From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Fall 1998 Volume 5, Issue 4

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

Congress passed the Mammography Quality Standards Reauthorization Act of 1998 (H.R. 4382) in September, amending the Public Health Service Act to revise and extend the MQSA program. The House of Representatives overwhelmingly passed the measure September 15, 401-1. It passed the Senate September 25 by unanimous consent and was signed by President Clinton October 9.

The new law (P.L. 105-248) includes a requirement effective April 28, 1999, that all mammography facilities send reports written in lay person's terms to all patients receiving mammography services. House Commerce Committee Chairman and bill cosponsor Rep. Tom Bliley (R-VA) said the measure improves mammography by providing patients — for the first time — direct notification of mammogram test results in terms they can understand.

"This bill provides more potent weapons for America's war on breast cancer," said Bliley. "Breast cancer kills 46,000 people each year. The fact that one in nine women will develop breast cancer at some point in their lives compels us to action."

P.L. 105-248 reauthorizes MQSA and adds the following provisions:

- Clarifies the responsibility of the mammography facility to retain mammogram records so that women have the ability to obtain the original of their mammogram.
- Mandates direct written notification to all patients of their exam results in lay person's terms.
- Permits FDA to conduct a limited demonstration project to determine the feasibility of inspecting mammography centers of excellence on a less than annual basis.

Consumer groups and the American College of Radiology have supported these changes. FDA will initiate work on associated regulations and policy guidance.

Draft MQSA Compliance Guidance Available

FDA announced in the August 27, 1998, Federal Register (FR) that a draft guidance document, "Compliance Guidance: The Mammography Quality Standards Act Final Regulations," is available for public review and comment. The guidance is intended to assist facilities and their personnel in meeting the MQSA final regulations, which become effective on April 28, 1999.

FDA invites written comments concerning the guidance during the formal comment period, up to November 25, 1998, and will continue to accept comments for 30 days beyond that date.

You may submit written comments concerning the guidance to the Dockets Management Branch (HFA-305); Food and Drug Administration, Rm. 1061; 5630 Fishers Lane, Rockville, MD 20852.

This guidance document represents FDA's current thinking on the

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What's Inside

From the Director . . .

FDA recently published draft guidance on the MQSA final regulations (see "Draft MQSA Compliance Guidance Available," page 1). We strongly encourage all facilities and interested parties to review the document, which can be obtained via fax, through our website, or the U.S. mail.

Please note that the guidance is not final and that FDA invites written comments up to November 25, 1998. The compliance guidance is intended to assist facilities and their personnel in meeting the MQSA final regulations, which become effective April 28, 1999.

Among other things, the document answers significant questions that facility personnel or interested parties have raised since the final regulations were issued in October 1997. Although it represents FDA's current thinking on the final regulations, we believe that facility staff may very well provide valuable recommendations for further refining the document.

After the formal 90-day period of public review and comment, FDA will continue accepting comments for another 30 days before finalizing the document. However, it's important to understand the distinction between the compliance guidance and the regulations themselves.

Guidance represents an approach to satisfying the requirements of the regulation. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

Unlike the regulations, which are mandatory, the compliance guidance does not create or confer any rights for, or on, any person. When referring to guidance, FDA uses non-mandatory language, such as "should," "may," "can," and "recommend." Regarding MQSA's statutory requirements, it is the responsibility of the facility to read, understand, and follow the requirements as mandated under the final regulations.

For further information about the compliance guidance, please contact Walid G. Mourad, Ph.D., Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or call 301-594-3332.

Direct Reports to Patients

On a different front, facilities should be aware of new language added to the MQSA reauthorization recently passed by Congress and signed by President Clinton. Beginning April 28, 1999, all mammography facilities must send reports to all patients receiving mammography services. The new statutory language reads that "a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person."

Consumer groups and the American College of Radiology asked Congress to make this statutory change as a means of avoiding mistakes and saving lives. FDA recognizes the sensitivity of this issue among referring physicians and facilities. Now that such language has been enacted, FDA will promulgate associated regulations via the notice and comment process and will subsequently work with interested parties to develop guidance.

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Quality and Radiation Programs

MammographyMatters
Fall 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:

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

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Facility Hotline

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

Annual Inspection of Certified Mammography Facilities

Reminder: Every certified mammography facility is required to undergo an annual inspection, even those not currently performing mammography.

As everyone in the mammography community should know by now, in order for a facility to maintain its certification, it must continue to meet the established minimum quality standards requirements as provided in the interim regulations (21 CFR §900.12). In summary, a certified facility must:

- have an annual survey conducted by a qualified medical physicist,
- undergo periodic audits and review by its accreditation body,
- permit an annual MQSA inspection of its equipment and records,
- pay an inspection fee, and
- correct all deficiencies found during inspections.

A facility that is unable to meet the above requirements is subject to compliance actions that FDA may take against it unless the facility relinquishes its certified status. To withdraw from certification, the facility should (1) notify its accreditation body and FDA of its decision (call the MQSA Facility Hotline: 1-800-838-7715) and (2) mail its certificate to FDA as soon as possible (FDA-MQSA, P.O. Box 6057, Columbia, MD 21045-6057).

Once its certification has been withdrawn, a facility cannot lawfully perform mammography. Should a facility decide to perform mammography services in the future, it must proceed through the accreditation process again.

MQSA Inspection Teleconference Scheduled

FDA has scheduled an MQSA Inspection Teleconference on Thursday, February 18, 1999, 1:00-4:30 p.m., to communicate to mammography facilities the agency's current thinking about inspections under the reauthorized MQSA final regulations.

The purpose of the teleconference is to answer the most important questions about the final regulations and to describe inspection procedures for facilities in time for them to prepare for the final regulations that become effective April 28, 1999.

Downlink sites will be available at some Veteran's Administration hospitals. Interested parties may also contact their State or local government agencies, health departments, or nearby hospital to check on the availability of a downlink at those sites. Viewers are encouraged to make video cassette

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On the Go: Mobile Units and MQSA

The previous issue of Mammography Matters presented highlights of the final MQSA regulations as they pertain to operators of mobile mammography units. This second article describes some of their real-life experiences and day-to-day challenges.

Readers are reminded that examples are just that — examples of successful approaches or strategies. FDA does not endorse or recommend a specific approach or strategy for how mammography facilities should perform their day-to-day operations.

Nearly all of Trinity Medical Center's mobile unit clientele are women living in rural areas of North Dakota.

Mobile mammography plays a vital role in the fight against breast cancer. It offers a convenient, quality, potentially life-saving procedure, especially for underserved, uninsured, and under-insured women and for women in rural locations.

Since making its inaugural run nearly a decade ago, Texas Mobile Health has performed more than 80,000 mammograms. Operating six days a week in Houston and six surrounding counties, Texas Mobile's two mobile vans and staff are busy, with each seeing 15 to 20 women daily, according to owner Chelette Baker.

Mobile mammography is used in all parts of the country. Connie Busch, Imaging Coordinator of Trinity Hospital's Mobile Mammography Services in Minot, North Dakota, reports that some 3,000 mammograms are performed annually via the facility's mobile unit, which travels to more than 30 communities, some extending more than 120 miles from Minot. And Mary Ann Madsen, Supervisor of Virginia Mason Medical Center's Mobile Services in Seattle, Washington, notes that the number of mammograms performed using her facility's mobile operation, which serves the metropolitan areas of Seattle and Tacoma, increased from 1,800 in 1996 to 2,300 in 1997.

Mobile mammography seems to be reaching its primary target audiences: historically underserved women and women who, despite certain risk factors, including age, have never had a mammogram. Statistics from Baker's operation indicate that about half of the women who use Texas Mobile's mammography services have no insurance or are underinsured. Madsen reports that about 20 percent of women accessing Virginia Mason's mobile mammography are having their first mammogram. And nearly all of Trinity's mobile unit clientele are women living in rural areas of North Dakota.

Day by Day

There is no "typical" day with mobile mammography. They visit different locations each day, from churches to department stores to satellite medical facilities to major corporations. And staff always have to be prepared for the unexpected.

One time, lightning struck one of Texas Mobile's units on its way to a scheduled stop. Luckily, no one was hurt, and the only damage was to the electrical circuitry of the bus, Baker recalls. As she points out, the operators and technologists on mobile units "must be proficient not only in their interactions with patients and with taking and processing films. They also must be able to check the oil in the [unit's] generator and be familiar with all the functions of the mobile coach or bus."

Despite some obvious day-to-day variations and dealing with potential weather problems, there is some routine to running a mobile mammography operation. Certain sites or loca-

tions are visited regularly. Texas Mobile, for example, travels to specific locations each month as part of CDC's (the Centers for Disease Control and Prevention) breast and cervical cancer screening program.

All three mobile operations track the exact number of examinations scheduled and have a route outlined for each day. And both Texas Mobile and Trinity try, to the extent possible, to bring along previous films to assist in assessing the patient and determining the need for additional or special views. Gathering a patient's films in advance also helps with the interpreting physician's subsequent evaluation.

In addition to performing mammography, daily "housekeeping" activities include recordkeeping, filing, tracking patients, and checking the next day's schedule. The work often takes staff well into the evening, frequently translating into 12-hour days. Additional preparations and other arrangements must be made for overnight trips, such as making sure that electrical hook-ups for the generator-powered x-ray equipment are in operation and available 24 hours a day.

Out and About

All three of the operations mentioned in this article own self-contained units. That is, the mobile coach or RV, which Virginia Mason's service uses, contains a waiting room or reception area, dressing rooms, and an examination room, where the mammogram is taken. Both Texas Mobile Health and Trinity Mobile Services use on-board processing, whereas Virginia Mason's Mobile Mammography has opted for batch processing, in which all films are processed at the end of the day at another location.

MQSA ensures that the quality of mammograms from mobile units are the same as those done at any other certified facility.

Units that do on-board processing ask women to wait until the films are processed and determined to be of diagnostic quality. With batch processing, women can leave after their films are taken but before their films are developed. If any of the films need to be repeated, the center contacts the woman after the films have been developed and arranges a subsequent appointment.

Advances in x-ray units, processing equipment and chemicals, and vehicle design have improved the quality of films from mobile units. Improvements in jack systems, air suspension, and levelers all help keep x-ray units and processors stable, even when road conditions aren't. Additional changes in medical coach design allow x-ray units and processors to run on generators independent of coach engine systems.

Patient Follow-Up

Patient contact, notification, and follow-up strategies are essential components to the delivery of mammography services.

At Texas Mobile, if the mammogram is normal, a card indicating a normal result is sent to the patient and a report goes out to her doctor (or clinic), with a recommendation for the date of the next follow-up visit. If the findings are suspicious or abnormal, staff at Texas Mobile call both the patient and her doctor, suggesting next steps, followed by a full report to the physician.

(Note that statutory language in the reauthorized MQSA recently passed by Congress requires written notication of test results in lay person's terms to all patients starting April 28, 1999. For more information, see page 1 of this issue of Mammography Matters.)

Trinity Mobile uses a computerized tracking system for scheduling and follow-up. In all cases, after the exam, the patient and her doctor receive a letter from the Trinity radiologist who has read and interpreted the patient's films. The patient's letter encourages the woman to call Trinity or her doctor directly with any questions. If a biopsy or any other additional test or exam is recommended, the letter will instruct the patient to contact her doctor for the follow-up care or referral. This computerized system provides backup, generating reminder slips if the patient doesn't follow up a month after initial notification.

At Virginia Mason, the interpreting physician contacts the patient's doctor directly, via phone and a letter, with the results of the mammogram. The letter and report to the doctor include specific recommendations for further steps, as appropriate. The patient is also sent a letter stating that the mammogram was read and that the results have been sent to her doctor; the letter

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On the Go

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also states, in general terms, the findings of the exam and outlines next steps.

MQSA and Mobile Mammography

Staff members from the three respective mobile units are working to ensure that the systems and procedures already in place for tracking, recordkeeping, follow-up, QA/QC checks, and immediate corrections of problems are revised and refined, as needed, to meet next April's final MQSA implementation date. In this respect, the three operators see MQSA as a means of encouraging their teams to continue to hone their skills.

There also appears to be an unanticipated plus from MQSA to the mobile mammography community. Both Busch and Baker have seen a shift in attitude toward mobile mammography in recent years, even among doctors, who have been referring more women to their services. And MQSA may be playing a role in this change.

"MQSA is a real boon for mobile mammography," says Baker. "It lets those consumers, doctors, and other health care professionals who might have had concerns about the quality of mammograms from mobile units know that mobile mammography is the same as mammography done in a hospital or other standing facility. MQSA levels the playing field, sets equal standards for quality, and provides quality reassurance."

For more information on mobile mammography, contact the National Mammography Marketing/Education Association, 1-800-755-9712.

Iowa and Illinois Commence States as Certifiers Demonstration Project

The States as Certifiers (SAC) Demonstration Project became operational in August 1998. Two participants were accepted into the project — the State of Iowa began to certify facilities on August 3 and the State of Illinois started August 5. While FDA continues to certify facilities in the rest of the country, these two States are certifying mammography facilities under MQSA within their respective boundaries.

Facilities with questions or certificate problems from Iowa should call Don Flater (515-281-3478); inquiries from Illinois should be directed to Paul Brown (217-785-9974).

The next phase of the SAC Demonstration Project will occur in 1999–2000. When additional qualified States apply and are accepted by FDA, they may participate in the certification process. States currently in the project will have the option to renew for the second year.

Meanwhile, regulations are under development with the expectation that they will be effective following the Demonstration Project. Under these regulations, any State may apply to become a certifying body.

MQSA Teleconference

Continued from page 3

copies of the teleconference for the benefit of others.

After January 15, 1999, you may call the Facility Hotline (1-800-838-7715) for up-to-date information about participating in the teleconference.

Periodically check FDA's website (www.fda.gov/cdrh/dmqrp.html) or its Facts-On-Demand (1-800-899-0381 or 301-827-0111) for additional information.

RSNA Conference

Plan to look for FDA staff and/or the MQSA exhibit (Booth Number 5550) at the Radiological Society of North America (RSNA) conference, November 28– December 4, in Chicago.

DMQRP Director John McCrohan and Associate Director Charles Finder will be panel members for a special focus session on the MQSA final regulations, "What You Should Do in the Next Five Months." The session is scheduled for Tuesday, December 1.

Facility Fined, Shut Down

On August 12, 1998, FDA announced settlement of a civil action against Community Medical Imaging (CMI) of Chicago, Illinois, which agreed to pay a $30,000 penalty for performing mammography examinations without proper certification. In addition, the facility and the president of the facility agreed to remove themselves from the mammography field for five years.

Under the settlement, CMI and its president will jointly pay $25,000. The facility's supervisory radiologist will pay $5,000.

CMI, which had been operating under provisional certification, was denied accreditation by the American College of Radiology (ACR) after failing to meet standards — primarily due to poor clinical image quality. It then obtained a new certificate after supplying false information to ACR and continued to do mammography even after being notified by FDA that it must cease operations.

FDA is concerned about the quality of mammograms taken at the facility during the uncertified period between September 1996 and March 1997 and has provided appropriate written information and guidance to all affected patients and their referring physicians.

Draft Guidance Available

Continued from page 1

final regulations implementing MQSA. It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

All guidance issued by FDA is structured according to the Good Guidance Practices (GGPs), which sets forth FDA's policies and procedures for developing, issuing, and using guidance documents (62 FR 8961, February 27, 1997). This MQSA guidance is issued as a Level 1 guidance, which, among other things, means it is directed to members of a regulated community. As such, the guidance is published and made available to the public to solicit their viewpoints. The "Compliance Guidance" will not be final until it is republished following any changes that may be made in connection with the current public comment process.

Additional guidance documents are currently being developed and will be placed on FDA's website as soon as possible.

How To Get the Guidance

A copy of "Compliance Guidance: The Mammography Quality Standards Act Final Regulation" may be downloaded from FDA's web site (www.fda.gov/cdrh/dmqrp.html). Or call FDA's Facts-On-Demand system at 1-800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 9, then press 1 to access DSMA Facts. At the second voice prompt press 2, and enter the document number (1259) followed by the pound sign (#). Follow the remaining voice prompts to complete your request. Please note that the document is 71 pages and won't be faxed until after 5 p.m.

If you prefer to have the guidance sent via the U.S. mail, single copies may be obtained from SciComm, Inc., P.O. Box 30224, Bethesda, MD 20824-9998. Fax 301-986-8015.

Confused About Processor Control Crossover?

This column provides facility personnel with hints about various technical and equipment issues involved in meeting MQSA requirements.

FDA continues to receive questions regarding the procedure to "crossover" from one emulsion batch of processor control film to another. The procedure is detailed in the 1992 and 1994 ACR QC Manuals. In 1996, the ACR came out with a clarification on the procedure, which will be included in their next revision of the manual scheduled for release by the end of 1998. This article explains why a crossover technique is necessary and how to do it.

Mammography film processor quality control (QC) uses a sensitometer and film to measure three important areas of film and processor performance: speed, contrast, and B + F densities. This procedure assumes that the sensitometer and film are constant, so that we can conclude that any changes in the three parameters reflect changes in processing. In practice, sensitometers are very precise and reproducible, and film is very constant within a given emulsion batch. Therefore, changes in speed, contrast, or B + F are usually due to changes in processing.

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

Film changes very slowly with time if stored properly. However, it may nevertheless exhibit significant and observable batch-to-batch variations attributable to normal variations in manufacturing. So when the user changes to a new box of quality control film, there may be differences in speed, contrast, or B + F that are attributable to changes in the film itself, not the processing.

The purpose of processor QC is to control the film processing, not the film. It is not appropriate to adjust processing (replenishment rates or temperature, for example) because of batch-to-batch variations in the film. The crossover procedure is a way to account for the normal changes in control film without confusing it with changes in processing.

Common misconceptions

There are two common misconceptions associated with the crossover procedure. Despite some thinking to the contrary, crossover is not performed to solve processing problems. The processing must be stable and in control. It is essential that processing be in control when conducting a crossover.

Second, new operating limits do not need to be established over a five-day period. Although the test is usually performed using five sheets of film from the old emulsion batch and five sheets of film from the new emulsion batch, the crossover can, in fact, be performed on a single day. The five-day averaging period for establishing the original quality control limits has apparently been confused with the five sheets of film recommended for crossover.

The essence of the crossover procedure is that when there is a difference in film optical density between the two emulsion batches, for example, + 0.05, then the new control chart limits need to be adjusted accordingly. If the original operating level for speed density was 1.31, the new one should be 1.36. This results in new action limits of 1.36 ± 0.15, with a lower limit of 1.21 and an upper limit of 1.51 (Figure 1). The old limits were 1.16 (lower limit) and 1.46 (upper limit).

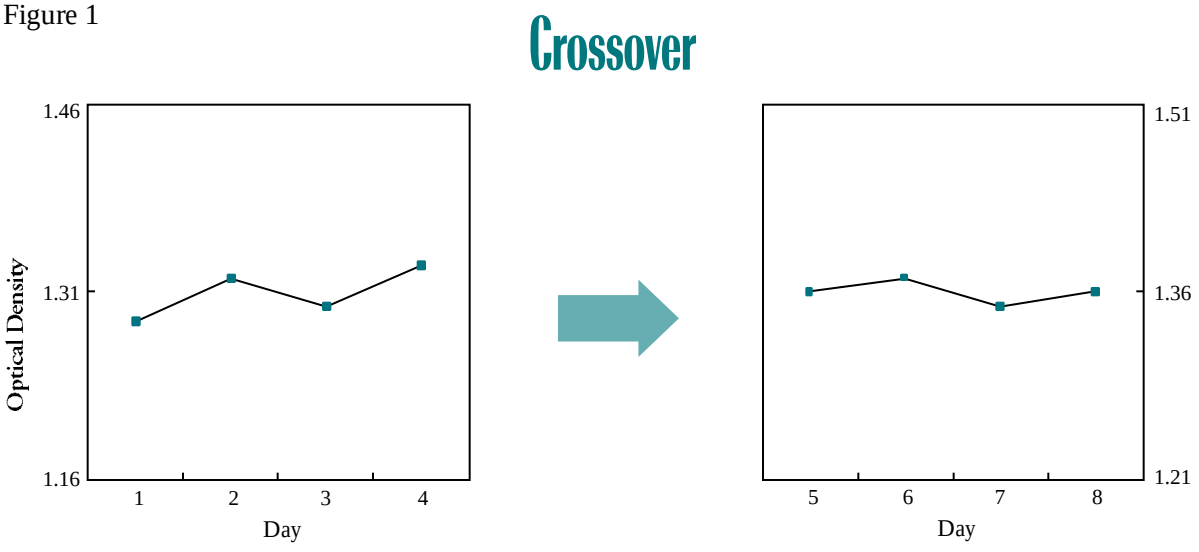
Take a moment to reread the previous paragraph. If you do not understand the procedure, check with your film technical representive or medical physicist.

Another useful hint related to crossover: avoid waiting until you are down to the last five sheets of old emulsion batch QC control film before conducting the test. What if you have processing problems at that time? You would have to get the processor back into control and then conduct the test. At that time you would no longer have enough film from the old emulsion batch to conduct the test. The crossover procedure should be conducted before the existing batch of old emulsion QC film has been depleted.

It is critical that the facility QC personnel, the technologist, and the medical physicist understand why crossover is being conducted. The knowledge of what crossover is, why it needs to be performed, and the acceptance of responsibility are critical in the maintenance of an effective QC program. Crossover brings to the table several additional players, including the film manufacturer and the film technical representative.

If the differences between the two film emulsion batches are significant (for example, if the differences exceed the facility's own QC action limits), it's important to bring this to the film manufacturer's attention. The facility should carefully document this difference, recording the two different emulsion batch numbers, and work with their film technical representative or medical physicist to correct the problem.

Figure 1



Box of Old Film
(Old Emulsion)
with Old Operating Levels

Box of New Film
(New Emulsion)
with New Operating Levels

Writing the Mammography Report

Meeting MQSA requirements: information interpreting physicians should know.

The final MQSA regulations concerning the content and terminology of mammography reports spell out certain requirements that I would like to bring to your attention. In the midst of one's busy practice, it's quite possible to forget that interpreting physicians have certain responsibilities under MQSA, especially as it affects our patients' reports.

Among the requirements:

- Although there is no specified format, every mammography report — whether to a self-referred patient or another physician — must be in writing and must include the name of the interpreting physician of record.
- The new statutory language in the MQSA reauthorization requires that as of April 28, 1999, a written lay language summary of the mammography report be sent to all patients by the mammography facility.
- Final assessment categories, as defined under the final MQSA regulations, must be assigned to each case, unless further work-up is necessary. Final assessment categories are to be assigned based on the findings of the mammogram being interpreted at the time and not predicated on future follow-up imaging that may be recommended.
- In cases where it is not possible to assign a final assessment category because additional work-up is necessary, the report must state reasons why this is the case and include the assessment "Incomplete: Need additional imaging evaluation."
- If the interpreting physician has any additional recommendations for the referring physician, these should be included.
- All clinical questions raised by referring providers should be addressed in the report.

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

In fulfilling these requirements, interpreting physicians will comply with the regulations and provide complete, informative, and comprehensive mammography reports to referring medical colleagues and self-referred patients.

Mammographic Final Assessment C ategories

MQSA regulations require interpreting physicians to categorize each mammogram using one of the following six descriptive terms:

- Negative
- Benign
- Probably benign
- Suspicious
- Highly suggestive of malignancy
- Incomplete: Need additional imaging evaluation

Although numerical assessment categories (such as Birads 1-5 described by the American College of Radiology) are in widespread use, they may not be substituted for one of the descriptive categories defined under FDA's regulations.

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.

Note: The first question listed below originally ran in the Spring 1996 issue of Mammography Matters. We are publishing it again in response to similar inquiries recently received.

Q I planned to use the mammography CMEs I earned at a major conference to help meet my continuing education requirement under MQSA. Since the conference took place after October 1, 1994, I knew that I couldn't attest to the training. I therefore planned to use the certificate issued by the conference organizers as the necessary documentation. The certificate, however, does not break down the numbers of hours among the several areas covered by the conference (for example, mammography, orthopedics, pediatrics, MRI, etc.). Because the certificate doesn't show the number of hours in mammography, how can I prove how many I earned? I contacted the conference organizers, but they have no record of my number of hours in mammography.

A In situations like this, we permit a limited use of attestation beyond the October 1, 1994, cutoff date. For such meetings, you need documentation showing the total number of CMEs earned (a certificate or letter, for example) and the number of CMEs which could have been earned in mammography (such as an agenda or letter). With this documentation, you can attest via the FDA-recommended form (see Mammography Matters, Fall 1994, page 7) to the number of mammography CMEs you actually received.

In the long run, we encourage conference organizers to provide a breakdown by area of CMEs received.

Q My question concerns random film checks. We are given a specific day on which we must submit a normal mammogram to the American College of Radiology (ACR). The mammogram must be interpreted as "normal." What do we do if none of the mammograms done on that specific day is read as normal? In our practice we see an average of three to five patients daily. We have numerous patients who are called back for spot compression or mag views that do turn out to be dictated as normal, but the initial report goes out as further views needed. What if there are no patients scheduled on the day that ACR says that these images must be taken?

A Regarding both of these questions, you should make other arrangements with ACR.

Q How long do facilities need to keep personnel records?

A Currently, under the interim regulations, there is no specific requirement regarding the retention of personnel records. However, the final regulations do include a specific requirement to keep personnel records for as long as an individual is employed at a facility and until the next inspection after the employee leaves the facility. Please, do not prematurely discard any records.

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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