From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Winter 1999 Volume 6, Issue 1

FINAL REGULATIONS UPDATE

FDA Changes Starting Date of Continuing Experience Requirement; Proposes Rule Change Resolving Collimation Conflict

FDA published a correcting amendment to the MQSA Final Regulations October 22, 1998, in the Federal Register (see Vol. 63, No. 204, pp. 56555-56559) that, among other things, changes the starting date of the continuing experience requirement for radiologic technologists and medical physicists. FDA also published a proposed rule change November 5, 1998, (see Vol. 63, No. 214, pp. 59750-59752) to resolve a collimation conflict between MQSA regulations and FDA's Electronic Product Radiation Control (EPRC) standards.

The previous wording of the final rule about the continuing experience requirements in Section 900.12(a)(2)(iv) and (a)(3)(iii)(B) read that these requirements be met "following the second anniversary date of the end of the calendar quarter" during which the technologist or physicist's initial requirements

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Inspections Under the Final Regulations

An important interaction between FDA and mammography facilities is the annual inspection. With the MQSA final regulations going into effect April 28, 1999, FDA is revamping materials to help facilities prepare for their inspections under the final regulations.

In June 1995, FDA produced "What a Mammography Facility Should Do To Prepare for the MQSA Inspection." This document was amended in June 1996 and will be revised again to cover changes implemented in the final rule. An associated speaker's kit with slides also is under development; FDA anticipates these materials to be available early spring 1999.

MQSA inspection procedures under the final regulations will continue to cover the following areas:

- Equipment performance (including phantom image quality and dose).
- Quality assurance (QA) records (see Q&A column, page 15, for more information).
- Quality control (QC) records and tests, including the technologist's tests and the medical physicist's annual survey report.
- Medical audit and outcome analysis records.
- Medical records (mammography reports and films).
- Personnel qualification records.

Some of the new documentation requirements include establishing written procedures for infection control, as well as for collecting and resolving consumer complaints.

A facility normally will receive at least five business days advance notice before an inspection. The inspector will attempt to schedule a mutually agreeable inspection date.

FDA estimates that the on-site inspection time for a facility with a

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What's Inside

From the Director . . .

After years of developing and fine-tuning regulations to help ensure that mammography meets high-quality standards nationwide, we're on the home stretch to implement the MQSA final rule on April 28, 1999. I want to thank the numerous facility personnel, inspectors, manufacturer representatives, and consumers who contributed to building a system of which we can all be proud.

Of course, the work to improve the system continues. FDA is now making every effort to ensure that facilities understand their obligations under the law and the final regulations. We're already well into our second round of issuing compliance guidance for public review and comment.

Keep checking our website (www.fda.gov/cdrh/dmqrp.html) for up-to-date guidance and other important information. We're redoing the site to include an interactive, knowledge-based search engine that will help you find the appropriate information or policy guidance. The search engine should be especially helpful for facilities preparing for inspections under the final regulations.

Update on the final regulations

Other items I want to bring to your attention include "what's new" in the final regulations, the most significant being the requirement to provide *all patients* a report in lay language that

summarizes the mammography exam results. Congress enacted this provision as part of the Mammography Quality Standards Reauthorization Act signed into law by President Clinton in October 1998.

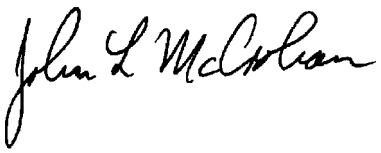
In addition, FDA has published technical amendments (see article, page 1, this issue) to correct some errors that had crept in during the publication of the MQSA final regulations in 1997 and to otherwise clarify requirements before they become effective April 28, 1999. Also, FDA proposed a rule change to resolve a conflict between MQSA and other FDA regulations governing the manufacture of x-ray equipment.

How to prepare for the MQSA inspection

According to our most recent survey, 71 percent of facilities said our 1995 document, "What a Mammography Facility Should Do To Prepare for the MQSA Inspection" was a "very useful" resource. In light of the final regulations, we're updating that document and an associated speaker's kit with slides. This issue of Mammography Matters provides highlights.

We're also producing a live satellite teleconference February 18, 1999, to answer your questions or concerns about MQSA requirements related to personnel, reporting exam results to patients, equipment, or any other areas covered in the final rule. (See page 5 for more information.) If you have any questions or concerns, please convey your message through the MQSA Facility Hotline (1-800-838-7715) or through an e-mail link on our upcoming revised website.

If you're unable to view the teleconference, videotape copies of the event will be available for a fee through NTIS. For more information, call NTIS at 703-605-6186.



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Quality and Radiation Programs

MammographyMatters
Winter 1999

Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested organizations and individuals.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

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Facility Hotline

Call the facility telephone hotline (1-800-838-7715) for more information about FDA certification or inspections.

Don't Delay Reaccreditation

Make sure you check the expiration date on your FDA certificate and begin the reaccreditation process at least nine months before your certificate expires. Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during annual inspections that it continues to meet the MQSA standards.

Since it's unlawful to perform mammography with an expired FDA certificate, don't delay getting reaccredited. Start the process by contacting your accreditation body — the American College of Radiology or the States of Arkansas, California, and Iowa.

Remember, it's up to you to request an application from the accreditation body, complete it, return it, and pass reaccreditation in time for FDA to issue you a new certificate before your current one expires.

Under some circumstances, FDA may allow for an extension if your accreditation body is experiencing delays in processing applications. However, FDA will grant an extension only if you applied for reaccreditation in a timely manner.

Of Note

The National Consortium of Breast Centers is holding its National Breast Center Development Conference April 29, 30, and May 1, 1999 at the MGM Grand Hotel in Las Vegas, NV. The conference is free to consortium members; it costs $175 for non-members.

A Pre-Conference program, "Compliance with the Final Federal MQSA Regulations," will be offered April 28. Category I continuing education credits also will be available for physicians and radiological technologists.

For more information, call the National Consortium of Breast Centers, 219-267-8058, or see its website, www.breastcare.org.

Monsees Leads MQSA Advisory Committee

Since assuming leadership as chair of the National Mammography Quality Assurance Advisory Committee (NMQAAC) in May 1998, Dr. Barbara Monsees has guided committee meeting discussions by broadly soliciting viewpoints from NMQAAC's diverse panel.

"Since the final regulations go into effect in April," says Monsees, "our recent focus has been to help the FDA develop a guidance document for both facilities and regulators. Although some of the rules are straightforward, some of the issues we have discussed have been contentious. My job is to let all opinions be heard."

NMQAAC panel members are drawn from among physicians, medical physicists, radiologic technologists, and other health professionals with significant experience in mammography. At least four members come from national breast cancer advocacy or consumer health organizations with strong backgrounds in dealing with breast cancer and mammography from a public health viewpoint.

Dr. Barbara Monsees

Chief of the Breast Imaging Section at the Mallinckrodt Institute of Radiology, Monsees attended previous committee meetings as an observer and participant before being asked to serve as the NMQAAC chair.

Discussions at the most recent meeting in November 1998 focused on MQSA compliance guidance under the final regulations, MQSA reauthorization, the States as Certifiers program, and voluntary stereotactic accreditation programs. The meetings provide an opportunity for open public presentation and discussion from interested individuals and organizational representatives.

The committee advises FDA on a range of issues related to implementing MQSA, including personnel issues, equipment, quality control, as well as areas of future consideration such as digital mammography and interventional mammography.

The next NMQAAC meeting will be scheduled during the first half of 1999.

Final Regulations Update

Continued from page 1

were met "or October 28, 1997, whichever is later."

For most radiologic technologists and medical physicists, this wording means that they would be checked during inspections for compliance with this requirement beginning after January 1, 2000. This date is well after the effective date of the regulations; however, for some time after this date, the 24-month averaging period, during which compliance would be assessed, begins before the effective date of the final rule.

To avoid such a retroactive effect of the regulation, the date in these two provisions has been changed from October 28, 1997 (the date of publication of the final rule), to April 28, 1999. This means that checking for compliance with these requirements during inspections will begin after June 30, 2001, and in all cases, the 24-month averaging period will fall completely after the effective date of the final rule.

In another update to the final rule, FDA is proposing to resolve the collimation conflict by changing Section 900.12(e)(5)(vii)(A) so that the x-ray field will be allowed, but not required as at present, to extend to or beyond the non-chest wall sides of the image receptor. This would permit facilities whose systems are not presently capable of "blackening" the films to these edges to continue to use those systems without the need of either applying for an alternative requirement or purchasing a retrofit.

Live FDA Satellite TELECONFERENCE!

Facility Inspections Under the Mammography Quality Standards Act (MQSA) Final Regulations

Date: Thursday, February 18, 1999
Satellite test time: 12:00–1:00 p.m. Eastern
Time: 1:00–4:30 p.m. Eastern

C-band Satellite Viewing Coordinates:
2/18 1200-1630 ET
GE2, Transponder 11C
85 degrees West
Vertical D/L Polarity
D/L Freq. 3920 MHz

This live teleconference will cover what you need to know to prepare for MQSA inspections conducted when the final regulations become effective on April 28, 1999.

Get your questions or concerns about the final regulations addressed during the conference by panel members from FDA.

Presentations will focus on information your FDA inspectors will be checking for the first time related to new requirements, such as: 1) personnel, 2) equipment, 3) reporting of exam results to patients, and 4) the consumer complaint mechanism. Changes in the approach to quality assurance will also be discussed.

If you want to view the teleconference, make arrangements now with a nearby location (hospital, university, or government office) where a broad band analog satellite downlink site is available.

You can get more information about viewing sites, by checking FDA's website (www.fda.gov/cdrh/dmqrp.html) under "What's New" or by calling the Facility Hotline (1-800-838-7715).

Medicare Reimbursement for Mammography Services

Medicare reimburses fees associated with mammography services at FDA-certified facilities. Occasionally, legitimate Medicare claims are denied by Health Care Financing Administration (HCFA) intermediaries. How does this happen and what can patients, physicians, and mammography facilities do to resolve this issue?

Every week, FDA provides an updated electronic file to HCFA with the certification status of all U.S. mammography facilities. HCFA subsequently makes this facility file available to their intermediaries and carriers who handle reimbursements. However, sometimes the intermediaries do not receive the entire file.

When intermediaries receive Medicare claims for mammography services, they check the file to determine whether or not the facility in question is FDA certified. Occasionally, the portions of the facility file available to an intermediary or carrier may not contain the record for a certified facility, and valid claims may be denied.

When valid claims are denied, the claimant should first try to resolve the problem with the intermediary or the carrier. If this is unsuccessful, the claimant should then contact the person in the appropriate regional HCFA office (see list below for future reference). In the event that these issues cannot be resolved at the regional level, the parties should then contact the appropriate person at the central office. Note that in some offices the Medicare Part A and Part B contacts are different.

Physicians who file claims for interpreting mammographic examinations should include on the HCFA-1500 claim form the FDA facility ID number of the facility where the mammogram(s) they read were performed. The facility ID number can be found in the lower right hand corner of the MQSA certificate. Claims will be denied if this number is not on the form. If physicians are denied reimbursement, they should contact the appropriate HCFA office.

HCFA Mammography Contacts

(Updated August 31, 1998)

Region I (Boston): MA, ME, NH, VT, CT, RI
Ellen Hamblin, 617-565-1240 (Part A/B)
e-mail: ehamblin@hcfa.gov

Region II (New York): NJ, NY, PR, VI
Michael Britton, 212-264-3663 (Part B)
e-mail: mbritton@hcfa.gov
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Region III (Philadelphia): DE, DC, MD, PA, VA, WV
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Region IV (Atlanta): AL, NC, SC, FL, GA, KY, MI, TN
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Region V (Chicago): IL, IN, MI, MN, OH, WI
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Region VI (Dallas): TX, OK, NM, ARK (Part A) TX, LA, ARK, NM (Part B)
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Region VII (Kansas City): IA, NE, KS, MO
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Darcy Jakopchek, 816-426-6317 (Outreach)
e-mail: djakopchek@hcfa.gov

Region VIII (Denver): CO, MT, ND, SD, UT, WY
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Joanne Spalding, 410-786-3352 (back-up for Wendy)
e-mail: jspalding@hcfa.gov
Linda Gregory, 410-786-6138 (Intermediary - Part A)
e-mail: lgregory@hcfa.gov
Faith Ashby, 410-786-6145 (back-up for Linda)
e-mail: fashby@hcfa.gov

New MQSA Equipment Requirements

The MQSA final regulations equipment standards, most of which go into effect April 28, 1999, are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

Outlined below are some of the new equipment requirements contained in the final rule. In drafting the regulations, FDA relied heavily on the recommendations of groups such as the equipment focus groups convened by the American College of Radiology, with the support of the U.S. Centers for Disease Control and Prevention. FDA believes that most mammography equipment manufactured in recent years will meet many, if not all, of these requirements, but older equipment may have to be retrofitted or replaced.

Effective April 28, 1999

- The tube-image receptor assembly must remain locked in any position at which it can be operated and remain locked if the power to the unit is interrupted. If it can "float" after interruption of power, the unit will be ruled non-compliant. [900.12(b)(3)]
- The unit must provide at least two image receptors (18 x 24 cm and 24 x 30 cm sizes), each with its own moving grid and compression paddle, matched to the film size. [900.12(b)(4) and 900.12(b)(8)(ii)(A)]
- Units with magnification must provide for magnification studies to be performed without a grid between the source and image receptor. [900.12(b)(4)(iii)]
- If the unit has a light beam that passes through the x-ray beam limiting device, it must be sufficiently bright: 160 lux or 15 foot-candles at the maximum SID. [900.12(b)(5)(ii)]
- If the unit is used to perform non-interventional problem-solving procedures (i.e., diagnostic mammography) it must have magnification capabilities that provide at least one magnification from within the range of 1.4 to 2.0. [900.12(b)(6)]
- The compression paddle of the unit must be straight across at the chest wall edge (applies only to paddles used for normal views). Except for paddles specially designed otherwise, the paddles must be flat and parallel to the breast-support table, and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the paddle when compression is applied. [900.12(b)(8)(ii)]
- The unit must display the manually set technique before exposure and must display the resultant kVs and mAs (or mA and time) after any exposure terminated by the automatic exposure control (phototimed). [900.12(b)(9)]
- The size and available positions of the AEC detector shall be clearly indicated at the X-ray input surface of the breast-compression paddle. [900.12(b)(10)(ii)(A)]
- In AEC mode, the unit must maintain the optical density of the film within plus or minus 0.30 of the average optical density, as tested by a medical physicist. (Until October 28, 2002, a technique chart may be used in conjunction with the AEC to meet this requirement.) [900.12(e)(5)(i)(A)]
- The unit must produce a radiation output rate of 513 mR/second, measured at 28 kV for an exposure 3 seconds long, at 4.5 cm above the breast support. [900.12(e)(5)(x)]

Effective October 28, 2002

- The unit must provide a power-driven initial compression that can be activated from both sides of the patient. It must also provide a fine adjustment of the compression, operable from both sides of the patient. [900.12(b)(8i)]
- In AEC mode, the unit must maintain the optical density of the film within plus or minus 0.15 of the average optical density, as tested by a medical physicist. [900.12(e)(5)(i)(B)]
- The unit (and entire imaging system) must resolve 11 line pair/mm (bars perpendicular to the anode-cathode axis) and 13 line pair/mm (bars parallel to the anode-cathode axis). This requirement must be met regardless of the measured focal-spot size. [900.12(e)(5)(iii)]
- The unit must produce a radiation output rate of 800 mR/second, measured at 28kV for an exposure 3 seconds long, at 4.5 cm above the breast support. [900.12(e)(5)(x)]

INTERPRETING PHYSICIANS

Personnel Requirements Under the Final Regulations

MQSA Final Regulations – Effective April 28, 1999	Changes From Interim Regulations
▶ Be licensed to practice medicine.	No change.
AND	
▶ **EITHER** be certified by an FDA-approved body in radiology or diagnostic radiology (ABR, AOBR, RCPSC), **OR** have at least 3 months documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection.	Mammography training required for non-board certified interpreting physicians who are **not already qualified under the interim regulations** was increased from 2 to 3 months.
AND	
▶ Have 60 hours documented Category I CME in mammography, at least 15 of which must have been acquired in the 3 years immediately prior to the physician meeting his/her initial requirements.	For interpreting physicians **not already qualified under the interim regulations,** the CME requirement has been increased from 40 hours and now must be Category I. Limit placed on when 15 hours of the CME is earned.
AND	
▶ Have read/interpreted mammograms from exams of 240 patients within the 6 months immediately prior to the physician's qualifying date or in any 6 months within the last two years of residency if the physician becomes board certified at first possible opportunity.	Limits have been placed on the time period when this requirement can be met in order to assure that the initial experience is recent when physician becomes qualified to work independently.
AND	
▶ The interpreting physician must receive at least 8 hours of training in any mammographic modality* for which he or she was not previously trained before beginning to use that modality.	New requirement that will become more significant when a mammographic modality other than screen-film becomes available.
AND	

Interpreting Physicians

MQSA Final Regulations – Effective April 28, 1999	Changes From Interim Regulations
▶ Continue to interpret or multi-read at least 960 mammographic examinations over a 24-month period. **	Previous policy of permitting multi-reading has been made a regulation.
AND	
▶ Earn at least 15 Category I CME in a 36-month period, at least 6 of which must be related to each mammographic modality used. ***	CME must now be Category I. At least 6 of the 15 CME credits must be related to each modality used.
ALSO	
Requalification requirements have been added that must be met by physicians who fail to meet the continuing education and/or continuing experience requirement.	The regulations now incorporate the former continuing education and continuing experience requalification policies. Completion of requalification permits the physician to resume independently interpreting mammograms after failing to meet the continuing education and/or continuing experience requirement.

* **Mammographic modality** – This means a technology for radiology of the breast, e.g. screen-film or xeromammography. Digital mammography will be considered a mammographic modality when it becomes commercially available, but ultrasound and MRI imaging of the breast are not mammographic modalities because they are not radiography of the breast.

** **Continuing education** – The interpreting physician must begin to meet this requirement on the date when he or she met his/her initial requirements or on October 1, 1994, whichever is later. This beginning date is unaffected by whether the physician immediately begins interpreting mammograms after meeting the initial requirements or delays doing so for any reason such as fellowships, other assignments, illness, and so forth. The physician will be allowed at least 36 months to earn his or her first 15 CEUs. After that time, the 36 months will be a floating time period counted back from, at the facility's choice, (1) the date of the inspection, (2) the date of the last day of the previous calendar quarter, or (3) any date in between. The floating time period thus selected will be used whether or not the physician interprets mammograms during the entire 36-month period.

*** **Continuing experience** – The interpreting physician must begin to meet this requirement on the date when he or she met his/her initial requirements or on October 1, 1994, whichever is later. This beginning date is unaffected by whether the physician immediately begins interpreting mammograms after meeting the initial requirements or delays doing so for any reason such as fellowships, other assignments, illness, and so forth. The physician will be allowed at least 24 months to perform his or her first 960 interpretations. After that time, the 24 months will be a floating time period counted back from, at the facility's choice, (1) the date of the inspection, (2) the date of the last day of the previous calendar quarter, 3) or any date in between. The floating time period thus selected will be used whether or not the physician interprets mammograms during the entire 24-month period.

RADIOLOGIC TECHNOLOGISTS

Personnel Requirements Under the Final Regulations

Final Regulations - Effective April 28, 1999	Changes From Interim Regulations
▶ Be licensed to perform general radiographic procedures in a State; **OR** have general certification from an FDA approved body (ARRT, ARCRT).	No changes.
AND	
▶ Technologists **not already qualified under the interim regulations** must meet the mammography-specific training requirements by having at least 40 hours of documented training in mammography, including: 1) training in breast anatomy & physiology, positioning & compression, QA/QC techniques, imaging of patients with breast implants, **AND** 2) performance of a minimum of 25 mammography examinations under direct supervision of an appropriate MQSA-qualified individual, **AND**	Specific number of hours and specific training including the performance of examinations now required.
3) at least 8 hours of training in using any mammographic modality* before beginning to use that modality independently.	New requirement that will become more significant when a mammographic modality other than screen-film becomes available.
AND	
▶ **Continuing education**** – Earn at least 15 CEUs in a 36-month period that must include at least 6 CEUs in each mammographic modality* used.	At least 6 of the 15 CEUs must be related to each mammographic modality used.
AND	
▶ **Continuing experience***** – Technologists must perform at least 200 mammography examinations in a 24-month period.	Continuing experience is now required.
ALSO	

Radiologic Technologists

Final Regulations - Effective April 28, 1999	Changes From Interim Regulations
Requalification requirements have been added that must be met by technologists who fail to meet the continuing education and/or continuing experience requirement.	The regulations now incorporate the former continuing education requalification policy and add a new continuing experience requalification process. Completion of requalification permits the technologist to resume independently performing mammograms after failing to meet the continuing education and/or continuing experience requirement.

* **Mammographic modality** – This means a technology for radiography of the breast, e.g., screen-film or xeromammography. Digital mammography will be considered a mammographic modality when it becomes commercially available, but ultrasound and MRI imaging of the breast are not mammographic modalities because they are not radiography of the breast.

** **Continuing education** – The radiologic technologist must begin to meet this requirement on the date when he or she met his/her initial requirements or on October 1, 1994, whichever is later. This beginning date is unaffected by whether the technologist immediately begins performing mammography examinations after meeting the initial requirements or delays doing so for any reason such as other assignments, illness, and so forth. The technologist will be allowed at least 36 months to earn his or her first 15 CEUs. After that time, the 36 months will be a floating time period counted back from, at the facility's choice, (1) the date of the inspection, (2) the date of the last day of the previous calendar quarter, or (3) any date in between. The floating time period thus selected will be used whether or not the technologist performs mammography examinations during the entire 36-month period.

*** **Continuing experience** – The radiologic technologist must begin to meet this requirement on the date when he or she met his/her initial requirements or on April 28, 1999, whichever is later. This beginning date is unaffected by whether the technologist immediately begins performing mammography after meeting the initial requirements or delays doing so for any reason such as other assignments, illness, and so forth. The technologist will be allowed at least 24 months to perform his or her first 200 mammography examinations. After that time, the 24 months will be a floating time period counted back from, at the facility's choice, (1) the date of the inspection, (2) the date of the last day of the previous calendar quarter, or (3) any date in between. The floating time period thus selected will be used whether or not the technologist performs mammography examinations during the entire 24-month period.

MEDICAL PHYSICISTS

Personnel Requirements Under the Final Regulations

MQSA Final Regulations – Effective April 28, 1999	Changes From Interim Regulations
▶ EITHER be licensed or approved by a State, **OR** be certified in a specialty and by a body approved by FDA (ABR, ABMP).	No change.
AND	
▶ EITHER have a master's degree or higher in a physical science, 20 semester hours of physics, 20 contact hours of training in mammography surveys, and experience in conducting mammography surveys of at least 10 units and at least 1 facility, **OR** by April 28, 1999, have qualified as a medical physicist under the interim regulations, have a bachelor's degree or higher in a physical science, 10 semester hours of physics, 40 contact hours of training in survey of mammography facilities, and experience in conducting mammography surveys of at least 20 units and at least 1 facility.	New requirement designed to ensure that all physicists meet minimum initial training and experience levels. The bachelor's degree route is available only to those who met the interim requirements before April 28, 1999 and had on that date maintained all of their qualifications.
AND	
▶ Before surveying units of any mammographic modality,* must have at least 8 hours of training with that modality.	New requirement that will become more significant when a mammographic modality other than screen-film becomes available.
AND	
▶ Earn at least 15 CME/CEUs in a 36-month period, at least 6 of which must be related to each mammographic modality for which physics services are provided. **	At least 6 of the 15 CME/CEUs must be related to each mammography modality for which the physicist provides services.
AND	

Medical Physicists

MQSA Final Regulations – Effective April 28, 1999	Changes From Interim Regulations
▶ Survey at least 2 mammography facilities and a total of at least 6 mammography units within a 24-month period. **ALSO**	New requirement – The 2 facility surveys can be 2 surveys of the same facility as long as they are at least 10 months apart. Similarly, more than 1 survey of the same unit can be counted as long as they are at least 2 months apart.
Requalification requirements have been established for physicists who fail to meet the continuing education and/or continuing experience requirement.	The regulations now incorporate the former continuing education requalification policy and add a new continuing experience requalification process. Completion of requalification permits the physicist to resume independently providing physics services after failing to meet the continuing education and/or continuing experience requirement.

* **Mammographic modality** – This means a technology for radiography of the breast, e.g., screen-film or xeromammography. Digital mammography will be considered a mammographic modality when it becomes commercially available, but ultrasound and MRI imaging of the breast are not mammographic modalities because they are not radiography of the breast.

** **Continuing education** – The medical physicist must begin to meet this requirement on the date when he or she met his/her initial requirements or on October 1, 1994, whichever is later. This beginning date is unaffected by whether the physicist immediately begins providing physics services to mammography facilities after meeting the initial requirements or delays doing so for any reason such as fellowships, other assignments, illness, and so forth. The physicist will be allowed at least 36 months to earn his or her first 15 CEUs, after that time, the 36 months will be a floating time period counted back from, at the facility's choice, (1) the date of the inspection, (2) the date of the last day of the previous calendar quarter, or (3) any date in between. The floating time period thus selected will be used whether or not the physicist provides physics services to mammography facilities during the entire 36-month period.

*** **Continuing experience** – The medical physicist must begin to meet this requirement on the date when he or she met his/her initial requirements or on April 28, 1999, whichever is later. This beginning date is unaffected by whether the physicist immediately begins providing physics services to mammography facilities after meeting the initial requirements or delays doing so for any reason such as fellowships, other assignments, illness, and so forth. The physicist will be allowed at least 24 months to perform his or her first 2 facility surveys and 6 unit surveys. After that time, the 24 months will be a floating time period counted back from, at the facility's choice, (1) the date of the inspection, (2) the date of the last day of the previous calendar quarter, (3) any date in between. The floating time period thus selected will be used whether or not the physicist provides physics services to mammography facilities during the entire 24-month period.

Physician to Physician by Miguel R. Kamat, M.D., M.P .H.

Sign Up Now for Stereotactic Accreditation

Few facilities currently participate in voluntary stereotactic accreditation programs

Facilities performing stereotactic breast procedures should participate in voluntary stereotactic accreditation programs. Under the Mammography Quality Standards Act, FDA has authority to regulate interventional mammography but currently has exempted these procedures from the requirements of both the interim and final regulations.

The National Mammography Quality Assurance Advisory Committee (NMQAAC) recommended that FDA continue with the exemption, but only if stereotactic facilities participate in currently available voluntary accreditation programs, such as those administered by the American College of Radiology (ACR) and the American College of Surgeons (ACS).

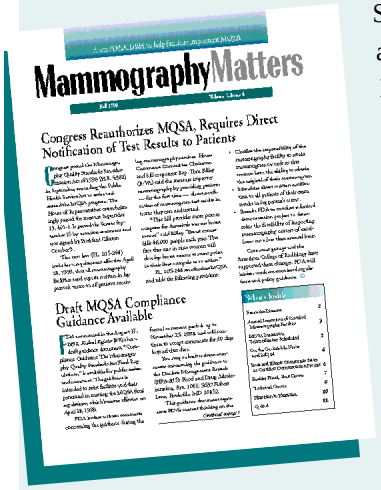
Miguel R. Kamat, M.D., M.P.H., Radiologist/Mammographer, Division of Mammography Quality and Radiation Programs

Of the 2,900 stereotactic breast biopsy units in the United States, only 13 percent are enrolled in either the ACR or ACS programs.

To ensure that public health is not compromised, FDA urges all facilities to become accredited. Participation in voluntary accreditation programs helps assure patients that they are receiving quality care. Full participation may obviate the need for a Federal regulatory program.

So, if you haven't already done so, now is a good time to sign up.

NOTICE


Mammography Matters

Congress Reauthorizes MQSA, Requires Direct Notification of Test Results to Patients

Draft MQSA Compliance Guidance Available

Starting with the Fall 1999 issue of Mammography Matters, FDA will stop printing and mailing copies of the newsletter. FDA will publish only an electronic version of Mammography Matters on the Internet. To receive e-mail alerts and highlights of new issues when they are available on the Internet, simply fill out the information below and send it to MQSA c/o SciComm, P.O. Box 30224, Bethesda, MD 20824-9998. Fax: 301-986-8015.

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Q & A

Q & A is a regular column in Mammography Matters. We welcome your questions and will publish answers to any that are of general interest. Send your questions to Mammography Matters, FDA/CDRH (HFZ- 240), 1350 Piccard Drive, Rockville, MD 20850, Fax 301-594-3306.

The questions presented here are taken from the compliance guidance released for public comment in August 1998. The answers to these questions are taken directly from the regulations and so are final, unlike some of the other guidance, which may be modified after the public comment period.

Q Regarding quality assurance, what are the responsibilities of the lead interpreting physician?

A In general, the lead interpreting physician must ensure that the quality assurance program meets the required standards. This includes personnel assignments, all equipment quality control tests, records, and corrective actions, the annual physicist's survey, and medical audit and outcomes analysis. He or she must ensure that individuals assigned to quality assurance tasks are qualified to perform these tasks and that their performance is adequate.

Regarding medical outcome audits, he or she must either review and discuss the audit results with other interpreting physicians or assign this task to another interpreting physician (the reviewing interpreting physician). For facilities with only one interpreting physician, the responsibility for medical outcome audits rests solely with that individual.

Q What quality assurance (QA) records must be maintained? Where and for how long?

A The facility must maintain quality assurance (QA) records that show:

- Personnel responsibilities — qualified mammography personnel assigned to appropriate QA tasks.
- Technique charts/tables — the mammography techniques and procedures used in conducting mammograms.
- Quality control (QC) test records — QC test procedures, test performance and monitoring, data analysis, and timely corrective action for each.
- Procedures for safety and protection of patients and personnel.

These records must be maintained until the next annual inspection that would verify compliance or until an individual test has been performed two additional times at the required frequency, whichever is longer.

This requirement means that records for semi-annual tests may, and records for annual tests will, have to be kept longer than the period between two successive annual inspections.

"Verifying compliance" implies that, if QC records for a given test are found to be deficient and the facility is cited during an annual inspection, these records must be kept until the facility corrects the problem to FDA's satisfaction.

Inspections Under the Final Regulations

Continued from page 1

single x-ray machine will continue to be about six hours. It takes the inspector approximately one hour to test each mammography x-ray unit and darkroom/film processor combination. The remainder of the time is spent reviewing facility records. As such, it's best to schedule a block of time for the testing of equipment to minimize any inconvenience to patient care.

"Since FDA began MQSA inspections and an associated quality assurance program in early 1995, there have been high rates of satisfaction with the process," says DMQRP Director John McCrohan. "I'm confident that the changeover to inspections under the final rule will go smoothly and that we will continue to work in partnership with the facilities to ensure all patients receive the high-quality mammography they deserve."

Name and Address Changes

Each facility must notify its Accreditation Body of any changes in its mailing information, such as new contact person, change of address (including new usage of a P.O. Box), or change of facility name. If your mailing label code includes ACR, SAR, SCA, or SIA, then this is your address as it appears in the official address files and you must inform your Accreditation Body of any changes.

All other subscribers should submit any address changes or cancellation notices to: MQSA, c/o SciComm, Inc., P.O. Box 30224, Bethesda, MD 20824-9998. Fax 301-986-8015.

Accreditation, Certification, and Commercial Products

FDA neither endorses nor requires the use of any specific x-ray system component, measuring device, software package, or other commercial product as a condition for accreditation or certification under MQSA.

Any representations, either orally or in sales literature, or in any other form, that purchase of a particular product is required in order to be accredited or certified under MQSA should be reported to FDA immediately so that appropriate action may be taken.

Mammography Matters is a publication of the Food and Drug Administration, Center for Devices and Radiological Health

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