comments on the guidance documents.

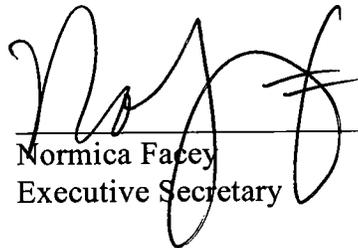
FINAL REMARKS

After some brief additional comments, **Ms. Facey** thanked consumer representatives Margaret Volpe and Nancy Finken for their time and dedication to the Committee, noting that this would be their last meeting. She further stated that all the meeting materials, presentations, and written statement would be available online at the FDA website under the Advisory Committee page.

ADJOURNMENT

Chairman Rosen adjourned the meeting.

I certify that I attended this meeting on January 25, 2010 and that these minutes accurately reflect what transpired.



Normica Facey
Executive Secretary

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