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

Mammography Matters

Winter 2000 Volume 7, Issue 1

Full Field Digital Mammography Approved for Use in MQSA-Certified Facilities

On January 28, 2000, FDA approved the Senographe 2000D Full Field Digital Mammography (FFDM) system for marketing. ~~and immediate use in facilities that are MQSA screen-film certified~~. [Correction: Only facilities that are screen-film certified **AND have specific FDA approval to use digital mammography on patients** may lawfully use an FFDM system. If you plan to purchase or install an FFDM system, please refer to http://www.fda.gov/cdrh/mammography/digital.html to find out how to extend your MQSA certification to include FFDM.] Developed by General Electric, this is the first approved full field mammography system that produces digital images using a solid-state receptor, in contrast to analog images currently produced on radiographic film.

"Digital technology may enhance a woman's mammography experience by reducing the need for additional exposures and allowing for easy transfer of images—a real benefit to highly mobile patients," noted DMQRP Director John McCrohan.

As of January 28, 2000, the Senographe 2000D falls under the jurisdiction of the MQSA final regulations. At the present time, accreditation bodies are developing a process for accrediting FFDM units. Until further FDA notice, FFDM units are exempt from MQSA accreditation requirements.

To use an FFDM system lawfully, a facility must maintain its accreditation status for at least one screen-film system. The facility is subject to an annual on-site MQSA inspection of its FFDM system at the same time its screen-film system(s)

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Notice: Last Issue!

This is the last issue of Mammography Matters that FDA will print and distribute. Starting with the Spring 2000 issue, FDA will publish an electronic version of the newsletter, which you can access on the website at http://www.fda.gov/cdrh/mammography. You may also join FDA's Mammography e-mail ListServ (see "What's New" on the website) to receive newsletter highlights and other notices.

What's Inside

From the Director . . .

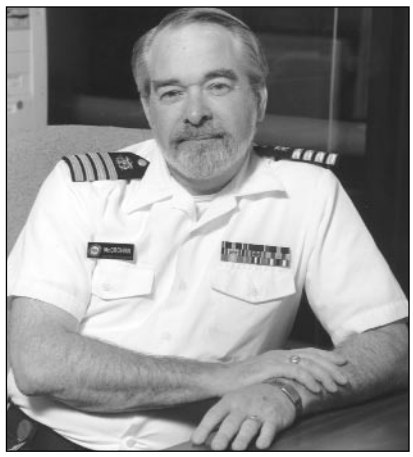
With the FDA approval of General Electric's Senographe 2000D digital mammography system, we have taken another step foward in the fight against breast cancer (see story, page 1).

Women having their mammograms done with a digital system will have essentially the same experience as they have now with screen-film mammography, and interpreting physicians will read hard copies of the digital images as they now read screen-film images. However, digital systems could reduce the need for some women to have additional exposures, while allowing interpreting physicians to quickly and easily exchange digital images. As effective as screen-film mammography in detecting breast cancer, digital mammography promises to enhance mammography through these additional benefits.

Which facility can use the newly approved full field digital mammography system? Any facility accredited under MQSA for at least one screen-film system can add a digital mammography unit. To then extend MQSA certification to include use of a digital system, facilities must provide FDA with required system information. ~~but—we are pleased to announce—they may use the digital system while this information is under review (as would be the case if they added a new screen-film unit).~~ Please refer to http://www.fda.gov/cdrh/mammography/digital.html to find out how to extend your MQSA certification to include FFDM.

Interpreting Physicians: Worlds Apart

Being able to quickly retrieve and exchange digital images may provide significant advantages for interpreting physicians whose practices range from work in remote locations to those in busy suburban settings. In this issue, we feature two interpreting physicians who capture both ends of that spectrum (see story, page 4).



Hans Tschersich, M.D., and Leora Sachs, M.D., offer a fascinating contrast in locale and day-to-day work in mammography. Tschersich works in the remote, untamed outdoors of Alaska, while Sachs practices in a high-volume HMO in the Washington, DC metropolitan area. Both are dedicated to the health of their patients and MQSA's mission of improving the quality of mammography for everyone. We commend them for their service.

MQSA Inspection Results under the Final Regulations

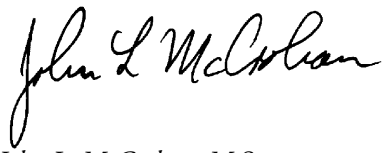
FDA has been conducting inspections under the final regulations since July 1999, when our new MQSA inspection software was ready to use (see story, page 8). Although "serious" and "moderate" non-compliance findings have increased since we implemented this software, this increase largely reflects a few new requirements as well as changes in the non-compliance levels of a number of older requirements.

We are confident that the number of citations will decrease as all of us in the mammography community become more familiar with requirements under the final regulations. More important, we applaud the efforts of facilities and MQSA inspectors in making compliance with the final regulations a reality.

Farewell

Finally, I want to express my gratitude to Carole Sierka, the founding editor of Mammography Matters. *Carole retired from government service in December 1999, after working with FDA for more than 15 years. She brought extraordinary competence and good cheer to the task of managing our outreach activities, and she will be sorely missed.*

Evelyn Wandell, production manager of Mammography Matters, *takes over as editor with this issue. We are confident that this publication will continue to provide facilities and interested parties with MQSA information in a timely and accessible manners.*



John L. McCrohan, M.S.
Director, Division of Mammography
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MammographyMatters
Winter 2000

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/mammography.html**

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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.

MQSA Information Available on Website

FDA recently upgraded its Mammography Program website (www.fda.gov/cdrh/mammography) to increase its usefulness to mammography facilities and the general public.

A core element of the website is the Policy Guidance Help System (PGHS) – a multi-document search engine providing FDA's current thinking on the final regulations that implement the Mammography Quality Standards Act (MQSA). The PGHS is regularly updated to incorporate newly approved guidance documents.

How do MQSA regulations and MQSA guidance differ? The regulations, effective April 28, 1999, are national quality standards for mammography services. Written by FDA, the regulations are based on MQSA of 1992 and the Mammography Quality Standards Reauthorization Act of 1998. They have the force of the law. Words such as shall, must, and require are used when stating statutory or regulatory requirements.

MQSA guidance, in contrast, interprets MQSA regulations and addresses compliance issues through a question and answer format. The guidance is meant to help facilities comply with the regulations, but does not have the force of the law. As guidance, it is intended to guide, not mandate, and facilities may identify other ways of meeting MQSA requirements.

The PGHS is organized by main topics. Each topic includes a list of subtopics containing guidance documents. Many of the subtopics begin with the regulatory citation related to the selected topic, followed by questions and answers offering guidance on how to comply with the regulation. Each topic concludes with a menu of linked key words and/or related topics, allowing the user a convenient path for pursuing related information.

Users also can download the current version of the PGHS for off-line reference. It is important, however, to check the website regularly to ensure that the off-line version that appears is the most recent available. The "last updated" information is on the PGHS Introduction page.

Other website news

Beginning with the Spring 2000 issue (Volume 7, Issue 2), the website will also offer a new electronic format of *Mammography Matters*. FDA has created an automated e-mail address list to notify subscribers when each new issue becomes available on-line and to disseminate other FDA announcements. A simple form, within the What's New and Publications section of the website, will allow users to subscribe to the e-mail notification list.

The new website also will include an updated FDA speech, "The Final Regulations with Inspection Guidance," and PowerPoint slides for use by anyone giving a presentation on the final regulations. The speech may be tailored to audience needs and ensures that a speaker can present information that is consistent with FDA's MQSA program. The speech and slides can be downloaded on-line from the website's Publications page.

From Alaska to Virginia

Interpreting Physicians' MQSA and Clinical Experiences

Interpreting physicians Hans Tschersich, M.D., and Leora Sachs, M.D, share a common profession but have widely different day-to-day experiences—largely defined by the location of their facilities. Tschersich, a native of Germany, lives and works on Alaska's Kodiak Island, where he reads roughly 600 mammograms a year at Providence Kodiak Island Hospital. Although that number is "rapidly increasing," Tschersich reports, it is far below the high-volume 3,500 mammograms that Sachs, a native New Yorker, reads annually at Kaiser Permanente in suburban Falls Church, Virginia.

Hans Tschersich, M.D.

Leora Sachs, M.D.

The images each facility evokes highlight their differences: The Kodiak Island hospital stands sentinel in the North Pacific, 300 miles from the nearest medical center, whereas Kaiser Permanente's Falls Church office is surrounded by the explosive residential and commercial growth of Northern Virginia.

The day-to-day experiences of each interpreting physician differ as well. For example, Tschersich defines his work as "general diagnostic radiology in a small rural hospital." Despite its remote location, "it is a new spacious facility with up-to-date equipment," he explained. Its distance from the nearest, larger medical center has helped ensure that it is well-staffed and equipped to deal with a wide variety of medical problems.

In addition to meeting the radiologic needs of the island's nearly 10,000 permanent residents, Tschersich and other facility staff work with an extremely mobile cosmopolitan population and the commercial fishermen injured in the region's many industrial accidents. And, he noted, the mobility that characterizes many of his patients makes it difficult to quickly get prior studies for comparison, especially for mammography patients. Nevertheless, for those mammography patients who make Kodiak Island their year-round home, Tschersich said, "It is easy to track them down if additional views and ultrasound exams of suspicious findings are needed."

In contrast, Sachs meets the needs of mammography patients through a large HMO facility, in which over 80 percent of its eligible members undergo routine screening. Moreover, with ready access to surgical data, Sachs and her peers are able to correlate their findings in almost all of their surgical patients. "As a multi-specialty group," she explained, "we have rapid and free communication with internists, surgeons, and pathologists, leading to a high level of cooperation and coordination of patient care."

Impact of MQSA

When asked about the impact of MQSA regulations on their practices and facilities, additional differences emerged in Tschersich's and Sachs' experiences. For example, in commenting on the need to document continuing experience, Sachs was brief. "Continuing medical education has always been documented, so this has not had significant impact."

The isolation that characterizes

Kodiak Island and that Tschersich treasures, however, adds a different twist to the impact of documenting continuing experience. Although he has not yet had difficulty documenting his continuing experience as Kodiak Island's sole radiologist, Tschersich noted that this requirement has limited the availability of relieving physicians.

"The increasing specialization of the younger physicians, who often don't practice mammography, and the limitation of older radiologists' practices will make it increasingly harder for radiologists in small facilities like mine to find properly credentialed locum tenens relief. This may make it harder to continue providing mammography services," he continued. "Credentialing in other areas, like ultrasound, will further complicate my situation," Tschersich added.

Medical outcome audits

Sachs and Tschersich noted different experiences regarding MQSA's requirement to conduct medical outcome audits. Having a group-practice model in place, Sachs said, makes it easy to do medical outcome audits at her facility, because radiologists have ready access to pathology reports. If anything, she continued, "This has been an interesting and thought-provoking experience." For example, through conducting medical outcome audits, "We have found that in our population, the highest cancer incidence is in our 40-50 age group, rather than the published over-50 age group," she explained.

Tschersich's experience in complying with the medical outcome audits regulation has been equally interesting—but for very different reasons. "Outcome audits are hard to conduct in small facilities with a small case load. Many suspicious cases are worked up somewhere else and results can be difficult to track down."

Even with MQSA in place, each interpreting physician was asked to suggest what facilities could do to further improve their practices. Both Tschersich and Sachs concurred that most facilities now practice excellent mammography. Tschersich credited MQSA with this excellence, noting that, "The quality of mammography has remarkably improved, thanks to MQSA and the associated attention to the quality of imaging and interpretation."

Tschersich continued, "Enforcing the use of diagnostic codes [for reporting mammography results] is very beneficial—but not always adhered to. It will take more monitoring and prodding to get recalcitrant practitioners in line. I am all for that." He described his vision of what he would like to see happen with small facilities. "Small facilities like mine should set up a pool of practitioners for double reading and frequent referral for consultation. The absence of another radiologist for a quick 'curb stone' consultation is one of the major drawbacks in my solo practice."

Sachs' response addressed the challenges many facilities still face. "Global problems remain," she explained. "Many women still do not undergo screening mammography and more effort is required to educate patients. Additional problems exist, for all facilities, in obtaining prior mammograms for comparison. Patients switch health insurance plans frequently and often do not remember where previous studies were performed."

Advice for patients

Beyond the challenges and opportunities facing facilities, what would Drs. Tschersich and Sachs advise women to expect from their facility and interpreting physician? Despite the differences in their facilities and their day-to-day mammography

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Bios on Featured Interpreting Physicians

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Mammography Today

FDA has prepared a consumer brochure for mammography patients and we encourage you to share this information with them (see **partial** text below and a PDF file of the complete brochure on our website). Although past brochures have effectively explained the importance of mammograms and the procedure itself, this brochure takes a different approach. It discusses consumer rights that are guaranteed for every woman under MQSA: having a high-quality mammogram in a certified facility, receiving exam results, obtaining original x-rays, and addressing their mammography concerns.

We are seeking organizations to partner with us in distributing this much-needed information. We encourage your response to the text and ideas on partnering and distribution. Please contact Pat Hoage, at pah@cdrh. fda.gov, or call 301-594-3332.

How can I be sure I'm getting a high-quality mammogram?

The Mammography Quality Standards Act (MQSA) is a federal law that makes sure every mammography facility meets quality standards. Mammography facilities include breast clinics, radiology departments in hospitals, mobile vans, private radiology practices, and other doctors' offices. FDA ensures that facilities all around the country meet MQSA standards, which apply to the following people at your facility:

- the technologist who takes your mammogram
- the radiologist who studies your mammogram
- the medical physicist who tests the mammography equipment.

To work in mammography, these professionals must have special training and education. In addition, because technology is always improving, they must keep up with any changes through ongoing education. MQSA also ensures that mammography equipment is tested regularly and maintained to operate properly.

Look for the MQSA certificate at your mammography facility. The certificate means that the facility has to undergo regular inspections to meet quality standards.

It's good to know that FDA protects me by regularly inspecting my facility. What happens if problems are found during an inspection?

Most facilities practice high-quality mammography and pass their inspections. If a problem were found during an inspection, the MQSA inspector would tell the facility what needs to be corrected so that it can pass inspection and continue to provide high-quality mammograms. Minor problems found at a facility often can be easily fixed.

Rarely, an inspector finds a more serious problem that could affect the quality of mammograms and their results. If this happened with your facility, for example, your facility or FDA would contact you and your doctor and suggest what you should do. You may need to have your mammogram repeated.

This information gives me confidence about the quality of my facility. How else does MQSA help me?

The law also aims to improve communication between you and your facility. As a result of MQSA, your facility must:

- ask if you have breast implants before performing your mammogram
- send you your mammogram results
- transfer your original mammograms upon your request to you or to a facility or doctor you specify
- address your concerns.

From the time you make a mammogram appointment to the time you get the results, you should understand what is happening and be sure that your questions are answered. The more you know, the better you can care for your own breast health.

What if I have breast implants?

When you call your facility to schedule a mammogram, tell them that you have breast implants. If your facility doesn't accept patients with implants, ask if they can give you the name of a facility that does. When you arrive for the exam, remind facility staff you have implants and will need a technologist trained in x-raying patients

with implants. This is important because breast implants can hide some breast tissue, which could make it difficult for the radiologist to see breast cancer when looking at your mammograms. If the technologist taking your mammograms knows you have implants **before** performing the exam, she will make sure that as much breast tissue as possible can be seen on your mammograms.

How will I get the results of my mammogram?

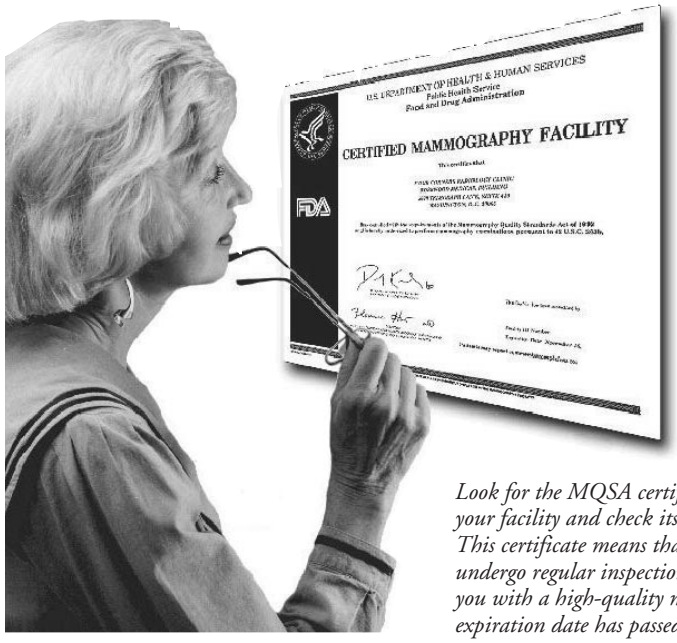
Your facility will give you the results of your mammogram in easy-to-understand language. It will give you these results at the time of your appointment or may choose to mail the results. If mailed, the letter containing your results must be sent within 30 days of your mammogram. The facility also will send your doctor a medical report of your mammogram results.

I thought "no news was good news." Wouldn't my doctor let me know if there was a problem?

Although the results of most mammograms are normal, don't assume that no news means that there are no problems. It is very important that you get the results of your mammogram. If you don't receive them within 30 days of your mammogram, call your mammography facility or doctor and ask for them.

If I don't have a doctor, who receives the medical version of my report?

In this case, your facility will send you both reports of your mammogram results—the version in easy-to-understand language and the medical version. If your facility thinks you should see a doctor, its staff will let you know and can recommend one.



Look for the MQSA certificate displayed at your facility and check its expiration date. This certificate means that your facility has to undergo regular inspections and should provide you with a high-quality mammogram. If the expiration date has passed, tell facility staff.

If I change facilities or need a second opinion, do I need my mammograms?

Yes, but be sure they are originals—not copies. By law, you are entitled to your original mammograms. A doctor needs to compare past mammograms with current ones to see if there have been any changes, and original mammograms are needed for this comparison. Ask your facility for your original mammograms and for a copy of the medical version of your report. You will probably be asked to fill out a form to release your medical records. You can ask the facility to send your records to another medical facility, to your doctor, or to you. Your facility may charge a fee for this service. If they do, it must not exceed the cost of providing this service.

I am on a regular schedule for mammograms and I do monthly breast self-exams. What if I notice a change in my breasts?

Although mammograms are very effective, they don't find all breast problems. If you find something unusual in either breast during your monthly breast self-exam (such as a lump, a thickening, or discharge from a nipple), call your doctor immediately. When checked, many breast changes are not cancerous—but only your doctor can know for sure.

What if I have a concern about my exam or facility?

If you have a concern about your exam or facility that you think could affect your health, follow these steps:

- Talk with a facility staff person. If he or she can't help you, you will be told who on their staff can address your concerns.

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Inspection Results under the Final Regulations: The First Six Months

On July 6, 1999, FDA implemented the new version of its MQSA inspection software, allowing the Agency to conduct MQSA inspections under the final regulations. Since implementation of this software, the number of facilities with the most serious findings ("level 1") and those with moderate findings ("level 2") has increased. The number of facilities with only minor findings ("level 3") and with "no findings" has decreased.

Several factors explain these changes. First, after five years' experience under the interim regulations, FDA decided to "raise the bar" in quality standards in the final regulations. Thus, the Division of Mammography Quality and Radiation Programs changed the threshold values for many level 3 and level 2 citations to level 2 and level 1 citations, respectively. Consequently, the number of level 2 and level 1 findings increased for film processing, quality control (QC) records, and the survey report requirements.

Second, FDA introduced new requirements for consumer complaints, infection control, mammography report assessment categories, and communication of results to patients. Thus, findings in these areas also increased.

Third, although FDA designed the new inspection software to capture all changes under the final regulations, it did not design it to capture the dates or the period when some daily or weekly QC records were missed. Because inspections in the first year under the final regulations include QC records generated under both the interim and the final regulations, the new software incorrectly generated citations under the final regulations for QC actions that occurred before April 28, 1999. Despite FDA's efforts to avoid erroneous data entries, several such entries were made, resulting in inappropriate citations.

FDA expects citations to decrease as the mammography community becomes more familiar with the requirements under the final regulations.

Finally, during the transition to the new inspection software, several erroneous citations resulted from changes in how inspectors can update data on unit accreditation status. As the new software was being implemented, unit accreditation data, which is automatically transferred from an accreditation body's database into FDA's database, was sent to inspectors as part of the facility inspection record. Prior to implementation of the new software, inspectors had been able to create and update this data even though it had not been automatically sent to them. Confusion resulted when the new software did not allow inspectors to do this updating, as they were not used to checking data on unit numbers and accreditation status before determining which units were "in use" at a facility. This resulted in many erroneous "unit not accredited" citations.

In response to the sudden increase in level 1 citations last September, FDA developed a program to identify questionable citations and correct erroneous ones. Most of the erroneous citations issued during inspections conducted in the first six months under the new inspection software have been corrected. DMQRP expects to continue this reconciliation process through May 2000. To complete this effort, FDA will notify all affected facilities about these corrections in the near future.

Despite the increase in citations, the inspection results under the first six months of the new inspection software are similar to results generated during the first year of inspections under the interim regulations. FDA anticipates a gradual decrease in the number of facilities cited at all levels, as the mammography community becomes more familiar with the requirements under the final regulations.

FDA Publishes Draft Guidance Document #3

On December 8, 1999, FDA published Draft Guidance Document #3 on its website (http://www.fda.gov/cdrh/mammography) and announced its availability in the *Federal Register.* As with Guidance Documents #1 and #2, the public may submit comments and suggestions on the proposed guidance over a 90-day period.

As discussed in the Fall 1998 issue of *Mammography Matters* (Volume 5, Issue 4), the MQSA guidance that FDA issues follows the Good Guidance Practices (GGP) protocol. In essence, FDA receives questions from the mammography community, develops and publishes proposed guidance, receives and evaluates comments from the public, and finalizes the guidance. The approved guidance is then published as a final document on the Guidance page of the FDA Mammography website. The guidance is also incorporated into the Policy Guidance Help System. The draft guidance issued in Documents #1 and #2 has been finalized and those documents are available on the website along with the updated Policy Guidance Help System.

In one instance in Draft Document #3, FDA has departed from its normal pattern of stating an issue and presenting the proposed guidance and is specifically requesting comments from the public. The issue concerns the fine adjustment compression control (under 900.12(b)(8)(i): Equipment, Application of compression).

> ***Question:*** *With machines such as the GE 500T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement?*
>
> ***Answer:*** *The intent of this regulation is to provide a predictable, controlled incremental adjustment that can be used for final patient positioning and customization of compression. The Agency has received differing opinions about whether tapping the compression foot pedal produces this type of fine adjustment. Through this document, FDA is soliciting additional public comment before making its final decision on this requirement which becomes effective in the year 2002.*

"This is only one of many issues covered in Document #3 that can have an impact on how facilities conduct their business," says Charles Finder, M.D., Associate Director of the Division of Mammography Quality and Radiation Programs. "Interested parties should review the document and send us their comments."

The draft guidance in Document #3 addresses issues in the following categories: Inspections – General; Definitions; Personnel – General; Interpreting Physician; Radiologic Technologist; Medical Physicist; Equipment; Medical Records; Quality Assurance – General; Quality Assurance – Records; Quality Control Tests – General/Other Than Annual; Quality Control Tests – Annual; Medical Physicist's Annual Survey; Mammography Medical Outcomes Audit; and Consumer Complaint Mechanism.

You may obtain a copy of the draft Document #3 from the FDA mammography website (see above) on the Guidance page or from the CDRH Facts on Demand at 1-800-899-0381 using a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt, press 2. Then enter the document number 1496 followed by the pound sign (#). Follow the remaining voice prompts to complete your request. Longer documents are usually faxed after normal business hours.

Q & A

The following questions and answers come from FDA's Policy Guidance Help System, part of the Mammography Program website (www.fda.gov/cdrh/mammography) to help facilities comply with MQSA regulations. People with questions about MQSA guidance should refer to the Help System for approved FDA answers. FDA welcomes any questions about MQSA or its Mammography Program.

Q Can experience obtained in a Veterans Administration (VA) facility count towards meeting the continuing experience requirement?

A Yes. Experience obtained in VA facilities can be used to meet the continuing experience requirement. VA facilities are recognized by MQSA in that they operate under rules that are substantially equivalent to MQSA, are accredited by FDA approved accreditation bodies, and undergo annual inspections performed by MQSA inspectors.

Q Concerning motion of tube-image receptor assembly, could you clarify what is meant by the statement that the mechanism "shall not fail in the event of power interruption"?

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

The system must prevent motion until the operator determines that such motion is acceptable. Depending on the circumstances in each facility, the time required for the operator to safely remove the patient from the unit may vary. Therefore, the length of time required for the system to remain locked in place will also vary. However, removing the patient from the unit can usually be accomplished in a minute or less. Note: systems that lack built-in mechanisms to prevent unintended gantry motion may meet the requirement using external battery backup or mechanical mechanisms that prevent unintended motion for the amount of time it takes to remove the patient from the machine.

Q Our mammography exams are interpreted off-site. Do we need to have a viewbox, hot light, and masking materials on-site?

A No. Facilities are required to have these items where the exams are interpreted, but are not specifically required to have them where the exams are produced. However, FDA recommends that the above items be provided to the technologists as an aid in performing their duties.

Q What documentation should I get when a patient, or an individual acting on the behalf of the patient, or the patient's physician requests the release of the patient's records? How long should I keep this documentation?

A Facilities should request that the patients, physicians, or individuals acting on behalf of patients sign a release form, or submit a written release request; however, if the facility chooses to accept oral transfer requests, a notation should be made in a log. Other documentation may also be possible. Facilities should check to see if State or local laws related to release of records require additional documentation.

The documentation should be retained for at least as long as the facility would have had to keep the patient's mammograms.

Digital Mammography

Continued from page 1

is/are inspected. Further, as a prerequisite for the extension of its MQSA certification to include continued use of the FFDM system, the facility must provide DMQRP/FDA with documentation indicating that it:

- Follows the quality assurance program and quality control tests, actions limits, and frequencies outlined in the manufacturer's quality control manual.
- Employs personnel who meet all applicable requirements, which include eight hours of digital-related initial training for all personnel who begin using the digital system after April 28, 1999, the effective date of the MQSA final regulations.
- Provides an FFDM equipment evaluation, performed by a qualified medical physicist. This evaluation must be performed six months before submitting materials to FDA.

After reviewing these materials for assurance of mammography quality, FDA will issue a letter to the facility extending its certificate to include the FFDM unit.

Interpreting Physicians

Continued from page 4

experiences, both interpreting physicians agreed that having caring, concerned staff is critical to a woman's mammography experience.

Equally important, Sachs noted, is for women to "check the credentials of staff and interpreting physicians and the reputation of the facility in their community." Tschersich agreed, reinforcing the need for a patient to be "well-informed and actively interested in her own health."

"Women should not be shy about asking questions important to them and should be suspicious of a place that treats them too hurriedly," said Tschersich. Being active in seeking information is important, he continued, because patients rarely know if they are receiving medical care of good or poor quality. "Judging the quality of medical care mainly by the level of conveniences provided can be deceiving and dangerous," Tschersich concluded.

Both interpreting physicians also commented on the unique qualities they bring to women undergoing mammography. "I have a special interest in women's imaging," Sachs responded, "and have gained significant experience in interventional breast procedures, including ultrasound core biopsy and stereotactic breast biopsy." Tschersich cited the enjoyment he derives from working in a small facility where he can establish easy contact with patients and the community.

On a personal note, both interpreting physicians had no hesitation in explaining why they choose to work where they do. Sachs enjoys the amenities of the highly urbanized Washington, DC area. "I appreciate its wealth of cultural and educational opportunities," she explained. For Tschersich, in contrast, it is his "love of untrammeled nature and the ocean environment, which offer everything from hiking in the Alaskan wilderness to coastal kayaking." He appreciates the small-town atmosphere, simple life, and relationships he can develop with interesting people with many talents from many parts of the world. "Modern telecommunications allow us to be as much involved with the 'outside world' as we wish," he concluded.

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- If the facility cannot resolve your concerns, ask for the name, address, fax number, e-mail address, or phone number of the contact person at your facility's accreditation body to contact about your complaint. Be sure to provide them with your name, address, and phone number. (Note: The American College of Radiology requests that all complaints to them be in writing. State accrediting bodies will also accept phone calls.) The name of the accreditation body is on the MQSA certificate displayed at your facility.
- If your facility's accreditation body doesn't resolve your concerns, write to FDA at: Center for Devices and Radiological Health, Office of Health and Industry Programs, Division of Mammography Quality and Radiation Programs (HFZ- 240) Rockville, Maryland 20850. Or call 1-800-838-7715.

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