

Comments and suggestions may be submitted at any time for Agency consideration to Charles Gunzburg, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next

more detailed information regarding the regulations.

MQSA requires each facility conducting mammography in the United States (except those of the

- meet quality standards for personnel, equipment, maximum allowable radiation dose, quality assurance, medical audit and outcome analysis, medical recordkeeping and reporting
- be accredited by a Food and Drug Administration (FDA)-approved accreditation body (AB) (currently, the American College of Radiology [ACR] and the States of Iowa, California, and
- be certified to perform mammography by the FDA, the States of Illinois or Iowa, or another State certification body approved by the FDA (each certified facility must prominently

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

Determination that the equipment has been designed specifically for mammography.

To meet item number 2, 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 for each x-ray

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

- X-ray unit accreditation status
- Equipment evaluation for new/repared equipment
- Annual survey reports (both the most recent and the previous one)
- Evidence of post-move performance testing for mobile units
- QC test records

Note: Under both 1. and 2. the unit still must have passed an 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.

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

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 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. Although these records must be maintained and available for review, not all records will always be evaluated during each inspection. However, the

- 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

more frequently than the annual tests in _____ and will normally fall under the responsibility of _____

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.

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).

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

___ the continuing experience and education requirements of items 4 and 5.

Have a general/full license to perform radiographic procedures issued by a State.

Have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, ___ the last day of the calendar quarter preceding the inspection, ___

The starting date for meeting this requirement is April 28, 1999, or the 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 24 months after the technologist's starting date.

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 ___ the last day of the calendar quarter preceding the inspection, ___ 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 starting date for meeting the continuing education requirements is the later of October 1, 1994, or the technologist's starting date. Failure to meet the continuing education requirements will not be considered a noncompliance until 36 months after the technologist's starting date.

As with the physicians, FDA recommends that the facilities update the education and experience

The starting date for this requirement is April 28, 1999 or the date on which the physicist

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 records created on or after April 28, 1999, the inspector will also verify that 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.

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. At a minimum, the system must track "positive mammographic findings," which refers to mammograms interpreted as "Suspicious" or "Highly suggestive of malignancy." 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 _____ within 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is later. The first and all subsequent audit _____ within 12 months and be reviewed by a "reviewing interpreting physician" appointed by the facility. The "reviewing 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

__ 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. For violations related to the quality control (QC) tests described in paragraph 900.12(e)(8)(ii)(B), the facility must complete repairs within

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

- Daily QC tests - *900.12(e)(1)*,
 - base plus fog
 - mid-density
 - density difference
- Weekly QC tests - *900.12(e)(2)*

useful items, including current information about the mammography program. If you have questions on how to prepare for inspections, call FDA's Mammography Program at (800) 838-7715, or FAX your

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,

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	QC records (&charts) for the last 12 months or since the last	Before any further clinical films are processed.

	0.03 OD.	inspection, whichever is longer. QC test films for the last 30 days.	
"	Established operating level for MD, ± 0.15 OD.		
"	Established operating level for DD, ± 0.15 OD.		
Phantom QC- Weekly	Established operating level for OD at center of \geq the minimum OD must be ≥ 1.2 at any time.	QC charts & records for the last 12 months or since the last inspection, whichever is longer. Phantom images for the last 12 weeks.	
"			
"			
Fixer retention in film- Quarterly		QC Records since the last inspection or for the past three tests, whichever is longer.	Within 30 days of the date
Repeat Analysis- Quarterly	Operating level for repeat or reject rate is $< 2\%$ change (up or down) from previous rate.		
Darkroom Fog- Semi-annually	≤ 0.05 .	QC Records since last inspection or for the past three tests, whichever is longer. Fog QC films from the previous	Before any further clinical films are processed.
Screen-Film Contact- Semi-annually		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
Compression Device Semi-annually	Compression force ≥ 111 newtons (25 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.

Annual Quality Control Tests

Test	Final Regulation	Regulatory Action		corrective action*
AEC				Within 30 days of the date of the test.
kVp				
Focal spot	900.12(e)(5)(iii)			
HVL				
Air Kerma and AEC reproducibility				
Dose		Exceeds 3.0 mGy (0.3 rad) per exposure.		
X-ray field / light field / compression device alignment	900.12(e)(5)(vii)	Paddle visible on		Within 30 days of the date of the test.
Screen speed uniformity	900.12(e)(5)(viii)			
System artifacts				

		physicist.		
Radiation output	900.12(e)(5)(x)	Less than 4.5 mGy/sec (513 mR/sec).	"	"
Automatic decompression control				
Any applicable modality tests				Before any further examinations are

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

Acceptable Documents For Interpreting Physicians

Requirement	Obtained Prior to	Obtained 10/1/94-	Obtained after 4/28/99
State License			
Board Certification (ABR, AOBR, or RCPSC)			
Formal Training (2 months-interim regs)	1. Letters or other documents from US or Canadian residency	1. Letters or other documents from US or Canadian residency	1. Letters or other documents from US or Canadian residency

(3 months-final regs)			
Initial Medical Education (40 hours-interim regs) (60 hours/15 in last 3 years-final regs)	3. CME certificates 4. Letter or other document confirming in-house or formal	2. CME certificates 3. Letter or other document confirming in-house or formal	2. CME certificates 3. Letter or other document confirming in-house or formal training (category I)
Initial Experience (any 6 month period-interim regs) (last 6 months vs 6 months in last 2 years of residency-final regs)	2. Letter or other residency or training mammography facility	residency or training mammography facility - done under direct	residency or training mammography facility - done under direct
	5. Letters, certificates or other documents from manufacturers' or other formal training	4. Letters, certificates, or other documents from manufacturers' or other formal training	4. Letters, certificates, or other documents from manufacturers' or other formal training

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)			
Continuing Mammographic Modality Specific Education-final regs		4. Letters, certificates, or other documents from manufacturers' or other formal training	
Requalification- Experience-done under direct supervision		1. Letter, table, facility documentation from residency or training mammography facility	1. Letter, table, facility documentation from residency or training mammography facility
Requalification-		1. CME certificates	1. CME certificates

Education	(category I or II)	(category I)
	2. Confirming letters from CME granting organizations	2. Confirming letters from CME granting organizations

Attachment 5

Acceptable Documents For Radiologic Technologists

Requirement	Obtained Prior to	Obtained 10/1/94-	Obtained after 4/28/99
State Licensure			
Board Certification (ARRT or ARCRT)	1. Original/copy of current certificate 2. Confirming letter from certifying board 3. Pocket card/copy of	1. Original/copy of current certificate 2. Confirming letter from certifying board 3. Pocket card/copy of	1. Original/copy of current 2. Confirming letter from 3. Pocket card/copy of
Initial Training (~40 hours-interim regs) (40 hours with 25 supervised exams-final regs)	3. CEU certificates 4. Letter or other document confirming in-house or formal	2. CEU certificates 3. Letter or other document confirming in-house or formal training 4. Approved courses	2. CEU certificates 3. Letter or other document confirming in-house or formal training
Initial			1. Mammography modality

<p>Mammography Modality Specific Training (8 hours-final regs)</p>	<p>2. Mammography modality specific CEU certificates</p> <p>3. CEU certificates plus agenda, course outline, or syllabus</p> <p>4. Confirming letters from CEU granting organizations</p> <p>5. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>	<p>modality specific CEU certificates</p> <p>2. CEU certificates plus agenda, course outline, or syllabus</p> <p>3. Confirming letters from CEU granting organizations</p> <p>4. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>	<p>specific CEU certificates</p> <p>2. CEU certificates plus agenda, course outline, or syllabus</p> <p>3. Confirming letters from CEU granting organizations</p> <p>4. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>
<p>Continuing Experience (200/24 months-final regs)</p>			<p>1. Letter, table, facility documentation from training program or mammography facility</p>
<p>Continuing Education (15 CME/36 months)</p>		<p>3. Formal training</p> <p>4. Letters, certificates, or other documents from manufacturers' or other formal training</p>	<p>1. CEU certificates</p> <p>2. Confirming letters from</p> <p>3. Formal training courses</p> <p>4. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>
<p>Continuing Mammographic Modality Specific Education-final regs</p>		<p>2. CEU certificates (plus agenda, course outline,</p> <p>3. Confirming letters from CEU granting</p>	<p>1. Mammography Modality Specific CEU certificates</p> <p>2. CEU certificates (plus agenda, course outline or</p> <p>3. Confirming letters from</p>

		4. Letters, certificates, or other documents from manufacturers' or other formal training	4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Requalification-Experience-final regs-done under direct supervision			1. Letter, table, facility documentation from training program or mammography facility (done under direct
Requalification-Education		3. Letter or other document confirming in-house or formal training 4. Letters, certificates, or other documents from manufacturers' or other formal training	1. CEU certificates 2. Confirming letters from 3. Letter or other document confirming in-house or formal training 4. Letters, certificates, or other documents from manufacturers' or other formal training courses

Acceptable Documents For Medical Physicists

Requirement	Obtained Prior to 10/1/94		Obtained after 4/28/99
State Licensure or Approval	1. State license or approval/copy with 2. Confirming letter from State licensing board	1. State license or approval/copy with 2. Confirming letter from State licensing board	1. State license or approval/copy with 2. Confirming letter from State licensing board

<p>Board Certification (ABR or ABMP)</p>	<p>1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR</p>	<p>1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR</p>	<p>1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR</p>
<p>Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway - alternative)</p>	<p>1. Original/copy of 2. Confirming letter from college or university</p>	<p>1. Original/copy of 2. Confirming letter from college or university</p>	<p>1. Original/copy of 2. Confirming letter from college or university</p>
<p>Initial physics education-final regs (20 semester hours) (10 semester hours -alternative)</p>	<p>1. College or university 2. Confirming letter from college or university</p>	<p>1. College or university 2. Confirming letter from college or university</p>	<p>1. College or university 2. Confirming letter from college or university</p>
<p>Survey Training-final regs (20 contact hours) (40 contact hours -alternative)</p>	<p>4. Letter or other document confirming in-house or formal training 5. Training gained performing surveys</p>	<p>3. Letter or other document confirming in-house or formal training 4. Training gained performing surveys</p>	<p>3. Letter or other document confirming in-house or formal training 4. Training gained performing supervised</p>
<p>Initial Experience-</p>		<p>1. Copy or coversheet of</p>	<p>1. Copy or coversheet of</p>

<p>final regs (1 facility-10 units) (1 facility-20 units -alternative)</p>	<p>2. Copy or coversheet of survey 3. Letter from facility or listing from company providing the physics survey services documenting performance of survey done</p>	<p>survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done</p>	<p>survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision</p>
<p>Initial Mammography Modality Specific training (8 hours-final regs)</p>	<p>modality specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CME/CEU granting 5. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>	<p>modality specific CME/CEU certificates 2. CME/CEU certificates plus agenda, course outline, or syllabus 3. Confirming letters from CME/CEU granting 4. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>	<p>modality specific CME/CEU certificates 2. CME/CEU certificates plus agenda, course outline, or syllabus 3. Confirming letters from CME/CEU granting 4. Letters, certificates, or other documents from manufacturers' or other formal training courses</p>
<p>Continuing Experience (2 facilities-6 units/24 months-final regs)</p>			
<p>Continuing Education (15 CME/36 months)</p>		<p>1. CME/CEU certificates 2. Confirming letters from CME/CEU granting 3. Letters, certificates, or other documents from manufacturers' or other</p>	<p>1. CME/CEU certificates 2. Confirming letters from CME/CEU granting 3. Letters, certificates, or other documents from manufacturers' or other</p>

		formal training courses	formal training courses
Continuing Mammographic Modality Specific Education-final regs	N/A	<ol style="list-style-type: none"> 1. Mammography modality specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses 	<ol style="list-style-type: none"> 1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Requalification-Experience-final regs-done under direct supervision			<ol style="list-style-type: none"> 1. Copy or coversheet of survey done under direct 2. Letter from facility or listing from company providing the physics performance of survey done under direct
Requalification-Education		<ol style="list-style-type: none"> 1. CME/CEU certificates 2. Confirming letters from CME/CEU granting 3. Letters, certificates, or other documents from manufacturers' or other formal training courses 	<ol style="list-style-type: none"> 1. CME/CEU certificates 2. Confirming letters from CME/CEU granting 3. Letters, certificates, or other documents from manufacturers' or other formal training courses

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