From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Spring 1999 Volume 6, Issue 2

Guidance in Communicating Results

Facilities must provide a written summary of the results of the mammographic examination (both screening *and* diagnostic) in lay terms to *all patients* within 30 days, including patients who have no referring health care provider.

- If the final assessment in the mammography report is "Suspicious" or "Highly suggestive of malignancy," the lay summary and recommended course of action must be communicated to the patient as soon as possible, preferably within 5 days of the examination. One way to achieve this is through direct verbal communication with the patient. However, such verbal communication must be followed up with a written lay summary. Congress' intent was for patients to receive a permanent record of their results. Consequently, any verbal communication must be supplemented with written communication.
- Use of the U.S. mail services is one acceptable method of delivering the report. Confirmation of the receipt of these results is not required. It is also acceptable to hand the written communication to the patient at the time of the examination.
- Each facility should set up its own effective communication system that works within the framework of its operation. A system that works well for one facility and its patients may not work well for another.
- Some examples of lay language letters can be found in Chapter 4 of the "Quality Determinants of Mammography" (see accompanying article) and on FDA's website.

MQSRA Requires Written Reports to All Patients

With the MQSA Reauthorization Act of 1998, facilities are now required to provide a written lay-language summary of mammography results to all examinees. FDA has developed and published guidance on its web page (www.fda.gov/cdrh/dmqrp.html, select "Guidance For Industry and Compliance"), addressing the questions that have been received regarding this requirement.

Also on the web page are copies of seven examples of lay-language letters taken from Chapter 4 of the "Quality Determinants of Mammography" that facilities may use as models in developing their own letters. These letters should be viewed only as examples, and facilities should tailor them to meet the specific cultural needs of their local populations. The approach taken by these examples meets the requirement of directly communicating results to patients.

The "Quality Determinants of Mammography" is one of three guidelines addressing quality mammography published by the Agency for Health Care Policy and Research (AHCPR) in October 1994. Each of these guidelines is directed to a different audience: 1) "Quality

Continued on page 6

What's Inside

From the Director . . .

I'm happy to report that the quality of mammography services in the United States keeps improving because of the professional dedication and commitment to MQSA standards demonstrated at facilities across the nation.

We've seen improvements in the technical indicators of mammography quality. The "Technical Corner" column (see page 4) summarizes comparative data in areas such as radiation dose, phantom image scores, film processing, and darkroom fog level that point to measurable quality improvements in recent years.

Since the passage of MQSA in 1992, and its subsequent reauthorization last fall, FDA has worked in partnership with facilities, manufacturers, consumers, and State inspectors to develop and implement regulations designed to improve the odds that life-threatening breast cancers can be detected early and treated.

As most of you know, April 28, 1999, marked the day that MQSA final regulations took effect. Compliance with the regulations helps ensure that patients receive the best possible mammography services, regardless of which facility they've chosen. To meet that objective, we've worked very hard to provide facilities with appropriate regulatory guidance.

This February, FDA produced a successful MQSA Satellite Teleconference that provided an interactive platform for more than 2,200 viewers, mostly facility personnel, who tuned in to get answers to their questions about regulatory requirements. If you were unable to view this program, you may order a video copy from the National Technical Information Service (see page 6 for ordering information). Compliance guidance documents with additional answers to questions we've received are available for review and downloading from our website (see www.fda.gov/cdrh/dmqrp.html).

MQSA Policy Help System

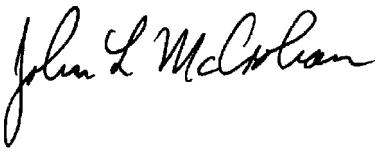
All the MQSA regulatory guidance material and other informational documents are being compiled into our MQSA Policy Help System. When it's complete, the system will provide an online resource that users can access via our website on the Internet.

The system will allow you to search for answers to specific policy questions through an indexed list of topics and key words. When you select a particular subject – accreditation and certification process, for example – you'll see the regulatory citation, approved guidance, and any other appropriate information or references.

The advantage of this system is that it puts all appropriate information on a particular subject at your fingertips. You won't have to flip through hundreds of pages of documents to quickly get the answers to your questions. We're excited to offer this service to you shortly and hope that all facilities take advantage of this opportunity to get MQSA regulatory information on the Internet.

Announcement

Texas was approved as an MQSA accreditation body beginning April 28, 1999, the effective date of the MQSA final regulations. Texas becomes the fourth state approved as an accreditation body, joining Iowa, Arkansas, and California.



John L. McCrohan, M.S.
Director, Division of Mammography Quality and Radiation Programs

MammographyMatters
Spring 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:

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 L. McCrohan, M.S., Director, DMQRP, CDRH

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

David Heffernan, Managing Editor

Evelyn Wandell, Production Manager

Robin Foster, Designer

Other contributors: Cathy Akey, Anne Bowen, Roger Burkhart, Charles Finder, Orhan Suleiman

Facility Hotline

Call the facility telephone hotline **(1-800-838-7715)** or fax **(410-290-6351)** for more information about FDA certification or inspections.

Clarifications

Please note the following clarifications on the "Personnel Requirements Under the Final Regulations" charts from the Winter 1999 issue of *Mammography Matters:*

Interpreting Physicians, page 9

- The first bullet item should conclude with three asterisks and refer to the continuing experience requirement footnote.
- The second bullet item should conclude with two asterisks and refer to the continuing education requirement footnote.

Radiologic Technologists, page 10, second bullet item #3, add the following text to the second column titled, "Changes From Interim Regulations":

- All RTs, regardless of whether or not they qualified under the interim regulations, need at least 8 hours of training in using any mammographic modality before beginning to use that modality independently.

Medical Physicists, page 12

- In the last bullet item regarding the continuing education requirement, please replace the words "at least 6" with the word "some."

Medical Physicists, page 13

- The first bullet item should conclude with three asterisks and refer to the continuing experience requirement footnote.

Name and Address Changes

Each facility **must** notify its **Accreditation Body** of any changes or corrections 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, SIA,** or **STX,** then this is your address as it appears in the official address files and you **must inform your Accreditation Body of any changes.**

Notice

The Facility Hotline will no longer take questions on 90-day extensions and applications for interim notices. Direct these questions to your accreditation body or check the "Quick Tips" on the MQSA website.

Technical Trends Demonstrate Improved Mammography Quality in the United States

This column highlights some of the findings in "Mammography in the 1990s: The United States and Canada," an article by Suleiman, Spelic, Houn, McCrohan, and Symonds appearing in the February 1999 issue of Radiology.

The article we published in the February 1999 issue of *Radiology* analyzes data from surveys of diagnostic x-ray facilities, including mammography facilities prior to the enactment of the Mammography Quality Standards Act (MQSA) of 1992, and compares these facilities with mammography facilities inspected under MQSA. We also had the opportunity to compare these data with a first-time-ever survey of Canadian mammography facilities. Our overall conclusion is that mammography quality in the United States is better today than it has been at any other time.

Orhan H. Suleiman, M.S., Ph.D., Chief, Radiation Programs Branch, Division of Mammography Quality and Radiation Programs

Dose and Image Quality

Figure 1 shows what has happened in mammography. It shows how radiation dose has been reduced over the years, along with the continued improvement in image quality.

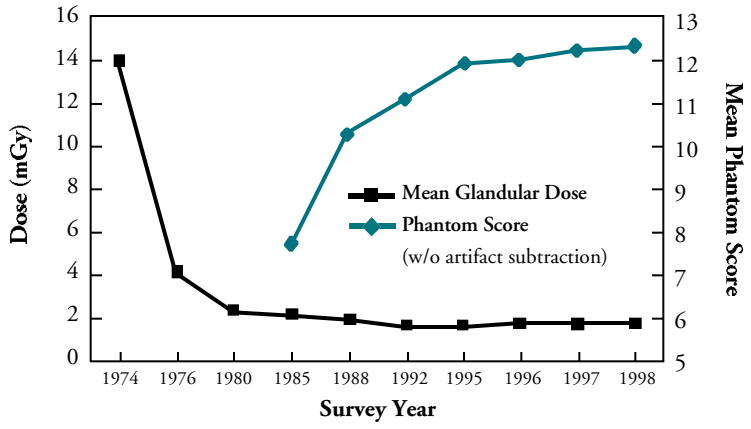
The main reason for the reduction in radiation dose was the shift away from direct film exposure, which was dominant in the early 1970s, to lower dose technologies such as xeromammography and screen-film mammography. Today, literally all mammography is conducted using screen-film. Another major reason for the dose reduction is the attention to quality film processing during these years.

Since 1985, when image quality was first assessed with a phantom that had 16 image quality test objects, we have observed continued improvement in image quality. Reasons for the improvement are the use of lower x-ray beam qualities, the use of grids, and the trend toward higher film optical densities, all of which improve contrast.

MQSA Quality Standards Are Effective

Using MQSA standards as criteria for evaluation, 6 percent of MQSA facilities had film-processing speeds of less than 80 in 1995, compared with 23 percent of Canadian mammography facilities surveyed in 1995. In 1997, under MQSA, only 1 percent of U.S. mammography

Figure 1. Dose and Phantom Score, Selected Years



Technical Corner *(continued)*

facilities failed to meet this minimum criteria. However, using the same criteria for film processing, 50 percent of dental facilities surveyed in 1993, 27 percent of facilities conducting abdominal radiography in 1995, and 16 percent of private offices conducting chest radiography in 1994, failed to meet these minimum standards.

Perhaps the simplest measure of a facility's commitment to quality may be whether or not their darkroom fog levels are low enough to safely handle x-ray film. The percentage of MQSA inspected facilities exceeding a fog level of 0.05 was 17 percent in 1995 and 16 percent in 1997, while 51 percent of the surveyed Canadian darkrooms exceeded this level of fog. In the United States, 58 percent of facilities conducting abdominal radiography in 1995, 62 percent of facilities conducting chest radiography in 1994, and 62 percent of pre-MQSA mammography facilities failed to meet this minimum standard.

In summary, mammography quality in the United States is better now than at any other time. Although there has been a slight increase in dose in recent years, the radiation dose associated with mammography is still historically very low. Other measures of facility quality such as darkroom fog levels and film processing quality also demonstrate that mammography facilities have the best quality of all diagnostic facilities surveyed.

For more details, please refer to the scientific paper.

Resident Interpreting Physician: Two Paths Meet MQSA Requirements

How does a current resident physician qualify as an interpreting physician under MQSA's final regulations? There are two paths that residents can pursue, depending on whether he/she becomes Board Certified at the first allowable time. Radiology residents graduating after April 28, 1999, must be either Board Certified in Diagnostic Radiology or have at least 3 months of documented formal training in mammography, in addition to meeting other initial requirements.

In the first case, the resident physician passes the Boards at the first allowable time. Before beginning independent mammographic interpretation, the physician must provide documents to show that he/she:

1. Is licensed to practice medicine.
2. Is Board Certified in Diagnostic Radiology.
3. Has 60 hours of Category I CME in mammography (hours of training received in residency are equivalent to Category I CME).
4. Has interpreted, under direct supervision, at least 240 mammographic examinations within a 6-month period sometime during the last 2 years of the residency program.

In the second case, the resident physician does not take, fails, or conditions the Boards at the first allowable time. Before beginning independent mammographic interpretation, the physician must provide documents showing that he/she:

1. Is licensed to practice medicine.
2. Has 3 months of documented formal training in mammography.
3. Has 60 hours of Category I CME in mammography (hours of training received in residency are equivalent to Category I CME). These 60 hours may be part of the 3 months of training and do not have to be an additional 60 hours over and above the requirement in #2 above.
4. Has interpreted, under direct supervision, at least 240 mammographic examinations within the 6-month period immediately prior to the date the physician qualifies as an interpreting physician.

Note that when a resident physician becomes Board Certified at the first allowable time, then the fourth requirement of reading 240 mammographic examinations can have taken place during any 6-month period during the last 2 years of his/her residency. Otherwise the reading under direct supervision must take place in the 6 months immediately preceding the date the physician qualifies as an interpreting physician.

Documentation showing these requirements were successfully completed by means of the training, education, and experience obtained in the residency program must come from the program itself. All resident physicians, even those not planning on performing mammography, are advised to obtain such documentation from their programs before leaving for their new positions.

Credit Available for Viewing MQSA Teleconference

FDA is accepting 3 continuing education credits for personnel who viewed the live MQSA Teleconference on February 18, 1999. In order to receive this credit, the person viewing the teleconference must get documentation from a responsible official present at the downlink site, stating that the person was indeed present for the entire teleconference.

FDA will also accept 3 continuing education credits for personnel who review a videotape of the MQSA Teleconference in a formal in-house training setting with a discussion or question-and-answer period at the end of the tape.

MQSA inspectors will ask to see a letter (or other appropriate documentation) from the facility (or viewing site) stating that the personnel who reviewed the teleconference video in a formal setting were present for the entire viewing and the discussion or question-and-answer period. When applying this policy to interpreting physicians, the viewing of the videotape must have taken place prior to April 28, 1999; after this date only category I CME is acceptable toward meeting the interpreting physician continuing education requirement.

The MQSA Teleconference provided information about what mammography facility personnel and inspectors need to prepare for MQSA inspections conducted under the final regulations after the April 28, 1999 effective date. Presentations focused on new requirements related to: 1) personnel, 2) equipment, 3) reporting of exam results to patients, and 4) the consumer complaint mechanism. Also covered was the approach to quality assurance. The material presented is useful to facilities for understanding MQSA final regulations, and will be valuable in helping to improve mammography quality.

With a viewing audience of more than 2,220 facility personnel, and numerous telephone calls and fax comments and questions, the teleconference was one of the most successful ever produced by FDA.

Copies of teleconference videotapes

Videotaped copies (2 tapes/set) of the teleconference can be purchased through the National Technical Information Service (NTIS). The cost is $135 plus $5 for shipping and handling. For NTIS ordering information, phone (703) 605-6186.

MQSRA Requires Written Reports to All Patients

Continued from page 1

Determinants of Mammography" (publication number 95-0632) contains information specifically directed to facilities; 2) "High-Quality Mammography: Information for Referring Providers" (publication number 95-0633) contains information of specific relevance to referring health care providers; and 3) "Things to Know About Quality Mammograms" (publication number 95-0634) is directed to consumers with versions available in both English and Spanish.

Copies of these documents can be obtained by calling the AHCPR clearinghouse at 1-800-358-9295. Currently, there is no charge for the "Quality Determinants of Mammography" guideline when requested by facilities. The publication is a useful reference document for helping to provide quality mammography services, *but it was written before MQSA, so some of the text is not current for the final regulations.*

You can download these documents by going to the AHCPR website (http://www.ahcpr.gov) and selecting "Clinical Information." Next, scroll down the screen and click on *"Clinical Practices Guidelines Online."* This in turn will take you to a page with four topics of interest to select from: "Clinical Practice Guidelines," "Quick Reference Guides for Clinicians," "Consumer's Guides (English)," and "Consumer's Guides (Spanish)." Scroll down to item 13, Quality Mammography, in your chosen topic of interest and select it.

At the next screen, select "Table of Contents," "View" and follow the instructions.

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.*

A number of facilities have asked if their equipment needs to be replaced or modified to meet the requirements of the final r egulations related to "motion of the tube-image receptor assembly." To address these concerns, we have compiled all our current guidance on this matter, which follo ws:

21 CFR 900.12(b)(3) Motion of tube-image receptor assembly. (i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. (ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

Q What is meant by the term "power interruption?"

A Power interruption in this context means interruption of external electrical power to the mammography unit. It does not refer to internal system failure.

Q What motion requirements must the tube-image receptor assembly meet?

A There is no specific range of motion that the assembly must provide. However, once fixed in any operating position intended by the equipment design, it must remain fixed in that position, even during power interruption.

Q Could you clarify what is meant by the statement that the mechanism "shall not fail in the event of power interruption"?

A This means that if the power to the x-ray system is unexpectedly terminated during an examination, the image receptor assembly will not move without operator intervention. This requirement is intended to provide additional safety for the patient in the event of power interruption during an examination and to prevent patient injury that might occur if the assembly moves.

The system must prevent motion until the operator determines that such motion is acceptable. Depending on the circumstances in each facility, the time required for the operator to safely remove the patient from the unit may vary. Therefore, the length of time required for the system to remain locked in place will also vary. However, removing the patient from the unit can usually be accomplished in a minute or less. Note: systems that do not have built-in mechanisms to prevent unintended gantry motion may meet the requirement using external battery backup or mechanical mechanisms that prevent unintended motion for the amount of time it takes to remove the patient from the machine.

Q How much tube-image receptor assembly motion is acceptable before a unit would be noncompliant with 900.12(b)(3)(ii)?

A The amount of acceptable motion is dependent on the circumstances in each facility and should be evaluated on an individual basis. The intent of this regulation is to assure patient safety during power interruptions. Facilities should evaluate their machines to determine if the amount of gantry motion during power interruptions is sufficient to allow their typical patient to fall, be twisted, or be pulled from the position that they were placed in by the technologist to such an extent that injury could occur. If such injury could reasonably occur, the regulation has not been met.

SPECIAL NOTICE

Mammography Facility Staff:

To get a ***quick response*** to your questions about MQSA Accreditation, Certification, Inspections, Policy, Guidance, and other concerns, call our MQSA Facility Hotline at 1-800-838-7715, or send a fax to 410-290-6351, rather than submitting your questions by E-mail.

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

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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