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

MammographyMatters

Spring 2000 Volume 7, Issue 2

Ensuring High-Quality Mammography: Spotlight on Inspectors

With the five-year anniversary of the MQSA Inspection Program last fall, FDA began honoring inspectors who have provided five years of service in making high-quality mammography a reality. Given this milestone, now is an appropriate moment to highlight two of our program's dedicated inspectors. Tom Garvin, a seasoned FDA inspector from Milwaukee, Wisconsin, was one of the first to go through the Agency's training program in 1994. Mary James hails from Columbia, South Carolina, where she has served as a State inspector for less than one year.

Tom Garvin

Working with the MQSA Inspection Program from Day One

"My career with FDA began in the late 1970s—a time before specialization of inspectors was widespread," Tom Garvin recalled. Originally conducting food inspections, Garvin was tapped to receive training in Diagnostic X-ray Surveys in 1979. This career turn allowed him to perform x-ray field tests on a variety of equipment, serve as the principal inspector performing medical device inspections at the many General Electric facilities in his native Wisconsin, and conduct radiological inspections/injury investigations before becoming an x-ray auditor in 1988.

Based on his extensive experience with FDA's radiological health programs, Garvin was asked in 1993 to serve as an advisor to FDA as it implemented MQSA. His years of experience qualified him to provide the "field perspective" in the planning and implementation of FDA

Continued on page 3

Visit the New Mammography Program Website

The new and improved Mammography Program website, launched in April, contains information of great use to facilities, consumers, and others in the mammography community. The easily navigable site has sections on the Mammography Quality Standards Act (MQSA), regulations guidance, facilities, the Mammography Program Advisory Committee, and information for consumers. It allows quick access to past and current issues of *Mammography Matters,* our on-line quarterly newsletter, and other Program publications, including the recently released brochure, *Mammography Today.* The site also offers a section that lists and links to other resources for mammography information. Last, the new site provides up-to-date mammography information (see "What's New") and allows you to give us your feedback.

What's Inside

From the Director . . .

This newsletter issue marks a turning point on many levels. We have "gone electronic." Heralding another transition to technology is our increased use of the Mammography ListServ, which allows us to contact all subscribers to the list. Information available through the ListServ includes newsletter highlights, which link you directly to the newsletter article you select, and other MQSA news and alerts.

Beyond these electronic advances, however, Mammography Matters *has reached a new level in its mission. The final MQSA regulations are in place, MQSA inspections are being conducted under the new regulations, and a mechanism to extend certification to digital mammography units has been developed. In sum, many of the goals FDA set to ensure high-quality mammography for women have been met—and this newsletter has helped inform you of our steps toward meeting those goals.*

As new objectives and challenges emerge in our continued effort to support the mission of MQSA, we invite you to participate in molding the content of future issues of this newsletter. What aspects of MQSA would you like to read about? What do you think others in the mammography community should know? Together, let's be sure that what we communicate provides the information you need. Please contact our editor, Evelyn Wandell (epw@cdrh.fda.gov) with your feedback.

Spotlight on Inspectors

This past January, we reached the five-year anniversary of the beginning of MQSA inspections. FDA has been honoring inspectors who share this anniversary in years of service. What an appropriate time to highlight two inspectors who work day-to-day with facilities to ensure high-quality mammography (see story, page 1).

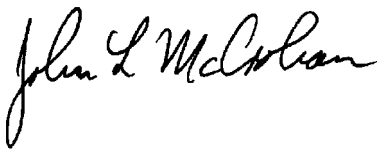
Tom Garvin, a veteran FDA inspector from Milwaukee, Wisconsin, went through the Agency's training program in 1994, after working with FDA's radiological health programs since the 1970s. Mary James, of Columbia, South Carolina, became a State inspector last July, building on six years of work using her certifications in mammography and quality management. With different backgrounds, but a shared dedication to enabling facilities in their delivery of quality mammography services, both inspectors are to be commended for their services.

Digital Mammography for Clinical Exams

In our last issue, we announced FDA approval of the GE Senographe 2000 D Full Field Digital Mammography (FFDM) system. Before facilities use this system, however, they must be MQSA screen-film certified; if certified, they should then submit an application to FDA to add the FFDM system to their MQSA certification. The application will require facilities to demonstrate that they meet personnel and quality control requirements. If needed, FDA may ask a facility for additional information before granting approval to use this technology for clinical examinations. Please turn to "Adding the FFDM System to Your MQSA Certificate" (page 4) for further details.

Consumer Concerns

Finally, we are interested in sharing stories on occasion that highlight how facilities handle their consumers' concerns. If you have a story to share that may be of help and interest to other facilities—also likely to be dealing with a similar situation—please e-mail Evelyn Wandell at epw@cdrh.fda.gov.



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

MammographyMatters
Spring 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.

Articles may be reproduced or adapted for other publications. Comments should be addressed to:

Mammography Matters
FDA/CDRH (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

Fax 301-594-3306

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

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

Evelyn Wandell, Editor

David Heffernan, Managing Editor

Robin Foster, Designer

Other contributors: Helen Barr, Anne Bowen, Pam Chissler, Joanne Choy, Kathy Franke, Tim Haran, Pat Hoage, Martha Pien

Facility Hotline

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

Spotlight on Inspectors

Continued from page 1

and State inspector training. "My fellow x-ray auditors and four select State personnel became the first guinea pigs for MQSA training courses," Garvin joked. Among the first group of MQSA Auditors FDA selected in 1994, he works closely with 12 State inspectors in four states in this role.

Beyond his professional experience, Garvin has a B.S. in Zoology, including more than 100 semester hours in the biological and physical sciences. To maintain his inspection

Tom Garvin

proficiency, he conducts independent and joint audit inspections and attends professional meetings, such as those sponsored by the Radiological Society of North America and the Conference of Radiation Control Program Directors.

Drawing on his professional experience and education, Garvin works to ensure that the inspection experience is positive for the facilities he inspects. He cited the MQSA Inspection Program as a role model that fosters a positive attitude by distributing educational materials to the facilities—unparalleled in Garvin's experience within FDA. MQSA also has created a cooperative environment through its policy of pre-announcing inspections, allowing facilities to adjust patient schedules and review their inspection documentation, which reduces onsite inspection time.

Mary James

Building on a Registered Mammographer Background

Certified as an MQSA inspector in July 1999, Mary James has worked in mammography since 1993, when she obtained her Associates Degree in Allied Health. James is a registered technologist and holds advanced certifications in mammography and quality management. Before becoming an inspector, she worked in a hospital for two years and then in a private practice outpatient radiology office, where she served as the quality control (QC) technologist for five years. In addition to performing mammograms in that practice, James performed sterotactic breast biopsies, DEXA bone density scans, ultrasound procedures, fluoroscopy exams, and plain films.

"I worked with a wonderful group of radiologists, who taught me about mammography and always expected me to perform at my personal best," James said. In addition to these radiologists, she credits the technologists, medical physicists, inspectors, service technicians, film representatives, and especially her patients

Continued on page 6

Adding the FFDM System to Your MQSA Certificate

Now that FDA has approved the General Electric (GE) Senographe 2000 D Full Field Digital Mammography (FFDM) system, what steps should you take before using this new technology for clinical examinations? To put these steps in context, keep in mind that use of the FFDM system falls under MQSA. Until FDA notifies you otherwise, the GE Senographe 2000 D system is exempt from MQSA accreditation requirements. However, only MQSA screen-film certified facilities may lawfully use this system.

If your facility is already screen-film certified, contact Ruth Fischer, FDA's Chief of the Mammography Standards Branch (telephone 301/594-3332; fax 301/594-3306). If your facility is not screen-film certified, apply to an FDA-approved accreditation body for screen-film accreditation. FDA will issue your facility a certificate once the accreditation body tells the Agency it has accredited your facility.

Once you contact FDA for information on how to add the FFDM system to your current MQSA certification, you will be sent (a) a letter detailing the steps you need to take and (b) a document outlining the certification requirements for personnel and quality control you must meet. For a preview of this information, go to the Digital Mammography section on the Facilities page of FDA's Mammography Program website.

Your facility should then submit an application providing the information FDA has requested. Of note, you should also:

- Provide a list of all individuals who meet the personnel requirements under 900.12(a)(i) and currently perform mammography services on an FFDM system. Include whether their starting date in this modality was BEFORE or AFTER April 28, 1999.
- Provide a satisfactory FFDM equipment evaluation performed by a qualified medical physicist no more than six months before your application date.
- Follow the manufacturer's guidelines for quality assurance and quality control tests, as described in the manufacturer's manual. Submit the results of tests performed during the first six months after beginning clinical examinations with the new FFDM unit. Results should be submitted within one month of this six-month testing period.

In reviewing your application, FDA may ask you for additional information before sending you a Letter of Acceptance or a Letter of Denial. Once you receive a Letter of Acceptance, your FFDM system will be added to your certificate and you may begin to use it for clinical examinations. If you receive a Letter of Denial, FDA will work with you to resolve the problems preventing your acceptance.

After your facility is approved to use the FFDM system, you must maintain accreditation status for at least one screen-film system. In addition, your FFDM system is subject to an annual onsite MQSA inspection when your screen-film systems are inspected.

Inspection Fee Payment Reminder

The Mammography Quality Standards Act (MQSA) requires FDA to charge all facilities a fee for each annual inspection. Facilities are required by law to pay that fee, unless they are granted an exemption as a "government entity" (see Government Entity Declaration form included with inspection bill). Facilities that repeatedly refuse to pay the inspection fee will be subject to FDA certificate suspension proceedings. A facility with a suspended certificate may not legally perform mammography.

FDA Addresses Consumer Issues

Soon after joining FDA's Mammography Program in October 1999, Deputy Director Helen Barr, M.D., completed a comprehensive review of consumer issues that had been directed to FDA between September 1998 and July 1999. After hearing consumers' perspectives first-hand in her 12 years as a practicing radiologist, Dr. Barr was interested in understanding the issues consumers were raising at the agency level.

Of the more than 400 messages received by FDA through the Facility Hotline in the 10-month period examined, 41 percent were from consumers, Barr reported. Twenty-two percent of consumer calls were requests for basic information, including:

- The names and locations of certified facilities within a geographic region,
- Information on contacting the National Cancer Institute for facility referrals and answers to breast cancer inquiries, and
- The website address for the Mammography Program.

An additional 15 percent of consumer calls were questions or complaints about the release of original mammograms, particularly the fees that consumers were being charged for this service. The remaining 63 percent, Barr noted, covered wide-ranging topics, such as:

- Breast tissue biopsies,
- Alleged misinterpretation of mammograms,
- Digital mammography,
- Ultrasound,
- Lay summaries,
- Pain with compression during mammography,
- Unclean facilities,
- Issues unrelated to mammography (such as chest x-rays), and
- Radiation safety.

Although these issues were brought to FDA's attention through calls placed to its Facility Hotline number, similar consumer messages also were received through e-mails to dmqrp@scicomm.com, direct calls to DMQRP, or calls forwarded from other FDA consumer lines.

Barr explained that all consumer messages, regardless of how they are received, are forwarded to outreach specialists, who address consumers' questions and concerns. Although FDA will respond to all consumer inquiries it receives, it encourages consumers to use the Facility Hotline number (1-800-838-7715) to receive a prompt response. Facilities should continue, however, to try to resolve consumer issues themselves or refer consumers to their accrediting body.

Mammography Today Update!

Thanks for your enthusiastic response to our brochure, *Mammography Today* (partial text of the brochure appeared in the Winter 2000 issue). The mammography facilities we heard from found it easy to read and full of useful information. Most important, they believe the brochure contains information that women would like to have.

Although printed copies of the brochure are not yet available, we encourage you to download the PDF version from the FDA Mammography Program website (www.fda.gov/cdrh/mammography), arrange to print two-color copies, and distribute it to your mammography patients. Questions or feedback? Contact Patti Hoage at pah@cdrh.fda.gov or call 301/594-3332.

Spotlight on Inspectors

Continued from page 3

for building her knowledge base.

That base never stops expanding, as James works to maintain her certification as an MQSA inspector. Similar to her past efforts to keep current as a registered mammographer, she reported, "I attend mammography seminars and take advantage of my affiliation with the American Society of Radiologic Technologists by using the directed readings in mammography."

Like Garvin, James goes the extra mile to make the inspection process a positive experience. Commenting on the anxiety some facility staff feel when she calls to schedule an inspection, James tries to ease their fears by letting them know what to expect during the inspection and informing them that they will receive a faxed confirmation that details the inspection process. "If facilities know you share their goal of ensuring the quality of their mammography program to provide the best patient care, the inspection will be a positive experience," she explained.

Mary James

An Educational Experience

Garvin and James agree that setting a positive tone includes making the inspection educational—one of FDA's goals. In fact, Garvin noted, inspectors "go out of their way to educate facilities on compliance issues." This information exchange occurs when inspectors act as resources via the phone or during the inspection or by some States distributing policy documents and technical data to sites within their jurisdiction. In sum, Garvin said, "The philosophy of the FDA field staff and State inspectors has been to guide facilities so they can voluntarily achieve compliance."

James believes that the goal of making an inspection educational has been largely achieved. Having been on both sides of an inspection allows her to project an attitude that the inspection provides an educational benefit to a facility's QC program. "I don't want technologists to feel I am looking for something to be wrong so that I can cite them. I want to be sure their program is working at its best to provide the highest quality images to their patients," she explained. James imparts educational information by helping facilities understand the reasons behind the QC program and regulations. "If I were to just cite them for a violation, I would be doing an injustice to the reason behind an inspection. I tell the facilities about websites that help clarify the final regulations, updates, and *Mammography Matters,*" she noted.

But how do Garvin and James avoid "crossing the line"—educating facilities without acting as a consultant? Garvin explained that he offers independent suggestions without steering facilities toward a specific commercial product or service. For James, maintaining the distinction between the two roles means not telling a facility how its QC program should be run, particularly because "what works best for one facility does not always work for another. I simply help the facilities understand the regulations and the reasons behind them."

Inspection Findings

To ensure accuracy in measurements among facility inspections, FDA calibrates mammography test equipment annually. We asked our two inspectors if facilities were interested in this information. Probably not, said Garvin, although "I think they presume we are using calibrated equipment. As regulators, it is critical that our equipment be traceable to a national standard." James, in contrast, thinks facilities are interested in this information, "especially when there is a violation that involves testing with our equipment." However, she usually discusses equipment calibration with facilities "only if they question my results or ask about my equipment."

Occasionally, a facility disagrees with the inspection findings. Garvin and James were asked to comment on what recourse a facility has in this situation. Garvin first noted that of the more than 2,000 inspections in his district since the first MQSA inspections in January 1995, only about six have had disputed items. However, he explained, when a site does disagree with findings, it should voice its concerns during the exit interview. If

Continued on page 7

Spotlight on Inspectors

Continued from page 6

the inspector erred, he or she can revise the Post-Inspection Report at that time. "The inspector's supervisor should be informed of any significant concerns. Should concerns persist, the FDA auditor or FDA Facility Hotline are suitable conduits for voicing these issues," Garvin concluded.

James concurred that a facility should discuss its disagreement with the findings with the inspector. And, she continued, "the facility can contact my supervisor, who can review my records and inspection report." Like Garvin, James advised, "If the issue cannot be resolved at that level, the facility can contact the FDA to question the findings."

Impact of Final Regulations

With the passage of the final MQSA regulations in April 1999, what effect, if any, have Garvin and James seen in inspection findings? Garvin commented that he has seen an increase in the Level-1 and Level-2 noncompliance findings. "The most common Level-1 finding has been from failure to perform a weekly phantom test." For Level-2 citations, the most common have involved the Complaint File and Infection Control Policies. "Many sites didn't realize they had a regulatory obligation to report serious unresolved complaints to their accreditation body," he explained.

James also has seen an increase in infection control and phantom image findings, noting as well increased findings in the assessment category

Continued on page 8

Recognizing Inspectors' Service

MQSA-certified inspectors play a significant role in the success of the mammography program. Since FDA launched its MQSA Inspection Program in 1995, highlights include:

- Conducting approximately 47,000 inspections.
- Increasing facility compliance with the national standards.
- Increasing the percentage of facilities passing the phantom image test during their facility inspection to 98 percent, from 89 percent in 1992.
- Achieving a high level of satisfaction among facilities with inspectors' technical and professional performance.

We are pleased that many of the originally certified MQSA inspectors, who started with the program five years ago, are still inspecting facilities. To show its appreciation for their service, FDA is presenting these inspectors with a Certificate of Appreciation in the month following his or her fifth anniversary.

As of April 2000, the following inspectors have completed five years of service and received their certificates.

Robert G. Antonsen
Terry Bolen
Daniel Borek
Kelly Cameron
Elaine Carter
Reggie Cope
Jeanne Crosby
Robert E. Davis
Robert N. Davis
Eustace Douglas
George Eicholtz
Jennifer Elee
John Ferris
Jack Ferruolo
Warren Freier
Roger Gailey
David Gaisior
Thomas Garvin
Richard Glass
Ed Gloor
Bruce Gossett
Vidya Goyal
Scotty Hargrave
Tom Harhay
June Hawkinson
Sid Heidersdorf
Shanna Hellmuth
Caroline Hibbs
Barbara Ignatz
Debra Jackson
Ed Janik
George Jones
Gayle Keane
Julie Keightley
Leroy Klotz
Judy Koch
Paul E. Koehn
Murray Kurzman
John Langston
Michael Leal
Dwight Leeseberg
Larry Legro
Jackie Lockwood
Bonnie Long
Scott Mantyla
Neann Manubay
Jodie Mathews
Bruce Matkovich
John Mays
Michael Mays
Steven Mays
Deborah McGee
Stacey Melick
Joel Mims
Angela Moak
Leanne Myers
Lynn Nakasone
Joseph Noble
Susan North
Gerald O'Connor
Judith Odonovich
Stan Orchel, Jr.
Joji Ortego
Don Parry
Dorothy Pender
Al Perlas
Leonard Pesetsky
Linda Plusquellic
Joseph Pryber
Robert Rapcinski
Madhavi Reddy
Paula Richardson
Myron Riley
James Rochon
Jenny Rollins
Larry Rourk
Richard Sanborn
Eleanor Schoenblum
Mark Sciranka
Robert Scott
Paul Simpson
Karen Smallwood
Glenn Smith
Mary Ann Spohrer
Charles Spyr
Edward Stagen
Dennis Swartz
Abraham Thomas
Pamela Tubbs
Bill Van Pelt
Nelson Warren
Robert Watkins

Spotlight on Inspectors

Continued from page 7

and consumer complaint areas. "Most of these increases have resulted from misinterpretation of the wording of the final regulations," she explained. "Some facilities are unaware of the MQSA Guidance documents, which can clarify misinterpretation. I give these facilities the website address for the Policy Guidance Help System [PGHS] or, if they do not have Internet access, copies of these documents or the Facts-on-Demand number," James concluded.

Effect of New Software and Laptops

Garvin and James also discussed the impact of FDA's new inspection software, implemented in July 1999. Garvin doesn't believe the new software has impacted the facilities "to any great degree," although James noted the "overall positive impact on the inspection process." Garvin explained that as the compliance contact for the Inspection Program with the Minneapolis District, he finds that changes to the Compliance-Tracking software have been far more significant. "Once an inspection is uploaded from the inspector's laptop, I have access not only to the Post-Inspection Report, but to all of the inspector's comments and other data entry items. This advance has resulted in improved customer service in responding to facilities that submit corrective action plans."

James noted that because the new software provides previous dates and information, inspectors spend less time looking for information that wouldn't have changed from year to year. She added that although the software lacks flexibility in some finding areas, inspectors can use the inspector remark areas for additional comments.

Both inspectors concluded their remarks on the new software by citing the benefits of another software tool, the MQSA Final Regulations PGHS. Garvin praised this system as a "superb resource that greatly simplifies finding help on all MQSA topics by correlating the regulations to FDA policies." He encourages sites to access this search engine online or download it for offline browsing. James added that the search engine is "very useful when trying to locate information during an inspection."

To help facilitate reporting of inspection data and access to the PGHS, FDA began providing inspectors with laptops in 1994. Have laptops made the inspection process more efficient? "Very much so," said Garvin, pointing to FDA's Minneapolis District's completion of 500+ inspections each year with only 12 inspectors, most of whom are State employees with duties beyond MQSA. James noted that "the laptop is a tremendous help in inspection efficiency, allowing me to follow the software and see areas that are complete and missing information. With the missing data report, I can be sure all inspection areas are covered."

> **"Without a doubt, by setting a high standard for facility certification, MQSA has profoundly impacted the early detection of breast cancer and made an overall improvement in patient care."**
>
> *Mary James, State Inspector*
> *Columbia, South Carolina*

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.

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 What are appropriate charges for the transfer of mammography records and can the facility charge the cost of making copies of the films to the patient?

A Appropriate charges for transfer of mammography records could include: 1) administrative costs incurred in logging in the request, 2) retrieving the appropriate films and reports, 3) having the patient sign a release (if not already done), 4) packaging and mailing charges for the materials, and 5) photocopying costs incurred in making copies of the report.

Facilities may, but are not required to, make copies of the mammography films. If these copies are requested by the patient or are mandated by State regulations, then the cost of making the copies can be charged to the patient. If the facility wishes to keep copies for its own benefit, the cost cannot be charged to the patient.

If requested by the patient, facilities must be able to produce documentation (an itemized bill, for example) that the charges do not exceed the costs associated with this service.

Q If there is more than one lesion identified on the mammographic examination, do I need to have a final assessment category for each lesion or just one assessment for the entire mammographic examination?

A One overall assessment category for the entire mammography examination is required, and it should be based on the most suspicious lesion or finding. However, individual assessments for other lesions, along with recommendations for their management, may also be included in the report.

Q If a facility issues an "addendum" or "comparison" report after the initial mammography report has already gone out, are these reports required to have an overall final assessment category? Must the "addendum" or "comparison" report also be provided to the referring health care provider and the patient, even if there is no change in the final assessment category or recommended course of action?

A Yes to both questions. The report issued after additional testing that is covered under MQSA (e.g., coned, repeat, magnification views) or following comparison with old films should reflect the final assessment category for the case following these additional tests or comparison studies. A report of this nature must be communicated to the referring health care provider or the self-referred patient, just as any other report would be. In addition, a lay summary of the "addendum" or "comparison" report sent to the health care provider (or self-referred patient) must be provided to all patients, even if there is no change in the final assessment category or recommended course of action. For the specific case where there is no significant change in the report, a simple statement that the comparison has been performed and that there is no overall change would satisfy the requirement. If the "addendum" merely stated that the referring health care provider had been notified of the results of the patient's examination, the addendum lay summary could be a simple statement informing the patient of that fact.