The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #2; 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

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The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #2

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, regulations, or both.

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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.

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 Radiologic Technologists/Initial Training/Obtained Prior to 10/1/94	
1. ~~Attestation~~ 2. ~~Letter or other document from training program~~ 3. ~~CEU certificates~~ 4. ~~Letter or other document confirming in-house or formal training~~	1. Attestation 2. Letter or other document from training program 3. CEU certificates 4. Letter or other document confirming in-house or formal training 5. ARRT(M) Mammography certificate 6. California Mammography certificate 7. Arizona Mammography certificate 8. Nevada Mammography certificate
Acceptable Documents for Radiologic Technologists/Initial Training/Obtained 10/1/94-4/28/99	
~~1. Letter or other document from training program~~ ~~2. CEU certificates~~ ~~3. Letter or other document confirming in-house or formal training~~ ~~4. Approved courses~~	1. Letter or other document from training program 2. CEU certificates 3. Letter or other document confirming in-house or formal training **4. Approved RT training courses** 5. ARRT(M) Mammography certificate 6. California Mammography certificate 7. Arizona Mammography certificate 8. Nevada Mammography certificate
Acceptable Documents for Radiologic Technologists/Continuing Experience	
~~Continuing Experience (200/24 months-final regs~~	Continuing Experience (200/24 months-final regs)
Approved courses satisfying the initial Radiologic Technologist training requirement if obtained between 10/1/94 and 4/28/99	
1. ~~Successful completion of "A Three Day Mammography Course for Technologists" provided by Medical Technology Management Institute of Milwaukee, Wisconsin. Denise Sedmak, 1-800-765-6864.~~ 2. ~~Successful completion of "Initial Training in Mammography" provided by Mammography Imaging Specialists of Portland, Oregon. Joanie Wilmot, 503-659-5022, or Kathleen Durrell, 503-579-4662.~~ 3. ~~Successful completion of "Mammography Instruction for Radiologic Technologists" provided by Oakland Community College of Southfield, Michigan. Carolyn Nacy, 810-552-2610.~~ 4. ~~Successful completion of "Three Day Mammography Workshop" provided by the Mammographers Radiological Society of Miramar,~~	1. Successful completion of "A Three Day Mammography Course for Technologists" provided by Medical Technology Management Institute of Milwaukee, Wisconsin. Denise Sedmak, 1-800-765-6864. 2. Successful completion of "Initial Training in Mammography" provided by Mammography Imaging Specialists of Portland, Oregon. Joanie Wilmot, 503-659-5022, or Kathleen Durrell, 503-579-4662. 3. Successful completion of "Mammography Instruction for Radiologic Technologists" provided by Oakland Community College of Southfield, Michigan. Carolyn Nacy, 810-552-2610. 4. Successful completion of "Three Day Mammography Workshop" provided by the

Old Guidance	New Guidance
~~Florida. Judy Sorge, 954-981-7120.~~ 5. ~~Successful completion of "Mammography - Quality Performance Assurance," provided by Rad Tech Resources, Inc. of Indianapolis, Indiana. Terri Von Tobel, 317-780-5840.~~ 6. ~~Successful completion of "Achieving Quality Images 3-Day Mammography Seminar" provided by Achieving Quality Images of East Grand Rapids, Michigan at 1-800-522-3439.~~ 7. ~~Successful completion of "Mammography" provided by Rose State College of Midwest City, Oklahoma. Jo Bishop at 405-733-7569.~~ 8. ~~Successful completion of "Initial Mammography Training" provided by Mammography Accreditation Consultants of Rock Hall, Maryland. Judith Hagerty and Jerry Lockwood at 1-800-570-2511.~~ 9. ~~Successful completion of "Initial Training in Mammography " provided by Mid South X-Ray Company of Jackson, Mississippi. Becky Hollis at 601-825-9998.~~	Mammographers Radiological Society of Miramar, Florida. Judy Sorge, 954-981-7120. 5. Successful completion of "Mammography - Quality Performance Assurance," provided by Rad Tech Resources, Inc. of Indianapolis, Indiana. Terri Von Tobel, 317-780-5840. 6. Successful completion of "Achieving Quality Images 3-Day Mammography Seminar" provided by Achieving Quality Images of East Grand Rapids, Michigan at 1-800-522-3439. 7. Successful completion of "Mammography" provided by Rose State College of Midwest City, Oklahoma. Jo Bishop at 405-733-7569. 8. Successful completion of "Initial Mammography Training" provided by Mammography Accreditation Consultants of Rock Hall, Maryland. Judith Hagerty and Jerry Lockwood at 1-800-570-2511. 9. Successful completion of "Initial Training in Mammography " provided by Mid South X-Ray Company of Jackson, Mississippi. Becky Hollis at 601-825-9998.
Acceptable Documents for Medical Physicists	
	Add "FDA Approval Letter" to the following requirements in all time periods. 1. State Licensure or Approval 2. Board Certification 3. Degree in physical science 4. Initial physics Education 5. Survey training 6. Initial Experience
Mobile Units Equipment Quality Control (under Equipment) Question 3	
~~Question: How does a facility demonstrate satisfactory performance for mobile units after they are moved to a new location?~~ ~~Answer: For those facilities with mobile units, each mammography unit must be tested after moving to a new examination location and before examining any patients to verify the adequacy of the image quality produced by each unit.~~ ~~As an example of an acceptable test, a phantom image can be taken in the AEC mode (or the mode used clinically) after the move but prior to patient~~	Question: How does a facility demonstrate satisfactory performance for mobile units after they are moved to a new location? Answer: For those facilities with mobile units, each mammography unit must be tested after moving to a new examination location and before examining any patients to verify the adequacy of the image quality produced by each unit. As an example of an acceptable test, a phantom image can be taken in the AEC mode (or the mode used

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~~examination. This image is then either processed and evaluated at the mobile unit site (if possible), or processed off-site and evaluated to verify performance prior to examining patients. A passing score for this phantom image verifies that the unit is performing adequately after moving and before patient examination.~~ ~~Another example is to (1) for a given kVp, record the mAs resulting from a phantom exposure (in the AEC mode under typical clinical conditions or the mode used clinically); (2) compare that mAs to a standard mAs value previously established as ensuring output consistency; and (3) if the two readings are within +/- 10%, proceed with clinical examinations; otherwise take corrective actions to bring the two values within this limit before proceeding with clinical examinations. A crucial follow-up to this test by the facility is to process (using a processor in control) and score the phantom image taken in step (1) at the earliest time available and before batch processing any of the clinical images. If this phantom fails because of any processing problems, the problems should be corrected prior to processing any of the clinical images. If the phantom image fails due to a non-processor problem, the mobile facility should still process all the films. Each clinical exam should be evaluated individually to determine whether any of the patients have to be recalled to have their images repeated. The entire imaging chain must be checked and adjusted or repaired prior to further clinical use.~~ ~~Other tests designed by qualified personnel (the medical physicist should be consulted) could be acceptable but may have to be evaluated by the inspector on a case-by-case basis.~~	clinically) after the move but prior to patient examination. This image is then either processed and evaluated at the mobile unit site (if possible), or processed off-site and evaluated to verify performance prior to examining patients. A passing score for this phantom image verifies that the unit is performing adequately after moving and before patient examination. Another example is to (1) for a given kVp, record the mAs resulting from a phantom exposure (in the AEC mode under typical clinical conditions or the mode used clinically); (2) compare that mAs to a standard mAs value previously established as ensuring output consistency; and (3) if the two readings are within +/- 10%, proceed with clinical examinations; otherwise take corrective actions to bring the two values within this limit before proceeding with clinical examinations. A crucial follow-up to this test by the facility is to process (using a processor in control) and score the phantom image taken in step (1) at the earliest time available and before batch processing any of the clinical images. If this phantom fails because of any processing problems, the problems should be corrected prior to processing any of the clinical images. If the phantom image fails due to a non-processor problem, the mobile facility should still process all the films. Each clinical exam should be evaluated individually to determine whether any of the patients have to be recalled to have their images repeated. The entire imaging chain must be checked and adjusted or repaired prior to further clinical use. If the facility takes a phantom image as part of its post-move/pre-examination testing, it must document the phantom image score. The facility must keep the written records of post-move/pre-examination tests for the last 12 months or since the last inspection, whichever is longer, and the phantom images for the last 30 days. Other tests designed by qualified personnel (the medical physicist should be consulted) could be acceptable but may have to be evaluated by the

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	inspector on a case-by-case basis.
Infection Control (under Quality Assurance/Equipment) Question 1	
~~Question: What infection control procedures are required under MQSA?~~ ~~Answer: Facilities must establish and follow a protocol for cleaning and disinfecting mammography equipment that has come in contact with blood or other body fluids or potentially infectious materials. MQSA inspectors will be looking for such a protocol or procedure that the facility is following. A sign-off sheet recording cleaning after each patient is not required. For additional guidance on this, refer to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), any additional State and local regulations on this subject that may be applicable to the facility, and manufacturer's procedures specific to their equipment.~~	Question: What infection control procedures are required under MQSA? Answer: Facilities must establish and follow a protocol for cleaning and disinfecting mammography equipment that has come in contact with blood or other body fluids or potentially infectious materials. MQSA inspectors will be looking for such a protocol or procedure that the facility is following. Although recording routine cleaning after each patient is not required, some type of log or chart is needed documenting that infection control procedures were performed each time the mammography equipment came into <u>contact with blood or other potentially infectious agents</u>. For additional guidance on this, refer to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), any additional State and local regulations on this subject that may be applicable to the facility, and manufacturer's procedures specific to their equipment.
Communication of Results to Patients Question 20 (under Medical Records and Reports)	
	Question: Must a facility provide the patient with a written lay summary even if the results are incomplete and additional imaging is needed? Answer: Yes. Even if the facility verbally transmits the results to the patient, the facility must provide, within 30 days of the examination, a written lay summary indicating that additional imaging is required. If the results of the follow-up examination are available within 30 days of the initial examination, the facility has the option of combining the results into one lay summary (rather than providing two lay summaries). If one combined lay summary is provided, it must state specifically that it refers to both the initial and the follow-up examinations. If the results of the follow-up examination are not available within 30 days of the initial examination, the facility must provide two lay summaries, one for the initial examination and one for the follow-up.

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	Each must be provided within 30 days of the examination it covers.
Weekly Equipment Quality Control Tests Question 16 (under Quality Assurance/Equipment)	
	Question: We use the BACE mode in our Bennett machine to image our patients with the standard breast. In this mode the unit automatically determines the exposure technique factors based on the thickness of the compressed breast. During normal clinical use, the breast compresses and the system provides accurate thickness readings and technique factors. However, when we use this mode (as required by the regulations) for the weekly phantom test, we do not compress the phantom (to avoid damaging the paddle or the phantom) leading to inaccurate thickness readings. These inaccurate thickness readings may cause the unit to select inappropriate exposure technique factors. Can we <u>manually</u> adjust the scale to the thickness of the standard breast before we expose the phantom using the BACE mode? Given the situation described above, is it permissible to expose the phantom using the AEC (see **Phantom Images Exposed in Fully Automatic Mode if that is the Clinically Used Technique**), rather than the BACE mode? Answer: You are permitted to manually adjust the scale to the thickness of the standard breast before exposing the phantom using the BACE mode. Because you do not use the AEC mode to image your patients with the standard breast, you may <u>not</u> use the AEC mode to perform the weekly phantom test.
Direct Supervision of RTs and MPs Question 3 (under Definitions)	
~~Question: What does it mean to be under the direct supervision of a qualified medical physicist?~~ ~~Answer: For the performance of a medical physicist survey, direct supervision means that the supervisor is present to observe and correct, as needed, the performance of the trainee. This requires that the supervisor be in the room during the time the survey is being conducted. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the trainee are corrected before the equipment is used on patients.~~	Question: What does it mean to be under the direct supervision of a qualified medical physicist? Answer: For the physics survey and/or equipment evaluation, direct supervision means that the supervisor (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by

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	the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility. Furthermore, when conducting a physics survey, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.
Signature on Survey Report Question 1 (under Inspection/Survey)	
~~Question: Can a physicist sign-off on all the physics surveys that are done by his surrogates whether or not he/she did the actual survey (i.e., was not actually present during the survey at the facility)?~~ ~~Answer: No, the qualified physicist would have had to present during the survey. The important issue here is that the name of the physicist who conducted the survey be identified in the report and he or she is the one that must be qualified and checked for the proper credentials during the inspection. If more than one person was present to conduct the survey, as would occur during direct supervision, that other person must be identified in the report. On-site presence during the survey means that the person either conducted the survey or was present in the x-ray or test room, as a supervisor for another, not yet qualified person who conducted the survey.~~	Question: Can a medical physicist sign-off on a physics survey done by a surrogate if the medical physicist was not present during the survey? Answer: No. The qualified physicist (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) would have to be present during the survey and, at a minimum, provide direct supervision over his/her surrogate (supervisee). Direct supervision means that the qualified medical physicist (supervisor) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility. Furthermore, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the

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	supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed. The supervisor must sign the survey report. The qualifications of the supervising medical physicist will be checked during the inspection. The names of all those being supervised must also be identified in the report.
Equipment Evaluations Question 4 (under Quality Assurance/Equipment)	
	Question: Can a medical physicist sign-off on an equipment evaluation done by a surrogate if the medical physicist was not present during the evaluation? Answer: No. The qualified physicist would have to be present during the equipment evaluation and, at a minimum, provide direct supervision over his/her surrogate (supervisee). Direct supervision means that the supervisor (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the tests are completed.

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	The supervisor must be identified in the report. The qualifications of the supervising medical physicist will be checked during the inspection. The names of all those being supervised should also be identified in the report.
Medical Physicist Annual Survey Question 3 (under Quality Assurance/Equipment)	
~~Question: Individuals providing physics services to mammography facilities must meet initial and continuing education requirements (900.12 (a)(3)). The training and experience needed to meet those qualifications must be acquired by providing physics services to facilities. To allow new people to acquire the necessary training, FDA has said that they can carry out these actions under the direct supervision of qualified individuals. Also, medical physicists who have met the initial qualifications but fail to meet the continuing education requirement must requalify in order to practice independently. During their requalification period, the medical physicist must practice under direct supervision. This raises the question of, "what constitutes direct supervision?"~~ ~~Answer: The goal of direct supervision is to provide reasonable assurance that any mistakes made by the physicist-in-training or the requalifying physicist are corrected before harm is done to the patients.~~ ~~Direct supervision during the survey of the facility's equipment and QA/QC program means that the supervising physicist is present to observe and correct, as needed, the performance of the physicist-in-training and the requalifying physicist. This requires that the supervising physicist be present during the majority of the time the survey is being conducted.~~ ~~This requirement applies to any survey conducted after October 1, 1994, by physicists who have not satisfied the initial qualifications (physicist-in-training) or by those physicists that are undergoing requalification.~~	Question: Individuals providing physics services to mammography facilities must meet initial and continuing education requirements (900.12 (a)(3)). The training and experience needed to meet those qualifications must be acquired by providing physics services to facilities. To allow new people to acquire the necessary training, FDA has stated that they can carry out these actions under the direct supervision of qualified individuals. Also, medical physicists who have met the initial qualifications but fail to meet the continuing education requirement must requalify in order to practice independently. During their requalification period, the medical physicist must practice under direct supervision. This raises the question of, "what constitutes direct supervision?" Answer: Direct supervision means that the supervisor (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility. Furthermore, when conducting a physics survey, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued.

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	The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.
Quality Assurance Program Question 7 (under Quality Assurance/General)	
~~Question: How should facilities document performance of the required QC tests to comply with the regulations?~~ ~~Answer: Performance of the required QC tests must include clear and legible documentation. The documentation must include the dates when the tests were performed. For each test result that falls outside the action limits, the documentation must also include the date and the corrective actions taken and their results. The data and results should be properly charted or tabulated. Facilities may consult any appropriate quality control manual for examples of charts and tables or establish their own format for documenting the test data and the results.~~	Question: How should facilities document performance of the required QC tests to comply with the regulations? Answer: Performance of the required QC tests must include clear and legible documentation. The documentation must include test results and the dates when the tests were performed. For each test result that falls outside the action limits, the documentation must also include the date and the corrective actions taken and their results. The data and results should be properly charted or tabulated. Facilities may consult any appropriate quality control manual for examples of charts and tables or establish their own format for documenting the test data and the results.
Decompression Annual Quality Control Test Question 4 (under Quality Assurance/Equipment)	
~~Question: The regulations state that while in automatic decompression override status, mammography equipment must provide "maintenance of compression" after completion of an exposure or in case of a power interruption. What degree of compression and for how long must it be maintained?~~ ~~Answer: The intent of this requirement is that systems in override status allow the continuation of compression so that it is not released in a manner likely to cause patient injury. The facility should evaluate system use in their clinical setting. Those systems used for both invasive and non-invasive procedures provide the greatest potential for injury. In this context, the degree of compression and the time for which it is maintained should be assessed with regard to the potential for patient injury.~~	Question: The regulations state that while in automatic decompression override status, mammography equipment must provide "maintenance of compression" after completion of an exposure or in case of a power interruption. What degree of compression and for how long must it be maintained? Answer: The intent of this requirement is that systems in override status allow the continuation of compression so that it is not released in a manner likely to cause patient injury. The facility should evaluate system use in their clinical setting. The concerns for non-interventional procedures relate to the stability and balance of the patient and the potential falling hazard resulting from unexpected release. Although interventional mammography is not covered under current regulations, these procedures add the concern of uncontrolled needle withdrawal and attendant tissue damage and we recommend that these units be tested against the same requirement.

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	Non-interventional units that were not designed to provide automatic release after the completion of an exposure or upon power interruption also are not covered under this requirement. However, we recommend that such units be tested to assure that they meet their design intent. In each context, the degree of compression maintenance and the time for which it needs to be applied should be assessed with regard to the likely potential for patient injury. Any problems identified by the physicist should be evaluated together with other responsible facility personnel and should be based on the use of the system in their specific clinical setting.
Equipment Evaluations Question 1 (under Quality Assurance/Equipment)	
~~Question: When are "additional mammography equipment evaluations" required and who must conduct the evaluations?~~ ~~Answer: Whenever a new unit or processor is installed, disassembled and reassembled at the same or a new location, or major components are changed or repaired, an evaluation of the mammography unit or image processor is required. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist.~~ ~~This additional evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. For a new unit,~~	Question: When are "additional mammography equipment evaluations" required and who must conduct the evaluations? Answer: Whenever a new unit or processor is installed, or a unit or processor is reassembled, or major components are changed or repaired, an evaluation of the mammography unit or image processor is required. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist. The equipment evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. The equipment

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~~an equipment evaluation is needed before the unit is used on patients unless the unit has already undergone a full survey. In this situation, the facility must follow the accreditation body procedures. Keep in mind that under MQSA, the facility has the ultimate responsibility for ensuring image quality and patient safety. If changes or repairs to the system are anticipated, contact the facility's accreditation body to inquire whether the change affects a major component and requires an evaluation.~~ ~~The equipment evaluation must be performed by a qualified medical physicist or by an individual under the direct supervision of the medical physicist. These evaluations will be used to determine whether the new or changed equipment meets the requirements of applicable standards in 900.12(b) and (e). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. A facility should maintain documentation that shows the date(s) on which a mammography equipment evaluation was performed, who performed the evaluation, and that any identified problems were corrected before the equipment was used on patients. A facility must maintain this documentation until the next inspection that verifies compliance.~~	evaluation must be performed by a qualified medical physicist or by an individual under the direct supervision of the medical physicist. The evaluation will be used to determine whether the new or changed equipment meets the requirements of applicable standards in 900.12(b) and (e). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The facility must maintain (until the next inspection that verifies compliance) the report of the equipment evaluation and all documentation showing that all problems identified in the equipment evaluation were corrected before the equipment was used on patients. The report should document the date(s) on which the mammography equipment evaluation was performed and who performed the evaluation.
Use of Test Results Question 2 (under Quality Assurance/Equipment)	
	Question: How should a facility document the corrective actions that have been taken in response to quality control tests that fall outside the action limits and how should it document the effectiveness of those actions? Answer: The corrective actions taken should be documented by the individual who took the actions. The documentation can be in the form of a service report or any other document that lists the actions taken. The documentation required on the effectiveness of the corrective actions depends upon their nature. For corrective actions involving major repairs, the facility's medical physicist must perform an equipment evaluation after completion of the

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	corrective actions. The report of that evaluation showing that the equipment now meets the requirements will serve as documentation that the corrective actions were effective. For corrective actions that did not require a major repair, the facility must document that the failed tests were repeated following the corrective actions and that the test results are now within the action limits. In this case, the test may be performed by any person with adequate training, not just the medical physicist. See Draft Guidance Document #4 **Table: Medical Physicist Involvement in Equipment Repairs.**
Weekly Equipment Quality Control Tests Question 8 (under Quality Assurance/Equipment)	
~~Question: When performing the weekly phantom QC test, should we use film from the box currently being used to produce clinical exams or film from the box used for quality control purposes?~~ ~~Answer: It is recommended that the phantom image evaluation test be performed using films from the box currently being used to produce clinical mammograms. If dedicated boxes of QC films are used for the phantom tests, the chance of detecting problems with the clinically used film is sacrificed.~~ ~~FDA realizes that, due to differences in emulsion batches, a phantom image test with films from a new box may show variance in optical density and density difference greater than the allowed limits (when measured against the operating level established with films from the previous box). In such a case, facilities are advised to first check the whole imaging chain including the processor performance (facilities may wish to contact their medical physicist for help with this process). If no problems are detected, the facility may assume the change is due to different film emulsions. They may then adjust their typical clinical technique factors to meet the phantom optical density requirements.~~	Question: When performing the weekly phantom QC test, should we use film from the box currently being used to produce clinical exams or film from the box used for quality control purposes? Answer: It is recommended that the phantom image evaluation test be performed using films from the box currently being used to produce clinical mammograms. If dedicated boxes of QC films are used for the phantom tests, the chance of detecting problems with the clinically used film is sacrificed. FDA realizes that, due to differences in emulsion batches, a phantom image test with films from a new box may show variance in optical density and density difference greater than the allowed limits (when measured against the operating level established with films from the previous box). In such a case, facilities are advised to first check the whole imaging chain including the processor performance (facilities may wish to contact their medical physicist for help with this process). If no problems are detected, the facility may assume the change is due to different film emulsion batches. They may then adjust their typical clinical technique factors to meet the phantom optical density requirements.
Weekly Equipment Quality Control Tests Question 12 (under Quality Assurance/Equipment)	
~~Question: If the OD for the weekly phantom test falls below 1.20, must the unit be recalibrated or can we~~	Question: If the optical density (OD) for the weekly phantom test falls below 1.20 (and/or changes by

Old Guidance	New Guidance
~~adjust the density setting to obtain a 1.20 OD?~~ ~~Answer: If the OD at the center of the phantom image falls below the required minimum of 1.20 OD, the facility should take the following steps:~~ ~~1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images.~~ ~~2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications.~~ ~~3. Check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images (assuming that the facility has been tracking mAs and has been using the same kVp and film emulsion/screen combination). If the mAs has changed by more than 15%, the medical physicist should be called to check the entire imaging chain, including the mammography unit.~~ ~~4. Adjust the density control setting (if no problems are found in steps 2 and 3) to obtain a density of at least 1.20 OD at the center of the phantom image.~~ ~~5. Adjust the density control settings used clinically to be consistent with the changes in step 4.~~ ~~If the density again falls below 1.20 OD the next time the phantom image is performed (using the film from the same box and the same density and processor settings), the facility should consult with its physicist and check the entire imaging chain before performing mammograms.~~	more than +/- 0.20 from the established operating level), must the unit be recalibrated or can we adjust the density setting to obtain a 1.20 OD? Answer: If the OD at the center of the phantom image falls below the required minimum of 1.20 (and/or changes by more than +/- 0.20 from the established operating level), the facility should follow pathway A, B, or C; below, based on the situation at the facility: A. If the film is of a different type (e.g., switch from Min-R 2000 to Min-R E) from the previous week's passing test, the facility should establish new phantom QC operating levels. B. If the film emulsion batch is unchanged from the previous week's passing test: 1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images. 2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications. 3. If the facility has been tracking mAs, check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images. If the mAs has changed by more than 15%, and the facility has been using the same kVp, the same mammography unit density setting, and the processor is operating within its action limits, then the medical physicist should be called to check the entire imaging chain, including the mammography unit. If the mAs has not changed by more than 15%, then proceed with step 4. If the facility has <u>not</u> been tracking mAs, the

Old Guidance	New Guidance
	facility should consult with its medical physicist for what to do next. 4. If no problems are found in steps 2 and 3, adjust the density control setting to obtain an optical density of at least 1.20 at the center of the phantom image (or obtain an optical density within +/- 0.20 of the established operating level). 5. Adjust the density control setting used clinically to be consistent with the changes made in step 4. C. If the film is of the same type but of a different emulsion batch from the previous week's passing test, the facility should follow the steps as described in B 1 through 5. If the optical density again falls below 1.20 (and/or changes by more than +/- 0.20 from the established operating level) the next time the weekly phantom test is performed, the facility should follow the appropriate pathway (based on the film emulsion used) from the following three options: a. If film of a different type (e.g., switch from Min-R 2000 to Min-R E) is used, the facility should establish new phantom QC operating levels. b. If film of the same emulsion batch is used (assuming the same kVp and mammography unit density settings are used, and the processor is operating within its action limits), the facility should consult with its physicist and check the entire imaging chain before performing mammograms. c. If film of the same type (but not of the same emulsion batch) is used, the facility should repeat steps B 1 through 5.
Weekly Equipment Quality Control Tests Question 13 (under Quality Assurance/Equipment)	
~~Question: If the OD for the weekly phantom test changes by more than +/- 0.20 from the established operating level, must the unit be recalibrated or can we~~	Delete question and answer.

Old Guidance	New Guidance
~~adjust the density setting to bring the OD within the action limits of the operating level?~~ ~~Answer: If the OD changes by more than +/- 0.20 from the established operating level, the facility should take the following steps:~~ ~~1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images.~~ ~~2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications.~~ ~~3. Check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images (assuming that the facility has been tracking mAs and has been using the same kVp and film emulsion/screen combination). If the mAs has changed by more than 15%, the medical physicist should be called to check the entire imaging chain, including the mammography unit.~~ ~~4. Adjust the density control setting (if no problems are found in steps 2 and 3) to obtain a density within +/- 0.20 of the established operating level.~~ ~~5. Adjust the density control settings used clinically to be consistent with the changes in step 4.~~ ~~If the density again changes by more than +/- 0.20 from the established operating level (using the film from the same box and the same density and processor settings), the facility should consult with its physicist and check the entire imaging chain before performing mammograms.~~	
Daily QC Tests Question 5 (under Quality Assurance/Equipment)	
	Question: We are sending our densitometer out for a regularly scheduled calibration. While it is gone, how

Old Guidance	New Guidance
	can we continue with our daily quality control program until it is returned? Can we use a "loaner" densitometer or perform some substitute test in the interim? Answer: The daily processor quality control is required prior to processing patient films. No alternative is currently available to verify processor performance without a densitometer. If your facility plans to use a loaner densitometer, reintroduce one into service after repair/calibration, or obtains a new densitometer, you should contact your medical physicist for instructions on how to proceed.
Medical Physicist Continuing Education Question 6 (under Personnel/Medical Physicist)	
~~Question: May medical physicists count general medical physics continuing education not related to mammography or general continuing education in mammography unrelated to medical physics?~~ ~~Answer: Yes, all continuing education credits related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography may be acceptable toward meeting the continuing education requirement. Diagnostic medical physics continuing not directly related to mammography or general continuing education in mammography unrelated to medical physics would also be acceptable. However, physicists must make sure they obtain continuing education appropriate to each mammographic modality evaluated by them.~~	Question: May medical physicists count general medical physics continuing education not related to mammography or general continuing education in mammography unrelated to medical physics? Answer: Yes, all continuing education credits related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography may be acceptable toward meeting the continuing education requirement. Diagnostic medical physics continuing education not directly related to mammography or general continuing education in mammography unrelated to medical physics would also be acceptable. However, physicists must make sure they obtain continuing education appropriate to each mammographic modality evaluated by them.
Application to an Accreditation Body Question 9 (under Accreditation and Certification)	
~~Question: When a facility moves, relocates, or changes its name, is the certificate still valid? What should the facility do to ensure that it continues to receive MQSA mailings?~~ ~~Answer: When a facility moves, relocates, or changes its name, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require (in the case of a move). Once those requirements are satisfied, the accreditation body will inform FDA of the facility's new address. FDA will~~	Question: A facility moves or relocates and the address on its certificate is no longer correct. Is the certificate still valid? Answer: When a facility moves or relocates, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. Once those requirements are satisfied, the accreditation body will inform FDA of the facility's new address. FDA will then issue a new certificate to the facility reflecting the new address.

Old Guidance	New Guidance
~~then issue a new certificate to the facility reflecting the new address.~~ ~~Until the new certificate is received, the facility must prominently display its original certificate. The certification expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. The original certificate must be returned to FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~ ~~Additionally, only the accreditation bodies have the authority to modify the facility mailing list. Therefore, if a facility fails to notify its accreditation body of a change of address, it will not continue to receive MQSA mailings, such as Federal Register notices.~~	Until the new certificate is received, the facility must prominently display its original certificate. The expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new certificate arrives, the original certificate should not be displayed. The facility should file or destroy the original certificate after it receives the new certificate.
Certificate Question 3 (under Definitions)	
~~Question: A facility has changed its name but has the same owner, personnel, and equipment. Is the certificate still valid even though the facility name is different?~~ ~~Answer: When a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. Once the facility has complied with the accreditation body's requirements, it will inform FDA of the facility's new name. FDA will then issue a new certificate to the facility.~~ ~~Until the new certificate is received, the facility must prominently display its original certificate. The certification expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. The original certificate must be returned to FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~	Question: A facility has changed its name but has the same owner, personnel, and equipment. Is the certificate still valid even though the facility name is different? Answer: When a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. Once the facility has complied with the accreditation body's requirements, it will inform FDA of the facility's new name. FDA will then issue a new certificate to the facility. Until the new certificate is received, the facility must prominently display its original certificate. The expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new certificate arrives, the original certificate should not be displayed. The facility should file or destroy the original certificate after it receives the new certificate.
Certificate Question 4 (under Definitions)	

Old Guidance	New Guidance
~~Question: A facility moves or relocates and the address on its certificate is no longer correct. Is the certificate still valid?~~ ~~Answer: When a facility moves or relocates, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. Once those requirements are satisfied, the accreditation body will inform FDA of the facility's new address. FDA will then issue a new certificate to the facility reflecting the new address.~~ ~~Until the new certificate is received, the facility must prominently display its original certificate. The certification expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. The original certificate must be returned to FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~	Question: A facility moves or relocates and the address on its certificate is no longer correct. Is the certificate still valid? Answer: When a facility moves or relocates, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. Once those requirements are satisfied, the accreditation body will inform FDA of the facility's new address. FDA will then issue a new certificate to the facility reflecting the new address. Until the new certificate is received, the facility must prominently display its original certificate. The expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new certificate arrives, the original certificate should not be displayed. The facility should file or destroy the original certificate after it receives the new certificate.
Certificate Question 5 (under Definitions)	
~~Question: What should a facility do if it closes or decides that it will no longer provide mammography services?~~ ~~Answer: The facility must immediately return its certificate to the FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~ ~~The facility should also contact its accreditation body and inform it that the facility is no longer practicing mammography.~~	Question: What should a facility do if it closes or decides that it will no longer provide mammography services? Answer: The facility should contact its accreditation body and inform it that the facility is no longer practicing mammography. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.
Definition of Certificate Question 3 (under Accreditation and Certification)	
~~Question: A facility has changed its name but has the same owner, personnel, and equipment. Is the certificate still valid even though the facility name is different?~~	Question: A facility has changed its name but has the same owner, personnel, and equipment. Is the certificate still valid even though the facility name is different?

Old Guidance	New Guidance
~~Answer: When a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. Once the facility has complied with the accreditation body's requirements, it will inform FDA of the facility's new name. FDA will then issue a new certificate to the facility.~~ ~~Until the new certificate is received, the facility must prominently display its original certificate. The certification expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. The original certificate must be returned to FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~	Answer: When a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. Once the facility has complied with the accreditation body's requirements, the accreditation body will inform FDA of the facility's new name. FDA will then issue a new certificate to the facility. Until the new certificate is received, the facility must prominently display its original certificate. The expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new certificate arrives, the original certificate should not be displayed. The facility should file or destroy the original certificate after it receives the new certificate.
Definition of Certificate Question 4 (under Accreditation and Certification)	
~~Question: A facility moves or relocates and the address on its certificate is no longer correct. Is the certificate still valid?~~ ~~Answer: When a facility moves or relocates, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. Once those requirements are satisfied, the accreditation body will inform FDA of the facility's new address. FDA will then issue a new certificate to the facility reflecting the new address.~~ ~~Until the new certificate is received, the facility must prominently display its original certificate. The certification expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. The original certificate must be returned to FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~	Question: A facility moves or relocates and the address on its certificate is no longer correct. Is the certificate still valid? Answer: When a facility moves or relocates, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. Once those requirements are satisfied, the accreditation body will inform FDA of the facility's new address. FDA will then issue a new certificate to the facility reflecting the new address. Until the new certificate is received, the facility must prominently display its original certificate. The expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new certificate arrives, the original certificate should not be displayed. The facility should file or destroy the original certificate after it receives the new certificate.
Definition of Certificate Question 5 (under Accreditation and Certification)	
~~Question: What should a facility do if it closes or~~	Question: What should a facility do if it closes or

Old Guidance	New Guidance
~~decides that it will no longer provide mammography services?~~ ~~Answer: The facility must immediately return its certificate to the FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~ ~~The facility should also contact its accreditation body and inform it that the facility is no longer practicing mammography.~~	decides that it will no longer provide mammography services? Answer: The facility should contact its accreditation body and inform it that the facility is no longer practicing mammography. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.
General Requirements for Accreditation and Certification Question 1 (under Accreditation and Certification)	
~~Question: What should a facility do if it closes or decides that it will no longer provide mammography services?~~ ~~Answer: The facility must immediately return its certificate to the FDA at:~~ ~~FDA MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057.~~ ~~The facility should also contact its accreditation body and inform it that the facility is no longer practicing mammography.~~	Question: What should a facility do if it closes or decides that it will no longer provide mammography services? Answer: The facility should contact its accreditation body and inform it that the facility is no longer practicing mammography. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.
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?~~ ~~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. Return its facility certificate to its certifying body. For facilities certified by FDA , the certificate~~	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? 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;

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~~should be mailed to P.O. Box 6057 Columbia, MD 21045-6057;~~ ~~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.~~	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.
Letters with Inspection Report and Facility Comments (under Inspection/Report)	
~~Discussion:~~ ~~Facilities need to understand how to respond if they have received multiple levels of findings. Facilities need to respond to any inspections with Level 1 and/or 2 violations in writing (Level 1 after FDA has sent the facility a letter; for Level 2 and repeated Level 3 findings, the facility must respond within 30 days after they receive their inspection results). Non-repeated Level 3 findings do not need to be addressed in writing. However, these findings must be corrected and these corrections would normally checked during the next annual inspection. Please attempt to make sure that facility personnel understand what they should do and/or what will happen after the inspection is over.~~	Discussion: Facilities need to understand how to respond if they have received multiple levels of findings. Facilities need to respond to any inspections with Level 1 and/or 2 violations in writing (Level 1 and repeated Level 2 after FDA has sent the facility a letter; for Level 2 and repeated Level 3 findings, the facility must respond within 30 days after they receive their inspection results). Non-repeated Level 3 findings do not need to be addressed in writing. However, these findings must be corrected and these corrections would normally be checked during the next annual inspection. The inspector should make sure that facility personnel understand what they should do and/or what will happen after the inspection is over.

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~~Corrective Action Communication:~~ ~~For any facility inspection, the inspector should give facility personnel three separate documents:~~ ~~1. One of four different cover letters (the letters were developed for the maximum level of finding during an inspection);~~ ~~2. The "How to Interpret the Inspection Report and Respond to the FDA" document; and~~ ~~3. The post-inspection report (MQSA Facility Inspection Report).~~ ~~These documents, along with verbal instructions, should be issued to the appropriate personnel at the facility. Inspectors are strongly encouraged to attempt to discuss the findings with the most responsible official available at the time of the inspection. Also, attempt to make sure that facility personnel understand that they should submit their response to the appropriate FDA district (or regional) office, with the State radiation control office receiving a copy. You might also mention that the facility response to the inspection findings should not be sent to the FDA address in Columbia. That address should only be used if the facility intends to comment on the inspection process in general.~~ ~~Facility Comments:~~ ~~Facilities should be instructed only to use the 800 number (which is included of the "How to Interpret the Inspection Report and Respond to the FDA" document) for general comments about the inspection process and general MQSA questions, not to ask inspection-specific questions. If personnel at a facility have inspection-specific questions relevant to an upcoming or recent inspection, they should contact the MQSA Inspector. who conducted the inspection, or the State radiation control office. If the inspector cannot answer the questions, the FDA district office or DMQRP should be contacted.~~	Corrective Action Communication: For any facility inspection, the inspector should give facility personnel two separate documents: 1. One of six different cover letters (the letters were developed for the maximum level of finding during an inspection); 2. The post-inspection report (MQSA Facility Inspection Report). These documents, along with verbal instructions, should be issued to the appropriate personnel at the facility. Inspectors are strongly encouraged to attempt to discuss the findings with the most responsible official available at the time of the inspection. The inspector should also attempt to make sure that facility personnel understand that they should submit their response to the appropriate FDA district (or regional) office, with the State radiation control office receiving a copy. The inspector might also mention that the facility response to the inspection findings should not be sent to the FDA address in Columbia. That address should only be used if the facility intends to comment on the inspection process in general. Facility Comments: Facilities should be instructed only to use the Facility Hotline number (1-800-838-7715) for general comments about the inspection process and general MQSA questions, not to ask inspection-specific questions. If personnel at a facility have inspection-specific questions relevant to an upcoming or recent inspection, they should contact the MQSA Inspector who conducted the inspection, or the State radiation control office. If the inspector cannot answer the questions, the FDA district office or DMQRP should be contacted.
Extension of the 14 Month Limit (under Inspection/Survey)	

Old Guidance	New Guidance
~~Discussion:~~ ~~Policy:~~ ~~When there is an extenuating circumstance(s), such as an impending move, which makes it impractical to have the annual physicist's survey performed within a 14-month time period, facilities should contact their State or the FDA District Office (whichever conducts their annual inspections) and request permission to defer the current survey until after the move has been completed, or until the extenuating circumstance(s) is no longer applicable.~~ ~~The facility must explain, in writing, the reason for the request and establish a reasonable schedule showing the date by which the deferred physics survey will be completed. The State or FDA, based on the facility's history and circumstances, may at their discretion, approve a delay for such cases. If needed, States may consult with the FDA on a case-by-case basis.~~ ~~When the State or the district office approves a delay for the annual physicist survey and the MQSA inspection is conducted before the approved delay is over, then the inspector should enter a CLAIMED as an answer to the question SURVEY REPORT AVAILABLE: and record the reason for this in the printable Remarks for the SURVEY REPORT section.~~ ~~The facility should be instructed to send a copy of the report to the inspector once the physicist survey is performed. The inspector will then need to evaluate the survey report, edit the inspection record (answer the physics survey questions), and re-upload the inspection data to DMQRP.~~ ~~Background:~~ ~~The Statute and the regulations require that a physicist's survey be performed annually. As a matter of policy, FDA has allowed facilities up to 14 months between the date of the MQSA inspection and the most recent physicist's survey to meet this requirement. While this policy has worked reasonably well in most cases, possible situations may exist in which adhering to this policy would place an undue burden on a facility.~~ ~~One such situation is when a facility plans to move to~~	Discussion: Policy: When there is an extenuating circumstance(s), such as an impending move, which makes it impractical to have the annual physicist's survey performed within a 14-month time period, facilities should contact their State or the FDA District Office (whichever conducts their annual inspections) and request permission to defer the current survey until after the move has been completed, or until the extenuating circumstance(s) is no longer applicable. The facility must explain, in writing, the reason for the request and establish a reasonable schedule showing the date by which the deferred physics survey will be completed. The State or FDA, based on the facility's history and circumstances, may at their discretion, approve a delay for such cases. If needed, States may consult with the FDA on a case-by-case basis. When the State or the district office approves a delay for the annual physicist survey and the MQSA inspection is conducted before the approved delay is over, then the inspector should enter an “X” (“X” denotes not applicable) as the answer to the question SURVEY REPORT AVAILABLE: and record the reason for this in the printable Remarks for the SURVEY REPORT section. The facility should be instructed to send a copy of the report to the inspector once the physicist survey is performed. The inspector will then need to evaluate the survey report, edit the inspection record (answer the physics survey questions), and re-upload the inspection data to DMQRP. Background: The Statute and the regulations require that a physicist's survey be performed annually. As a matter of policy, FDA has allowed facilities up to 14 months between the date of the MQSA inspection and the most recent physicist's survey to meet this requirement. While this policy has worked reasonably well in most cases, possible situations may exist in which adhering to this policy would place an undue

Old Guidance	New Guidance
~~a new location on a date that either coincides with or slightly exceeds 14 months from the date of their most recent physics survey. Requiring a physics survey before such an impending move, simply to meet the annual requirement for the limited time period before the facility moves, would not serve the intent of the regulation. Remember that the facility will be required by their accreditation body to have a physics survey after the move. If exceptions were allowed to the 14-month policy to permit facilities to defer the physicist's survey until they have moved to the new address, an unnecessary burden would be lifted from these facilities. FDA reviewed the situation described above and has issued the above policy.~~	burden on a facility. One such situation is when a facility plans to move to a new location on a date that either coincides with or slightly exceeds 14 months from the date of their most recent physics survey. Requiring a physics survey before such an impending move, simply to meet the annual requirement for the limited time period before the facility moves, would not serve the intent of the regulation. Remember that the facility will be required by their accreditation body to have a physics survey after the move. If exceptions were allowed to the 14-month policy to permit facilities to defer the physicist's survey until they have moved to the new address, an unnecessary burden would be lifted from these facilities. FDA reviewed the situation described above and has issued the above policy.
Use of Claimed or C (under Inspection/General)	
~~Discussion:~~ ~~1. There is five-business day limit for the facility to provide claimed documentation. Inspectors are instructed not to deviate from this time frame except under special circumstances (see item 7 below). After April 28, 1999, the facility would also be cited for lack of personnel documentation. There would be no upload of the inspection until the five business days have passed.~~ ~~2. If the facility were able to provide adequate documentation within five days, the inspector would upload the inspection without any Claimed data. The inspector would also need to print the post inspection report to remove the claimed items and mail this report to the facility.~~ ~~3. If the facility is not able to provide adequate documentation within five days or inadequate documentation is provided, the inspector would print a new report changing any Claimed data to Level 1 and/or 2 findings. The new printed report would be mailed to the facility (along with a new cover letter, if a higher level of findings is now present for the inspection). The inspector would now upload the inspection. The facility is now responsible for~~	As of March 1, 2001, inspectors will no longer be able to use the Claimed "C" option. In the case where a facility is unable, at the time of the inspection, to supply proper documentation of meeting a requirement but claims to have such documentation, the inspector should: 1. Leave the item blank. The inspection software will include this item in the missing data report. 2. The inspector should delay uploading the inspection for up to 5 business days. If the facility supplies the proper documentation, the inspection should be revised accordingly, uploaded to FDA as usual, and a printed post inspection report should be provided to the facility. If the facility does not supply the proper documentation within 5 business days, the inspection question(s) should be answered "NO". The inspection should then be uploaded to FDA as usual, and a printed post inspection report with the new non-compliance should be provided to the facility. Note: In those cases where the facility's inability to provide the necessary documentation within the 5 day period is beyond the facility's control, the inspector should contact the Inspector HelpDesk for further

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~~responding to Level 2 findings within 30 business days or will get a Warning Letter for Level 1 findings.~~ ~~4. If the FDA district gets documentation that personnel were qualified at the time of the inspection in response Level 1 and/or 2 findings (that were changed from Claimed data), the district would edit the inspection record to remove those Level 1 and/or 2 findings. The district would print a new, revised post-inspection report and mail it to the facility with the adequate response letter. For Level 1 findings, if the claimed documentation is provided to the district office prior to the issuance of the Warning Letter, the letter would not need to be issued. However, if the letter must be issued to comply with time frames, the letter would indicate that the findings were based on the facility not being able to provide documentation at the time of the inspection.~~ ~~5. If the district must update an inspection, the reason for the change should be recorded in the appropriate Remarks section of the inspection record. Changes to personnel findings ('Claimed' to 'No' or 'No' to 'Claimed') should be recorded in the appropriate section (interpreting physician, radiologic technologist, or medical physicist).~~ ~~6. If the FDA district can no longer edit an uploaded inspection (inspection too old), the district would inform DMQRP about the need for a change in the inspection record. DMQRP would change the inspection record and send the changed report to the district by E-mail, so the district could mail the report to the facility with the adequate response letter.~~ ~~7. Special exception – in cases where documentation is missing and, in the inspector's judgment, through no fault of the facility, a facility may be given up to 30 days (and in rare cases longer) to provide the documentation. An example of this type of problem would be no current medical licenses for interpreting physicians at the facility, due to problems with the licensing boards. The inspector will still be responsible for uploading the inspection within five business days (with the Claimed data) and~~	instructions.

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~~also responsible for notifying the district about the circumstances that would justify allowing the facility an extended time period to provide claimed documentation. The deadline for providing the documents, along with the reason for the extension should be explained in the appropriate printed Remarks section. The inspector would also be responsible for informing the facility that the documentation should be forwarded to the FDA district office for final evaluation.~~ ~~Note:~~ ~~The above policy only mentioned documentation related to the personnel area. Inspectors may use the Claimed data for the survey report that is claimed by the facility. For claimed survey reports, the same procedure should be followed as for personnel documentation.~~	
Corrected Before Inspection (CBI) Policy (under Inspection/Report)	
~~Discussion:~~ ~~An inspector should not routinely cite a facility for Level 2 or 3 noncompliant finding(s) that occurred since the last inspection and were then corrected before the current inspection. These corrected problems could be in any areas of the inspection. The most likely areas where this policy could be applied would be for quality control testing or personnel qualifications. Consideration needs to be given to those facilities that discover and correct their problem(s) before the problem(s) gets worse. Inspectors should use the printable Remarks Section to record the problematic finding(s) and that it had been CBI. During the exit interview at the end of the inspection, the inspector should remind facility personnel that the noncompliance should not be allowed to recur. The historical record entered into the Remarks Section(s) and the discussion during the exit interview is important, should the facility have serious problems later and FDA considers action against the facility in the future.~~ ~~Since inspector observations and judgment are crucial~~	Discussion: An inspector should not routinely cite a facility for Level 2 or 3 noncompliant finding(s) that occurred since the last inspection and were then corrected before the current inspection. These corrected problems could be in any part of the inspection. The most likely areas where this policy could be applied would be for quality control testing or personnel qualifications. Consideration needs to be given to those facilities that discover and correct their problem(s) before the problem(s) gets worse. Inspectors should use the printable Remarks Section to record the problematic finding(s) and verify that it had been CBI. During the exit interview at the end of the inspection, the inspector should remind facility personnel that the noncompliance should not be allowed to recur. The historical record entered into the Remarks Section(s) and the discussion during the exit interview is important, should the facility have serious problems later and FDA considers action against the facility in the future. Since inspector observations and judgment are crucial

Old Guidance	New Guidance
~~in making a determination as to whether a facility has permanently corrected a problem, the following examples are provided as some guidance to help you in making this determination.~~	in making a determination as to whether a facility has permanently corrected a problem, the following examples are provided as some guidance to help the inspector in making this determination.
~~When a noncompliance is found to have previously occurred, but is no longer present at the time of the inspection, the facility should be able to provide an explanation of what actions were taken to correct the problem. If facility personnel do not know why/how the problem was resolved or do not even know the problem existed, an inspector may assume that the noncompliance was not corrected by actions of the facility personnel. Furthermore, noncompliant item(s) that are corrected during the inspection ("on-the-spot" corrections) are not to be treated as though they were "corrected before inspection." So in both of the above scenarios the facility should be cited (i.e., the noncompliant item not having been identified as a problem by facility personnel with actions taken to permanently correct it, and/or the correction of a noncompliant finding at the time of an inspection).~~	When a noncompliance is found to have previously occurred, but is no longer present at the time of the inspection, the facility should be able to provide an explanation of what actions were taken to correct the problem. If facility personnel do not know why/how the problem was resolved or do not even know the problem existed, an inspector may assume that the noncompliance was not corrected by actions of the facility personnel. Furthermore, noncompliant item(s) that are corrected during the inspection ("on-the-spot" corrections) are not to be treated as though they were "corrected before inspection." So in both of the above scenarios the facility should be cited (i.e., the noncompliant item not having been identified as a problem by facility personnel with actions taken to permanently correct it, and/or the correction of a noncompliant finding at the time of an inspection).
~~There is another example when inspectors should cite a facility. This is when there was a noncompliant finding cited during the prior year's inspection, the facility corrected the problem after that inspection, then the same noncompliance occurred again, and was again corrected by the facility. While this facility has corrected the problem(s), its corrective actions did not result in a permanent fix, and as such, the noncompliance is likely to occur again. In this type of situation, the facility should be cited.~~	There is another example when inspectors should cite a facility. This is when there was a noncompliant finding cited during the prior year's inspection, the facility corrected the problem after that inspection, then the same noncompliance occurred again, and was again corrected by the facility. While this facility has corrected the problem(s), its corrective actions did not result in a permanent fix, and as such, the noncompliance is likely to occur again. In this type of situation, the facility should be cited.
~~Lastly, the CBI policy is not to be confused with the "C" Option policy where facilities may "claim" that that the facility meets a specific requirement, but that documentation was not present at the time of the inspection. Problems found under the CBI policy are actual violations of MQSA, but FDA has decided by policy not to cite facilities that correct these minor problems prior to the inspection. When the "C" Option is used, the inspector does not know whether a violation exists until the missing documentation can be evaluated [or the facility cannot produce any~~	Background: During the initial stages of the inspection program, FDA recognized that there would be a transition period after October 1, 1994, during which some facility staffs might still not be fully informed of the details of the MQSA requirements. During this period, there was the possibility that even facilities whose staffs believed they were in full compliance

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~~documentation].~~ ~~Background:~~ ~~During the initial stages of the inspection program, FDA recognized that there would be a transition period after October 1, 1994, during which some facility staffs might still not be fully informed on the details of the MQSA requirements. During this period, there was the possibility that even facilities whose staffs believed they were in full compliance with the regulations would actually unknowingly be falling short in one or more areas. It was also possible that as the facility staffs became more knowledgeable about the MQSA requirements, they would themselves discover and correct the deficiencies before their first inspection. In fact, FDA received several calls from facilities and inspectors about such situations. The callers wondered if the facilities would or should be penalized for a problem that had existed for some time after October 1, 1994, but had been corrected. In nearly all cases, this situation occurred in the personnel area and involved a staff member who on being found to be unqualified was either given additional training or was no longer used by the facility in the mammography area. FDA realized that if a deficiency was declared in such situations, it would be in the position of telling facilities to correct problems that they had already corrected, perhaps even months earlier. Not only would this not contribute to improving the quality of mammography, but would not recognize facilities that had already taken actions on their own to correct problems. These facilities are not equivalent to those that waited for inspectors to tell them action was needed.~~ ~~Therefore on May 8, 1995, FDA issued its "corrected-before-inspection" (CBI) policy to the inspectors stating that facilities should not be cited for problems that had existed for some time after October 1, 1994, but had been CBI. Although violations were not to be cited in such situations, inspectors were instructed to indicate that the problem had existed and been corrected in the Remarks section related to each area~~	with the regulations would actually unknowingly be falling short in one or more areas. It was also possible that as the facility staff became more knowledgeable about the MQSA requirements, they would themselves discover and correct the deficiencies before their first inspection. In fact, FDA received several calls from facilities and inspectors about such situations. The callers wondered if the facilities would or should be penalized for a problem that had existed for some time after October 1, 1994, but had been corrected. In nearly all cases, this situation occurred in the personnel area and involved a staff member who on being found to be unqualified was either given additional training or was no longer used by the facility in the mammography area. FDA realized that if a deficiency was declared in such situations, it would be in the position of telling facilities to correct problems that they had already corrected, perhaps even months earlier. Not only would this not contribute to improving the quality of mammography, but would not recognize facilities that had already taken actions on their own to correct problems. These facilities are not equivalent to those that waited for inspectors to tell them action was needed. Therefore on May 8, 1995, FDA issued its "corrected-before-inspection" (CBI) policy to the inspectors stating that facilities should not be cited for problems that had existed for some time after October 1, 1994, but had been CBI. Although violations were not to be cited in such situations, inspectors were instructed to indicate that the problem had existed and been corrected in the Remarks section related to each area and during the exit interview to remind the facility staff that the problem should not be allowed to reoccur. This was intended as a basis for more stringent action against facilities that might be tempted to abuse this policy. On January 2, 1997, this policy was modified to exclude level 1 findings from those findings that have been CBI that would not be cited against the facility. Problems that could result in a Level 1 finding would

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~~and during the exit interview to remind the facility staff that the problem should not be allowed to reoccur. This was intended as a basis for more stringent action against facilities that might be tempted to abuse this policy.~~ ~~On January 2, 1997, this policy was modified to exclude level 1 findings from those findings that have been CBI that would not be cited against the facility. Problems that could result in a Level 1 finding would be cited against the facility, but the Warning Letter to the facility would recognize that the violation(s) were CBI and address the specific actions expected from the facility for those items.~~	be cited against the facility, but the Warning Letter to the facility would recognize that the violation(s) were CBI and would address the specific actions expected from the facility for those items.
Direct Supervision of Interpreting Physicians Question 2 (under Definitions)	
~~Question: During annual MQSA inspections, mammography personnel are sometimes found to not meet one or more of the personnel qualifications. May this individual (interpreting physician) continue to lawfully provide mammography services to the facility?~~ ~~While an individual's qualifications are still under evaluation (e.g., a "Claimed" answer has been entered in response to one or more of the qualification questions), that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual. The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.~~	Question: During annual MQSA inspections, mammography personnel are sometimes found to not meet one or more of the personnel qualifications. May this individual (interpreting physician) continue to lawfully provide mammography services to the facility? Answer: While an individual's qualifications are still under evaluation, that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual. The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.
Direct Supervision of RTs and MPs Question 4 (under Definitions)	
~~Question: During annual MQSA inspections, mammography personnel are sometimesfound to not meet one or more of the personnel qualifications. May this individual (medical physicist, radiologic technologist) continue to lawfully provide mammography services to the facility?~~	Question: During annual MQSA inspections, mammography personnel are sometimes found to not meet one or more of the personnel qualifications. May this individual (medical physicist, radiologic technologist) continue to lawfully provide mammography services to the facility?

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~~While an individual's qualifications are still under evaluation (e.g., a "Claimed" answer has been entered in response to one or more of the qualification questions), that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual. The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.~~	Answer: While an individual's qualifications are still under evaluation, that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual. The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.
MQSA Inspection Questions (under Inspector's Questions)	
~~Discussion:~~ ~~Following are the questions that MQSA inspectors will address during the course of the annual inspection.~~ ~~Mammography Quality Standards Act (MQSA)~~ ~~V 3.1 Inspection Questions under the Final Regulations~~ ~~3.10 Medical Physicist's Survey~~ ~~List (of all units except those not in use since the previous inspection)~~ ~~Information~~ ~~Survey report available?~~ ~~("c": claimed items)~~ ~~Date of previous survey~~ ~~Date of current survey~~ ~~Survey conducted or supervised by~~ ~~Action taken (if called for in Report)?~~ ~~3.11 Personnel~~ ~~Status (Evaluate, Hold)~~	Discussion: Following are the questions that MQSA inspectors will address during the course of the annual inspection. Mammography Quality Standards Act (MQSA) V 3.2 Inspection Questions under the Final Regulations 3.10 Medical Physicist's Survey List (of all units except those not in use since the previous inspection) Information Survey report available? Date of previous survey Date of current survey Survey conducted or supervised by Action taken (if called for in Report)? 3.11 Personnel Status (Evaluate, Hold) Lead interpreting physician [ ] – one only may be

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~~Lead interpreting physician [ ] – one only may be checked~~	checked
~~Name xxx [FIRST, M.I., LAST] (caps, separate fields)~~	Name xxx [FIRST, M.I., LAST] (caps, separate fields)
~~UPIN~~	UPIN
~~Evaluation~~	Evaluation
~~Rules qualifying under (interim, final) [select one]~~	Rules qualifying under (interim, final) [select one]
~~If you selected the interim rules:~~	If you selected the interim rules:
~~Initial qualifications under interim rules met? (prior to 4/28/99) (y/n/c)~~	Initial qualifications under interim rules met? (prior to 4/28/99) (y/n)
~~- Licensed?~~	- Licensed?
~~- Certified or 2 months training?~~	- Certified or 2 months training?
~~- 40 CME hours~~	- 40 CME hours
~~- Initial experience adequate? (240 exams/6 months)~~	- Initial experience adequate? (240 exams/6 months)
~~If you selected the final rules:~~	If you selected the final rules:
~~Initial qualifications met? (y/n/c)~~	Initial qualifications met? (y/n)
~~- Licensed?~~	- Licensed?
~~- Certified or 3 months training?~~	- Certified or 3 months training?
~~- 60 category I CME hours?~~	- 60 category I CME hours?
~~- Initial experience adequate? (240 exams/6 months)~~	- Initial experience adequate? (240 exams/6 months)
~~Date completed initial requirements~~	Date completed initial requirements
~~New modality training (8 hours) (if applicable)(y/n/c/x)~~	New modality training (8 hours) (if applicable)(y/n/x)
	Continuing experience
~~Continuing experience~~	Continuing experience adequate? (960 exams/24 months) (y/n/x)
~~Continuing experience adequate? (960 exams/24 months) (y/n/c/x)~~	If “n”, then:
~~If “n”, then:~~	Number of exams in 24 months
~~Number of exams in 24 months~~	
	Continuing education
~~Continuing education~~	
	CME credits adequate? (15/36 m) (y/n/x)
~~CME credits adequate? (15/36 m) (y/n/c/x)~~	If “n”, then
~~If “n”, then~~	Number of CME’s in 36 months
~~Number of CME’s in 36 months~~	

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~~3.11.2 Technologists~~	3.11.2 Technologists
~~List (if more than one)~~	List (if more than one)
~~Information~~	Information
~~Status (Evaluate, Hold)~~ ~~Name yyy [FIRST, M.I., LAST] (caps, separate fields)~~	Status (Evaluate, Hold) Name yyy [FIRST, M.I., LAST] (caps, separate fields)
~~Evaluation~~	Evaluation
~~Rules qualifying under (interim, final) [select one]~~	Rules qualifying under (interim, final) [select one]
~~If you selected the interim rules:~~	If you selected the interim rules:
~~Initial qualifications under interim rules met? (prior to 4/28/99) (y/n/c)~~ ~~- Licensed or certified~~ ~~- Training specific to mammography~~	Initial qualifications under interim rules met? (prior to 4/28/99) (y/n) - Licensed or certified - Training specific to mammography
~~If you checked the final rules:~~ ~~Initial qualifications met? (y/n/c)~~ ~~- Licensed OR Certified? (y/n/c)~~ ~~- 40 supervised hours of training adequate?(y/n/c)~~	If you checked the final rules: Initial qualifications met? (y/n) - Licensed OR Certified? (y/n) - 40 supervised hours of training adequate?(y/n)
~~Date completed initial requirements~~	Date completed initial requirements
~~New modality training (8 hrs.) (if applicable) (y/n/c/x)~~ ~~- Continuing experience adequate? [200 exams/24months] (y/n/c/x)~~	New modality training (8 hrs.) (if applicable) (y/n/x) - Continuing experience adequate? [200 exams/24months] (y/n/x)
~~Continuing education~~	Continuing education
~~CEU credits adequate? (15/36 months) (y/n/c/x)~~ ~~If "n", then :~~ ~~Number of CEU's in 36 months~~	CEU credits adequate? (15/36 months) (y/n/x) If "n", then : Number of CEU's in 36 months
~~3.11.3 Medical Physicists~~	3.11.3 Medical Physicists
~~List (if more than one)~~ ~~Information~~	List (if more than one) Information
~~Status (Evaluate, Hold)~~	Status (Evaluate, Hold)

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~~Name zzz [FIRST, M.I., LAST] (caps, separate fields)~~ ~~Evaluation~~ ~~Degree qualifying under (Masters or higher, Bachelors, None) [select one]~~ ~~If you selected "Masters (or higher)":~~ ~~Initial qualifications met? (y/n/c)~~ ~~- Certified or state licensed/approved? (y/n/c)~~ ~~- Masters degree in a physical science? [w/20 sem. hrs. in physics] (y/n/c)~~ ~~- 20 contact hours of training in surveys? (y/n/c)~~ ~~- Experience in conducting surveys? (1 facility & 10 units) (y/n/c)~~ ~~If you selected "Bachelors":~~ ~~Alternative initial qualifications met before 4/28/99? (y/n/c)~~ ~~- Certified or state licensed/approved? (y/n/c)~~ ~~- Bachelor's degree in a physical science [w/10 sem. hrs in physics] (y/n/c)~~ ~~(physical science: physics, chemistry, engineering, radiation science)~~ ~~- 40 contact hrs. training in surveys (after Bachelors) (y/n/c)~~ ~~- Experience in conducting surveys (after Bachelors) (1 facility & 20 units) (y/n/c)~~ ~~Date completed initial requirements~~ ~~-New modality training (8 hours) (if applicable) (y/n/c/x)~~ ~~Continuing experience adequate? (2 facilities & 6 units/24months) (y/n/c/x)~~	Name zzz [FIRST, M.I., LAST] (caps, separate fields) Evaluation Degree qualifying under (Masters or higher, Bachelors, None) [select one] If you selected "Masters (or higher)": Initial qualifications met? (y/n) - Certified or state licensed/approved? (y/n) - Masters degree in a physical science? [w/20 sem. hrs. in physics] (y/n) - 20 contact hours of training in surveys? (y/n) - Experience in conducting surveys? (1 facility & 10 units) (y/n) If you selected "Bachelors": Alternative initial qualifications met before 4/28/99? (y/n) - Certified or state licensed/approved? (y/n) - Bachelor's degree in a physical science [w/10 sem. hrs in physics] (y/n) (physical science: physics, chemistry, engineering, radiation science) - 40 contact hrs. training in surveys (after Bachelors) (y/n) - Experience in conducting surveys (after Bachelors) (1 facility & 20 units) (y/n) Date completed initial requirements -New modality training (8 hours) (if applicable) (y/n/x) Continuing experience adequate? (2 facilities & 6 units/24months) (y/n/x)
Retention of Personnel Records (under Personnel/General)	
~~Inspector Instructions:~~ ~~1. Answer the personnel qualification questions with "Y, N, C, or X," as appropriate for the~~	Inspector Instructions: 1. Answer the personnel qualification questions with "Y, N, or X," as appropriate for the verification

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~~verification dates defined in the examples above ("C" denotes claimed and "X" denotes not applicable).~~ ~~2. If at least 24 months have not passed since an interpreting physician met his/her initial qualifications, the answer for the "~~ ~~continuing experience requirement?" question should be "X."~~ ~~3. If at least 24 months have not passed since a radiologic technologist or medical physicist met his/her initial qualifications or on 7/1/01 (whichever is later), the answer for the continuing experience requirement question should be "X."~~ ~~4. Use the same approach as in the second paragraph to answer the "continuing education" question for all three personnel categories (note in this case that the averaging period is 36 months and the first date this becomes applicable is 10/1/97).~~	dates defined in the examples above ("X" denotes not applicable). 2. If at least 24 months have not passed since an interpreting physician met his/her initial qualifications, the answer for the "continuing experience requirement?" question should be "X." 3. If at least 24 months have not passed since a radiologic technologist or medical physicist met his/her initial qualifications or on 7/1/01 (whichever is later), the answer for the continuing experience requirement question should be "X." 4. Use the same approach as in the second paragraph to answer the "continuing education" question for all three personnel categories (note in this case that the averaging period is 36 months and the first date this becomes applicable is 10/1/97).
Direct Supervision of Interpreting Physicians Question 7 (under Definitions)	
~~Question: Can direct supervision of an interpreting physician be provided exclusively through the use of telemammography?~~ ~~No. At the present time, teleradiology systems have not been approved for primary interpretation of mammograms. Because of this, direct supervision of an interpreting physician cannot be provided exclusively through the use of telemammography. This issue will be revisited when soft copy interpretation of full-field digital mammography or teleradiology systems specifically designed for mammography are approved for clinical use.~~	Question: Can direct supervision of an interpreting physician be provided exclusively through the use of telemammography? Yes. With the approval of primary soft copy interpretation using Full Field Digital Mammography systems, it now is possible to provide direct supervision of an interpreting physician exclusively through the use of an FDA approved telemammography system.
Interpreting Physician New Mammographic Modality Training Question 5 (under Personnel/Interpreting Physician)	
	Question: 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

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	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 provider, etc.). For more information see, **acceptable documents for interpreting physicians** in the Policy Guidance Help System (PGHS).
Interpreting Physician New Mammographic Modality Training Question 6 (under Personnel/Interpreting Physician)	
	Question: 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

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	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 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.
Interpreting Physician New Mammographic Modality Training Question 7 (under Personnel/Interpreting Physician)	
	Question: 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

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	begun interpreting FFDM images before April 28, 1999, as qualified to instruct other interpreting physicians in this area.
Interpreting Physician New Mammographic Modality Training Question 8 (under Personnel/Interpreting Physician)	
	Question: 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.
Interpreting Physician New Mammographic Modality Training Question 9 (under Personnel/Interpreting Physician)	
	Question: I'm an interpreting physician and received training in digital image receptors used for stereotactic biopsy. Can that training count toward the 8 hours of training specific to FFDM? Answer: Training received in digital image receptors used for stereotactic biopsy can count toward the 8 hours of training specific to FFDM <u>if the training is essentially the same as that being given for FFDM</u>. For example, if the interpreting physician received training in the manipulation of stereotactic digital images, <u>and the FFDM manipulation of images is essentially the same as with stereotactic</u>, that training could count toward the 8 hours of training specific to FFDM.
Radiologic Technologist New Mammographic Modality Training Question 5 (under Personnel/Radiologic Technologist)	
	Question: 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

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	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.
Radiologic Technologist New Mammographic Modality Training Question 6 (under Personnel/Radiologic Technologist)	
	Question: 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 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

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	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.
Radiologic Technologist New Mammographic Modality Training Question 7 (under Personnel/Radiologic Technologist)	
	Question: 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

Old Guidance	New Guidance
	technologists in this area.
Radiologic Technologist New Mammographic Modality Training Question 8 (under Personnel/Radiologic Technologist)	
	Question: 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.
Radiologic Technologist New Mammographic Modality Training Question 9 (under Personnel/Radiologic Technologist)	
	Question: I'm a radiologic technologist and received training in digital image receptors used for stereotactic biopsy. Can that training count toward the 8 hours of training specific to FFDM? Answer: Training received in digital image receptors used for stereotactic biopsy can count toward the 8 hours of training specific to FFDM <u>if the training is essentially the same as that being given for FFDM</u>. For example, if the radiologic technologist received training in the performance of a QC test for stereotactic digital image receptors, <u>and the FFDM QC test is essentially the same as the stereotactic QC test</u>, that training could count toward the 8 hours of training specific to FFDM.
Radiologic Technologist New Mammographic Modality Training Question 10 (under Personnel/Radiologic Technologist)	
	Question: What is the training requirement for a QC technologist working with digital units? Answer: The QC technologist at a facility using a FFDM unit must be a qualified radiologic technologist who also meets the training requirement for performing FFDM examinations.
Medical Physicist New Mammographic Modality Training Question 4 (under Personnel/Medical Physicist)	

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	Question: 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 information see, **acceptable documents for medical physicists** in the PGHS.
Medical Physicist New Mammographic Modality Training Question 5 (under Personnel/Medical Physicist)	
	Question: 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

Old Guidance	New Guidance
	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 can also be counted towards the medical physicist's continuing education requirement.
Medical Physicist New Mammographic Modality Training Question 6 (under Personnel/Medical Physicist)	
	Question: 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

Old Guidance	New Guidance
	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.
Medical Physicist New Mammographic Modality Training Question 7 (under Personnel/Medical Physicist)	
	Question: 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.
Medical Physicist New Mammographic Modality Training Question 8 (under Personnel/Medical Physicist)	
	Question: I'm a medical physicist and received training in digital image receptors used for stereotactic biopsy. Can that training count toward the 8 hours of training specific to FFDM? Answer: Training received in digital image receptors used for stereotactic biopsy can count toward the 8 hours of training specific to FFDM <u>if the training is essentially the same as that being given for FFDM</u>. For example, if the medical physicist received training in the performance of the Modulation Transfer Function (MTF) QC test for stereotactic digital image receptors, <u>and the FFDM QC test is essentially the same as the stereotactic QC test</u>, that training could count toward the 8 hours of training specific to FFDM.
Quality Control Technologist Question 1 (under Definitions)	
	Question: What is the training requirement for a QC technologist working with digital units? Answer: The QC technologist at a facility using a FFDM unit must be a qualified radiologic technologist who also meets the training requirement for performing FFDM examinations.

Old Guidance	New Guidance
Communication of Results to Patients Question 21 (under Medical Records and Reports)	
	Question: Our facility's lay summaries are accessible to our patients on computer. Because of this, we do not print out summaries to send to the patients. Will providing the lay summary through the use of computers (e.g., E-mail) be acceptable under the final regulations? Answer: Computer generated lay summaries are acceptable under the final regulations. The facility may develop appropriate procedures for providing these lay summaries to their patients. Where electronic means (e.g., E-mail) will successfully provide the lay summaries to the patients, they may be used. However, where electronic means can't achieve this goal, hard copy (paper) lay summaries must be provided.