The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #3; Final Guidance for Industry and FDA

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This document modifies and updates guidance appearing in the Policy Guidance Help System.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Inspection Support Branch
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Charles Finder at (301) 594-3332 or email caf@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/mammography, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1386 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #3

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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Background

The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance referable to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: www.fda.gov/cdrh/mammography/guidance-rev.html
This compliance guidance document serves to update the Policy Guidance Help System to be consistent with more recently issued guidance.

Guidance information is periodically updated. Individuals wishing to get automatic notification of such updates may subscribe to our E-mail ListServe by visiting http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.

Old Guidance	New Guidance
Acceptable Documents for Interpreting Physicians- Initial Mammographic Modality Specific Training-8 hours-final regs Obtained Prior to 10/1/94	
1. Attestation 2. Mammography Modality Specific CME certificates (Category I or II) 3. CME certificates (Category I or II) plus agenda, course outline or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses	1. Attestation for training or experience with investigational units 2. Mammography Modality Specific CME certificates (Category I or II) 3. CME certificates (Category I or II) plus agenda, course outline or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality
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Old Guidance	New Guidance
	documenting experience in the new mammographic modality
Focal Spot Condition QC Test Question 1 (under Quality Assurance/Equipment)	
Question: Does the condition of the focal spot have to be measured at all possible magnification values? Answer: The facility is required to evaluate the focal spot condition only for the clinically used magnification factor as close to 1.5 as can be achieved with the system.	Question: Does the condition of the focal spot have to be measured at all possible magnification values? Answer: The facility is required to evaluate the focal spot condition in the magnification mode only if magnification is clinically used and then at the magnification factor as close to 1.5 as can be achieved with the system
Weekly Equipment Quality Control Tests Question 11 (under Quality Assurance/Equipment)	
Question: When performing the weekly phantom image test must we monitor kVp and/or mAs? Answer: No. The only requirements on the weekly phantom image test are that the phantom image achieve at least the minimum phantom score established by the accreditation body and must be within the action limits established for the 3 optical density requirements. FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate an equipment problem and should be further evaluated. Mobile facilities should be aware of the following if they are monitoring mAs as part of their post-move-pre-exam testing. Performing the post-move-pre-exam test in the Full-Auto mode may be inappropriate (due to the variability of kVp and mAs as previously mentioned). In such cases, the facility should use the AEC mode to perform the post-move-pre-exam test, even if they use the Full-Auto mode for their patients with the standard breast. Note: The weekly phantom	Question: When performing the weekly phantom image test must we monitor kVp and/or mAs? Answer: No. The only requirements on the weekly phantom image test are that the phantom image achieve at least the minimum phantom scores established by the accreditation body and must be within the action limits established for the 3 optical density requirements. FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate an equipment problem and should be further evaluated. Mobile facilities should be aware of the following if they are monitoring mAs as part of their post-move-pre-exam testing. Performing the post-move-pre-exam test in the Full-Auto mode may be problematic (due to the variability of kVp and mAs as previously mentioned). In such cases, the facility may: 1. Use the AEC mode to perform the post-move-pre-exam test, even if they use the Full-Auto mode for their patients with the standard breast. Note: The

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QC test must be performed using the same clinical conditions that the facility uses for its patients with the standard breast.	weekly phantom QC test must be performed using the same clinical conditions that the facility uses for its patients with the standard breast. OR 2. Use the Full-Auto mode and establish baseline mAs values corresponding to the specific kVp values usually encountered during phantom testing. If the mAs value is within 10% of the baseline value for the post exposure kVp value, the unit has passed that portion of the post-move-pre examination test.
Weekly Equipment Quality Control Tests Question 17 (under Quality Assurance/Equipment)	
	Question: What is considered adequate weekly phantom QC monitoring for a facility that has multiple processors and multiple units? Answer: The answer depends on whether the units and processors are used interchangeably, whether the processors are matched (**established operating levels** for mid density and density difference for all processors are within 0.05 optical density), and whether each processor is operating within its own pre-established action limits. If the processors are <u>not</u> matched and the facility is processing clinical films from its multiple units interchangeably through its processors, the facility must conduct the weekly phantom image test for each unit-processor combination. In this example, if a facility has 5 units and 2 processors, a total of 10 phantom images must be performed each week. If the processors are matched and the facility is processing clinical films from its multiple units interchangeably through its processors, it is acceptable to produce a weekly phantom image from <u>all</u> units and process them through any processor, as long as each processor is tested with a phantom image at least once each week of use. (Note: in this scenario each processor must be operating within its own pre-established action limits). This will reduce the number of phantom images that must be performed. In this example, if a facility has 5 units and 2 processors, a total of 5 phantom images must be performed each week. Note: At least 1 phantom

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	image must be processed through each processor.
Accreditation and Certification Overview Question 4 (under Accreditation and Certification)	
	Question: We are a private radiology practice that applied for and became accredited and certified as a mammography facility. We do not own a mammography x-ray unit or employ a radiological technologist qualified to perform mammography. We had applied for accreditation using the x-ray unit and technologist from a certified mobile facility that visits our practice periodically. Do we have to be inspected separately from the mobile facility and who is responsible for correcting any problems found? Answer: If your facility and the mobile facility are both certified, you are both required to be inspected annually. Your facility and the mobile facility may, under certain circumstances, qualify under our **Inspection Fee Consolidation policy**, which could reduce your inspection fee cost. Regarding who is responsible for correction of problems, both facilities would be responsible for assuring that all aspects of mammography are in compliance prior to performing examinations on patients.
Mobile Units Equipment Quality Control Question 5 (under Quality Assurance/Equipment)	
	Question: We use FDA's guidance for mobile facilities where we produce a phantom image after a move of the mobile unit and we monitor the mAs. We then process the phantom image later, prior to processing the mammograms. If we move the mobile unit more than once per week, do we also have to produce a weekly phantom image in addition to the phantom produced after each move? Answer: If you use the mode of operation and/or technique factors used clinically for a standard breast for the phantom images that you produce after each move, you do not have to perform an additional weekly phantom image.
Transfer of Records Question 5 (under Medical Records and Reports)	
	Question: We have an FFDM unit and do not keep hardcopy of our exams (we retain the images electronically). When patients request the release of their exam, we create a hardcopy for them. May we

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	charge the patient for the cost of creating the hardcopy? Answer: The facility may not charge for creating the first hardcopy version of the mammogram. However, if the patient requests a second copy of the mammogram, the facility may pass the costs of that reproduction on to the patient.
Medical Physicist Continuing Education Question 1 (under Personnel/Medical Physicist)	
Question: Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important? Answer: Yes, the date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements. For medical physicists and radiologic technologists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians has been either October 1, 1994 or the date on which someone initially qualifies, whichever is later.	Question: Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important? Answer: Yes, the date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements. The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists is either October 1, 1994, or the date on which someone initially qualifies, whichever is later. For continuing experience for medical physicists and radiologic technologists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians is either October 1, 1994 or the date on which someone initially qualifies, whichever is later.
Medical Physicist Continuing Experience Question 1 (under Personnel/Medical Physicist)	
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begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does he/she determine this date and why is this so important? Answer: Yes, the date a medical physicist must begin meeting the continuing experience and continuing education requirements is the date on which he/she completed all of the initial requirements and are allowed to practice independently at mammography facilities or conducting medical physicist surveys. This is used as the starting date for evaluating continuing experience and continuing education requirements. For radiologic technologists and medical physicists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians has been either October 1, 1994, or the date on which someone initially qualifies, whichever is later.	begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does he/she determine this date and why is this so important? Answer: Yes, the date a medical physicist must begin meeting the continuing experience and continuing education requirements is the date on which he/she completed all of the initial requirements and are allowed to practice independently at mammography facilities or conducting medical physicist surveys. This is used as the starting date for evaluating continuing experience and continuing education requirements. For continuing experience for medical physicists and radiologic technologists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians is either October 1, 1994, or the date on which someone initially qualifies, whichever is later. The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.
Radiologic Technologist Continuing Education Question 2 (under Personnel/Radiologic Technologist)	
Question: Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important? Answer: Yes, the date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography	Question: Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important? Answer: Yes, the date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice

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New Mammographic Modality Training- Interpreting Physician Question 11- Medical Physicist Question 10- Radiologic Technologists Question 12	
	Question: We do not have an FFDM unit at our facility, however, some of our personnel use an FFDM unit at another facility. Are we responsible for maintaining documentation showing that these people have received their initial training in the new mammographic modality? Answer: No. Only the facility at which these personnel are actually using the FFDM unit is responsible for maintaining the documentation.
Frequency of Medical Outcomes Audit Analysis Question 2 (under Medical Outcomes Audit)	
	Question: How long must we maintain the records of our medical outcomes audit? Answer: The medical outcomes audit is a quality assurance record and as such must be maintained for at least 2 years. If the facility has obtained actual pathology reports, those should be maintained until the next annual inspection.
Contents of Records and Reports Question 16 (under Medical Records and Reports)	
	Question: When we assign a negative assessment to the mammography report, our reporting system automatically generates a normal lay summary. We have patients that have negative mammograms but for other reasons we want that person to have further work-up or even biopsy. In such cases can we assign a different assessment category to the mammography

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	report so the correct lay summary automatically goes out? Can the medical report and lay summary have recommendations that are not the ones normally associated with a specific assessment category? Answer: The decision of which assessment category to assign to a specific mammography report is left up to the interpreting physician. With respect to recommendations, the interpreting physician can make any recommendation he or she believes appropriate.
General Equipment Requirement Question 1 (under Equipment)	
Question: Are all regulated mammography units in the facility required to be accredited and, if so, what documentation is necessary to establish that this has been done? Answer: Yes. The facility should have documentation showing that each unit has been accredited by the accreditation body or, for new units, showing that the unit has passed an equipment evaluation or medical physicist's survey and that the application for accreditation of the unit has been submitted. There are three cases where the units in use in the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without extenuating documentation), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), or 3) the unit is an experimental one installed and used under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990 or other FDA approved research protocol. The requirements for accreditation of these units is dependent on the rules of the facility's accreditation body. Note that under both 1) and 2) the unit still must have passed an equipment evaluation or survey and each such unit will be tested by the MQSA inspector, regardless of its accreditation or ownership status.	Question: Are all regulated mammography units in the facility required to be accredited and, if so, what documentation is necessary to establish that this has been done? Answer: Yes. The facility should have documentation showing that each unit has been accredited by the accreditation body or, for new units, showing that the unit has passed an equipment evaluation and that the application for accreditation of the unit has been submitted. There are three cases where the units in use in the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without extenuating documentation), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), or 3) the unit is an experimental one installed and used under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990 or other FDA approved research protocol. The requirements for accreditation of these units is dependent on the rules of the facility's accreditation body. Note that under both 1) and 2) the unit still must have passed an equipment evaluation and each such unit will be tested by the MQSA inspector, regardless of its accreditation or ownership status.
Audit Interpreting Physician Citation (under Medical Outcomes Audit)	
Citation: 900.12(f)(3): Audit interpreting physicians. Each facility shall designate at least one interpreting	Citation: 900.12(f)(3): Audit interpreting physicians. Each facility shall designate at least one interpreting

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physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and for notifying other interpreting physicians of their results and the facility of the aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.	physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and for notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.
Radiologic Technologist Continuing Education Question 14 (under Personnel/Radiologic Technologists)	
	Question: I qualified as an MQSA radiologic technologist in the past and have been performing mammography for several years. I recently passed the test for the ARRT(M) certificate. Can I claim 24 CEU credit hours for earning this certificate toward my continuing education requirement? Answer: Yes. You can claim 24 credit hours toward the continuing education requirement for a period of time up to 36 months from the date of obtaining the ARRT(M) certificate.
Application for Extension of Provisional Certificate (under Accreditation and Certification)	
Discussion: A facility operating under a six-month provisional certificate (including a provisional reinstatement certificate) may be eligible for a single 90-day extension to its provisional certificate. (A facility operating under a three-year certificate is not eligible for a 90-day extension.) If the accreditation process is not completed within the six-month provisional period, a facility may apply to FDA, through its accreditation body, for a 90-day extension. To be eligible for a 90-day extension, a facility should have made a good faith effort to have submitted all necessary images and information in accordance with the accreditation body's schedule (i.e., to have completed accreditation in the six month provisional period).	Discussion: A facility operating under a six-month provisional certificate (including a provisional reinstatement certificate) may be eligible for a single 90-day extension to its provisional certificate. (A facility operating under a three-year certificate is not eligible for a 90-day extension.) If the accreditation process is not completed within the six-month provisional period, a facility may apply to FDA, through its accreditation body, for a 90-day extension. To be eligible for a 90-day extension, a facility should have adhered to the accreditation body's schedule in submitting the necessary images and information (i.e., to have completed accreditation in the six month provisional period) and provide evidence that there would be a significant adverse

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To apply for a 90-day extension a facility should submit a request to its accreditation body that includes: 1. The facility's accreditation body and FDA identification numbers; 2. An explicit request for a 90-day extension; 3. A description of circumstances that make the extension necessary, including what the facility is or will do to complete accreditation; 4. A specific description of how access to mammography will be reduced for the community or population served by the facility; 5. The name of a contact person, phone number, and fax number. The accreditation body will review the request and forward it, with its recommendation for or against the extension, to the FDA for a decision. FDA should then review the request and inform the facility and the accreditation body of its decision. In general FDA should be expected to follow the recommendation of the accreditation body. A facility that does not receive a 90-day extension must cease performing mammography when its provisional certificate expires, or when notified by FDA that accreditation has been denied, whichever is first.	impact on access to mammography in the geographic area served if such facility did not obtain an extension. To apply for a 90-day extension, a facility should contact its accreditation body. Note: The MQSA Facility Hotline no longer answers questions related to 90-day extensions. Consult with the accreditation body on this issue. The accreditation body will review the request and forward it, with its recommendation for or against the extension, to the FDA for a decision. FDA will then review the request and inform the facility and the accreditation body of its decision. A facility that does not receive a 90-day extension must cease performing mammography when its provisional certificate expires, or when notified by FDA that accreditation has been denied, whichever is first. Additionally, the facility should contact its accreditation body about how to resume the accreditation process.
Equipment Failing to Meet Requirement (under Quality Assurance/Equipment)	
Question: t the time of the inspection, a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service? Answer: No. However, the unit must be replaced, modified or repaired as soon as possible. The facility	Question: At the time of the inspection, a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service? Answer: No. However, the unit must be replaced, modified or repaired as soon as possible. The facility

Old Guidance	New Guidance
may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients.	may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients and the facility remains subject to possible citation.
Air Kerma and AEC Reproducibility Annual Quality Control Test Question 1 (under Quality Assurance/Equipment)	
	Question: Do units with multiple AEC detectors have to have each detector tested individually for AEC reproducibility? Answer: Where a mammography unit has multiple AEC detectors designed to function independently, each detector must be tested separately (e.g., different AEC detectors for the different size cassette holders or more than one independently selectable AEC detector in a single cassette holder). Where a mammography unit has multiple AEC detectors designed to function as a single unit, the AEC detector <u>unit</u> must be tested. For example, a single detector that can be moved to different positions needs to have the detector tested at only one of those positions. A system with three fixed detectors, each of which can be selected individually, needs to have all three detectors tested. A large field detector that automatically selects its active area needs to be tested only as a single detector.
Recordkeeping Question 4 (under Medical Records and Reports) and Transfer of Records Question 4 (under Medical Records and Reports)	
Question: With the introduction of Full Field Digital Mammography, what constitutes a mammogram, the digital data or the hard copy film? Answer: There are two sections of the recordkeeping requirement that are affected by the introduction of digital mammography. The first deals with retention of the mammography films. For purposes of film retention, the facility must maintain, in retrievable form, either the digital data or hard copy films for the specified periods of time. For purposes of transferring	Question: With the introduction of Full Field Digital Mammography, what constitutes a mammogram, the digital data or the hard copy film? Answer: There are two sections of the recordkeeping requirement that are affected by the introduction of digital mammography. The first deals with retention of the mammography films. For purposes of film retention, the facility must maintain, in retrievable form, either the digital data or hard copy films for the specified periods of time. For purposes of

Old Guidance	New Guidance
films, the facility must be able to provide the medical institution, physician, health provider, patient or patient's representative, with hard copy films of primary interpretation quality.	transferring films, the facility must be able to provide the medical institution, physician, health provider, patient or patient's representative, with hard copy films of primary interpretation quality. Facilities may transfer digital images electronically as long as that is acceptable to the recipient (e.g., between two FFDM facilities)
Application of Compression Question 3 (under Equipment)	
Question: With machines such as the GE 500T and 600T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement? Answer: Yes. After receiving input from the National Mammography Quality Assurance Advisory Committee, comments from the public, and performing its own evaluation, FDA has determined that, with proper use, fine compression can be achieved with GE 500T and 600T units by tapping the foot pedal. While FDA recognizes that fine compression can be achieved using these mammography units, the specifics of the compression device require the technologist to pay additional attention during the application of compression. Where this causes clinical problems, facilities may want to consider modifying the compression device to allow for more consistent operator control. Facilities wishing to modify their units may contact their GE service representative for more information. Before a facility decides to modify the compression device, the facility should assure itself that the unit meets all the other new requirements (AEC performance, maximum compression force, focal spot condition and radiation output) that go into effect on October 28, 2002.	Question: With machines such as the GE 500T and 600T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement? Answer: Yes. After receiving input from the National Mammography Quality Assurance Advisory Committee, comments from the public, and performing its own evaluation, FDA has determined that, with proper use, fine compression can be achieved with GE 500T and 600T units by tapping the foot pedal. While FDA recognizes that fine compression can be achieved using these mammography units, the specifics of the compression device require the technologist to pay additional attention during the application of compression. Where this causes clinical problems, facilities may want to consider modifying the compression device to allow for more consistent operator control. Facilities wishing to modify their units may try contacting third-party vendors offering such modifications for more information. Before a facility decides to modify the compression device, the facility should assure itself that the unit meets all the other new requirements (AEC performance, maximum compression force, focal spot condition and radiation output) that go into effect on October 28, 2002.
Equipment Evaluations Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs (Automatic Exposure Control)	
Thickness compensation internal* adjustment Y MP conducts evaluation in person	Thickness compensation internal* adjustment N MP oversight
Equipment Evaluations Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs (X-ray Unit)	
kVp, mA or time internal* adjustments	kVp, mA or time internal* adjustments

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Y MP conducts evaluation in person	N MP oversight Manufacturer's software modifications Y MP conducts evaluation in person
Equipment Evaluations Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs (Bucky (New to Facility) Replacement)	
AEC also replaced Y MP conducts evaluation in person AEC not replaced N MP oversight	AEC sensor also replaced Y MP conducts evaluation in person AEC sensor not replaced N MP oversight
Infection Control (under Quality Assurance/Equipment)	
Citation: 900.12(e)(I3)(i), (ii), (iii). Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall: (i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and (ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or (iii) If adequate manufacturer's recommendations are nor available, comply with generally accepted guidance on infection control, until such recommendations become available.	Citation: 900.12(e)(13)(i), (ii), (iii). Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall: (i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and (ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or (iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.
Accreditation and Certification Overview Discussion and Questions 1 and 2 (under Accreditation and Certification)	
Discussion: Accreditation and certification are two separate processes and both are required of mammography facilities under MQSA. Before a mammography facility can legally perform mammography, it must be certified. To begin the process, it must first contact its selected accreditation body (the ACR or the States of Arkansas, California,	Discussion: Accreditation and certification are two separate processes and both are required of mammography facilities under MQSA. Before a mammography facility can legally perform mammography, it must be certified. To begin the process, it must first contact its selected accreditation body (the ACR or the States of Arkansas, California,

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Iowa, or Texas if the facility is located in one of those states) and apply for accreditation. When the application has been accepted for review, the accreditation body will notify FDA, which will then send the facility a six-month provisional certificate. The facility must collect the clinical images and other data that will be needed for completion of the accreditation process and respond to all requirements of the accreditation body in a timely manner. If the facility has not completed the accreditation process prior to the expiration of the provisional certificate, it must cease performing mammography. A facility that has diligently pursued its accreditation may qualify for a 90-day extension of the provisional certificate. A new facility whose application has been accepted by an accreditation body should receive its FDA certificate within 7 to 10 days after FDA has been notified. Prior to that, the facility will receive an Interim Notice within 2 to 3 business days. A facility that has not received its Interim Notice after 3 business days should notify the Mammography Quality Assurance Program by fax at 1-410-290-6351. The facility should prominently display this interim notice until it receives its FDA Mammography Facility Certificate. Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during its annual inspections that it continues to meet the MQSA quality standards. Interested parties may find out which mammography facilities are certified as follows: · The FDA MQSA Website (http://www.fda.gov/cdrh/mammography) has a link to "Listing of FDA Certified Mammography Facilities" that lists facilities by selected state or by specified three-digit zipcode area. This information is updated weekly. · The National Cancer Institute (NCI) has	Iowa, or Texas) and apply for accreditation. When the application has been accepted for review, the accreditation body will notify FDA, which will then send the facility a six-month provisional certificate. The facility must collect the clinical images and other data that will be needed for completion of the accreditation process and respond to all requirements of the accreditation body in a timely manner. If the facility has not completed the accreditation process prior to the expiration of the provisional certificate, it must cease performing mammography. A facility that has adhered to the accreditation body process timeframes may qualify for a 90-day extension of the provisional certificate. A new facility whose application has been accepted by an accreditation body should receive its FDA certificate within 7 to 10 days after FDA has been notified. Prior to that, the facility will receive an Interim Notice within 2 to 3 business days. A facility that has not received its Interim Notice after 3 business days should notify the Mammography Quality Assurance Program by fax at 1-410-290-6351. The facility should prominently display this interim notice until it receives its FDA Mammography Facility Certificate. Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during its annual inspections that it continues to meet the MQSA quality standards. Interested parties may find out which mammography facilities are certified as follows: · The FDA MQSA Website (http://www.fda.gov/cdrh/mammography) has a link to "Listing of FDA Certified Mammography Facilities" that lists facilities by selected state or by specified three-digit zipcode area. This information is updated weekly. · The National Cancer Institute (NCI) has information regarding breast cancer and

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information regarding breast cancer and mammography, including a list of FDA-certified mammography facilities in a caller's area through their hotline: 1-800-4-CANCER (1-800-422-6237). · A complete listing of all certified facilities may be ordered from the National Technical Information Service (NTIS) for a fee. The information is updated quarterly and is provided on 3-1/2" diskettes in ASCII format. Call 1-800-363-2068 or 1-703-605-6060 to order either a single disk (SUB 5286/Code D01) or a one-year subscription (SUB-5386).	mammography, including a list of FDA-certified mammography facilities in a caller's area through their hotline: 1-800-4-CANCER (1-800-422-6237). · A complete listing of all certified facilities may be ordered from the National Technical Information Service (NTIS) for a fee. The information is updated quarterly and is provided on 3-1/2" diskettes in ASCII format. Call 1-800-363-2068 or 1-703-605-6060 to order either a single disk (SUB 5286/Code D01) or a one-year subscription (SUB-5386).
Question 1: Under what circumstances may FDA issue Interim Notices? Facilities may call the FDA hotline to request assistance when they have not received a certificate or have other questions pertaining to certification, or they may contact their accreditation body with a similar request, and the accreditation body may contact FDA to request issuance of an interim notice. In all cases the following criteria should be used by FDA to determine whether an interim notice should be issued to a facility. FDA may issue an Interim Notice to a mammography facility under the following two sets of circumstances: 1) CERTIFICATE DELAY: There may be a delay in issuing or delivering a certificate to a facility that has met the requirements for a provisional or provisional reinstatement certificate, or has completed accreditation or reaccreditation and the facility's certificate has or is about to expire. 2) REACCREDITATION OR ACCREDITATION COMPLETION DELAY: There may be a delay in completing reaccreditation or accreditation beyond the expiration date of a facility's certificate for various reasons such as delay in completion of clinical image review. For a facility to be eligible to receive an interim notice, all of the	Question 1: Under what circumstances may FDA issue Interim Notices? Facilities may call the FDA hotline to request assistance when they have not received a certificate or have other questions pertaining to certification, or they may contact their accreditation body with a similar request, and the accreditation body may contact FDA to request issuance of an interim notice. The following criteria will be used by FDA to determine whether an interim notice should be issued to a facility. FDA may issue an Interim Notice to a mammography facility under the following two sets of circumstances: 1) CERTIFICATE DELAY: There may be a delay in issuing or delivering a certificate to a facility that has met the requirements for a provisional or provisional reinstatement certificate, or has completed accreditation or reaccreditation and the facility's certificate has or is about to expire. 2) REACCREDITATION OR ACCREDITATION COMPLETION DELAY: There may be a delay in completing reaccreditation or accreditation beyond the expiration date of a facility's certificate for various reasons such as delay in completion of clinical image review. For a facility to be eligible to receive an interim notice, all of the following criteria should be met:

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following criteria should be met: a) the facility has an expired or expiring three year FDA Mammography Facility Certificate, or the facility has an expired or expiring provisional certificate and accreditation is imminent; b) the reaccrediting facility has applied for reaccreditation in a timely manner, i.e., at least six months prior to the expiration date of the its certificate. Facilities receive ample notice from their AB's seven to nine months prior to expiration of their accreditation, that they should apply for reaccreditation. FDA considers six months prior to certificate expiration to be a minimum time frame that is adequate for reaccreditation; c) the facility has shown a good faith effort in completing the accreditation/reaccreditation process in a timely manner, i.e., submitted its clinical images and other information in time to complete normal review within the six-month accreditation/reaccreditation window; and d) the delay should not otherwise be due to inappropriate facility activities. Question 2: What should a facility do if its certificate expires before it is accredited or reaccredited? If a facility's certificate expires before it has been accredited or reaccredited, it must immediately stop performing mammography or it may be subject to civil monies penalties of up to $10,000 per examination. Before the certificate expires, a facility should contact its accreditation body to see if it meets the requirements for an Interim Notice or 90-day extension.	a) the facility has an expired or expiring three year FDA Mammography Facility Certificate, or the facility has an expired or expiring provisional certificate and accreditation is imminent; b) the reaccrediting facility has applied for reaccreditation in a timely manner, i.e., at least six months prior to the expiration date of its certificate. Facilities receive ample notice from their AB's several months prior to expiration of their accreditation, that they should apply for reaccreditation. FDA considers six months prior to certificate expiration to be a minimum time frame that is adequate for reaccreditation; c) the facility has adhered to the accreditation body process timeframes, i.e., submitted its clinical images and other information in time to complete normal review within the six-month accreditation/reaccreditation window; and d) the delay should not otherwise be due to inappropriate facility activities. Question 2: What should a facility do if its certificate expires before it is accredited or reaccredited? If a facility's certificate expires before it has been accredited or reaccredited, it must immediately stop performing mammography or it may be subject to civil monies penalties of up to $10,000 per examination. Before the certificate expires, a facility should contact its accreditation body to discuss its options for continuing to perform mammography.
Recordkeeping Question 2 (under Medical Records and Reports)	
Question: A facility ceases operations and closes its doors. What actions should it take to avoid future MQSA problems and how should it deal with retention of mammographic medical records?	Question: Before a facility permanently stops performing mammography, what actions should it take to avoid future MQSA problems and how should it deal with retention of mammographic medical records?

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Answer: When a facility ceases operations and closes its doors, it should do the following: 1. Inform its accreditation body that it will no longer be performing mammography; 2. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate; 3. Notify its State radiation control program; 4. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less that 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. Facilities should check with State or local agencies to determine if their requirements are more stringent. If the option in number 4 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.	Answer: Before a facility permanently stops performing mammography, it should do the following: 1. Inform its accreditation body that it will no longer be performing mammography; 2. Notify its State radiation control program; 3. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less that 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. The facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine if their requirements are more stringent. Note: Radiology practices and other medical facilities that still see patients but have permanently stopped performing mammography, may choose to keep the patients' medical records rather than transfer them to another facility (unless the patient requests such a transfer). If the option in number 3 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested and that former patients are made aware of that mechanism. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

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	<u>Once the facility ceases operation, the MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.</u> Due to the fact that some facilities have not followed the above recommendations, FDA has been receiving inquiries from patients complaining that their mammography facility has closed, that they were not informed, and that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that the facility notify us of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to: FDA/CDRH/OHIP/DMQRP Attention: Closed Facility Notification of Records Retention 1350 Piccard Drive, HFZ-240 Rockville, MD 20850 Facilities certified by States (currently Iowa or Illinois) may send the above information to: <u>Iowa:</u> Bureau of Radiological Health Iowa Department of Public Health 401 SW 7th Street, Suite D Des Moines, IA 50309 Or call 515-281-3478 <u>Illinois:</u> Office of Radiation Safety Department of Nuclear Safety 1035 Outer Park Drive Springfield, IL 62704 Or call 217-785-9974
Infection Control Question 2 (under Quality Assurance/Equipment)	
Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for infection control? Answer: To meet the MQSA requirements for infection control, the facility must: 1. provide written documentation that describes	Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for infection control? Answer: To meet the MQSA requirements for infection control, the facility must: 1. provide written documentation that describes

Old Guidance	New Guidance
the infection control procedures used by the facility. If reference material is cited in the facility's description of its procedures, the facility must have a copy of the referenced material. The procedures used by the facility must comply with applicable Federal, State and local regulations as well as manufacturer's recommendations. 2. have logs or charts indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials.	the infection control procedures used by the facility. If reference material is cited in the facility's description of its procedures, the facility must have a copy of the referenced material. The procedures used by the facility must comply with applicable Federal, State and local regulations as well as manufacturer's recommendations. 2. have documentation (e.g., logs or charts) indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials. In those cases where there has <u>not</u> been an episode of contamination since the last inspection, the facility should make that clear to the inspector.
Contents of Records and Reports Question 1 (under Medical Records and Reports)	
Question: Under MQSA, what medical records are facilities required to maintain? Answer: FDA will accept signatures on the reports that are not hand-generated (i.e., computer- generated, mechanically generated, or stamped) provided that the qualified interpreting physician is identified on the report. FDA will also accept another qualified, interpreting physician's signature, provided that the original interpreting physician is identified on the report. It is not required that the name of the technologist be included in the written interpretation.	Question: What types of signatures are acceptable on mammography medical reports? Answer: FDA will accept hand-written signatures on the reports as well as those that are not hand-written (i.e., computer- generated, mechanically generated, or stamped) provided that the qualified interpreting physician is identified on the report (last name and first initial at a minimum). FDA will also allow another person to countersign or initial the report, provided that the original interpreting physician is identified on the report. It is not required that the name of the technologist be included in the written interpretation.
Interpreting Physician New Mammographic Modality Training Questions 2,5,6,7,8 (under Personnel/Interpreting Physician)	
Question 2: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities? Answer: The term mammographic modality refers to a technology for radiography of the breast. Examples are screen-film mammography and xeromammography. An example of a new mammographic modality that may be available in the near future is digital mammography. Personnel whose training pertained solely to screen-film mammography	Question 2: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities? Answer: The term mammographic modality refers to a technology for radiography of the breast. Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is digital mammography. Personnel whose training pertained solely to screen-film

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would be required to obtain 8 hours of training in digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, this 8 hour training requirement would not apply. New modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer. For interpreting physicians, this does not have to be category I continuing medical education. Question 5: Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the interpreting physician began interpreting Full Field Digital Mammography (FFDM) images? Answer: Yes. Interpreting physicians who began interpreting FFDM images before April 28, 1999, the effective date of the final regulations, are exempt from the requirement for 8 hours of training with that mammographic modality. However, these interpreting physicians must document their exemption. If the experience was gained before October 1, 1994, this may be done by attestation (e.g., an FDA attestation form indicating where and when the FFDM interpretations were performed) or by documentation (e.g., a letter from an appropriate official at the facility where the interpretations were performed). If the FFDM interpretation were performed after October 1, 1994, attestation is not acceptable. For more information see, acceptable documents for interpreting physicians in the PGHS. Interpreting physicians who begin working with FFDM after April 28, 1999 must have 8 hours of training in that mammographic modality before independently interpreting FFDM examinations. Interpreting physicians must document this training using the same methods as those used to document other training (certificates, letters from the training	mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, they are considered to have met the 8 hour requirement. New modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer. For interpreting physicians, this does not have to be category I continuing medical education. Question 5: Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the interpreting physician began interpreting Full Field Digital Mammography (FFDM) images? Answer: Yes. Interpreting physicians who began interpreting FFDM images before April 28, 1999, the effective date of the final regulations, are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these interpreting physicians must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM interpretations were performed. An example of acceptable documentation would be a letter from an appropriate official at the facility where the interpretations were performed. For more information see, **acceptable documents for interpreting physicians** in the PGHS. Interpreting physicians who begin working with FFDM after April 28, 1999 must document that they had 8 hours of training in that mammographic modality before independently interpreting FFDM examinations. Interpreting physicians must document this training using the same methods as those used to document other training (certificates, letters from the

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provider, etc.). For more information see, acceptable documents for interpreting physicians in the Policy Guidance Help System (PGHS). Question 6: Are there any requirements for the content of the FFDM training and are they affected in any way by changes in the field such as the publication of a new QA manual, FDA approval of soft copy interpretation, or the introduction of a new model of FFDM by a manufacturer? Answer: The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the interpreting physician's area of responsibility that are unique to the FFDM system (such as computer manipulation of images). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. If this training is category I CME, such training can also be counted towards the interpreting physician's continuing education requirement. FDA strongly recommends that interpreting physicians who received their 8 hours of FFDM training (or were exempted from it) and did not receive any training in soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently manipulate and interpret soft copy images. If category I CME, such training can also be counted towards the interpreting physician's continuing education requirement. For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above with "soft copy" interpretation should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the interpreting physician's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any interpreting physician who has not already met the 8	training provider, etc.). For more information see, **acceptable documents for interpreting physicians** in the Policy Guidance Help System (PGHS). Question 6: Are there any requirements for the content of the FFDM training and are they affected in any way by changes in the field such as the publication of a new QA manual, FDA approval of soft copy interpretation, or the introduction of a new model of FFDM by a manufacturer? Answer: The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the interpreting physician's area of responsibility that are unique to the FFDM system (such as computer manipulation of images). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. If this training is category I CME, such training can also be counted towards the interpreting physician's continuing education requirement. FDA strongly recommends that interpreting physicians whose 8 hours of FFDM training did not include any training in soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently manipulate and interpret soft copy images. If category I CME, such training can also be counted towards the interpreting physician's continuing education requirement. For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above with "soft copy" interpretation should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the interpreting physician's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any interpreting physician who has not already met the 8 hour requirement. Interpreting physicians who have

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hour requirement. Interpreting physicians who have previously met this requirement or have been exempted from it, should also receive training in the new unique features under a qualified instructor before beginning to use them independently. If category I CME, such training can also be counted towards the interpreting physician's continuing education requirement. Question 7: What qualifications have to be met by the individual providing the training? Answer: The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes interpreting physicians who have previously met the 8 hour requirement for FFDM training or were exempted from it by virtue of having begun interpreting FFDM images before April 28, 1999, as qualified to instruct other interpreting physicians in this area. Question 8: I'm an interpreting physician and worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99. Does that exempt me from having to obtain 8 hours of training specific to FFDM? Answer: No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to exempt someone from the 8 hours of training specific to FFDM.	previously met this requirement should also receive training in the new unique features under a qualified instructor before beginning to use them independently. If category I CME, such training can also be counted towards the interpreting physician's continuing education requirement. Question 7: What qualifications have to be met by the individual providing the training? Answer: The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes interpreting physicians who have previously met the 8 hour requirement for FFDM training as qualified to instruct other interpreting physicians in this area. Question 8: I'm an interpreting physician and worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99. Am I considered to have met the 8 hours of training specific to FFDM? Answer: No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.
Medical Physicist New Mammographic Modality Training Questions 1,4,5,6,7 (under Personnel/Medical Physicist)	
Question 1: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities? Answer: The term mammographic modality refers to a technology for radiography of the breast. Examples are screen-film mammography and	Question 1: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities? Answer: The term mammographic modality refers to a technology for radiography of the breast. Examples of long available mammographic modalities are

Old Guidance	New Guidance
xeromammography. An example of a new mammographic modality that may be available in the near future is digital mammography. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, this 8-hour training requirement would not apply. New modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer. Question 4: Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the medical physicist began providing services for FFDM units? Answer: Yes. Medical physicists who began surveying FFDM units before April 28, 1999, the effective date of the final regulations, are exempt from the requirement for 8 hours of training with that mammographic modality. However, these medical physicists must document their exemption. If the experience was gained before October 1, 1994, this may be done by attestation (e.g., an FDA attestation form indicating where and when the FFDM surveys were performed) or by documentation (e.g., a letter from an appropriate official at the facility where the surveys were performed). If the surveys were performed after October 1, 1994, attestation is not acceptable. For more information see, acceptable documents for medical physicists in the PGHS. Medical physicists who begin working with FFDM after April 28, 1999 must have 8 hours of training in that mammographic modality before independently surveying FFDM units. Medical physicists must document this training using the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more	screen-film mammography and xeromammography. An example of a relatively new mammographic modality is digital mammography. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, they are considered to have met the 8 hour requirement. New modality training can be in many forms, including, but not limited to, graduate training, special training courses, continuing medical education, and training provided by the manufacturer. Question 4: Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the medical physicist began providing services for FFDM units? Answer: Yes. Medical physicists who began testing and performance evaluations of FFDM units before April 28, 1999, the effective date of the final regulations, are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these medical physicists must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM testing and performance evaluations were performed. An example of acceptable documentation would be a letter from an appropriate official at the facility where the work was done. For more information see, **acceptable documents for medical physicists** in the PGHS. Medical physicists who begin working with FFDM after April 28, 1999 must document that they had 8 hours of training in that mammographic modality before independently surveying FFDM units. Medical physicists must document this training using

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information see, acceptable documents for medical physicists in the PGHS. Question 5: Are there any requirements for the content of the FFDM training and are they affected in any way by the changes in the field such as the publication of a new QA manual, FDA approval of soft copy interpretation, or the introduction of a new FFDM model by a manufacturer? Answer: The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the medical physicist's area of responsibility that are unique to the FFDM system (such as FFDM QC testing to be performed by the medical physicist). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. Such training can also be counted towards the medical physicist's continuing education requirement. FDA strongly recommends that medical physicists who received their 8 hours of FFDM training (or were exempted from it) and did not receive any training in QC tests related to soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently manipulate and interpret soft copy images. For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the medical physicist's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any medical physicist who has not already met the 8 hour requirement. Medical physicists who have previously met this requirement or have been exempted from it, should also receive training in the new unique features under a qualified instructor before beginning to use them independently. Such training	the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information see, **acceptable documents for medical physicists** in the PGHS. Question 5: Are there any requirements for the content of the FFDM training and are they affected in any way by the changes in the field such as the publication of a new QA manual, FDA approval of soft copy interpretation, or the introduction of a new FFDM model by a manufacturer? Answer: The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the medical physicist's area of responsibility that are unique to the FFDM system (such as FFDM QC testing to be performed by the medical physicist). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. Such training can also be counted towards the medical physicist's continuing education requirement. FDA strongly recommends that medical physicists whose 8 hours of FFDM training did not include any training in QC tests related to soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently perform such tests. For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the medical physicist's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any medical physicist who has not already met the 8 hour requirement. Medical physicists who have previously met this requirement should also receive training in the new unique features under a qualified instructor before beginning to evaluate them

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can also be counted towards the medical physicist's continuing education requirement. Question 6: What qualifications have to be met by the individual providing the training? Answer: The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes medical physicists who have previously met the 8 hour requirement for FFDM training or were exempted from it by virtue of having begun to provide services for FFDM units before April 28, 1999, as qualified to instruct other medical physicists in this area. Question 7: I'm a medical physicist and surveyed stereotactic biopsy systems with digital image receptors prior to 4/28/99. Does that exempt me from having to obtain 8 hours of training specific to FFDM? Answer: No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to exempt someone from the 8 hours of training specific to FFDM.	independently. Such training can also be counted towards the medical physicist's continuing education requirement. Question 6: What qualifications have to be met by the individual providing the training? Answer: The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes medical physicists who have previously met the 8 hour requirement for FFDM training as qualified to instruct other medical physicists in this area. Question 7: I'm a medical physicist and surveyed stereotactic biopsy systems with digital image receptors prior to 4/28/99. Am I considered to have met the 8 hours of training specific to FFDM? Answer: No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.
Radiologic Technologist New Mammographic Modality Training Questions 1,5,6,7,8 (under Personnel/Radiologic Technologists)	
Question 1: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities? Answer: The term mammographic modality refers to a technology for radiography of the breast. Examples are screen-film mammography and xeromammography. An example of a new mammographic modality that may be available in the near future is digital mammography. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin providing	Question 1: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities? Answer: The term mammographic modality refers to a technology for radiography of the breast. Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is digital mammography. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin

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services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, this 8 hour training requirement would not apply. New modality training can be in many forms, including, but not limited to, initial training, special training courses, continuing medical education, and training provided by the manufacturer. Question 5: Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the radiologic technologist began performing examinations with FFDM units? Answer: Yes. Radiologic technologists who began performing FFDM examinations before April 28, 1999, the effective date of the final regulations, are exempt from the requirement for 8 hours of training with that mammographic modality. However, these radiologic technologists must document their exemption. If the experience was gained before October 1, 1994, this may be done by attestation (e.g., an FDA attestation form indicating where and when the FFDM examinations were performed) or by documentation (e.g., a letter from an appropriate official at the facility where the examinations were performed). If the exams were performed after October 1, 1994, attestation is not acceptable. For more information see, acceptable documents for radiologic technologists in the PGHS. Radiologic technologists who begin working with FFDM after April 28, 1999 must have 8 hours of training in that mammographic modality before independently performing FFDM examinations. Radiologic technologists must document this training using the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information see, acceptable documents for radiologic technologists in the PGHS. Question 6: Are there any requirements for the content of the FFDM training and are they affected in	providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, they are considered to have met the 8 hour requirement. New modality training can be in many forms, including, but not limited to, initial training, special training courses, continuing medical education, and training provided by the manufacturer. Question 5: Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the radiologic technologist began performing examinations with FFDM units? Answer: Yes. Radiologic technologists who began performing FFDM examinations before April 28, 1999, the effective date of the final regulations, are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these radiologic technologists must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM examinations were performed. An example of acceptable documentation would be a letter from an appropriate official at the facility where the examinations were performed. For more information see, **acceptable documents for radiologic technologists** in the PGHS. Radiologic technologists who begin working with FFDM after April 28, 1999 must document that they had 8 hours of training in that mammographic modality before independently performing FFDM examinations. Radiologic technologists must document this training using the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information see, **acceptable documents for radiologic technologists** in the PGHS. Question 6: Are there any requirements for the

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any way by the changes in the field such as the publication of a new QA manual, FDA approval of soft copy interpretation, or the introduction of a new FFDM model by a manufacturer? Answer: The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the radiologic technologist's area of responsibility that are unique to the FFDM system (such as the procedure for performing a FFDM examination or FFDM QC testing to be performed by the radiologic technologist). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. Such training can also be counted towards the radiologic technologist's continuing education requirement. FDA strongly recommends that radiologic technologists who received their 8 hours of FFDM training (or were exempted from it) and did not receive any training in QC tests related to soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently manipulate and interpret soft copy images. For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the radiologic technologist's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any radiologic technologist who has not already met the 8 hour requirement. Radiologic technologists who have previously met this requirement or have been exempted from it, should also receive training in the new unique features under a qualified instructor before beginning to use them independently. Such training can also be counted towards the radiologic technologist's continuing education requirement.	content of the FFDM training and are they affected in any way by the changes in the field such as the publication of a new QA manual, FDA approval of soft copy interpretation, or the introduction of a new FFDM model by a manufacturer? Answer: The 8 hours of initial training related to FFDM should include practical (hands-on) training in any aspects of the use of such systems in the radiologic technologist's area of responsibility that are unique to the FFDM system (such as the procedure for performing a FFDM examination or FFDM QC testing to be performed by the radiologic technologist). The remainder of the 8 hours, if any, can be didactic or practical training related to any aspect of FFDM. The instruction must be provided by a qualified instructor. Such training can also be counted towards the radiologic technologist's continuing education requirement. FDA strongly recommends that radiologic technologists whose 8 hours of FFDM training did not include any training in QC tests related to soft copy interpretation, obtain such practical training under a qualified instructor before beginning to independently perform such tests. For other changes that can occur in the field, such as introduction of a new quality control manual by the manufacturer or the introduction of a new model of a FFDM unit, the same general principle as described above should be followed. If the new manual or model introduces new unique features to an FFDM system that fall into the radiologic technologist's area of responsibility, practical training under a qualified instructor on those features should be included in the training of any radiologic technologist who has not already met the 8 hour requirement. Radiologic technologists who have previously met this requirement should also receive training in the new unique features under a qualified instructor before beginning to use them independently. Such training can also be counted towards the radiologic technologist's continuing education requirement.

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Question 7: What qualifications have to be met by the individual providing the training? Answer: The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes radiologic technologists who have previously met the 8 hour requirement for FFDM training or where exempted from it by virtue of having begun to perform FFDM images before April 28, 1999, as qualified to instruct other radiologic technologists in this area. Question 8: I'm a radiologic technologist and worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99. Does that exempt me from having to obtain 8 hours of training specific to FFDM? Answer: No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to exempt someone from the 8 hours of training specific to FFDM.	Question 7: What qualifications have to be met by the individual providing the training? Answer: The individual providing the training must be a qualified instructor. A qualified instructor is defined in 21 CFR 900.2(oo) as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. FDA recognizes radiologic technologists who have previously met the 8 hour requirement for FFDM training as qualified to instruct other radiologic technologists in this area. Question 8: I'm a radiologic technologist and worked with stereotactic biopsy systems with digital image receptors prior to 4/28/99. Am I considered to have met the 8 hours of training specific to FFDM? Answer: No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.
Medical Physicist Acceptance Testing Report under Inspection/Survey	Medical Physicist Mammography Equipment Evaluation Testing Report under Inspection/Survey
Discussion: If the medical physicist survey report (which you review as part of an MQSA inspection) is an acceptance testing survey report for a new x-ray unit (i.e., the unit's first survey), be aware that, at the time of the survey, the physicist may not have known the exact kVp that the facility would be using for imaging the average breast. By the time of your inspection, the facility will probably have established this typical clinical value and it may differ from the value(s) the physicist used during the acceptance testing. During the acceptance testing, if the physicist used a kVp that is different from what the facility is now	Discussion: If the medical physicist survey report (which you review as part of an MQSA inspection) is a mammography equipment evaluation for a new x-ray unit (i.e., the unit's first survey), be aware that, at the time of the survey, the physicist may not have known the exact kVp that the facility would be using for imaging the average breast. By the time of your inspection, the facility will probably have established this typical clinical value and it may differ from the value(s) the physicist used during the acceptance testing. During the mammography equipment evaluation

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using as the "average clinical kVp," DO NOT cite the facility for survey report inspection questions which ask "Done at the kVp normally used clinically?" as long as the kVp(s) that was tested is within the usual range of kVp's used for mammography of an average breast.	testing, if the physicist used a kVp that is different from what the facility is now using as the "average clinical kVp," DO NOT cite the facility for survey report inspection questions which ask "Done at the kVp normally used clinically?" as long as the kVp(s) that was tested is within the usual range of kVp's used for mammography of an average breast.
Medical Physicist Survey - kVp Values Used During Testing under Inspection/Survey	
Discussion: The term "kVp normally used clinically" should be considered as synonymous with the terms “clinical kVp” or “typical kVp.” We have required the physicists to perform some tests at the kVp normally used clinically at the facility (except for surveys that are done before the facility has established that value, such as surveys of new units in new facilities). We have also allowed a latitude of +/- 1 kVp for this clinical kVp versus the kVp used in the survey tests of reproducibility (both for kVp and AEC performance), HVL, dose, and phantom image evaluation (i.e., for all inspection questions where "the kVp used clinically," appears.) For example, if the clinical kVp was 26, the test could be done at 25 kVp, 26 kVp, or 27 kVp. Likewise, fractional kVp values could be rounded off to the nearest integer without citing a noncompliance. Note: There may be cases where the technique factors that the facility was using at the time of the survey are different from the ones in use at the time of the inspection. In such cases, the technique factors in use at the time of the survey should be applied. For the kVp accuracy test and the kVp tracking portion of the AEC performance test, only the values used clinically at the facility need to be tested, up to a maximum of 3 values. If only 1 or 2 kVp’s are used, only those kVp’s need to be tested). If three or more kVp's are used, only three of those used need to be tested. Also, in the case of kVp tracking portion of the AEC performance test, if only 1 value of kVp is used clinically, the test only needs to include	Discussion: The term "kVp normally used clinically" should be considered as synonymous with the terms “clinical kVp” or “typical kVp.” We have required the physicists to perform some tests at the kVp normally used clinically at the facility (except for surveys that are done before the facility has established that value, such as surveys of new units in new facilities). We have also allowed a latitude of +/- 1 kVp for this clinical kVp versus the kVp used in the survey tests of reproducibility (both for kVp and AEC performance), HVL, dose, and phantom image evaluation (i.e., for all inspection questions where "the kVp used clinically," appears.) For example, if the clinical kVp was 26, the test could be done at 25 kVp, 26 kVp, or 27 kVp. Likewise, fractional kVp values could be rounded off to the nearest integer without citing a noncompliance. Note: There may be cases where the technique factors that the facility was using at the time of the survey are different from the ones in use at the time of the inspection. In such cases, the technique factors in use at the time of the survey should be applied. For the kVp accuracy test and the kVp tracking portion of the AEC performance test, only the values used clinically at the facility need to be tested, up to a maximum of 3 values. If only 1 or 2 kVp’s are used, only those kVp’s need to be tested). If three or more kVp's are used, only three of those used need to be tested. Also, in the case of kVp tracking portion of the AEC performance test, if only 1 value of kVp is used clinically, the test only needs to include that kVp.

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Acceptable Subject Areas and Documentation for the Continuing Education and Initial Training Requirements Question 2 (under Personnel/General)	
	Question: What information items must a training/CME/CEU certificate contain before it is considered acceptable documentation toward meeting an initial or continuing requirement? Answer: Regardless of the variety of formats used by training providers, each certificate must, at a minimum, contain the following 5 items of information in order to comply with the regulations. Some or all of the items listed below can be filled-in by the recipient of the training/CME/CEU, if done on a certificate provided by the training/CME/CEU provider. 1. Identification of the training/CME/CEU provider ▪ This usually will be the name of a teaching institution, educational or professional society, private training organization, or medical facility. ▪ If a signature block (identification of an individual representative of the training/CME/CEU provider) appears on the certificate, it must be filled in, otherwise the certificate is considered incomplete and therefore unacceptable. However, certificates without any signature block are acceptable. 2. Name of the person receiving the training/CME/CEU 3. Date(s) the training/CME/CEU was provided ▪ If the training provided occurred over a long period, e.g., the dates indicated on the certificate extend over months or years, the number of credits within the 36 month counting period applicable to the current inspection must be identified on the certificate or in accompanying documents. 4. Training/CME/CEU subjects(s) ▪ Initial training must be in the subjects required by the regulations for the applicable personnel group (interpreting physician, radiologic

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	technologist or medical physicist). ▪ Continuing education must be in initial training subjects or other subjects related to the diagnosis or treatment of breast disease, or other areas that will aid facility personnel in improving the quality of mammography. ▪ If the certificate is not specific as to subject matter, facility personnel may be able to use "Attestation For Continuing Education After October 1 1994" as described in the Policy Guidance Help System. 5. Number of training/CME/CEU credits awarded ▪ Interpreting physician credits must be identified as Category I (unless being used for initial new mammographic modality training). ▪ If the certificate indicates the person may "claim up to "X" credits" in acceptable training/CME/CEU subjects, the inspector should assume "X" credits were awarded, unless the certificate indicates that fewer credits were actually earned.
When the Inspector Finds a Facility Using an Expired Certificate Question 1 (under Inspection/General)	
Question: What should an inspector do when he/she finds a facility performing mammography and is in possession of only an expired MQSA facility certificate? Answer: Step 1: The inspector should determine whether the expired certificate on display is the only certificate that the facility has; keeping in mind that the facility may have forgotten to replace the expired certificate with the current certificate when they received it in the mail. Step 2: If facility personnel indicate that they have only the expired certificate, the inspector should confirm that they are/have been performing mammography and get as much information about what is going on with the facility as possible (e.g., has the facility submitted an application/reapplication to their accreditation body recently, have they received a	Question: What should an inspector do when he/she finds a facility performing mammography and is in possession of only an expired MQSA facility certificate? Answer: Step 1: The inspector should determine whether the expired certificate on display is the only certificate that the facility has; keeping in mind that the facility may have forgotten to replace the expired certificate with the current certificate when they received it in the mail. Step 2: If facility personnel indicate that they have only the expired certificate, the inspector should confirm that they are/have been performing mammography and get as much information about what is going on with the facility as possible (e.g., has the facility submitted an application/reapplication to their accreditation body recently, have they received a

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response yet, has there been a change in the name of their facility recently, etc.?). The inspector should tell facility personnel that taking mammograms when their certification is expired is unlawful. Step 3: The inspector should call the FDA while at the facility. You may use either of the following two routes to reach DMQRP. A. Call the MQSA Inspector Helpdesk at (301) 827-1241, or B. Call the Facility Helpline at 1(800) 838-7715, tell the telephone operator who you are ask that he/she call the MQSA Inspector Helpdesk immediately and have a DMQRP staff member call you at the facility ASAP (As Soon As Possible). A DMQRP staff member will call you right back. At this time, FDA will review the records regarding the certification status of this facility. Based on the information revealed during this review, FDA will advise the inspector regarding any additional instructions for conducting the inspection. Step 4: The inspector should instruct facility personnel to immediately return their expired certificate to the FDA at the following address: FDA MQSA P.O. Box 6057 Columbia, MD 21045-6057 Step 5: As of October 1998, the MQSA was amended to allow FDA to inspect mammography facilities, regardless of whether they are certified at the time of the inspection or not. Therefore, you should proceed with your inspection and document any problems that are found.	response yet, has there been a change in the name of their facility recently, etc.?). The inspector should tell facility personnel that taking mammograms when their certification is expired is unlawful. Step 3: The inspector should call the FDA while at the facility. To do that, call the MQSA Inspector Helpdesk at (301) 827-1241 and press "0" to get immediate assistance from DMQRP. At this time, FDA will review the records regarding the certification status of this facility. Based on the information revealed during this review, FDA will advise the inspector regarding any additional instructions for conducting the inspection. Step 4: The inspector should take possession of their expired certificate. Step 5: As of October 1998, the MQSA was amended to allow FDA to inspect mammography facilities, regardless of whether they are certified at the time of the inspection or not. Therefore, the inspector should proceed with the inspection and document any problems that are found.
General Equipment Requirement Question 3 (under Equipment)	
Question: At the time of the inspection, a mammographic unit is found to not meet one or more	Question: At the time of the inspection, a mammographic unit is found to not meet one or more

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of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service? Answer: No. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients.	of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service? Answer: No. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients and the facility remains subject to possible citation.