

# **The Mammography Quality Standards Act Final Regulations: Preparing for MQSA Inspections; Final Guidance for Industry and FDA**

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Food and Drug Administration  
Center for Devices and Radiological Health  
Inspection Support Branch  
Division of Mammography Quality  
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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.

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# **The Mammography Quality Standards Act Final Regulations: Preparing for MQSA Inspections**

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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](http://www.fda.gov/cdrh/mammography/guidance-rev.html)

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

# **Introduction**

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

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

# PREPARING FOR MQSA INSPECTIONS

This document contains an overview of the annual inspection process and is intended to help facilities prepare for MQSA inspections under the final regulations. It supersedes guidance previously issued on May 5, 1999. This guidance describes facility responsibilities and recommends actions that a facility may take, before an inspection, to minimize both facility disruption and inspection time. In large part the material has been excerpted from the Policy Guidance Help System provided on the internet site mentioned above which you may consult for more detailed information regarding the regulations.

MQSA requires each facility conducting mammography in the United States (except those of the Department of Veterans Affairs) to:

- meet quality standards for personnel, equipment, maximum allowable radiation dose, quality assurance, medical audit and outcome analysis, medical recordkeeping and reporting requirements;
- be accredited by a Food and Drug Administration (FDA)-approved accreditation body (AB) (currently, the American College of Radiology [ACR] and the States of Arkansas, California, Iowa, and Texas);
- be certified to perform mammography by the FDA, or an FDA approved State certification body (each certified facility must prominently display its certificate where it can be viewed by mammography patients); and
- maintain its certified status by:
  - maintaining its accreditation,
  - having an annual survey performed by a qualified medical physicist,
  - undergoing an annual inspection conducted by an MQSA inspector ,
  - paying an inspection fee (and, where applicable, re-inspection fees), and
  - correcting any deficiencies found during these processes.

NOTE: The Centers for Medicare and Medicaid Services accepts MQSA certification as evidence of compliance with mammography quality standards. Only facilities with a current MQSA certificate will be eligible to receive Medicare/Medicaid payment for screening and diagnostic mammography.

## SCOPE OF THE MQSA FACILITY INSPECTION

During each inspection, MQSA inspectors assess a facility's compliance with MQSA quality standards. Facilities must correct all deficiencies found. **Inspections will not cover any new regulation before its effective date.** To reduce the inspection time, the scope of the standard inspection questions has been limited to items that FDA believes have the most direct bearing on facility performance and mammographic quality. However, the facility remains responsible for meeting all requirements of the regulations, not only those specifically listed in the inspection procedures. Concurrent with the MQSA inspection, States may inspect for some items that are required by their laws and regulations. However, these items will not affect the facility's compliance with MQSA or the associated MQSA inspection fee.

Under MQSA, each facility location will be inspected at least annually for the following:

- Equipment performance
- Quality Assurance (QA) records
- Quality Control (QC) records and tests
  - Technologist tests
  - Medical physicist's annual survey report
  - Mammography equipment evaluations, if any
- Personnel qualification records
- Medical records (mammography reports and films) and lay summaries
- Medical audit and outcome analysis records

Mobile mammography facilities may provide services at multiple locations under the same certificate. Each location is recognized by FDA as a part of that facility. Each such site may be inspected. The scope of inspections at sites where mobile mammography activities are conducted will vary depending on the type of mammography services provided at each location, with or without the mobile x-ray system being at that location. The facility representative may request details regarding tests and record requirements for scheduled inspections of such sites from the inspector during the prior notification and scheduling process discussed below.

### **PRIOR NOTIFICATION**

Normally, the inspector will provide the facility with an advance notice of at least five business days, before an inspection. The inspector will work with the facility in scheduling the inspection to minimize any inconvenience to the facility.

### **INSPECTION DURATION**

Based on our experience, the average on-site inspection of a facility with a single x-ray unit/film processor combination takes between five and six hours. Approximately one hour will be required to evaluate the equipment with the remainder being spent reviewing facility procedures and records. To minimize any interference with patient care, FDA suggests that the facility schedule a block of time for the testing of each x-ray unit and film processor combination. To help minimize disruption to the facility's activities, as well as to reduce the inspection time, FDA recommends that the facility organize and consolidate all records the inspector will need and have them readily available on the day of the inspection (such records are described more fully below). Facility personnel may conduct their usual duties during the inspection, but should be available if the inspector has questions or needs assistance.

### **INSPECTION PROCESS**

The inspector will first meet with facility-designated representatives to verify preliminary facility information and to briefly outline the proposed inspection agenda. At this time, the facility staff should request any special sequencing of the testing and records reviews so that the facility's normal schedule is interrupted as little as possible. A standard annual inspection will include the tests and records review outlined below. After inspection, the inspector will again meet with facility representatives for an exit interview.

## **SPECIFIC INSPECTION ITEMS**

The equipment and QA/QC requirements listed in items 2 and 4 below relate to screen-film mammography systems. Systems using other mammographic imaging modalities are required to follow a quality assurance program essentially the same as that recommended by the equipment manufacturer. During the inspection, the inspector will verify that this requirement is met.

### **1. Certificate Display**

Since October 1, 1994, no facility may legally perform mammography services unless it has a valid certificate issued under the MQSA regulations. Additionally, as described above, each such facility must prominently display that certificate in the facility. If a facility operates multiple locations under one certificate number, it may make copies of the original certificate or obtain additional originals from the certification authority for display at each location.

### **2. Equipment Tests**

FDA will inspect each x-ray system used by the facility for regulated mammography activities. This inspection includes equipment being leased by, loaned to, or evaluated for purchase, as well as equipment owned by the facility. For several of these tests, the inspector will use the facility's film and cassettes to ensure the applicability of the results to the facility. The inspector will also require assistance from facility personnel in setting up technique factors normally used by the facility for an average breast examination and operating the equipment, as well as any other preparatory work needed for each of the following elements:

- a) Determination that the equipment has been designed specifically for mammography. The x-ray unit satisfies this requirement as long as it meets all of the applicable MQSA requirements and is designated by the manufacturer and accepted by the FDA as appropriate for mammography. Equipment designed specifically for mammography, because of its unique characteristics, may also be useful for non-mammography procedures and such use is permitted.
- b) Determination that the system contains image receptors, moving grids, and compression paddles for both 18 x 24 cm and 24 x 30 cm image receptors.
- c) Confirmation that the x-ray system has a functioning post-exposure display of the actual x-ray focal spot and the target material used during each exposure. The display must be clear, legible, and visible to the operator at the unit or the operator control location. The actual mechanism can be achieved in any manner that provides the required information in an unambiguous fashion.
- d) Collimation assessment.
- e) Exposure reproducibility.
- f) Beam quality or half-value layer (HVL) measurement.
- g) Dose calculation for a cranio-caudal view of a standard breast.
- h) Processor evaluation. The regulations require that the facility set up and maintain the processor according to the specifications of the film manufacturer. Conformance with this requirement will be evaluated using the FDA's "Sensitometric Technique for Evaluation of Processing" (STEP) test to assess the processor performance.

- i) Darkroom fog.
- j) Phantom image quality evaluation.

NOTE: To meet item b, the facility must have at least one of each of the listed items for each mammography x-ray unit in the facility. There is no requirement that image receptor sizes other than the 18 X 24 and 24 X 30 be available for each unit in the facility. However, if a facility uses additional (not required by the regulations) image receptor sizes, the facility must have at least one moving grid and compression paddle for each such additional size. It is not necessary to have these items for each x-ray unit.

### **3. Records Inspection**

Facilities should maintain specific records regarding each regulated mammography system. These records cover:

- X-ray unit accreditation status
- Mammography equipment evaluation for new/repared equipment
- Annual physics survey reports (both the most recent and the previous one)
- Evidence of post-move performance testing for mobile units
- QC test records
- Evidence of any corrective actions taken and subsequent verification testing

The facility should have documentation showing that each x-ray unit has been accredited by the accreditation body. For a new unit, the facility must show that it has passed a mammography equipment evaluation prior to use on patients and that the application for accreditation of the unit has been submitted. For very new units (within five working days of installation), simply having the mammography equipment evaluation (see discussion below) and demonstrating that the application for accreditation is under preparation will be adequate to establish compliance.

There are three cases where a unit in use may not need to be accredited:

- a) The unit is a "loaner," while repairs to the facility's unit are taking place, or awaiting delivery of a replacement unit (limited to 30 days without extenuating documentation from the service or dealer organization showing reasons for delay in replacement or repair);
- b) The unit is installed in the facility for evaluation before purchasing (limited to 90 days maximum without accreditation); and
- c) The unit is an experimental one, installed and used under an FDA investigative device exemption or other FDA-authorized research protocol.

Note: Under both a) and b) above, the unit still must have passed a mammography equipment evaluation before use on patients. The above time frames and allowances are permitted under MQSA. Under State or local regulations and accreditation body policies, all such use may require registration or accreditation. Be sure to verify the requirements with these sources.

### **4. Quality Assurance and Quality Control Programs**

The QA program includes the designation of appropriate, qualified personnel to implement and oversee the QA process. These personnel must include a lead interpreting physician, medical physicist, and quality control technologist. The inspector will check to establish that qualified

personnel have been designated for each of these duties and that the facility has established a QA program, as required by the regulations, to "ensure the safety, reliability, clarity, and accuracy of the mammography services provided at the facility."

Evaluation of the QA program includes the review of QA procedures and records for all of the requirements outlined in 21 CFR 900.12(d) and (e). Facilities are required to retain the written QC records for each test specified by the regulations until the next annual MQSA inspection has established that the facility is in compliance with the QA requirements, or until the test has been performed two additional times at the required frequency, whichever is longer. The time periods for retaining sensitometric film strips and other films produced during the tests vary and are described below under the individual tests. Although these records must be maintained and be available for review, not all records will always be evaluated during each inspection. However, the inspector will always seek the QA/QC information listed below:

- Daily Processor Quality Control
  - Including actual sensitometric film strips for the previous 30 days of mammographic film processing and charting of the strips for the period specified above
- Weekly Phantom Images
  - Including phantom images for the previous 90 days, and records covering the remainder of the retention period specified above
- Quarterly Analysis of Fixer Retention in Film
- Quarterly Repeat Analysis
  - Conducted quarterly, regardless of the number of films obtained in the quarter, and should include all repeated and rejected clinical films obtained in the quarter. Large volume facilities may limit the analysis to those films collected after a minimum of 250 patient examinations.
- Semiannual Darkroom Fog
  - QC records and test strips must be retained for the period specified above
- Semiannual Screen-Film Contact
  - QC records and images from screen-film contact for the retention period specified above
- Semiannual Compression
- Personnel responsibilities and procedures for QA/QC testing. Records must be kept indefinitely.
- Other QA-related written policies, procedures, and records required by the regulations such as those relating to infection control, breast implants, and consumer complaints. Records must be kept indefinitely.
- Mammographic technique charts, and information pertinent to optimizing mammographic quality should also be available for inspection. Records should be kept indefinitely.

In general, the facility's QC records should show that all MQSA required tests were:

- conducted at the frequencies specified in the regulations (as a minimum), and
- followed by timely and effective corrective actions that were shown to be necessary (documentation of any corrective action is required).

Note regarding the Interpretation of Test Frequencies: In the past, some facilities have interpreted the words "weekly," "quarterly," and "semi-annually" in ways different from that

intended by FDA. Since October 1, 1999, FDA has interpreted the regulatory requirements for test frequencies as follows:

- Weekly Phantom Image Test: Must be performed each week in which mammograms are performed. However, the test need not be performed on the same day each week.
- Quarterly Tests: Must be performed 4 times a year or at a minimum once in each 3 month period in which mammograms are performed. The 4 months that are chosen must be spaced 3 months apart (such as February, May, August, and November.) However, for any of the 4 selected months, each test may be performed on any day (not necessarily the same day) in the month.
- Semi-annual Tests: Must be performed 2 times a year or at a minimum once in each 6 month period in which mammograms are performed. The 2 months that are chosen must be spaced 6 months apart (such as January and July). However, for any of the 2 selected months, each test may be performed on any day (not necessarily the same day) in the month.

For listing of the required QC test items, required frequencies, and examples of acceptable documentation, see [Attachments 2 and 3](#). The items appearing in [Attachment 2](#) must be performed more frequently than the annual tests in [Attachment 3](#) and will normally fall under the responsibility of the quality control technologist. Although the annual tests may be conducted more frequently than annually, they must be conducted by a MQSA-qualified medical physicist (or someone in training under his or her direct supervision) when performed as part of the annual survey or a mammography equipment evaluation. The results of the annual tests and any recommendations for corrective actions must be stated in the medical physicist's survey report.

## **5. Medical Physicist's Survey Report**

Each facility must undergo “at least once each year” a survey performed by a medical physicist. For various reasons it is often impractical for these annual surveys to be conducted exactly on the anniversary of the previous survey, therefore FDA will accept a range of 10 to 14 months since the previous survey as being adequate to satisfy the “at least once each year” requirement stated in the regulations. The facility must have available for the inspector the two most recent annual physicist survey reports. The reports must document the physicist's tests, the results, the evaluation of the technologist's QC testing, and include recommendations for any corrective actions resulting from the tests or review. The facility should also have evidence of its actions concerning each recommendation.

## **6. Mammography Equipment Evaluation**

When a new or an existing mammography facility obtains new mammographic equipment or processors, it must pass a mammography equipment evaluation conducted by a qualified medical physicist before such equipment is placed into service. In this context, "new" means new to the facility and may be previously used equipment. In addition, a medical physicist must perform a mammography equipment evaluation whenever such equipment is disassembled and then reassembled, either at the same or a new location, or whenever a major component is changed or repaired. The inspector will verify that appropriate records are available to document compliance with this requirement.

The medical physicist must provide the facility with sufficient documentation to clarify the testing performed and the results of the testing. All problems must be corrected, and the corrections documented, before the new or changed equipment is put into clinical service.

## **7. Personnel Qualifications**

The facility is required to maintain records documenting initial and continuing qualifications of all personnel who have performed or are performing the duties of interpreting physician, radiological technologist, or medical physicist, and all employees assigned to quality assurance tasks for the facility. Facilities are to ensure that new mammography personnel meet all applicable requirements prior to allowing them to provide mammography services. This requirement covers records for individuals who provide or have provided temporary and/or contract services for the facility, including personnel who may provide services offsite. Once an employee leaves, the facility is not expected to continue tracking their status. If personnel leave, the facility is expected to maintain their records until the next annual MQSA inspection has been completed and FDA has determined that the facility complies with all MQSA personnel requirements.

Facilities should be aware that their State(s) might have more stringent recordkeeping requirements. Check with your State(s) before making any final decisions regarding the disposition of any records.

The required personnel information is listed below and must be available for the inspector's review during the inspection.

### **Interpreting Physicians**

Interpreting physicians initially qualifying on or after the April 28, 1999 effective date of the final regulations, must meet all of the following requirements. Physicians who qualified under FDA's interim regulations (prior to April 28, 1999) are considered to have met the initial requirements listed in items 2 through 4 below. They may continue to interpret mammograms if they continue to meet the licensure requirement in item 1, the new modality training requirement for item 5 (if applicable), and the continuing experience and continuing education requirements for items 6 and 7.

- 1. Licensure:** Be licensed to practice medicine in a State.

#### **AND**

- 2. a. Board Certification:** Be certified in radiology or diagnostic radiology by any of the following bodies:
  - The American Board of Radiology (ABR)
  - The American Osteopathic Board of Radiology (AOBR)
  - The Royal College of Physicians and Surgeons of Canada (RCPSC)

#### **OR**

- b. Initial Training:** Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography (to include

instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection).

**AND**

- 3. Initial Category I Education:** Have a minimum of 60 hours of documented category I medical education in mammography (including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography). At least 15 of the required 60 hours must have been acquired within the 3 years immediately before the physician's initial qualification date. These 60 hours may be included in the 3 months of training specified in 2.b above. Hours received in residency training are considered equivalent to category I.

**AND**

- 4. Initial Experience:** Have interpreted or multi-read, under direct supervision of a qualified interpreting physician, at least 240 mammographic examinations within the 6-month period immediately before the date that the physician qualifies as an interpreting physician (or in any 6-month period during the last 2 years of a diagnostic radiology residency for physicians who become appropriately board certified at the first allowable time, as defined by the board).

**AND**

- 5. New Mammographic Modality:** Before an interpreting physician may begin independently interpreting mammograms produced by any mammographic modality in which the interpreting physician was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the physician must have at least 8 hours of training in that mammographic modality.

**AND**

- 6. Continuing Experience:** Have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two.

*The beginning date for meeting the continuing experience requirement is the later of October 1, 1994, or the individual's actual starting date (the date on which an individual met all applicable requirement to begin independently providing mammography services). Failure to meet the continuing experience requirement will not be considered a noncompliance until at least 24 months after the individual's starting date.*

**AND**

- 7. Continuing Education:** Have taught or completed at least 15 category I continuing medical education (CME) credits in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two. CME credits earned through teaching a course can be counted only once toward meeting the 15 credits required in any 36-month period. Such training shall include at least 6 credits of category I CME in each mammographic modality used by the interpreting physician.

*The beginning date for meeting the continuing education requirement is the later of October 1, 1994, or the individual's actual starting date (the date on which an individual met all applicable requirement to begin independently providing mammography services). Failure to meet the continuing education requirement will not be considered a noncompliance until at least 36 months after the individual's starting date.*

FDA permits multi-reading/interpreting of mammograms and summing of readings/interpretations from different facilities in calculating the total mammographic examinations for items 4 and 6 above. Multi-reading is defined as two or more physicians, at least one of whom is a fully qualified interpreting physician, interpreting the same mammogram. Multi-reading includes reading comparison mammograms not previously read by the physician.

So that facilities are aware of potential problems, FDA recommends that facilities update education and experience records at least quarterly.

Specific information on acceptable documentation for the interpreting physician's qualifications is listed in Attachment 4.

### **Radiologic Technologist**

Radiologic technologists initially qualifying on or after the April 28,1999 effective date of the final regulations must meet all of the following requirements. Radiologic technologists, who qualified under FDA's interim regulations (before April 28,1999) are considered to have met the initial training requirements listed in item 2 below. They may continue to perform mammograms if they continue to meet the licensure or certification requirements of item 1, any applicable new modality training requirement from item 3, and the continuing experience and education requirements of items 4 and 5.

1. **a. Licensure:** Have a general/full license to perform radiographic procedures issued by a State.

#### **OR**

- b. Board Certification:** Be certified by either of the following bodies:

- The American Registry of Radiologic Technologists (ARRT)
- The American Registry of Clinical Radiography Technologists (ARCRT)

#### **AND**

2. **Initial Training in Mammography:** Have at least 40 contact hours of mammography training, including breast anatomy, physiology, positioning, compression, quality assurance/quality control techniques, imaging of patients with breast implants, and the performance of 25 supervised examinations. The actual time spent performing supervised examinations may be included in the 40 hour total. As guidance, however, no more than 12.5 hours of the required 40 should come from the performance of examinations.

#### **AND**

3. **New Mammographic Modality:** Before a radiologic technologist may independently perform mammographic examinations using any mammographic modality in which the radiologic technologist was not previously trained (e.g., xeromammography, digital

mammography, screen-film mammography), the radiologic technologist must have at least 8 hours of training in the modality.

**AND**

4. **Continuing Experience:** Have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two.

*The beginning date for meeting this requirement is April 28, 1999, or the individual's actual starting date (date on which the individual initially qualifies to work independently), whichever is later. Failure to meet the technologist's continuing experience requirement will not be considered a noncompliance until the later of July 1, 2001, or at least 24 months after the technologist's starting date.*

**AND**

5. **Continuing Education:** Have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two. At least 6 of these CEUs must be in each of the mammographic modalities used by the technologist. CEUs earned through teaching a course can be counted only once towards meeting the units required in any 36-month period.

*The beginning date for meeting the continuing education requirements is the later of October 1, 1994, or the individual's actual starting date (date on which the individual initially qualifies to work independently), whichever is later. Failure to meet the continuing education requirements will not be considered a noncompliance until at least 36 months after the technologist's starting date.*

As with the physicians, FDA recommends that the facilities update the education and experience records at least quarterly.

Specific information on acceptable documentation for the technologist's qualifications is listed in Attachment 5.

**Medical Physicist**

There are no "grandparenting" provisions in the final MQSA regulations covering the medical physicist, and **ALL** physicists qualified prior to April 28, 1999, have additional criteria for qualification under the final regulations.

The qualifications for the medical physicist are relatively complicated. As an aid to understanding them, we have separated the medical physicist section into three parts.

- A. The requirements for those physicists who are qualifying through the "master's degree or higher" route
- B. The requirements for those who are qualifying through the "alternative initial requirements" approach covering education, training, and experience
- C. The continuing qualification requirements applicable to all physicists

All qualifying medical physicists must demonstrate compliance with either "A" or "B" below. The continuing education and experience requirements covered in "C" are applicable to all physicists.

**A.** All medical physicists qualifying under the "master's degree or higher" route must demonstrate:

**1. a. Licensure or approval:** Be licensed or approved by a State to perform mammography surveys.

**OR**

**b. Board Certification:** Be certified in diagnostic medical physics or medical physics by one of the following:

- i.** The American Board of Radiology (ABR)
- ii.** The American Board of Medical Physics (ABMP)

**AND**

**2. Education, training, and experience:**

**a. Degree:** Have at least a master's degree or higher in a physical science with at least 20 semester hours (30 quarter hours) of graduate or undergraduate physics.

**AND**

**b. Survey Training:** Have at least 20 contact hours of mammography facility survey training.

**AND**

**c. Initial Experience:** Have the experience of conducting surveys of at least 1 mammography facility and at least 10 mammography units.

**B.** Certain medical physicists may have qualified under the interim regulations before April 28, 1999, through the State approval or licensing mechanism or through the professional certification route without having the appropriate degree to meet the final regulations as described above. Such medical physicists may qualify under the "**Alternative Initial Qualifications**" route. Such individuals must demonstrate that, by April 28, 1999, they have achieved compliance with the following:

**1. a. Licensure or approval:** Be licensed or approved by a State to perform mammography surveys.

**OR**

**b. Board Certification:** Be certified in diagnostic medical physics or medical physics by one of the following:

- i.** The American Board of Radiology (ABR)
- i.** The American Board of Medical Physics (ABMP)

**AND**

2. Education, training, and experience:
  - a. **Degree:** Have a bachelor's degree in a physical science with at least 10 semester hours (15 quarter hours) of graduate or undergraduate physics. (This would include individuals having advanced degrees in non-physical science fields.)

**AND**

- b. **Survey Training:** Have at least 40 contact hours of mammography facility survey training. This training must have occurred after fulfilling the degree requirement in 2.a.

**AND**

- c. **Initial Experience:** Have the experience of conducting surveys of at least 1 mammography facility and at least 20 mammography units. This initial experience must have occurred after fulfilling the degree requirement in 2.a.

C. All medical physicists must meet the following requirements;

1. **New Mammographic Modality:** Before a physicist may begin independently performing surveys or mammography equipment evaluations on any mammographic modalities in which the physicist was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the physicist must have at least 8 hours of training in the modality.

**AND**

2. **Continuing Experience:** The physicist must have conducted a minimum of two mammography facility surveys and a total of six mammography unit surveys (or mammography equipment evaluations which cover all of the equipment survey items) during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two

*The beginning date for this requirement is April 28, 1999 or the individual's actual starting date (date on which the physicist initially qualifies to work independently), whichever is later. Failure to meet the physicist's continuing experience requirement will not be considered a noncompliance until the later of July 1, 2001 or at least 24 months after the physicist's starting date.*

**AND**

3. **Continuing Education:** Have taught or completed at least 15 continuing education units in medical physics or mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two. The continuing education must include more than 1 unit in each mammographic modality evaluated by the medical physicist. CEUs earned through teaching a course can be counted only once toward meeting the 15 units required in any 36-month period.

*The beginning date for this requirement is October 1, 1994, or the individual's actual starting date (date on which the physicist initially qualifies to work independently), whichever is later. Failure to meet the physicist's continuing education requirement will not be considered a noncompliance until at least 36 months after the physicist's starting date.*

NOTE: For meeting the requirements in items A.2.b., A.2.c., B.2.b., B.2.c., and C.2., FDA allows multiple testing of the same mammography unit. However, no more than one survey of a specific facility within a 10-month period can be counted toward the total requirement, and tests of the same unit cannot be counted more than once in any consecutive 60-day period. It is important enough to repeat that, for the alternative initial qualifications route, the training and experience in items B.2.b. and B.2.c. must have been obtained after the qualifying degree requirements are satisfied and before April 28, 1999.

Specific information on acceptable documentation for the physicist's qualifications is listed in Attachment 6.

### **All Personnel - Attestation**

FDA allows personnel to attest to certain training, education, or experience earned before October 1, 1994. Physician initial 2 or 3 months training and medical physicist degree requirements, including the required number of hours in physics, cannot be attested to at any time. In general, FDA does not intend to accept attestation for training, education, or experience obtained after October 1, 1994. However, FDA will accept a limited form of attestation for CME/CEUs earned after October 1, 1994, if a continuing education provider does not specifically document the number of hours earned in mammography. Such attestation will be acceptable if it includes documentation showing both the total number of CME/CEUs earned in the program and the total number of CME/CEUs specific to mammography that were available. If the meeting or other educational opportunity is limited to mammography, then only documentation from the provider of the number of CME/CEUs earned is needed (no attestation is required in this instance).

In certain situations, attestation will also be accepted for meeting the "new mammographic modality" requirement. Specifically, personnel who worked with investigational full field digital mammography systems prior to April 28, 1999, may attest to that experience. In addition, personnel who received mammography modality specific training prior to October 1, 1994 may attest to that training. All attestations must be in the proper format. (An attestation form is included as Attachment 1.)

## **8. Medical Records**

### **Patient Permanent Records**

Medical records must contain certain required types of information. To ensure that both the mammographic images and reports are being retained as required, and to verify they contain the information outlined below, the inspector will randomly select records for review. In general, the inspector will request reports from those examinations performed since the last MQSA inspection, or since the facility's certification, whichever is the most recent. However, inspectors may examine records from other time frames. The inspector will not attempt to assess the correctness of these reports, but will determine that the records are being generated, properly

maintained, and identify the interpreting physician who originally interpreted the mammograms. For those mammography medical reports created on or after April 28, 1999, the inspector will also verify that one of the following assessment categories appears in each: "Negative," "Benign," "Probably Benign," "Suspicious," "Highly suggestive of malignancy," or "Incomplete: Need additional imaging evaluation."

The facility is required to communicate the results, within 30 days of the examination, to the referring health care provider and to the patient (lay summary). In the case of self-referred patients, if a health care provider (or a responsible designee) is not named or is unavailable, then the report must be provided to the patient. Communications to the patient, if there is no health care provider, must include 1) the complete report of findings referenced above and 2) the summary written in lay terms that is required for all patients. When the assessment is "Suspicious" or "Highly suggestive of malignancy," the facility is required to communicate the results, as soon as possible, to the referring health care provider and to the patient (lay summary) and depending on health care provider availability, may need to send the complete report to the patient). Facility personnel should be prepared to explain the facility's procedure for communicating results to referring physicians and to patients and their mechanism for providing quick response for cases requiring such action.

FDA's concern is not the details of the communication system but rather:

- that one has been established by the facility,
- that it is in place, and
- that it meets the requirements of the regulations.

The inspector will verify that the communication system meets these criteria and that lay summaries are available. If patient records are stored in an electronic format, the inspector will ask the facility to assist in the selection and retrieval of the records to be inspected.

## **9. Mammography Medical Audit and Outcomes Analysis**

Each facility must establish and maintain a system to track positive mammographic findings and to correlate such findings with the biopsy results the facility obtains on an annual basis.

At a minimum, the system must track "positive mammographic findings," which refers to mammograms interpreted as "Suspicious" or "Highly suggestive of malignancy." MQSA leaves it up to each facility to use a tracking system that works best for it. This system must include a set of procedures to track mammograms, determine whether biopsies were done on the patient, determine (at a minimum) whether the biopsy specimen was benign or malignant, and report this information back to the interpreting physician. The system may be manual or computerized. Facilities must also include in their audit any patients that they become aware of who were subsequently found to have cancer that was not detected through their mammogram. The audit analysis must be initiated within 12 months after the date the facility becomes certified. The audit analysis must then be completed within an additional 12 months with subsequent audit analyses to be conducted at least once every 12 months. The analyses are to be reviewed by an "audit interpreting physician" appointed by the facility. The "audit interpreting physician" has multiple responsibilities listed in 900.12(f)(3) that must be covered in the facility's audit program.

The inspector will examine the audit system for the inclusion of the above items, ascertain how biopsy results are obtained, and request to see examples of biopsy results that the facility has obtained. If biopsies were recommended but no results were obtained, the facility must provide documentation of attempts to get this information.

## **REPEAT FINDINGS**

If a facility inspection finds "repeat" problems (deficiencies of the same type, either recurring or never corrected, found during the previous inspection), the post-inspection report provided to the facility will identify which findings have been repeated. Depending on their seriousness, these repeat deficiencies could result in the requirement of a written response from the facility, a follow-up inspection, and/or sanctions against the facility.

## **MOBILE MAMMOGRAPHY**

The QC for x-ray units used for mobile mammographic purposes must meet all of the requirements applicable to stationary mammography x-ray units plus the additional requirement of post-move, pre-clinical use performance testing. This additional test is to ensure the satisfactory performance of the unit after each move and before patients are imaged. The following are examples of acceptable tests:

- A phantom image can be taken in the AEC mode (or the mode used 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 inspector on a case-by-case basis. If a facility has any questions regarding the acceptability of such alternative

measures, they should obtain a ruling from FDA on the alternative before relying on such testing.

## **EXIT INTERVIEW**

During the exit interview with facility personnel, the inspector will review the results of the inspection and either leave a summary of findings or mail this summary to the facility within two weeks.

If major deficiencies are found, the facility will receive a letter, addressed to the facility's "Responsible Person," concerning these issues. The facility's "Responsible Person" is a person the facility has identified as having the authority to make vital operational and financial decisions concerning corrective actions that are required to bring the facility into compliance. All deficiencies should be corrected as soon as possible. Depending on the level of the severity of the problems, specific regulatory mandated time frames will be included in the letter. **The facility is required [21 CFR 900.12(e)(8)(ii)(A)] to correct problems found with the following areas of the QC program "before any further examinations are performed or any films are processed using the component of the mammography system that failed the test...."**

- Daily QC tests - *900.12(e)(1)*,
  - base plus fog
  - mid-density
  - density difference
- Weekly QC tests - *900.12(e)(2)*
  - phantom image quality
- Semiannual QC tests - *900.12(e)(4)*
  - Darkroom fog - *900.12(e)(4)(i)*
  - Screen-film contact - *900.12 (e)(4)(ii)*
  - Compression device performance - *900.12 (e)(4)(iii)*
- Annual QC tests - *900.12(e)(5)*
  - Dose - *900.12(e)(5)(vi)*
- Other modalities - *900.12(e)(6)*
- Mobile units - *900.12(e)(7)*

For violations related to the quality control (QC) tests described in paragraph 900.12(e)(8)(ii)(B), the facility must complete repairs within 30 days of discovering the problem. Facilities continuing to operate under deficient conditions could be subject to sanctions. Such sanctions could include a directed plan of correction, civil money penalties, or certificate suspension or revocation. Certain findings could also require a follow-up inspection to verify correction.

## **FOR MORE INFORMATION**

FDA maintains an MQSA Internet site at <http://www.fda.gov/cdrh/mammography>. The site contains many useful items, including current information about the mammography program. If you have questions on how to prepare for inspections, call FDA's Facility Hotline at (800) 838-7715, or FAX your request to (410) 290-6351.

**Attachment 1**  
**ATTESTATION FORM**

**Regarding Requirements of the Mammography Quality Standards Act**

Attestation must include as much of the following information as possible:

Name of the institution/facility where the applicable training or mammography reading/interpreting, or other activity, took place; name of the course(s) or training (where applicable); the attendance, reading/interpreting, or other activity dates; and the supervising/responsible person (where applicable) for the institution/facility.

Please provide these details in the space below. Attach additional sheets if necessary.

**I \_\_\_\_\_ attest that, to the best of my knowledge and my belief, the following information provided in this declaration is true and correct. I understand that FDA may request additional information to substantiate the statements made in this declaration:**

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**I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to \$10,000 fine and imprisonment of up to five years, or civil liability under the MQSA, or both.**

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Attestor's Signature and Title

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Date signed

Facility Name and Address (if applicable) (including zip code):

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Facility ID Number (if applicable) (from the Facility's MQSA certificate)

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## Attachment 2

### Quality Control Tests Other than Annual

Test & Frequency	Requirements for Acceptable Operation	Guidance for Acceptable Documentation Retention*	Timing of Required Corrective Action **
Processor QC-Daily	Established operating level for B+F, + up to 0.03 OD.	QC records (&charts) for the last 12 months or since the last inspection, whichever is longer. QC test films for the last 30 days.	Before any further clinical films are processed.
"	Established operating level for MD, $\pm 0.15$ OD.	"	"
"	Established operating level for DD, $\pm 0.15$ OD.	"	"
Phantom QC-Weekly	Established operating level for OD at center of image $\geq 1.2 \pm 0.20$ , but the minimum OD must be $\geq 1.2$ at any time.	QC records for the last 12 months or since the last inspection, whichever is longer. Phantom images for the last 90 days.	Before any further examinations are performed using the x-ray machine.
"	Established operating level for contrast, $\pm 0.05$ OD	"	"
"	Minimum score of 4 fibers, 3 speck groups, 3 masses.	"	"
Fixer retention in film-Quarterly	< 5 micrograms per square cm of residual fixer.	QC Records since the last inspection or for the past three tests, whichever is longer.	Within 30 days of the date of the test.
Repeat Analysis-Quarterly	Operating level for repeat or reject rate is < 2% change (up or down) from previous rate.	"	"
Darkroom Fog-Semi-annually	OD $\leq 0.05$ .	QC Records since last inspection or for the past three tests, whichever is longer. Fog QC films from the previous three tests.	Before any further clinical films are processed.
Screen-Film Contact-Semi-annually	All mammography cassettes used must be tested with a 40-mesh copper screen.	QC records since last inspection or for the past three tests, whichever is longer. S-F contact QC films from the previous three tests.	Before any further examinations are performed using the cassettes.
Compression Device Semi-annually	Compression force $\geq 111$ newtons (25 pounds). Effective 10/28/2002, initial power drive maximum compression force between 111 and 200 newtons (25 and 45 pounds).	QC records since last inspection or for the past three tests, whichever is longer.	Before examinations are performed using the compression device.

\* Guidance regarding the length of time for which the facility is required to keep QC records was given earlier under 900.12(d)(2).

\*\* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.

### Attachment 3 Annual Quality Control Tests

Test	Scope	Regulatory Action Levels	Timing of required corrective action*
AEC Performance Capability	All x-ray units. Thickness tracking (2-6 cm, appropriate kVp's). kVp Tracking (clinic. range).	OD exceeds the mean by more than $\pm 0.30$ (over 2-6 cm thickness range) [ $\pm 0.15$ after 10/28/2002]. Phantom image OD at center $< 1.20$ .	Within 30 days after test failure.
kVp Accuracy & Reproducibility	All x-ray units.	kVp accuracy outside $\pm 5\%$ of indicated /selected kVp. Reproducibility COV $> 0.02$ .	"
Focal spot/System Resolution	All x-ray units, all clinically used target materials and focal spots 1) Spot size measurement until 10/28/02 @ the most used SID 2) Resolution measurement Same as 1) but if mag mode is used, then test at SID w/mag value closest to 1.5 obtainable (used clinically or not) & for all clinically used mag screen-film combinations	See focal spot table in the regs. 11 cycles/mm with bars perpendicular to anode-cathode axis. 13 cycles/mm with bars parallel to anode-cathode axis.	"
HVL	All x-ray units. All clinically used target/filter combinations.	See HVL table in regulations.	"
Air Kerma & AEC Reproducibility	All x-ray units.	Reproducibility COV for each exceeds 0.05.	"
Dose	All x-ray units. All targets/filter combos used for the Standard Breast.	Exceeds 3.0 mGy (0.3 rad) per exposure (for the Standard Breast).	Before any further examinations are performed.
Phantom Image**	All x-ray units	$< 4$ fibers, 3 speck groups, 3 masses	"
X-ray field/light field X-ray field/IR Compression device/IR	All x-ray units. All combinations of collimators, image receptor sizes, targets & focal spots clinically used in full field imaging of the breast.	<b>X-ray/light field:</b> $> 2\%$ SID <b>X-ray field/IR:</b> Outside IR: $> 2\%$ SID (all sides.) Inside IR: less than full coverage at cw. <b>Comp. device/IR:</b> Outside IR: $>1\%$ SID Inside IR: Paddle visible on image	Within 30 days of the date of discovery.
Screen Speed Uniformity	All cassettes – sub-grouping allowed.	O.D. variation exceeds 0.30 from highest to lowest.	"
System Artifacts	All x-ray units and processors, all cassette sizes, all clinically used focal spots & target/filter combinations.	Determined by physicist.	"
Radiation Output	All x-ray units.	Output $< 4.5$ mGy/sec (513 mR/sec), and $< (7 \& 800)$ after 10/28/2002	"
Decompression	All x-ray units (if auto decompression is provided).	Failure of override mechanism, manual release, or status indicator.	"
Any applicable annual new modality tests	All x-ray units.	Depends on test.	Before clinical use.

\* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.

\*\* This is the same as the weekly phantom image test but it must also be performed annually by the medical physicist.

## Attachment 4

### Acceptable Documents For Interpreting Physicians

<b>Requirement</b>	<b>Obtained Prior to 10/1/94</b>	<b>Obtained 10/1/94-4/28/99</b>	<b>Obtained after 4/28/99</b>
State License	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>
Board Certification (ABR, AOBR, or RCPSC)	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Confirming letter from ACR</li> <li>4. Listing in ABMS directory</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Confirming letter from ACR</li> <li>4. Listing in ABMS directory</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Confirming letter from ACR</li> <li>4. Listing in ABMS directory</li> </ol>
Formal Training (2 months-interim regs) (3 months-final regs)	<ol style="list-style-type: none"> <li>1. Letters or other documents from US or Canadian residency programs</li> <li>2. Documentation of formal mammography training courses</li> <li>3. Category I CME certificates</li> </ol>	<ol style="list-style-type: none"> <li>1. Letters or other documents from US or Canadian residency programs</li> <li>2. Documentation of formal mammography training courses</li> <li>3. Category I CME certificates</li> </ol>	<ol style="list-style-type: none"> <li>1. Letters or other documents from US or Canadian residency programs</li> <li>2. Documentation of formal mammography training courses</li> <li>3. Category I CME certificates</li> </ol>
Initial Medical Education (40 hours-interim regs) (60 hours/15 in last 3 years-final regs)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter from residency program</li> <li>3. CME certificates</li> <li>4. Letter or other document confirming in-house or formal training</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter from residency program</li> <li>2. CME certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter from residency program</li> <li>2. CME certificates</li> <li>3. Letter or other document confirming in-house or formal training (Category I)</li> </ol>
Initial Experience (240) (any 6 month period-interim regs) (last 6 month vs 6 month in last 2 years of residency-final regs)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter or other document from residency or training program or mammography facility</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from residency or training program or mammography facility – done under direct supervision</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from residency or training program or mammography facility – done under direct supervision</li> </ol>
Initial Mammographic Modality Specific Training- 8 hours-final regs	<ol style="list-style-type: none"> <li>1. Attestation for training or experience with investigational units</li> <li>2. Mammography Modality Specific CME certificates (Category I or II)</li> <li>3. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CME granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> <li>6. Letter from facility where experience was obtained documenting experience in the new mammographic modality</li> </ol>	<ol style="list-style-type: none"> <li>1. Attestation for experience with investigational units</li> <li>2. Mammography Modality Specific CME certificates (Category I or II)</li> <li>3. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CME granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> <li>6. Letter from facility where experience was obtained documenting experience in the new mammographic modality</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME certificates (Category I or II)</li> <li>2. CME certificates (Category I or II) plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CME granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>

Continuing Experience (960/24 months)	N/A	1. Letter, table, facility logs or other documentation from residency or training program or mammography facility	1. Letter, table, facility logs or other documentation from residency or training program or mammography facility
Continuing Education (15 CME/36 months-interim regs) (15 Category I CME/36 months-final regs)	N/A	1. CME certificates (Category I or II) 2. Confirming letters from CME granting organizations 3. Letters, certificates or other documents from manufacturers' training courses	1. CME certificates (Category I) 2. Confirming letters from CME granting organizations
Continuing Mammographic Modality Specific Education-final regs	N/A	1. Mammography Modality Specific CME certificates (Category I or II) 2. CME certificates (Category I or II) plus agenda, course outline or syllabus 3. Confirming letters from CME granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME certificates (Category I) 2. CME certificates (Category I) plus agenda, course outline or syllabus 3. Confirming letters from CME granting organizations
Requalification-Experience–done under direct supervision	N/A	1. Letter, table, facility logs or other documentation from residency or training program or mammography facility	1. Letter, table, facility logs or other documentation from residency or training program or mammography facility
Requalification- Education	N/A	1. CME certificates (Category I or II) 2. Confirming letters from CME granting organizations	1. CME certificates (Category I) 2. Confirming letters from CME granting organizations

## Attachment 5

### Acceptable Documents For Radiologic Technologists

<b>Requirement</b>	<b>Obtained Prior to 10/1/94</b>	<b>Obtained 10/1/94-4/28/99</b>	<b>Obtained after 4/28/99</b>
State Licensure	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>	<ol style="list-style-type: none"> <li>1. State license/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. Pocket card/copy of license</li> </ol>
Board Certification (ARRT or ARCRT)	<ol style="list-style-type: none"> <li>1. Original/copy of current certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of current certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of current certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> </ol>
Initial Training (~40 hours-interim regs) (40 hours-25 supervised exams-final regs)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter or other document from training program</li> <li>3. CEU certificates</li> <li>4. Letter or other document confirming in-house or formal training</li> <li>5. ARRT(M) Mammography certificate</li> <li>6. California Mammography certificate</li> <li>7. Arizona Mammography certificate</li> <li>8. Nevada Mammography certificate</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from training program</li> <li>2. CEU certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Approved RT training courses</li> <li>5. ARRT(M) Mammography certificate</li> <li>6. California Mammography certificate</li> <li>7. Arizona Mammography certificate</li> <li>8. Nevada Mammography certificate</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from training program</li> <li>2. CEU certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> </ol>
Initial Mammography Modality Specific training-8 hours-final regs	<ol style="list-style-type: none"> <li>1. Attestation for training or experience with investigational units</li> <li>2. Mammography Modality Specific CEU certificates</li> <li>3. CEU certificates plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CEU granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> <li>6. Letter from facility where experience was obtained documenting experience in the new mammographic modality</li> </ol>	<ol style="list-style-type: none"> <li>1. Attestation for experience with investigational units</li> <li>2. Mammography Modality Specific CEU certificates</li> <li>3. CEU certificates plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CEU granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> <li>6. Letter from facility where experience was obtained documenting experience in the new mammographic modality</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CEU certificates</li> <li>2. CEU certificates plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Experience (200/24 months-final regs)	N/A	N/A	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from training program or mammography facility</li> </ol>

Continuing Education (15 CME/36 months)	N/A	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Formal training courses</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Formal training courses</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Mammographic Modality Specific Education-final regs	N/A	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CEU certificates</li> <li>2. CEU certificates (plus agenda, course outline or syllabus)</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CEU certificates</li> <li>2. CEU certificates (plus agenda, course outline or syllabus)</li> <li>3. Confirming letters from CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Requalification-Experience–final regs–done under direct supervision	N/A	N/A	<ol style="list-style-type: none"> <li>1. Letter, table, facility logs or other documentation from training program or mammography facility (done under direct supervision)</li> </ol>
Requalification- Education	N/A	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CEU certificates</li> <li>2. Confirming letters from CEU granting organizations</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>

## Attachment 6

### Acceptable Documents For Medical Physicists

<b>Requirement</b>	<b>Obtained Prior to 10/1/94</b>	<b>Obtained 10/1/94-4/28/99</b>	<b>Obtained after 4/28/99</b>
State Licensure or Approval	<ol style="list-style-type: none"> <li>1. State license or approval/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. State license or approval/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. State license or approval/copy with expiration date</li> <li>2. Confirming letter from State licensing board</li> <li>3. FDA Approval Letter</li> </ol>
Board Certification (ABR or ABMP)	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> <li>4. Confirming letter from ACR</li> <li>5. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> <li>4. Confirming letter from ACR</li> <li>5. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of certificate</li> <li>2. Confirming letter from certifying board</li> <li>3. Pocket card/copy of certificate</li> <li>4. Confirming letter from ACR</li> <li>5. FDA Approval Letter</li> </ol>
Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway)	<ol style="list-style-type: none"> <li>1. Original/copy of diploma</li> <li>2. Confirming letter from college or university</li> <li>3. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of diploma</li> <li>2. Confirming letter from college or university</li> <li>3. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Original/copy of diploma</li> <li>2. Confirming letter from college or university</li> <li>3. FDA Approval Letter</li> </ol>
Initial physics education-final regs  (20 semester hours-Master)  (10 semester hours-Bachelor)	<ol style="list-style-type: none"> <li>1. College or university transcripts</li> <li>2. Confirming letter from college or university</li> <li>3. Master or Bachelor degree specifically in physics</li> <li>4. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. College or university transcripts</li> <li>2. Confirming letter from college or university</li> <li>3. Master or Bachelor degree specifically in physics</li> <li>4. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. College or university transcripts</li> <li>2. Confirming letter from college or university</li> <li>3. Master or Bachelor degree specifically in physics</li> <li>4. FDA Approval Letter</li> </ol>
Survey Training-final regs  (20 contact hours-Master)  (40 contact hours-Bachelor)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Letter or other document from training program</li> <li>3. CME/CEU certificates</li> <li>4. Letter or other document confirming in-house or formal training</li> <li>5. Training gained performing surveys</li> <li>6. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from training program</li> <li>2. CME/CEU certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Training gained performing surveys</li> <li>5. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Letter or other document from training program</li> <li>2. CME/CEU certificates</li> <li>3. Letter or other document confirming in-house or formal training</li> <li>4. Training gained performing surveys</li> <li>5. FDA Approval Letter</li> </ol>
Initial Experience-final regs  (1 facility-10 units-Master)  (1 facility-20 units-Bachelor)	<ol style="list-style-type: none"> <li>1. Attestation</li> <li>2. Copy or coversheet of survey</li> <li>3. Letter from facility or listing from company providing the physics survey services documenting performance of survey done</li> <li>4. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Copy or coversheet of survey</li> <li>2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done</li> <li>3. FDA Approval Letter</li> </ol>	<ol style="list-style-type: none"> <li>1. Copy or coversheet of survey done under direct supervision</li> <li>2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision</li> <li>3. FDA Approval Letter</li> </ol>

Initial Mammography Modality Specific training- 8 hours-final regs	<ol style="list-style-type: none"> <li>1. Attestation for training or experience with investigational units</li> <li>2. Mammography Modality Specific CME/CEU certificates</li> <li>3. CME/CEU certificates plus agenda, course outline or syllabus</li> <li>4. Confirming letters from CME/CEU granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> <li>6. Letter from facility where experience was obtained documenting experience in the new mammographic modality</li> </ol>	<ol style="list-style-type: none"> <li>1. Attestation for experience with investigational units</li> <li>2. Mammography Modality Specific CME/CEU certificates</li> <li><b>3. CME/CEU certificates plus agenda, course outline or syllabus</b></li> <li>4. Confirming letters from CME/CEU granting organizations</li> <li>5. Letters, certificates or other documents from manufacturers' or other formal training courses</li> <li>6. Letter from facility where experience was obtained documenting experience in the new mammographic modality</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME/CEU certificates</li> <li>2. CME/CEU certificates plus agenda, course outline or syllabus</li> <li>3. Confirming letters from CME/CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Experience (2 facilities-6 units/24 months-final regs)	N/A	N/A	<ol style="list-style-type: none"> <li>1. Copy or coversheet of survey</li> <li>2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done</li> </ol>
Continuing Education (15 CME/36 months)	N/A	<ol style="list-style-type: none"> <li>1. CME/CEU certificates</li> <li>2. Confirming letters from CME/CEU granting organizations</li> <li>3. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CME/CEU certificates</li> <li>2. Confirming letters from CME/CEU granting organizations</li> <li>3. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Continuing Mammographic Modality Specific Education-final regs	N/A	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME/CEU certificates</li> <li>2. CME/CEU certificates (plus agenda, course outline or syllabus)</li> <li>3. Confirming letters from CME/CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. Mammography Modality Specific CME/CEU certificates</li> <li>2. CME/CEU certificates (plus agenda, course outline or syllabus)</li> <li>3. Confirming letters from CME/CEU granting organizations</li> <li>4. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>
Requalification-Experience- final regs-done under direct supervision	N/A	N/A	<ol style="list-style-type: none"> <li>1. Copy or coversheet of survey done under direct supervision</li> <li>2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision</li> </ol>
Requalification- Education	N/A	<ol style="list-style-type: none"> <li>1. CME/CEU certificates</li> <li>2. Confirming letters from CME/CEU granting organizations</li> <li>3. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>	<ol style="list-style-type: none"> <li>1. CME/CEU certificates</li> <li>2. Confirming letters from CME/CEU granting organizations</li> <li>3. Letters, certificates or other documents from manufacturers' or other formal training courses</li> </ol>