From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Spring 1998 Volume 5, Issue 2

Final MQSA Rule, Part 2

When the final Mammography Quality Standards Act (MQSA) rule takes effect April 28, 1999, it will reinforce previous efforts to ensure that all women nationwide receive quality mammography services.

By now, facilities should have received a copy of the final rule as published October 28, 1997, in the *Federal Register*, along with an overview guidebook. These materials are also available on the Internet (http://www.fda.gov/cdrh/dmqrp.html).

Facilities should note that a significant part of the *Federal Register* document is a preamble that covers public comments on the proposed regulations and FDA responses to them. This background information provides clarification and context for the final rule as it appears in the final 20 pages or so of the document.

FDA continues to use a variety of outreach vehicles to inform facilities and the interested public about changes resulting from the final rule. The previous issue of *Mammography Matters* addressed the final rule's personnel requirements for interpreting physicians, radiologic technologists, and medical physicists. It also covered, in general, some of the new equipment standards.

This issue covers reporting and recordkeeping, quality assurance, and alternative standards.

Reporting and Recordkeeping

The regulations require facilities to prepare written reports of mammography examinations, to have a system to communicate exam results to the patient, and to maintain mammography films for a specific period of time or transfer them to the patient upon request.

In addition to documenting key identification information, each mammography report must include an overall assessment of findings, classified in one of the following categories:

1. Negative — nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).
2. Benign — also a negative assessment.

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Get MQSA Information at Upcoming Conferences

Facilities or interested parties with questions about MQSA final regulations or other issues take note: FDA staff members regularly give presentations about MQSA activities at various meetings each year.

Most of these meetings also have courses offering continuing education credits. Contact the sponsoring organizations directly for more information regarding registration and topics. In the meantime, plan to look for FDA staff and/or the MQSA exhibit at the following conferences:

- May 17-20; 39th Annual Conference of Radiation Control Program Directors, Mesa, AZ; 502-227-4543.
- September 10-12; 18th Annual Breast Imaging Conference, Orlando, FL; 800-456-6781.
- November 28-December 4; Radiological Society of North America, Chicago, IL; 630-571-2670.

What's Inside

MammographyMatters
Spring 1998

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:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

Fax 301-594-3306

Back issues of *Mammography Matters* may be viewed on the Internet at www.fda.gov/cdrh/dmqrp.html

John McCrohan, M.S., Acting Director, DMQRP, CDRH

Carole Sierka, Editor; Chief, Outreach Staff, DMQRP, CDRH

David Heffernan, Managing Editor

Pam Chissler, Production Manager

Other contributors: Anne Bowen, Roger Burkhart, Miguel Kamar

Facility Hotline

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

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3. Probably benign — finding has a high probability of being benign.
4. Suspicious — finding without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.
5. Highly suggestive of malignancy — finding has a high probability of being malignant.

In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician.

Communicating results

A major addition from the interim rule is the provision of more specific requirements involving reports of examination results to patients. FDA believes that high-quality mammography extends from the production of high-quality mammographic images to the communication of results to the patient.

The final rule requires that each facility have a system to ensure that the results of each mammographic examination are communicated in a timely manner to *all* patients, whether or not they have a referring physician.

The final rule codified this essential reporting requirement as a performance outcome standard. Thus, the focus is placed on the desired performance outcome — the notification of the patient in a timely manner — and not on the method or specific conduit of the notification.

This system must assure that patients receive their exam results through the facility's own efforts or in cooperation with third parties (i.e., referring or named physicians, communication consultants, or other parties). A variety of methods may be used, including: written, verbal, telephone, or other cooperative arrangements.

When a facility uses a third party to communicate results (either written or verbally), a documented agreement between the facility and the third party that establishes this cooperative responsibility is highly recommended. This documentation may take the form of an attestation by the third party or letters of agreement, which inspectors will ask to review. Even if a third party is involved, the primary responsibility for ensuring that the system for communication of results is effective belongs to the facility.

FDA believes that written notification of results helps ensure that women are clearly and effectively notified of results of their mammograms. FDA endorses the "best practices" outlined in a series of recommendations published by the Agency for Health Care Policy and Research in Chapter 4 of its clinical practice guideline entitled, *"Quality Determinants of Mammography."* Please refer to page 55975 of the final regulations for excerpts of this publication.

System for self-referred patients

Facilities that accept patients who do not have a referring health care provider must maintain a system for referring such patients to a health

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care provider when clinically indicated. This system would involve establishing arrangements with health care providers that would accept these self-referred patients who require further clinical attention.

Identifying images

Facilities must ensure that each mammographic image has permanent and legible identifications on it that do not obscure anatomic structures in the image. The identification must include the name of the patient and additional patient identifiers, date of examination, view and laterality, facility name and location, technologist's identification, cassette/screen identification, and mammography unit identification (if there's more than one unit at the facility). Stick-on labels are acceptable.

Maintaining and transferring mammograms

Facilities must maintain mammography films and reports for at least five years. If no later mammograms of the patient are performed at the facility, then the facility must retain them for 10 years or for a longer period of time as required by State law.

The only exception to these rules is that upon written request by or on behalf of the patient, facilities must permanently or temporarily transfer original mammograms and copies of the patient's reports to a medical institution, the patient's health care provider, or the patient directly.

With the help of the National Mammography Quality Assurance Advisory Committee, FDA decided that the quality of copies of mammograms is not consistently good enough to permit their transfer in place of the originals. FDA believes each facility should be free to establish its own procedures for transfer of films. A facility that decides to charge a fee for this transfer must not charge more than the documented costs of the service.

Quality Assurance

The quality assurance (QA) sections in the final rule define staff responsibilities and related recordkeeping requirements for facilities' QA programs. The final rule also establishes equipment quality control requirements and outlines requirements for a facility's medical outcomes audit.

Staff responsibilities and recordkeeping requirements

The goals of the QA requirements are to ensure that equipment and personnel continue to perform at adequate levels. The interim requirements are familiar to facilities. The final rule describes staff responsibilities and recordkeeping requirements

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FDA Prepares for States as Certifiers Demonstration Project

FDA is proceeding with plans to implement its demonstration project on State certification of mammography facilities, as authorized under subsection (q) of the Mammography Quality Standards Act (MQSA) of 1992.

In November 1997, FDA sent all State Radiation Control Program Directors a notification and applications to participate in the project. The deadline for submitting applications was February 16, 1998. As of this writing, FDA is actively reviewing State applications. The demonstration project is expected to get underway starting July 1, 1998.

A States as Certifiers (SAC) Working Group was established in June 1996 to provide input into the development of the regulations and subsequently, the demonstration project, under the SAC program. The group includes representatives from States in each FDA region, FDA Regional Radiological Health Representatives, and the American College of Radiology.

To participate in the demonstration project, a State must have enacted laws and issued regulations that meet MQSA standards, have the legal authority and qualified personnel necessary to enforce the requirements of these regulations, devote adequate funds to the administration and enforcement of such requirements, and provide the Secretary of Health and Human Services with such information and reports as the Secretary may require.

Future issues of *Mammography Matters* will provide more information about the SAC program upon initiation of the demonstration project.

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that were not explicitly stated in the interim rule but were incorporated by referencing the American College of Radiology (ACR) manual.

The final rule adds a requirement that facilities identify a lead interpreting physician to be responsible for oversight of the QA program. This person may delegate responsibility for the QA tasks to another individual whose qualifications for and performance of the assignment are adequate.

All interpreting physicians are required to participate in the facility's medical outcomes audit program and to provide a feedback mechanism for the QA program. All personnel, including radiologic technologists and medical physicists, are responsible for ensuring that all necessary QA records are properly maintained.

Tasks associated with facility QA include ensuring that records are maintained on the following: employee qualifications to meet assigned quality assurance tasks; mammography techniques and procedures; quality control, including monitoring data, problems detected by analysis of the data, corrective actions, and effectiveness of the corrective actions; and safety and protection.

The final rule also specifies that quality control records must be maintained by the facility *either* until the next annual inspection has been completed and FDA has determined the facility is in compliance *or* until the quality control test has been performed and documented two additional times, whichever is longer.

Equipment tests

The final equipment quality control requirements represent a transition towards performance outcome standards. Facilities must test the performance parameters of their equipment at appropriate frequencies; must analyze test results promptly to determine if equipment performance is satisfactory; and, within specified time limits, must correct any identified problems.

In contrast to the interim rule, the final rule only specifies which tests are to be performed, their minimum frequency, a few requirements for test conditions, and the action limits for the test results. This leaves facility staff the freedom to choose test procedures that best fit their needs. Several of these specifications will not take effect until October 28, 2002, including the semiannual compression force test and more rigorous action limits for the annual tests of automatic exposure control performance and of radiation output.

Also, until October 28, 2002, the facilities can evaluate focal spot condition either by assessing system resolution or by measuring focal spot dimen-

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Facilities Advised To Delay Collimation Changes Until Further Word

FDA advises facilities to wait for further notice before changing their equipment's collimation based on the final MQSA regulations. The MQSA regulations are in conflict with the Electronic Product Radiation Control (EPRC) performance standards that mammography equipment manufacturers must meet under a 1968 law.

The conflict relates to x-ray field and image receptor alignment and must be resolved before it will be clear what action, if any, facilities will need to take.

FDA expects to resolve this issue before the April 28, 1999 effective date of the final MQSA regulations.

The EPRC standard requires that mammography units be manufactured with collimation to ensure that the x-ray field does not extend **beyond** the non-chest wall edges of the image receptor. In contrast, the MQSA final regulations, which go into effect April 28, 1999, state that the beam limiting devices must allow the x-ray beam to extend **to or beyond** those edges of the image receptor.

It is possible for manufacturers to meet both standards, if their units allow the beam to extend to the edges of the receptor. To meet the EPRC standards, however, some manufacturers have designed their units so that the x-ray field does not reach the image receptor edges, thus making it impossible to meet the MQSA regulations.

For further guidance, facilities are encouraged to refer to future issues of *Mammography Matters* and other relevant documents FDA will be issuing before the 1999 effective date.

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sion. However, after October 28, 2002, the facilities must assess system resolution to satisfy the MQSA requirement.

Facilities with screen-film systems must perform and evaluate a processor performance test on each day examinations are conducted before any clinical films are processed that day.

The most significant change regarding equipment quality assurance is the requirement that facilities perform a weekly phantom image test, rather than monthly as required under the interim rule.

The final rule requires facilities to perform two quarterly quality control tests; a test of fixer retention in film to check for insufficient washing and a repeat analysis to check repeat or reject rates against the previous quarter. Another significant change is that action limits for the repeat analysis test are now expressed in terms of change in the repeat rate from one test to the next instead of an absolute limit on retake rate.

Semiannual quality control tests include tests of darkroom fog, screen-film contact, and compression. A third significant change is that the final regulations do not specify an action limit for the screen-film contact test, due to a lack of consensus on the limit to be used. Facilities, therefore, have some flexibility in the limits they establish.

Facilities with screen-film systems must perform a number of tests annually, including: automatic exposure control test, kilovoltage peak accuracy and reproducibility, focal spot condition, beam quality or half-value layer, breast entrance air kerma and AEC reproducibility, dosimetry, x-ray field/light field/image receptor/compression paddle alignment, uniformity of screen speed, system artifacts, radiation output, and decompression.

The final regulations still require operators of non-screen-film equipment to follow manufacturer's quality assurance instructions in their program. This applies at present only to the few remaining operators of xeromammography units. If a new modality, such as digital mammography, becomes available, operators of such equipment will be required to follow the manufacturer's recommended quality assurance programs, at least initially. But, if the modality comes into widespread use, FDA expects to eventually amend the regulations to include specific quality assurance requirements for it.

Mobile units

Another change for equipment quality assurance is a requirement that acceptable mobile unit performance be verified after each relocation before examinations are performed. This change is in response to reports from mobile operators that moving their unit sometimes causes problems. No individual test is specified by this requirement, but the test used must verify that image quality remains adequate.

One example of an acceptable test method is the traditional procedure of verifying the adequacy of image quality by producing and evaluating a phantom image after each move and before patients are examined. Another example would be a test method based on demonstrating that variation in mAs value was within acceptable limits after each move and before any patient is examined. In this case, a phantom image should be developed with *each day's* clinical films and evaluated at the earliest possible date to confirm that the mAs method provides adequate assurance of acceptable image quality. Other methods may also be acceptable.

Surveys

A facility survey must be performed by a medical physicist at least once a year. This survey will cover the performance of the annual tests described previously and the weekly phantom image quality test. The physicist will evaluate results of all required tests conducted by the facility, as well as documentation of corrective actions taken.

Within 30 days of the survey, the medical physicist must send the survey report to the facility and include all appropriate documentation and background information.

Calibration of air kerma (exposure) measuring instruments

Instruments used by medical physicists in their annual surveys to measure the air kerma or the air kerma rate from a mammography unit must be calibrated at least once every two years and each time the instrument is repaired. The calibration method must be traceable to a national standard and the instrument must be calibrated with an accuracy of ± 6 percent (95 percent confidence level) in the mammography energy range.

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Infection control

Facilities must establish and comply with a system specifying procedures to follow in cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. Facilities must comply with existing Federal, State, and local infection control rules, as well as comply with manufacturer's recommendations for cleaning and disinfection.

Facilities must maintain documentation to show that infection control procedures are being followed.

Medical outcomes audit

To monitor the accuracy of mammography performed, each facility is required to establish and maintain a mammography medical outcomes audit program. This follow-up system *is required* for all positive mammograms. The regulations stipulate that the program be designed to ensure reliability, clarity, and accuracy of the interpretation of mammograms.

The primary changes reflected in the final rule are that the reviewing interpreting physician be assigned the responsibility of assuring that data are collected and analyzed on a regular basis, and that follow-up is conducted for all cases with positive mammographic outcomes. In addition, follow-up to collect pathology reports and similar data is required if a facility subsequently finds out that a patient has been diagnosed with breast cancer following a non-positive mammogram at that facility.

Each facility must analyze outcome data both for the aggregate facility database of mammograms and for mammograms interpreted by each physician at least once a year. The reviewing interpreting physician must review the audit data every 12 months and communicate results of the analysis to all physicians at the facility; identify issues based on the results; and record follow-up actions, if any are taken.

Alternative Standards

The final rule, as did the interim regulations, allows for alternative approaches to the regulatory requirements, if the facility can demonstrate that alternatives can provide equal or better quality mammography.

A significant change from the interim regulations is that Federal agencies are now allowed (along with State agencies that are not accreditation bodies) to apply for alternatives to the personnel requirements. As under the interim regulations, mammography facilities and accreditation bodies can apply for alternatives to all requirements discussed in this and the preceding issue of *Mammography Matters*. Similarly, manufacturers can still apply for alternatives to equipment and equipment quality assurance requirements.

Information provided in support of such application is the same in the final regulations as previously outlined in the interim regulations. The most significant change from the interim to the final regulations is that once FDA approves a request for an alternative standard, it now has the option of expanding that approval to cover all affected entities instead of requiring that each entity make its own application for approval.

Guidance Is Coming

In response to many questions about the final regulations, FDA is developing guidance, a process that includes a 90-day period for public comment after guidance is proposed in the *Federal Register*. An example of one commonly asked question concerns the kinds of documentation acceptable to FDA to show that a facility is communicating exam results to patients.

A notice is planned to appear in the *Federal Register* in July 1998, which will also be accessible on the Internet through the FDA web site, when proposed guidance on a number of questions will be available for public review and comment. Although this process requires more time before questions can be answered, FDA believes developing improved guidance makes it worthwhile.

FDA encourages individuals and facilities to continue asking questions on the final regulations, whether simple points of clarification or ones involving guidance. Facilities may use the telephone hotline (1-800-838-7715) for this purpose. If guidance must be developed first, we ask for your patience in receiving an answer.

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.*

Q I just received a copy of the MQSA final regulations and am overwhelmed by the size of the document. Can you provide any guidance on the best way to approach it?

A First review the "Small Entity Compliance Guide," which summarizes and highlights the final regs. The final regulations themselves can be found in the final pages of the *Federal Register* notice, beginning on page 55976. The first 95% of this notice consists of the preamble to the regulations in which FDA addresses comments received in response to the proposed final regulations. It also provides explanations and guidance for understanding the regulations.

Q The facility that performed my mammography exam last year is refusing to transfer the *original* films to the facility I am now using. My new facility tells me that my old facility is required by law to permanently transfer the original films upon my request. How can I get these films?

A Your new facility is correct. Under both the interim and the final regulations, a patient can request a facility to permanently transfer their records to another facility, a medical institution, a physician, or herself. A facility that refuses to transfer original films at the request of the examinee is in violation of MQSA regulations. If your old facility continues to refuse to transfer your films and reports, you should contact the facility's accreditation body, which is noted on their posted certificate, or call FDA's Facility Hotline at 1-800-838-7715 for guidance.

Q What is the requirement for technologist training in imaging patients with breast implants?

A From the many comments FDA received on its proposals for training in imaging patients with breast implants, it was clear that there was no consensus on the appropriate amount or type of such training. As a result, in the final regulations, FDA only listed this topic as among those that must be covered in the initial technologist training, without specifying the amount or type. This requirement applies to all technologists who meet their initial qualifications after April 28, 1999, whether they do imaging of patients with breast implants or not. Technologists who meet their initial qualifications before April 28, 1999, are grandparented as meeting this requirement.

Q Through reference to the ACR manuals, the interim regulations required the use of specific procedures for dark room, screen, and view box cleanliness, but I don't see this requirement in the final regulations. Am I missing something?

A No. Specific requirements for the frequency or method of cleaning were not included in the final regulations, but facilities will be required to have protocols for such cleaning, as well as documentation that the protocols were followed. This switch is in accordance with FDA's effort to focus attention on desired outcomes (in this case, adequate cleaning of these components of the mammography system) rather than the specific methods. For most of the QA/QC procedures, the ACR manual can still be used as the facility's protocol.

Name and Address Changes:

If your **mailing label code includes** either: **ACR, SAR, SCA,** or **SIA,** notify your **accreditation body** of any name and/or address changes.

Otherwise submit your address changes 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration (HFZ-240)
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

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