From FDA/CDRH to help facilities implement MQSA
www.fda.gov/cdrh/mammography

MammographyMatters

Fall 1999 Volume 6, Issue 4

Integrating Practice and Policy:

Helen Barr, M.D., Becomes DMQRP Deputy Director

After 12 years on the front lines of diagnostic radiology – with a focus on mammography – Helen Barr, M.D., will redirect her clinical skills and leadership strengths as Deputy Director of FDA's Division of Mammography Quality and Radiation Programs (DMQRP).

"After years of focusing on *individual* patient needs, I thought I could find professional growth in looking at mammography from a public health standpoint," said Dr. Barr.

A graduate of George Washington University School of Medicine and Health Sciences, Dr. Barr remained at the University for her post-graduate training. After completing her internship in internal medicine, she did her residency in diagnostic radiology, followed by a one-year fellowship in that specialty. Dr. Barr

Continued on page 4

When Patients Request the Transfer of Their Original Mammograms

The MQSA final regulations and the MQSA Reauthorization Act require facilities to transfer **original** mammograms to patients upon their request. (The specific citation and related guidance are presented at the end of this article.)

Original films are needed for comparison to other mammographic studies or for follow-up clinical procedures. Facilities should realize the importance of giving patients their **original** mammograms and not copies, which are considered inferior, when they request the transfer of mammography films.

The regulations also address the issue of charging fees for providing the original films to the patient. Facilities may not charge patients for copying their original mammograms, unless copies are requested by the patient or are mandated by State regulations for retention by the facility.

Furthermore, facilities should not attempt to persuade the patient to take copies of her mammogram, rather than the original films. If the facility wishes to keep copies for its own benefit, it cannot charge the patient.

The facility may charge the patient for the transfer of mammographic records as long as the charge does not exceed the documented cost of the transfer. Transfer fees may include costs the facility has incurred for the following administrative and overhead items:

- Logging in the request.
- Having the patient sign a release.
- Retrieving the mammography films and reports.
- Incurring photocopying costs in making copies of the reports for the patient.
- Packaging and mailing charges for the materials.

Note that while a facility may charge a transfer fee, it must not derive a financial profit from these

Continued on page 11

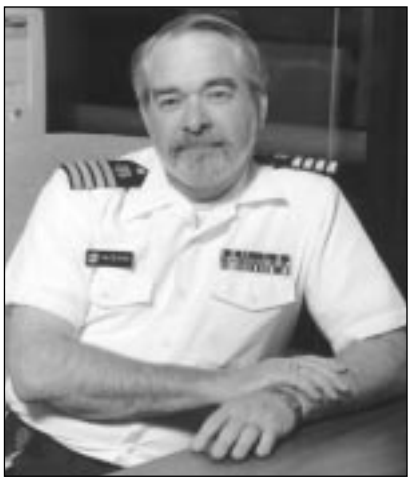
What's Inside

From the Director . . .

All of us involved with MQSA are going through a period of transition. After focusing on developing MQSA regulations, our emphasis now is helping facility personnel comply with the regulations. This effort includes fine-tuning annual inspections, issuing policy guidance, and clarifying areas of confusion.

To that end, this issue of Mammography Matters *covers some important items that warrant your attention. Our lead story is about charging patients for costs associated with the transfer of original mammograms. Transferring original mammograms upon request is a requirement under MQSA regulations. Although facilities may recover expenses, they may not profit from these services. Another article, "Using Acceptable Assessment Categories," on page 5, clarifies an issue that's cropped up during the first few months of inspections under the final regulations.*

I encourage you to continue raising questions by using the Facility Hotline. Remember that questions with broad policy implications may take some time to answer as they are developed into formal guidance. Draft guidance goes through a rigorous process that includes public review and comment before being approved. As I write this, we're close to completing the second guidance document and incorporating it into the Policy Guidance Help System available on the MQSA website.



Approving Physicists' Initial Requirements

On another front, we're making a new service available to respond to medical physicists' concerns about meeting the initial requirements under the final MQSA regulations. If you wish, send us your credentials and we'll determine if you meet the initial requirements. We will send you a letter indicating the requirements you have met. You can show this letter to the facilities you serve, in lieu of the more detailed credentials sent to us for evaluation. MQSA inspectors will accept the letter as adequate evidence that the listed requirements have been met.

The decision to use this service is entirely up to you. If you choose not to use this service, MQSA inspectors will continue to review your credentials during inspections. At that time, the inspectors also will continue to review the evidence establishing that you have met continuing requirements. Our review at headquarters is limited to establishing that the initial physicist requirements have been met. Physicists interested is using this service can obtain more information from our website.

Welcome Dr. Barr

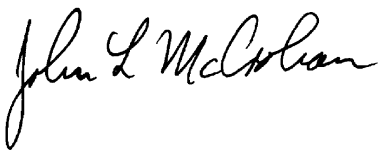
I'm delighted to welcome Dr. Helen Barr as DMQRP Deputy Director. A radiologist with 12 years of clinical experience in mammography, Dr. Barr brings a valuable facility perspective, with a clear understanding of patients' needs and rights, to future decisions on MQSA implementation. (See article on page 1 for more information on Dr. Barr.)

MQSA Refresher Course

For those of you attending the 1999 Radiological Society of North America meeting in Chicago, 1½ hours of Category 1 continuing education credit will be available to those taking the MQSA Refresher Course. This course will be offered on Tuesday, November 30, 8:30–10:00 a.m.

Also, be sure to stop by FDA's booth. We'll be demonstrating the Policy Guidance Help System, as well as other information tools available on our revised website.

See you in Chicago.



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

MammographyMatters
Fall 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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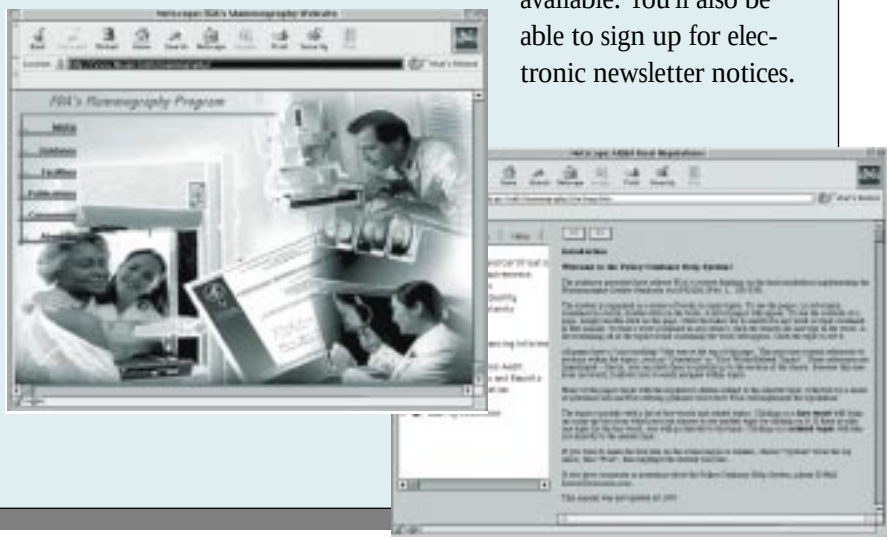
Facility Hotline

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

Check It Out!

A new website for FDA's Mammography Program — www.fda.gov/cdrh/mammography — features the Policy Guidance Help System to help facilities comply with MQSA regulations. Come back often and keep informed. FDA will post new MQSA information as it becomes available. You'll also be able to sign up for electronic newsletter notices.



Is Your Facility Information Correct?

All facilities should go the FDA's mammography website and check the accuracy of the address and phone number information in the "Certified Facilities" database for their facility. This information is supplied to the FDA by the Accreditation Bodies and all changes must originate with them. Therefore, if your facility's name, address, or telephone number needs to be corrected, you must notify your Accreditation Body and ask that they correct the information.

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.**

Natural Disasters and Compliance with MQSA Regulations

As Hurricane Floyd's recent devastation made clear, natural disasters can have widespread and unforeseen effects. One potential problem is a mammography facility's ability to comply with MQSA regulations in the aftermath of a natural disaster. Depending on the damage sustained by a facility, equipment and critical records could be damaged or destroyed.

To assist facilities in complying with MQSA regulations, any facility damaged by a natural disaster should:

- Inform its Accreditation Body as soon as possible of the situation and any change in the facility's location. The facility also should request instructions, from its Accreditation Body, if it cannot complete the accreditation process before its current accreditation expires.
- Record the dates for which quality control records have been lost or destroyed. Documentation should explain the reason these records were lost or destroyed and should be available for review by the Accreditation Body and the MQSA inspector.
- Notify a medical physicist and conduct an equipment evaluation if a new unit was purchased, an existing unit received major repairs, or a unit was disassembled and reassembled. The evaluation should be completed before clinical use of the equipment. A facility also may want to perform other tests to ensure that its equipment is performing properly.

A facility may contact FDA or its Accreditation Body for further information if a natural disaster has affected its operations. Together, FDA, MQSA inspectors, State programs, and Accreditation Bodies will work with facilities struck by natural disasters to help them resume practicing good quality mammography.

Helen Barr, M.D.

Continued from page 1

remained on the faculty as a clinical instructor for two additional years.

In her 10 years with Kaiser Permanente in Kensington, MD, Dr. Barr served as Lead Radiologist for eight years. For six years, she also functioned as the Mammography Modality Manager, overseeing nine mammography centers that performed about 60,000 mammograms each year, and directed the stereotactic and other interventional breast services. In addition, Dr. Barr served for a time as the acting Service Chief and was appointed to the Quality Assurance and the Clinical Operations Committees at Kaiser Permanente.

Having been on the "other side" of MQSA at the facility level, Dr. Barr believes she can bring a different perspective to MQSA decisions. Although she will not continue in private practice, Dr. Barr plans to continue reviewing mammograms to keep current with MQSA requirements for interpreting physicians. Maintaining this involvement will allow her to integrate the experiences of mammography facilities with the mandates of MQSA, she noted.

As the right hand to DMQRP Director John McCrohan, M.S., Dr. Barr wants mammography facilities to know "they are not alone out there. A big focus at FDA is to support the facilities, as evidenced by the Facility Hotline and the quarterly newsletter, *Mammography Matters*." She envisions the facilities and FDA as partners in ensuring high-quality mammography for American women. In noting that MQSA has "leveled the playing field" for mammography services, Dr. Barr pointed to MQSA's role in narrowing quality gaps between facilities so that any woman, anywhere, can know that she has received a good mammogram.

Just as her years of clinical experience have provided her with an understanding of the facility perspective, Dr. Barr also brings to this position great understanding of the patient's experience. She observed that women are becoming increasingly aware of their rights under MQSA, a phenomenon that will be strengthened by an upcoming DMQRP brochure that outlines those rights. In addition to informing patients through this easy-to-read brochure, "technologists and other patient advocates at the facilities can support patients' understanding of their rights," said Dr. Barr.

With a clear understanding of women's mammography needs and rights and the perspective of mammography facilities garnered through her hands-on experience, Dr. Barr hopes to bring a fresh perspective to the oversight of MQSA implementation.

Using Acceptable Assessment Categories

Since inspections began under the final MQSA regulations, FDA has learned that about 14 percent of facilities are not including final assessments on all their mammography reports or are using different wording for assessment categories than that approved in the final regulations. Confusion still exists about what constitutes an acceptable final overall assessment category.

As background, the goal of the assessment category classification system developed for the final regulations is to make the reporting of mammographic results clearer and more consistent. FDA's classification system is based on systems that were already in use, notably, the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS™). Although BI-RADS™ uses the same six assessment categories as approved in the final regulations, the wording they use to identify the categories differs slightly from that selected by FDA.

Many facilities and mammography reporting computer software companies still follow the wording used in BI-RADS™. At its July 12, 1999 meeting, the National Mammography Quality Assurance Advisory Committee unanimously agreed that FDA should be flexible, within limits, with facilities that use the six assessment category system but use different wording to describe the categories.

To guide MQSA inspectors and facilities, FDA has developed a list of commonly used "equivalent assessments" (see below). Although these equivalent assessments may use slightly different wording than that found in the final regulations, they do not change the meaning of any assessment category. Facilities using these equivalents will not be cited for MQSA violations. FDA will complete its efforts with facilities and software companies to bring uniformity to the language used in assessment categories.

Facilities should not interpret this to mean that they are excused from meeting the basic requirement that each mammography report include an overall assessment of findings. Inspectors will cite facilities that fail to use the final overall assessment category classification system or use wording that is unclear or changes the meaning of an assessment category.

Assessment Category Equivalents

The following examples are considered equivalent to the wording in the final regulations assessment categories (set in **bold face**) and are acceptable final overall assessments:

Negative
Negative Mammogram

Benign
Benign Finding
Benign Findings
Benign Abnormality
Benign Abnormalities
Benign Mammogram

Probably Benign
Probably Benign Finding
Probably Benign Findings
Probably Benign Abnormality
Probably Benign Abnormalities
Probably Benign - Short Interval Follow-up Suggested
Probably Benign Finding - Short Interval Follow-up Suggested
Probably Benign Mammogram

Suspicious
Suspicious Finding
Suspicious Findings
Suspicious Abnormality
Suspicious Abnormalities
Suspicious for Malignancy
Suspicious of Malignancy
Suspicious Abnormality - Biopsy Should Be Considered
Suspicious Finding - Biopsy Should Be Considered
Suspicious Mammogram

Highly Suggestive of Malignancy
Highly Suggestive for Malignancy
Highly Suggestive of Malignancy - Appropriate Action Should Be Taken

Incomplete: Need Additional Imaging Evaluation
Incomplete: Needs Additional Imaging Evaluation
Incomplete: Additional Imaging Evaluation Needed
Incomplete: Need Additional Imaging Evaluation - Comparison with Prior Studies
Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only Incomplete assessment category)
Incomplete Mammogram: Need Additional Imaging Evaluation

Facility Owner Sentenced in Mammography Fraud Case

On September 14, 1999, a federal court judge sentenced the owner of a mobile mammography facility to 18 months in prison, 36 months of supervised release, and ordered him to pay a $3,000 fine for activities related to operating his facility without having the required FDA certification. This was the first criminal prosecution of this type under MQSA.

The facility was denied accreditation in December 1996 and was not certified by FDA because it failed to meet the minimum quality standards for mammography. Nevertheless, the facility owner sent literature to a private employer in Virginia stating that the facility complied with all federal regulations and was accredited by the American College of Radiology. He also provided a fraudulent FDA certificate. The facility owner then illegally performed more than 100 mammograms and billed the employer approximately $5,760 for these services.

Illegal mammography services were also provided to women employed by two other companies located in Virginia. In addition, the facility owner defrauded an insurance company that reimbursed wellness benefits to the employees for the illegally performed mammograms.

"Most mammography facilities take seriously their obligation to meet standards and be certified so that women can be assured of high-quality screening for breast cancer. A facility that flouts the law is putting women at risk. Such action will not be tolerated," said FDA Commissioner Jane E. Henney, M.D.

Most mammography facilities take seriously their obligation to meet standards and be certified so that women can be assured of high-quality screening for breast cancer. A facility that flouts the law is putting women at risk. Such action will not be tolerated.

—FDA Commissioner Jane E. Henney, M.D.

"It is important for the vast majority of health-care practitioners who do a conscientious job and for the consumers who put their trust in the health-care profession that we continue our efforts to identify and prosecute those who abuse that great trust," said Robert P. Crouch, Jr., U.S. Attorney for the Western District of Virginia. "Working with law enforcement, with regulatory agencies, and with the medical profession, this U.S. Attorney's Office is committed to preventing such charlatans from harming the public."

When FDA received a report about suspected illegal activities, MQSA inspectors from its Baltimore District Office conducted an initial investigation. FDA's Division of Mammography Quality and Radiation Programs also notified the three employers about concerns regarding the quality of the uncertified facility's mammograms. At FDA's request, the companies informed the affected women about FDA's concerns and the agency's recommendation that they seek appropriate health-care follow-up.

The case was prosecuted based on an investigation conducted by FDA's Office of Criminal Investigations. In April, the facility owner pleaded guilty to two counts of mail fraud and one count of health-care fraud.

Y2K: FDA Readiness and Facility Compliance

FDA Ensures MPRIS Y2K Readiness

As the New Year approaches, governments and private industries world-wide face a challenge peculiar to our high-tech world: Will computers and information systems be able to distinguish between the years 1900 and 2000? An inability to make this distinction is known as the "Y2K glitch."

A glance at your MQSA Certificate will tell you why this glitch is important. Certificates for over 95 percent of MQSA facilities will expire after January 1, 2000, and FDA's computer systems must be able to recognize this and other dates after the new year. The Mammography Program Reporting and Information System (MPRIS), one of the Agency's mission-critical systems, handles all aspects of the MQSA program—from certification to inspection and provision of information to Medicare. All parts of MPRIS—software and hardware—must be free of the Y2K glitch for MQSA to run effectively.

To ensure a smooth transition to the new millennium, FDA began intense scrutiny of MPRIS in 1998. Last spring, FDA's Chief Information Office certified MPRIS as Y2K-compliant. This October, we subjected parts of the system to re-testing, which again found MPRIS fully compliant.

Facilities Target Compliance

Although FDA has worked closely since mid-1996 with many medical device manufacturers and the healthcare community to avoid Y2K problems, the Agency knows of a small number of devices that should be identified, checked, and—if needed—repaired. Included are medical devices that produce images in x-ray systems and diagnostic ultrasound systems. Date-related computer glitches in these devices could impact mammography accuracy. To protect your patients, complete the following steps:

1. If your facility is unsure if its medical devices are Y2K compliant:
   - Visit the Federal Y2K Biomedical Equipment Clearinghouse website at www.fda.gov/cdrh/yr2000/year 2000.html or
   - Contact FDA toll-free at 1-888-FDA-INFO (1-888-463-6332); Y2K concerns will be routed to a Y2K hotline through late March 2000.
2. If your equipment could be affected by the transition to Y2K, determine whether a Y2K compliance plan is in place within your organization. Assuming a plan is in place, check the stages that have been completed:
   - Awareness of Y2K problem and potential impacts
   - Plan for correction of non-Y2K-compliant systems
   - Implementation of corrections
   - Completion of post-testing
   - Compliance with Y2K transition.

   If a plan is not in place, contact FDA immediately for assistance in Y2K planning.
3. Determine if your organization has a contingency plan in place for potential Y2K failures, as recommended by FDA.

Reminder:
Preparing for MQSA Inspections

If you haven't already done so, go to FDA's mammography website (click on MQSA Inspection within the Facilities section) and get the "Preparing for MQSA Inspections" document. This useful document provides guidance to facilities as they prepare for their annual inspections.

A Look at Mammographic Radiation Dose

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

Did you know that the radiation dose from one mammography examination is roughly equivalent to less than three weeks of natural background radiation – the exposure all of us get from radioactive isotopes in our bodies, the environment, from rocks and building materials, radon, and cosmic rays?

Although the maximum allowed dose under MQSA for a single cranio-caudal view of the standard breast is 3 mGy, on average the radiosensitive tissue of the breast, that is the glandular tissue, receives a dose of only 1.6 mGy in a single exposure. This average dose is calculated from two measured values, entrance air kerma and beam half-value layer, which are acquired during MQSA inspections. The dose is calculated using a computer model of a breast compressed to 4.2 cm thickness and consisting of equal parts of adipose and glandular tissue. Even though some recent studies suggest that this model

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

thickness may be too thin to represent breast compression for the U.S. female population, the model is adequate as a baseline for assessing regulatory compliance. Regulatory bodies and the American College of Radiology (ACR) have used this model for decades.

The radiation dose each woman receives during a mammography exam varies, depending on factors such as breast size and type of breast tissue. For example, glandular tissue – the dominant tissue in the breast of younger women – absorbs more radiation than fatty adipose tissue. Also, the technical factors associated with the mammography x-ray unit will vary. These factors include the quality of the x-ray energy distribution and the quantity of the x-rays necessary to produce an adequate image.

Despite individual differences in dose, however, 1.6 mGy corresponds to the average amount of radiation energy (per mass of glandular tissue) absorbed by the breast in one mammographic exposure. To compare the breast dose to environmental radiation from other sources that put the entire body at risk of radiation detriment, the 1.6 mGy breast value must be normalized to a whole-body index of equivalent risk. This index is known as "effective dose," or **E**. For *two* exposures of *each* breast, a typical screening mammogram, the effective dose corresponds to 0.16 mGy. In summary, the radiation detriment attributable to one screening mammogram translates to the same risk associated with a whole-body effective dose of 0.16 mGy.

Comparing the 0.16 mGy effective dose from a screening mammogram to the 3 mGy average *annual* effective dose from all environmental background radiation, the conclusion is evident: The radiation risk from a screening mammogram is equivalent, on average, to that associated with 20 days of just living.

Continuing Experience Records – Who's Responsible?

Under MQSA, facilities – not individuals – are held responsible for ensuring that all personnel providing mammography services meet all applicable MQSA requirements, including the continuing experience requirement.

Because the continuing experience requirement is new for radiologic technologists and medical physicists under the final regulations, facilities did not have to begin keeping continuing experience records for these employees until April 28, 1999. FDA will not start inspecting for this requirement until after June 30, 2001. When that date arrives, the facility will need records dating back to April 28, 1999.

Although it is the facility's responsibility to maintain the continuing experience records for its staff, each individual should keep a copy for his or her own file.

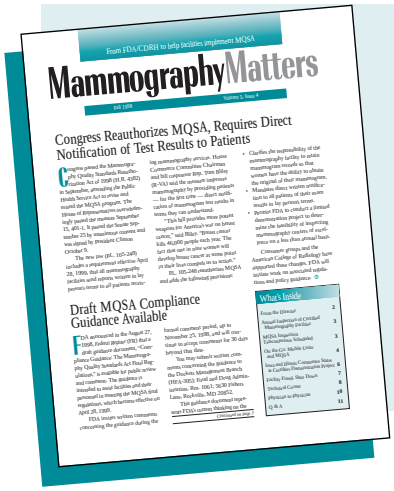
If you are working at more than one facility, you may need to combine the experience gained at all facilities to meet the continuing experience requirement. Each facility may ask you to provide documentation of your experience at the other facility(ies).

If you change jobs, your new facility will need to document that you meet all applicable MQSA requirements, including the continuing experience requirement, before allowing you to provide mammography services. Your facility will need the records you bring from your previous facility in order to be able to do this. These records will also be the starting point for your new facility's records of your continuing experience.

The records of your experience can't originate with you. The records that you keep must be copies of the facility records, not a separate count maintained by you. For help in maintaining your records, ask your facility(ies) to give you a copy of any report it develops that documents your experience. This information should be available because your facility will need to provide it to MQSA inspectors during their annual inspection.

If you should leave the facility, ask for a final report covering your experience through the last day of work at the facility. All records of your experience must be signed by a responsible official of the facility to be valid.

The bottom line for mammography personnel: You will benefit from maintaining records of your mammography experience. Although your facility is responsible for providing documentation showing that you meet the MQSA initial and continuing requirements, your mammography experience belongs to you as you follow your career path.


From FDA/CDRH to help facilities implement MQSA

MammographyMatters

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

Draft MQSA Compliance Guidance Available

What's Inside

FLASH!

Starting with the Spring 2000 issue of *Mammography Matters*, **FDA will stop printing and mailing free copies of the newsletter.** FDA will publish an electronic version of *Mammography Matters*, which will be available on the Internet.

Paid subscriptions to *Mammography Matters* will be available from the National Technical Information Service (NTIS), an agency in the U.S. Department of Commerce. To receive an order form, call the NTIS (1-800-363-2068) and ask for Title Order No. SUB9945.

Q & A

The following question comes from FDA's Policy Guidance Help System, part of the mammography program website to help facilies comply with MQSA regulations.

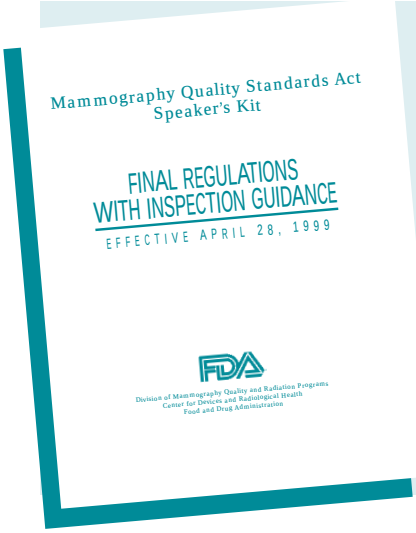
Q When are "additional mammography equipment evaluations" required and who must conduct the evaluations?

A Whenever a new unit or processor is installed, disassembled, and reassembled at the same or a new location, or major components are changed or repaired, an evaluation of the mammography unit or image processor is required. The medical physicist should decide which tests need to be performed following a particular repair and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist.

This additional evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. For a new unit, an equipment evaluation is needed before the unit is used on patients unless the unit has already undergone a full survey. In this situation, the facility must follow the accreditation body procedures. Keep in mind that under MQSA, the facility has the ultimate responsibility for ensuring image quality and patient safety. If changes or repairs to the system are anticipated, contact the facility's accreditation body to inquire whether the change affects a major component and requires an evaluation.

The equipment evaluation must be performed by a qualified medical physicist or by an individual under the direct supervision of the medical physicist.

These evaluations will be used to determine whether the new or changed equipment meets the requirements of applicable standards; see 900.12(b) and (e). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. A facility should maintain documentation that shows the date(s) on which a mammography equipment evaluation was performed, who performed the evaluation, and that any identified problems were corrected before the equipment was used on patients. A facility must maintain this documentation until the next inspection that verifies compliance.



New Speaker's Kit Available!

FDA has produced a new speaker's kit, MQSA Final Regulations with Inspection Guidance, that includes the speech, slides, transparencies, and background materials that can be used as handouts. The speech addresses changes to the final regulations, such as notification of examination results to patients,and some things that inspectors will be looking for during the annualinspections. This kit may be borrowed at no cost for a period of 30-days. It can also be downloaded from our website at www.fda.gov/cdrh/mammography.

To borrow a kit, fax or mail your request to: 1-301-986-8015 or MQSA, c/o SciComm, Inc., P.O. Box 30224, Bethesda, MD 20824-9998.

Testing Processor Performance – FDA Approves a New Alternative Requirement

Under the final regulations, FDA has approved a request for an alternative to sensitometric-densitometric testing of processor performance that facilities may use for up to 2 weeks when the sensitometer is unavailable. Similar to guidance described in the Summer 1995 issue of *Mammography Matters*, this alternative is based on evaluating a phantom image through measurements described in the final regulations; see 21 CFR 900.12(e)(1) and (2).

Under the alternative test, processor performance is considered satisfactory if:

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions;
2. The optical density of the film at the center of the phantom image changes no more than ± 0.20 from the established operating level; and
3. The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than ± 0.05 from the established operating level.

In addition:

4. To evaluate base + fog, an additional measurement of density must be made either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within + 0.03 of the established operating level.

Facility personnel must conduct this alternative test each day that clinical films are processed, before processing clinical films that day, and they must record and chart all results. Again, as with the original test, if processor performance fails to meet any part of the alternative test, personnel must correct the problem before processing is resumed.

Transfer of Mammograms

Continued from page 1

services. If requested by the patient, facilities must produce documentation (e.g., an itemized bill) that shows the charges do not exceed the costs associated with this service.

If a facility refuses to transfer records, a patient should first contact the facility's accredition body to intervene. Contact FDA, if necessary, via the Facility Hotline at 1-800-838-7715. Patients may write to FDA, P.O. Box 6057, Columbia, MD 21745-6057 if a facility overcharges for the transfer of films.

Regulatory Citation and Guidance

21CFR 900.12(c)(4)(ii),(iii): Each facility that performs mammograms: (ii) Shall upon request or on behalf of, by the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly; (iii) Any fee charged to the patients for providing the services of this paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.

Guidance question: What should a facility do if a patient (or someone acting on her behalf) requests permanent or temporary transfer of mammograms and/or reports?

Answer: The facility must transfer the original mammograms and copies of the patient's reports to the patient's designated recipient upon receiving a written request by the patient (or someone acting on her behalf). Facilities should be aware that the Federal law pertaining to transfer of original mammograms supercedes any conflicting State or local requirements.

The mammograms and reports may be sent to a medical institution, a health care provider, or to the patient. If the designated recipient is not available, the facility should work with the patient (or someone acting on her behalf) to designate an alternate destination.

Facility Fees and Patients

May charge

- Patient requests copies
- State mandates that facilities retain copies
- Transfer costs

May not charge

- Cost of originals
- Facility wishes to retain copies for its own benefit

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.

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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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