From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Summer 1998 Volume 5, Issue 3

McCrohan Succeeds Houn as DMQRP Director

After serving four and a half years as Director of FDA's Division of Mammography Quality and Radiation Programs (DMQRP), Florence Houn, M.D., is moving on to become Deputy Director of the Office of Drug Evaluation II in FDA's Center for Drug Evaluation and Research. (See "From the Director" column in this issue.) John McCrohan, DMQRP Deputy Director, succeeds Dr. Houn as Director.

Trained as a medical physicist with a master's degree in Radiological Sciences from the University of Washington, McCrohan has been an officer in the Public Health Service (PHS) since 1974, serving in FDA's Bureau of Radiological Health and its successor organization, the Center for Devices and Radiological Health. McCrohan currently holds the rank of Captain in the PHS.

In the mid-1970s, McCrohan was involved in the Breast Exposure: Nationwide Trends (BENT) program. His involvement in

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Final MQSA Rule, Part 3

With less than a year before the final Mammography Quality Standards Act (MQSA) rule takes effect on April 28, 1999, facilities should review their personnel operations, equipment, and procedures for regulatory compliance. Early preparation is critical, especially in areas that may require weeks or months of lead time to correct problems.

A checklist of key areas for facilities to review is included in this issue (see page 6). The two previous issues of *Mammography Matters* covered some of these major items in more detail. Areas covered included personnel requirements for interpreting physicians, radiologic technologists, and medical physicists; some of the new equipment standards; reporting and recordkeeping; and quality assurance.

Readers should note that back issues of *Mammography Matters* are available on the Internet (see www.fda.gov/cdrh/dmqrp.html). In addition, FDA is preparing draft guidance for implementing the final rule. Expected to be available for public review and comment July 1998, the first installment of this guidance will provide further clarification on various questions raised since the final rule was published in October 1997.

This issue touches on some of the new areas covered in the final rule: breast implant imaging, consumer complaints, and additional mammography review and patient notification.

Breast implant imaging

MQSA requires that specific attention be given to ensuring that patients with breast implants receive adequate examinations. This was not addressed in either the ACR accreditation program or the interim regulations, but has now been included in the final regs. The purpose is to ensure that the estimated 2 million women with breast implants can benefit from mammography services.

The final rule requires facilities to inquire about the presence of implants before the examination, and

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What's Inside

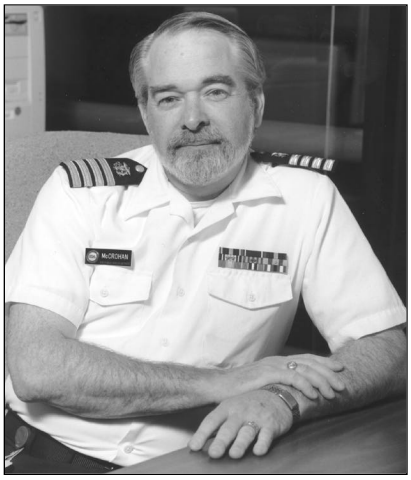
From the Director . . .

Replacing Florence Houn as DMQRP Director offers me the opportunity to personally acknowledge her years of service to improving the health of America's women and to recall some of the program's accomplishments under her tenure. She is a valued and trusted colleague, whose determination to improve the quality of mammography contributed to the program's documented success. I'm proud to continue efforts put in place under Dr. Houn's leadership now that she's moving on to meet new challenges at FDA's Center for Drug Evaluation and Research.

As some of you may know, in addition to serving as the DMQRP Director for the past four and a half years, Dr. Houn is an oncology instructor at Johns Hopkins School of Medicine. As Co-Director of Johns Hopkins' breast surveillance service, she sees women at high risk for breast and ovarian cancer and counsels them on early detection and prevention as well as risk management options. Dr. Houn is a champion in the fight against breast cancer.

During Dr. Houn's tenure as DMQRP Director, FDA has accomplished the following:

- *Publication of interim regulations on December 21, 1993, to provide a mechanism for accreditation and certification of mammography facilities by October 1, 1994.*
- *Publication on October 28, 1997, of more comprehensive final regulations, which become effective April 28, 1999. The final rule was developed with the advice of the National Mammography Quality Assurance Advisory Committee, composed of consumer and medical representatives, and took into consideration public comments from approximately 1,900 respondents to FDA's proposed regulations published April 3, 1996.*
- *Accreditation and certification of 10,161 mammography facilities as of December 31, 1997.*
- *Establishment of an outreach program to help facilities meet the regulations.*
- *Establishment of an inspection program in partnership with the states.*
- *Establishment of a compliance program to ensure that FDA regulatory requirements are adhered to, with an emphasis on assisting facilities in meeting the regulations.*

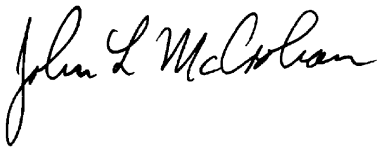


More important than the programmatic accomplishments is the success in enhancing the quality of mammography without adversely affecting access to this important procedure. As a nation, we have defined a common set of standards for providing safe, reliable mammography. By applying these standards consistently through a quality inspection program, in partnership with the facilities, we have significantly improved the proportion of facilities delivering quality mammography services that can provide life-saving diagnostic information in combating breast cancer.

There are many challenges before us, such as developing appropriate guidance, as we prepare to implement final regulations next year. Facilities should keep alert for notices regarding the availability of proposed guidance sometime this summer. The public will have a 90-day comment period after guidance is published in the Federal Register.

We're also developing new inspection procedures tied to the final rule, as well as the new States-as-Certifiers demonstration project as provided for by MQSA (see Spring 1998 Mammography Matters, *page 3).*

I look forward to continuing our strong partnership with facilities, established under Dr. Houn's leadership, in our mission to further improve the quality of mammography in the United States.



John L. McCrohan, M.S.
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MammographyMatters
Summer 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.

A Big Step Forward on Collimation Issue

The Spring 1998 issue of *Mammography Matters* noted that a conflict had been discovered between the final MQSA regulations and the Electronic Product Radiation Control (EPRC) performance standards that must be met by mammography equipment manufacturers. The conflict related to x-ray field and image receptor alignment. FDA is pleased to announce an interim measure that will eliminate this conflict for many facilities.

The final MQSA regulations require beam limiting devices to allow the x-ray beam to extend to or beyond the non-chest wall edges of the image receptor. To be certain to be in compliance with the EPRC requirement, some manufacturers have designed their units so that the x-ray field does not extend beyond the edges of the image receptor. Such units would not be in compliance with the final MQSA requirements.

FDA previously advised facilities to not change their equipment's collimation until this issue was resolved and it was clear what action, if any, would need to be taken. Recently, the agency approved an application from the General Electric (GE) Company for an alternative standard to the final MQSA regulations. This alternative will permit, **but not require,** units to have x-ray fields that extend beyond the edges of the image receptor up to a specified limit. To obtain approval of this alternative, which was granted under section 900.18 of the MQSA regulations, GE provided data for FDA review to show that their alternative provides as great or greater assurance of mammography quality as the original standard.

The approved alternative applies to all GE Senographe mammography systems, including those having model names 500, 600T, 800T, and DMR, and means that these systems will not have to be modified to be in compliance with the x-ray field-image receptor alignment requirements of the final MQSA regulations. The alternative becomes effective on April 28, 1999, the effective date of the final MQSA regulations. No time limit has been placed on the period of approval.

FDA expects to achieve a general resolution of this issue before April 28, 1999. In the meantime, facilities with concerns about meeting the final MQSA alignment requirement and whose units are not covered by the approved alternative have the option of encouraging the manufacturers of their units to apply for similar alternative standards.

MQSA Advisory Committee Update

The National Mammography Quality Assurance Advisory Committee, which advises FDA on a range of issues related to implementing MQSA, met in early May under the leadership of its new chair, Dr. Barbara Monsees, Chief of the Breast Imaging Section at the Mallinckrodt Institute of Radiology.

One of the key issues discussed at the May meeting was collimation of the x-ray field. The MQSA regulations regarding collimation are in conflict with the Electronic Product Radiation Control (EPRC) performance standards that mammography equipment manufacturers must meet under a 1968 law. (See "Facilities Advised To Delay Collimation Changes Until Further Work," Spring 1998 *Mammography Matters*, page 4.)

"Our recommendation was to amend both sets of regulations to avoid having many facilities modify their equipment at great expense," said Monsees. FDA expects to resolve this issue before the April 28, 1999, effective date of the final MQSA regulations. In the meantime, FDA recently approved an alternative standard to the final regulations that will eliminate this conflict for many facilities. (See "A Big Step Forward on Collimation Issue," page 3.)

The committee also reviewed proposed inspection procedures under the final regulations and in the future plans to take up further discussions on digital mammography and interventional mammography. With respect to interventional mammography, the committee will be looking at whether regulation is needed or whether similar results can be achieved through non-regulatory means, including voluntary accreditation.

At any given time, the committee has between 13 and 19 members, who are invited to serve for overlapping terms of up to four years. Members are drawn from among physicians, medical physicists, radiologic technologists, and other health professionals with significant experience in mammography. At least four members come from national breast cancer or consumer health organizations with expertise in mammography.

National Mammography Quality Assurance Advisory Committee, Current Members, Summer 1998

Barbara Monsees, M.D.
Chief, Breast Imaging Section
Mallinckrodt Institute of Radiology
Department of Radiology

Peter Dempsey, M.D.
Director of Outpatient Radiology
University of Alabama

Laura Moore-Farrell, M.D.
Director of Breast Imaging
Holt-Crock Clinic

Patricia Hawkins, M.P.H.
Eldercare Consultant
Oklahoma State Department of Health Eldercare Services

Ellen Mendelson, M.D.
Chief, Women's Imaging
The Western Pennsylvania Hospital
Department of Radiology

Michael Mobley, M.S., M.P.A.
Director-Division of Radiological Health
State of Tennessee

Sandra Nichols, M.D.
Director Arkansas Department of Health

Robert Pizzutiello, M.S.
President-Upstate Medical Physics, Inc.

Edward Sickles, M.D.
Professor of Radiology
UCSF Medical Center
Department of Radiology

Patricia Wilson, R.T.
Chief Technologist
Biltmore Imaging Center

Roland Fletcher, M.S.
Manager-Radiological Health Program-ARMA
Maryland Department of the Environment

David Winchester, M.D.
Professor and Chairman, Dept. of Surgery
Evanston Hospital

Kambiz Dowlat, M.D.
Associate Professor of Surgery
Rush-Presbyterian-St. Lukes Medical Center
Department of Surgery

Carolyn Brown-Davis
Executive Director
Breast Cancer Resource Committee

Kendra McCarthy, M.A.
Director, Administration for State of Virginia
Department of Mental Health

Robert Nishikawa, Ph.D.
Assistant Professor of Radiology
Department of Radiology
The University of Chicago

Ivis Febus-Sampayo
Coordinator-Latina Project of SHARE

Final MQSA Rule

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to select views that will maximize visualization of breast tissue.

Related to this section is an additional requirement in the personnel section specifying that all technologists who begin performing mammography after April 28, 1999, must have training in performing mammography on patients with breast implants.

Consumer complaints

Another new area of regulation requires each facility to establish a system for resolving serious consumer complaints related to mammography services. A "serious complaint" is defined as a report of a serious adverse event that significantly compromises clinical outcomes, such as poor image quality or a failure to communicate results. (Please refer to pages 55977-55978 of the final regulations for definitions of "adverse event," "consumer," and "serious adverse event.")

The complaint system provides patients and their representatives with a mechanism to report what they believe to be seriously deficient mammography services, and gives them the opportunity to have their complaints heard, investigated, and resolved.

The interim regulations required facilities to post an address where complaints could be registered with the accreditation body and to maintain records of all complaints. The final rule takes this requirement further to require the development of a complaint mechanism. This means that each facility must establish its own written and documented system for collecting and resolving consumer complaints.

FDA recognizes that facilities can effectively address most consumer complaints. In the final rule, only serious complaints (as defined previously) that cannot be resolved by facility staff are referred to the accreditation body (and eventually to FDA).

Facilities should keep consumer complaint records as part of their patient recordkeeping and should handle consumer complaint records with the same care as other records.

Additional mammography review and patient notification

The last new requirement in the facility quality standards section addresses additional mammography review and patient notification. For cases in which FDA believes that mammography quality has been compromised, facilities must provide clinical images and other relevant information for review by an accreditation body. This additional review will help FDA determine if serious conditions exist at a facility that would endanger public health such that notification of patients and their referring health providers is needed.

Facilities should note that FDA views patient notification as an infrequently used, cooperative action — not a first-line step — reserved for severe public health risks.

For example, patient notification may be warranted in cases where diagnoses of possible malignancy may have been missed due to grossly inadequate performance. Patients, their designees, health care professionals, or the public may have to be notified so that they may take appropriate action.

McCrohan Succeeds Houn

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mammography continued with the Nationwide Evaluation of X-ray Trends (NEXT) program that assessed the practice of mammography in 1985, 1988, and 1992. He has also served on numerous committees related to mammography under the auspices of the American College of Radiology, the Conference of Radiation Control Program Directors, and the National Council on Radiation Protection and Measurements.

In 1997, McCrohan received the prestigious Stanley J. Kissel, Jr. Award as PHS's Health Service Officer of the Year.

"Under Dr. Houn's leadership, DMQRP helped improve the quality of mammography in the United States," said McCrohan. "Her drive and determination in building DMQRP helped set a standard of documented success of which we're all very proud. As Dr. Houn moves on to new challenges, I look forward to continuing DMQRP's partnership with facilities in the mission of improving mammography, particularly as we prepare for implementing final MQSA regulations next year."

MQSA Compliance Checklist

When the final MQSA rule takes effect April 28, 1999, will your facility be in compliance? Don't wait until the last minute to address possible changes. Some standards in the final regulations may require weeks if not months to put into effect. The following checklist illustrates some examples of items that may require additional planning to ensure compliance. They also represent significant additions or changes from the interim regulations under which facilities have operated since December 1993.

Final Rule Section	Subject	Issue
§900.12(a)(2)	RTs' continuing experience requirements	RTs must perform a minimum of 200 mammographic examinations during a 24-month period.
§900.12(a)(4)	Retention of personnel records	Each facility must maintain records to document all of the qualifications of mammography personnel and make the records available for review by MQSA inspectors for as long as an individual is employed at the facility and until the next inspection after the employee leaves the facility. **Do not prematurely discard any records.**
§900.12(b)(3) through §900.12(b)(15)	Equipment	The final rule adds 13 equipment requirements. **Take the time now to compare your equipment against these standards.** FDA urges facilities to review these requirements carefully in consultation with the medical physicist responsible for conducting their annual survey. As an example of equipment problems that should be identified early to allow maximum time for correction, some facilities are finding it difficult to ensure that the tube-image receptor assembly is capable of being locked in any intended operating position and that the lock mechanism will not fail in the event of a power failure.
§900.12(c)	Reporting and Recordkeeping	Facilities must: • Establish a system to ensure the communication of mammography results to the patient.

		• Maintain a system to refer self-referred patients to a health care provider when clinically indicated. • Transfer original mammograms, not copies, during temporary transfers.
§900.12(e)	Quality Assurance — Equipment	Facilities must: • Perform weekly phantom image tests. • Ensure the calibration of air kerma (exposure) measuring instruments. • Establish and use infection control procedures.
§900.12(f)	Quality Assurance — Mammography Medical Outcomes Audit	Facilities must: • Conduct an audit analysis of outcome data for each physician and for the entire facility. • Conduct the audit analysis once a year. • Designate one interpreting physician to review the audit data every 12 months and communicate the results of the analysis to all physicians at the facility.
§900.12(g)	Procedures and Techniques for Patients with Breast Implants	Facilities must: • Inquire whether a patient has breast implants before the exam. • Perform mammograms on patients with breast implants that maximize visualization of tissue.
§900.12(h)	Consumer Complaint Mechanism	Facilities must: • Establish a written and documented system for collecting and resolving consumer complaints. • Maintain records of each serious consumer complaint for three years. • Provide directions for consumers to file serious complaints with the accreditation body. • Report unresolved serious complaints to the accreditation body.

On the Go:
Mobile Units and MQSA

As facilities become more familiar with the final MQSA regulations, there may be many questions regarding mobile mammography units. What's unique about operating a mobile unit? How does the final rule affect the operation of mobile units? Does the rule require anything that is specific to mobile units? If so, do the regulations provide guidance as to how these requirements should be met? Where can operators of mobile units go for more information?

Articles in this and the next issue of *Mammography Matters* focus on the operation of mobile units under MQSA, with some specific and unique examples.

Mobile units defined

MQSA defines "facility" as any setting or entity, including a mobile mammography unit, that performs any of the following mammography-related activities: operates equipment to produce a mammogram, processes mammograms, provides the initial interpretation of mammograms, and/or maintains viewing conditions for interpretation of mammograms.

An estimated 380 mobile mammography units operate in the United States. A survey conducted by the American College of Radiology (ACR) and the Centers for Disease Control and Prevention (CDC) found that 46 percent of mobile units were owned by hospitals, 20 percent were owned by radiologists or radiologic technologists, and 17 percent were owned by other entities such as the government or a corporation. An additional 17 percent of the units were leased or owned by more than one group or organization.

The day-to-day operation of mobile mammography units can vary considerably. In the most common setting, the mobile unit, which is based at a central site, travels to one or more satellite sites, where the technologist takes mammograms. The central site processes the mammographic films, sometimes several days later. In this case, all films are put in a "black bag," which shuts out light; films are kept in the bag until processing. This is referred to as batch processing. In this scenario, the central site keeps, at the very least, the units' quality assurance/quality control (QA/QC) records.

The final regs require mobile units to perform an equipment check every time the unit is moved and before any patient examination is done.

In contrast, a mobile unit may function as a self-contained operation; that is, the technologist takes the mammograms, processes the films, and keeps the records. Thus, processing is done "on board." In a third, less common scenario, each examination site — whether a central or a satellite site — processes all of its own films and keeps all of its own records.

In more complex settings, mammography-related activities are split between the mobile unit and the site where the mobile unit "parks," such as a small hospital that has a radiology department and x-ray machines but doesn't have a mammography unit. In this scenario, the mobile unit provides the technologist who performs the mammography examinations, while the hospital staff does patient intake and film processing and provides the interpreting physician. Thus, both the mobile unit and stationary site serve as "partial providers" of mammography services.

Filling a gap: Increasing access through mobile units

One primary goal of mobile mammography is to increase access to screening for breast cancer, especially among underserved, uninsured, and underinsured women and women in rural locations. Mobile units strive to achieve this goal through a variety of strategies. For example, mobile units usually provide lower cost exams and accept a higher number of self-referred patients than stationary or hospital-based units. Mobile units also increase availability of screening by going to places where women are — work sites, health clinics, community centers, health fairs, shopping malls and centers, places of worship, retirement homes and centers, and city streets.

The ACR/CDC survey found that two-thirds of mobile units performed only screening mammography, with nearly all of the remaining units performing both screening and diagnostic mammography. The mobile units in this survey operated at a high volume, performing an average of 20 mammograms per day.

Special challenges

Providing mobile mammography services is distinct in many ways from that in stationary facilities. Mobile unit operators and staff face a variety of issues that are of little or no concern to those running non-mobile units. Some of these issues include: following local parking and related regulations, patients follow up, onboard or batch film processing (with associated unique quality control problems), availability of equipment compatible with the mobile setting, environment and changes in seasons and weather, and sometimes very limited space for record storage.

Processing is a significant issue for mobile units. For example, with onboard processing, technologists can check the quality of the images produced onsite and obtain supplemental views at the time of the initial exam. Onboard processing also can reduce patient recalls and eliminate latent image fading, which can occur with batch processing when films are not processed for some time. On the other hand, units that do onboard processing have specific space requirements and must accommodate for mixing, spillage, and disposal of chemicals. These and other factors contribute to the added expense of running a unit with onboard processing.

Perhaps the greatest challenge associated with mobile mammography, however, is controlling the internal environment, especially in the face of extremes and/or changes in climate. Maintaining ambient temperature, humidity, and ventilation is critical to producing high-quality images consistently. Processing and other equipment used in mammography-related activities are very sensitive to environmental changes. Because of this sensitivity, some equipment is incompatible with mobile mammography, and equipment that is onboard must be monitored more frequently (and adjusted accordingly) than units at fixed sites. Such issues form the basis for the additional equipment checks required of mobile units under the final MQSA regulations.

What's new under the final MQSA rule

Prior to implementation of MQSA, the ACR had a voluntary program for accrediting each mammography unit. Under MQSA, the FDA conducts inspections and provides for certification of all mammography facilities, including mobile units.

MQSA states that requirements under the rule are universal to all units, whether fixed or mobile. Thus, for all intents and purposes, mobile units must meet the same criteria and the same standards as fixed units. **In addition, after the final regulations become effective on April 28, 1999, equipment checks must be performed on mobile units *every* time the unit is moved and before any patient examination is done.** Under this new quality assurance directive, a mobile unit operator is required to verify the performance of each unit to ensure that it produces adequate quality images. The final rule does not specify which test or tests to use to verify performance and leaves this decision to the unit's operator. However, FDA will be issuing guidance describing some acceptable methods. This change from the interim MQSA rule was made in response to reports from mobile operators that moving the location of their unit(s) sometimes caused problems in the quality of the mammograms produced.

Meeting the new requirement: Inspection and certification

Mobile units follow the same guidance as stationary facilities in meeting requirements for inspection and certification, with the additional equipment QC checks for mobile units, as described above. Inspections of mobile units do often require extra time and effort, however, and usually must be scheduled well in advance, requiring a high level of coordination among staff and inspectors.

Most complex are situations where mammography activities are split between the mobile unit and another group or facility. Often, explains FDA's Mike Divine, who specializes in MQSA compliance issues, the mobile units are the only certified mammography facility and, as such, are legally responsible for all mammography-related functions. Sometimes, the non-mobile site, such as a small hospital without mammography radiology equipment, certifies jointly with the mobile unit. In yet another scenario, both the mobile unit and its "partner" site are certified.

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Q & A

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

Q I submitted a question to FDA requesting clarification of a point under the final regulations but have not received an answer yet. In the past FDA has responded quickly to my questions. Why haven't I heard anything yet?

A Please be patient. Your question concerns an area in which guidance is currently being developed. Before the guidance is implemented, facilities will have a 90-day period to review and submit comments regarding the proposed guidance. The notice of the availability of the proposed guidance will be published in the *Federal Register* this summer, and the document itself will be available on the website (http://www.fda.gov/cdrh/dmqrp.html) and by mail. Submit your request by fax to 301-986-8015 or by mail to MQSA, c/o SciComm, Inc., P.O. Box 30224, Bethesda, MD 20824-9998.

Q Does FDA plan to distribute a poster or notice for facilities to display that informs patients with serious complaints, that cannot be resolved by the facility, about how to report those problems? If not, should facilities provide such notices?

A No. Although the final regulations provide a complaint mechanism, there is no requirement for facilities to post a sign or notice with instructions about registering consumer complaints. However, as a public service, facilities may wish to do so. Complaints that cannot be resolved at the facility should be forwarded to the facility's accreditation body. Facilities should provide consumers with instructions for filing complaints with the facility accreditation body. Also, the name and address of the accreditation body is listed on each facility's certificate, which must be prominently displayed.

Q The final regulations require training in each mammographic modality used by a physician, technologist, or physicist. Would you please clarify what is meant by mammographic modality? Only screen-film and xeromammography are mentioned as examples; what about MRI and ultrasound?

A Mammographic modality is defined as a technology used for radiography of the breast, which falls under MQSA authority. Since MQSA authority is limited to imaging with x-rays, MRI and ultrasound are not included; therefore personnel who use those modalities do not have to have training with them in order to meet MQSA requirements.

Q Since hardly anyone works with xeromammography any more and MRI and ultrasound are exempt, doesn't this really mean that, at present, most personnel only have to have training with screen-film systems?

A That's right. This further means that the specific mammographic modality training requirement will automatically be met while meeting the general initial training requirement. It will also be met for the continuing education requirement as long as 6 of 15 hours is with screen-film systems. But should another mammographic modality become accepted in the future (digital mammography seems the most likely candidate), personnel will have to receive additional training with that mammographic modality before they can lawfully begin to use it independently.

Q & A *(continued)*

Q I am giving a talk on the final regulations at an upcoming meeting. Does FDA have any materials that would help me prepare my speech?

A Yes. FDA has produced an *MQSA Final Regulations* Speaker's Kit consisting of a speech, slides, overheads, and additional background information in slide and overhead formats. Speakers may borrow these kits (pending availability) for a 30-day period at no charge. Submit your request by fax to 301-986-8015 or by mail to MQSA, c/o SciComm, Inc., P.O. Box 30224, Bethesda, MD 20824-9998. Be sure to include your name, organization, full address, phone and fax numbers. A copy of the speech is also available on FDA's website at http://www.fda.gov/cdrh/dmqrp.html.

Mobile Units

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At the very least, says Divine, the entity providing the technologist and the mammography unit must be certified. These situations present a unique challenge to inspectors, who must inspect the entire process. With joint certification, the inspection must be coordinated, and the two facilities and their staff and equipment must be available at the same time.

For more information . . .

Operators of mobile units can turn to a variety of resources for more information and assistance. Facilities and operators may want to access information on the Internet (www.fda.gov/cdrh/dmqrp.html) or call the facility telephone hotline (1-800-838-7715) for clarification of or guidance regarding the final regulations.

FDA Accepts Three More Training Courses

FDA has recently accepted successful completion of three more mammography-specific courses as meeting the technologist initial training requirements, even though they are less than 40 hours in length. The courses are:

Achieving Quality Images: 3-Day Mammography Seminar, provided by Achieving Quality Images of East Grand Rapids, Michigan at 1-800-522-3439.

Mammography, provided by Rose State College of Midwest City, Oklahoma. Contact Jo Bishop at 405-733-7569.

Initial Mammography Training, provided by Mammography Accreditation Consultants, Rock Hall, MD. Contact Judith Hagerty or Gerry Lockwood at 1-800-570-2511.

For more information on meeting this requirement, as well as other course listings, see *Mammography Matters*, Spring 1996, Fall 1996, and Spring 1997.

Address Change Reminder

Facilities must notify their ACCREDITATION BODY of any changes in their mailing address information, such as new contact person, change of address, or change of facility name.

FDA relies on the address information provided by the accreditation bodies and **cannot** change or modify a facility's address.

Failure to notify your ACCREDITATION BODY of any address changes may result in you're not receiving important MQSA mailings such as *Federal Register* notices or *Mammography Matters.*

Name and Address Changes:

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

Otherwise submit your address changes to: MQSA, c/o SciComm Inc., P.O. Box 30224, Bethesda, MD 20824-9998. Fax 301-986-8015.

Accreditation, Certification, and Commercial Products

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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ROUTE THIS ISSUE OF *MAMMOGRAPHY MATTERS* TO YOUR FACILITY'S:

☐ Mammographer
☐ Mammography Technologist
☐ Quality Assurance Staff
☐ Medical Physicist
☐ Administrator
☐ Other_____