

# **Revise MQSA Regulations Inspections, and Enforcement**

September 26-27, 2005

# Revise MQSA Regulations, Inspections, and Enforcement

## IOM Recommendations:

5. Modify regulations to clarify intent and to address current technology
6. Modify inspections by streamlining process, reducing redundancy, and addressing current technology. Strengthen enforcement for patient protection

# **IOM Recommendation 5**

**Modify Regulations to Clarify  
Intent and Address Current  
Technology**

# Modify MQSA Regulations

- A) Remove exemption for stereotactic breast biopsy procedures and develop regulations
- B) Develop regulations for digital mammography
- C) Update assessment categories to reflect BI-RADS; include “known biopsy-proven-malignancy”
- D) Establish luminance standard for viewing mammograms
- E) Eliminate modality-specific CME

# Modify MQSA Regulations

Key to recommended additions/deletions to regulations:

Added text:

**{changes to regulations}**

Deleted text:

**<changes to regulations>**

# Modify MQSA Regulations

A) Remove exemption for stereotactic breast biopsy procedures and develop regulations

## Section 900.2 (aa):

Mammography means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization **<or biopsy>** procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter

# Modify MQSA Regulations

## Rationale:

- Stereotactic breast biopsy uses mammographic x-ray imaging
- FDA indicated intent to regulate interventional (preamble to proposed final MQSA regulations dated April 3, 1996)
- Profession now has more experience with stereotactic procedures

# Modify MQSA Regulations

## B) Develop regulations for digital mammography

- Should develop a uniform set of quality control tests and test criteria
- Should not preclude performance of additional tests recommended by equipment manufacturer

# Modify MQSA Regulations

## C) Update assessment categories to reflect BI-RADS

### Section 900.12( c )(1)(iv):

Overall final assessment of findings, classified in one of the following categories:

- (A) “Negative:” Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained;
- (B) “Benign **{Finding(s)}**:” Also a negative assessment;
- (C) “Probably Benign **{Finding – Initial Short-term Follow-up Suggested:}**” Finding(s) has a high probability of being benign

# Modify MQSA Regulations

- (D) “Suspicious **{Abnormality – Biopsy Should Be Considered:}**” Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
- (E) “Highly Suggestive of Malignancy **{- Biopsy Should Be Considered:}**” Finding(s) has a high probability of being malignant;
- {(F) “Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken:” Reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy}**

# Modify MQSA Regulations

## Section 900.12( c )(1)(v):

In cases where no final assessment category can be assigned due to incomplete work-up, “Incomplete: Need Additional Imaging Evaluation **{and/or Prior Mammograms for Comparison}**” shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician. **{For cases rated 0 because of need for prior examinations, reassessment must be performed within 30 days to assign category}**

# Modify MQSA Regulations

## Rationale:

- More consistent with the 2003 BI-RADS categories to minimize confusion between interpreting physicians and other clinicians
- FDA has already approved the new category (F) in an alternative standard

# Modify MQSA Regulations

## D) Establish luminance standards for viewing mammograms:

- Proposed section 900.12(e)(5)(xii) [annual test]:  
**{Viewboxes used for interpreting mammograms and clinical image quality review by the technologist should be capable of producing a luminance of at least 3,000 candela per square meter. The illumination levels must be less than or equal to 20 lux}**
- Evaluation of viewboxes during inspection not recommended

# Modify MQSA Regulations

## Rationale:

- Viewing conditions critical to detect subtle contrast differences
- 1999 ACR Mammography Quality Control Manual has suggested standards

# Modify MQSA Regulations

## E) Eliminate the modality-specific CME requirement

### Section 900.12(a)(1)(ii)(B):

Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical 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. The facility will choose one of these dates to determine the 36-month period. **<This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice>**

# Modify MQSA Regulations

## Rationale:

- Eliminating the modality-specific CME requirement would allow a broader choice of educational opportunities, including those that focus on interpretive skills
- Interpreting physician has required initial 8 hours of training in new modalities
- Interpretation skills do not change with modality
- Similar sections for radiologic technologists (section 900.12(a)(2)(iii)(C)) and medical physicists (section 900.12(a)(3)(iii)(A)) would also be revised to eliminate modality-specific CME

# Modify MQSA Regulations

- **Section 900.4(c)(5)(i) – require review physicians for accreditation bodies specialize in mammography**

**{Have at least 50% of each year's practice in breast imaging, be currently actively practicing in the modality reviewed at an MQSA-certified mammography facility,}** meet the interpreting physician requirements specified in Sec. 900.12(a)(1) and meet such additional requirements as have been established by the accreditation body and approved by FDA

# Modify MQSA Regulations

## Rationale:

- Accreditation body reviewers evaluating the performance of facilities should have considerably more experience than the minimum under the regulations
- Also, reviewers evaluating images of a specific modality (e.g., digital) should have current experience with that modality

# Modify MQSA Regulations

## Section 900.4(e)(1)(i) – results of equipment evaluations

With its initial accreditation application, **{the results of}** a mammography equipment evaluation that was performed by a medical physicist no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in Sec. 900.12(e).

# Modify MQSA Regulations

## Rationale:

- The ACR currently requests only the equipment evaluation results with the initial accreditation application
- The FDA has approved this process

# Modify MQSA Regulations

Section 900.4(e)(1)(ii) – clarification and change timing of survey.

Prior to accreditation, an **{annual}** survey that was performed no earlier than **<6>{14}** months before the date of application for accreditation **{or accreditation renewal}** by the facility.

Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.

# Modify MQSA Regulations

## Rationale:

- Add “annual” and “or accreditation renewal” to be consistent with other regulations in this part
- Change to “14 months” to be consistent with the MQSA inspection and accreditation body processes
- Current regulations may force more than one annual survey in the same year

# Modify MQSA Regulations

**Section 900.4(e)(2)(iii) – delete section for reports of mammography equipment evaluations, surveys, and QC**

**<Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.>**

# Modify MQSA Regulations

## Rationale:

- Inspectors currently review annual surveys and equipment evaluations during annual inspection
- Submission to the accreditation body each year is redundant

# Modify MQSA Regulations

## Section 900.4(h)(1) – change to accreditation requirements

Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited, **{when notified by the facility}** and **{every three years during renewal}**, in a manner and at a time specified by FDA.

# Modify MQSA Regulations

## Rationale:

- Consistent with the suggested change to section 900.4(e)(2)(iii) regarding submission of survey results to accreditation bodies

# Modify MQSA Regulations

## Section 900.11(b)(1)(i) – change to certification requirements

In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by the FDA **{for accreditation of all mammography units}**. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

# Modify MQSA Regulations

## Rationale:

- Add “for all units” to ensure all new mammography units, including digital, are accredited

# Modify MQSA Regulations

**Section 900.11(b)(1)(iii) – new section for certification requirements**

**{Facilities must notify their accrediting body of new units and begin accreditation before use.}**

# Modify MQSA Regulations

## Rationale:

- Ensures all new equipment is reported to the accreditation body

# Modify MQSA Regulations

## Section 900.11(c) – change reinstatement policy

A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may **<be considered to be a new facility and thereby>** be eligible for a provisional certificate.

# Modify MQSA Regulations

## Rationale:

- The current wording about this confuses facilities
- A reinstated facility is not “considered to be a new facility”
- The facility retains their accreditation body ID number, their MQSA facility ID number, and their accreditation history

# Modify MQSA Regulations

## Section 900.12(a)(1)(ii)(A) – change to continuing experience for interpreting physicians

Following the second anniversary date **<of the end of the calendar quarter>** in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall 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 facility will choose one of these dates to determine the 24-month period>** {previous two calendar years. Continuing experience obtained outside of the U.S. is also acceptable.}

# Modify MQSA Regulations

## Rationale:

- Current timeframe for counting experience is confusing
- Basing these numbers on calendar years will simplify compliance
- Physicians who initially qualified in the U.S. under MQSA should not be prevented from using foreign experience
- Similar sections for radiologic technologists (section 900.12(a)(2)(iv)(A)) and medical physicists (section 900.12(a)(3)(iii)(B)) would also be revised to change the continuing experience time frame

# Modify MQSA Regulations

## Section 900.12(a)(1)(ii)(B) - change to continuing education for interpreting physicians

Following the third anniversary date **<of the end of the calendar quarter>** in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the **{previous three calendar years.} <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 facility will choose one of these dates to determine the 36-month period.>** This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

# Modify MQSA Regulations

## Rationale:

- The current timeframe for counting CME's is confusing
- Basing these numbers on calendar years will simplify compliance
- **Similar sections for radiologic technologists (section 900.12(a)(2)(iii)(C)) and medical physicists (section 900.12(a)(3)(iii)(A)) would also be revised to change CME the time frame**

# Modify MQSA Regulations

## Section 900.12(a)(3)(iii)(B) – changes to continuing experience for medical physicists

Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed **<at least two mammography facilities and a total of>** at least six mammography units 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 facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

# Modify MQSA Regulations

Section 900.12(a)(3)(iii)(B) – changes to continuing experience for medical physicists

## Rationale:

- It is difficult for medical physicists to provide services to more than one facility over a 24-month period
- Outside consulting is sometimes prohibited
- Ratio of units to facilities has increased (1.2 to 1.5)
- Many facilities have over 10 units
- Physicists have adequate experience surveying one facility

# **Modify MQSA Regulations**

**FDA Current Regulations: a physicist may currently satisfy the continuing experience requirement by providing services at a single facility**

# Modify MQSA Regulations

## Section 900.12(d)(1)(i) – changes to lead interpreting physician requirement

The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate. **{Lead interpreting physician must provide regular feedback to technologist on quality of images.}**

# Modify MQSA Regulations

## Rationale:

- Data from ACR onsite surveys suggest facilities could benefit from improved physician-technologist communication
- Requiring regular feedback may improve quality

# Modify MQSA Regulations

Section 900.12(e)(2)(i) – changes to weekly (phantom image) quality control tests

The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least ~~<1.2>~~ {1.40} when exposed under a typical clinical condition.

# Modify MQSA Regulations

## Rationale:

- Higher contrast films perform better at higher densities
- Should change optical density from 1.2 to 1.4 for other tests, including darkroom fog test (section 900.12(e)(4)(i)) and automatic exposure control performance test (section 900.12(e)(5)(i)(C)) for same reason

# Modify MQSA Regulations

## Section 900.12(e)(4)(ii) – change to screen-film contact

Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested **<semi>-{annually. The test shall also be carried out initially for all new cassettes as they are placed in service, and whenever reduced image sharpness is suspected.}**

# Modify MQSA Regulations

**Section 900.12(e)(4)(ii) – change to screen-film contact**

## **Rationale:**

- Only needs to be performed annually or for new cassettes
- Majority of rejected cassettes found upon initial use

# Modify MQSA Regulations

**FDA Current Guidance:** screen-film contact test must be performed on new cassettes prior to clinical use

# Modify MQSA Regulations

Section 900.12(e)(5)(ii) – change to kilovoltage peak (kVp) accuracy and reproducibility

Facilities with **{older three-phase}** screen-film systems shall perform the following quality control tests at least annually:

(ii) Kilovoltage peak (kVp) accuracy **<and reproducibility>**.

(A) The kVp shall be accurate within +/- 5 percent of the indicated or selected kVp at:

(1) The lowest clinical kVp that can be measured by a kVp test device;

(2) **<The most commonly used clinical>** kVp **{that is obtained when the accrediting body phantom is imaged with the mammography X-ray unit set to the most commonly used clinical AEC mode; and}**

# Modify MQSA Regulations

Section 900.12(e)(5)(ii) – change to kilovoltage peak (kVp) accuracy and reproducibility (cont.) -

(3) The highest available clinical kVp, and

(B) **<At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.>** {Newer units with medium- and high-frequency generators will not require this test.}

# Modify MQSA Regulations

## Rationale:

- Phrase “most commonly used clinical kVp” is confusing
- Different range of patient technique settings may be reviewed by the inspector versus medical physicist
- Data from DMIST trials show test rarely fails during annual survey
- Modern equipment voltage regulation is extremely tight
- Unnecessary on an annual basis, but retained for equipment evaluations

# Modify MQSA Regulations

## Section 900.12(e)(5)(ix) – changes to system artifact test

System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes **<and target-filter combinations,> {targets, and filters}** used clinically.

# Modify MQSA Regulations

**Section 900.12(e)(5)(ix) – changes to system artifact test**

## **Rationale:**

- To assess image quality and artifacts, only one test of focal spot size, filter, and target is necessary, not combinations

# Modify MQSA Regulations

**Current Approved Alternative Standard:**  
for the annual physics survey, all targets and filters have to be tested during the artifact test, not combinations. If any filter-related artifact is discovered during testing, all target-filter combinations must be tested. All combinations are to be evaluated during mammography equipment evaluations

# Modify MQSA Regulations

## Section 900.12(f) – changes to mammography medical outcomes audit

Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. **{Facilities with the same interpreting physicians should combine medical audit data.}** This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

# Modify MQSA Regulations

## Rationale:

- Medical audit data is more meaningful for high-volume facilities
- Facilities with same interpreting physicians should combine data across facilities for meaningful results
- The burden on individual facilities should be decreased
- Using “should” instead of “may” suggests aggregate data are preferred
- No noncompliance citations for facilities submitting nonaggregate data

# Modify MQSA Regulations

## Section 900.12(f)(1) – changes to mammography medical outcomes audit

General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians **<at the facility>** for:

# Modify MQSA Regulations

Section 900.12(f)(1) – changes to mammography medical outcomes audit (cont.)

{(i) Screening examinations, where a positive examination is defined as “Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison,” “Suspicious Abnormality--Biopsy Should Be Considered,” or “Highly Suggestive of Malignancy--Biopsy Should Be Considered,” and (ii) Diagnostic examinations, where a positive examination is defined as “Suspicious Abnormality--Biopsy Should Be Considered,” or “Highly Suggestive of Malignancy--Biopsy Should Be Considered”.}

# Modify MQSA Regulations

**Section 900.12(f)(1) – changes to mammography medical outcomes audit (cont.)**

**{(ii) Diagnostic examinations, where a positive examination is defined as “Suspicious Abnormality--Biopsy Should Be Considered,” or “Highly Suggestive of Malignancy--Biopsy Should Be Considered.”}**

# Modify MQSA Regulations

## Rationale:

- Combining data for screening with diagnostic examinations dilutes meaning of results
- Cannot compare facility/practice performance with current literature or established databases
- ACR BI-RADS Committee - audit of screening examinations requires recommendation for recall imaging (BI-RADS Category 0) be considered “positive”
- Make regulations more consistent with BI-RADS guidance

# Modify MQSA Regulations

## Section 900.13(a) – changes to FDA action following revocation of accreditation

If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks **<reaccreditation> {reinstatement.}** A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

# Modify MQSA Regulations

## Rationale:

- Accreditation bodies require a facility to “reinstate” rather than “reaccredit” following revocation of accreditation
- Reinstatement requires corrective action approved by accreditation body, reaccreditation doesn't

# **IOM Recommendation 6**

## **Modify Inspections and Strengthen Enforcement**

# Modify Inspections and Strengthen Enforcement

FDA should:

- A) Eliminate several onsite inspection tests, such as dose and other radiation tests
- B) Require facilities to cease performing mammography after two consecutive unsuccessful attempts at reaccreditation, even if MQSA certificate is still valid
- C) Require a facility that closes or has its certification revoked to notify patients and referring physicians. In addition, regulations for film retention should apply to facilities that close

# Modify Inspections and Strengthen Enforcement

**A) Several onsite inspection tests are redundant and have few failures**

- Dose failures during inspection almost nonexistent
- Dose testing monitored by ACR and medical physicist
- Other tests already done by medical physicists (beam quality, x-ray/film alignment, etc.)

# Modify Inspections and Strengthen Enforcement

No. of facilities (FY 2005)



\*Last noncompliance in 1997

# Modify Inspections and Strengthen Enforcement

- (B) FDA should have authority to require facilities to cease performing mammography after two consecutive unsuccessful attempts at reaccreditation**
  - FDA legal opinion: FDA cannot require facilities to cease mammography if their MQSA certificate has not expired

# Modify Inspections and Strengthen Enforcement

- C) Closed facilities or facilities with revoked certificates must notify patients and referring physicians. Film retention should apply to facilities that close**
- Complaints from patients who were not informed when their facility closed and were unable or unsure of how to access mammography records. If facilities are incapable of notification, FDA should notify patients and physicians