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MammographyMatters

Summer 2000 Volume 7, Issue 3

The Science of Safe Mammography: Medical Physicists at Work

Thanks to MQSA, mammography facilities across the nation must retain a medical physicist to conduct an annual survey and to establish, monitor, and oversee their quality assurance/quality control (QA/QC) programs and practices for mammography equipment. At many larger hospitals, full-time medical physicists are on staff to fill this responsibility, whereas smaller facilities often rely on part-time or consultant physicists.

In this issue, meet Melissa Martin and Bob Pizzutiello, both members of medical physicist consulting groups. Each goes to great lengths —literally—to provide coverage to mammography facilities in a broad region surrounding Los Angeles and throughout upstate New York, respectively.

Two Paths to a Career in Medical Physics

The opportunity to apply a fascination with physics to patient care drew Melissa Martin and Bob Pizzutiello to careers in medical physics. Martin recalls her journey toward this profession. After earning her undergraduate degree from Oklahoma State in Engineering Technology, with an emphasis in radiation and nuclear applications, she was searching for a way to apply this science to people. Through inquiries to graduate schools, Martin discovered and completed a UCLA graduate program in Medical Physics —a field, she says, that "provides the perfect opportunity to apply scientific principles to benefit medicine."

Pizzutiello's career path was inspired by undergraduate courses at the University of Rochester in physics, engineering, and biomedical engineering, an interest strengthened through his summer research projects in radiation physics and the biological effects of ultrasound. An M.S. in Electrical Engineering, also from the University of Rochester, soon followed. "I would definitely recommend students interested in the use of physics principles in the care of patients to pursue a medical physics career," Pizzutiello observed, adding, "The profession has members who work in basic science, research, and education, as well as in clinical applications."

Agreeing with Pizzutiello in noting the "unlimited opportunity medical physics offers to apply physics principles to the field of medicine," Martin also commented on future opportunities. "The Internet and vast computer power now available or not far in the future will allow development of images with a quality that we can only dream of," she explained.

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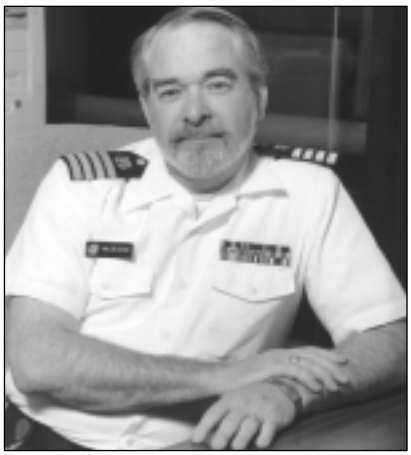
What's Inside

From the Director . . .

Now that Mammography Matters *is available only as an e-newsletter, we are assessing how best to tap technology to communicate with you, our readers. Just as the Mammography Program is evolving to meet new challenges, so too should this newsletter evolve and reflect our changing mission as communicators.*

One idea we are exploring is how to increase opportunities for more timely communication. Rather than having a quarterly newsletter, we may re-name our website Mammography Matters and use the site to present key mammography news as it emerges. To be sure you don't miss an important story, we would continue to use the ListServ to alert—and link—you to that news item. To sign up for FDA's Mammography ListServ, go to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mail/listman.cfm, which can be linked from the Newsletter section of the website (http://www.fda.gov/cdrh/mammography/newsletter.html). In the meantime, we plan to have a fall issue of Mammography Matters *in the usual format.*

In sum, mammography matters to all of us, and we are exploring how best to create a communication resource that reflects this priority. If you have ideas on creating a more



effective news forum—or comments on any other facet of this newsletter—please share them with our editor, Evelyn Wandell (epw@cdrh.fda.gov.).

The Science of Safe Mammography: Medical Physicists at Work

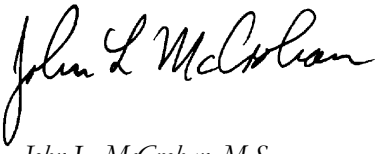
Ever wonder what medical physicists look for when surveying mammography equipment? Meet Melissa Martin, of California, and Bob Pizzutiello, a New Yorker, who discuss their work with facilities and the impact of the MQSA final regulations on their profession. We'll also explore the different journeys each took on the road to becoming a medical physicist and the challenges they face in continuing to ensure high-quality mammography.

Digital Mammography/FFDM

On Page 4 of the spring issue of Mammography Matters, *we discussed "Adding the FFDM System to Your MQSA Certificate." Facilities considering adding an FFDM unit should consult this article for information on how to remain MQSA compliant.*

Declining Use of Extended Cycle Processing

Extended cycle processing, a technique used by 37 percent of mammography facilities in 1995, is no longer as popular, with use having dropped to 7 percent of all facilities. In this issue, we explore the reasons for this decline.



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

MammographyMatters
Summer 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

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

Evelyn Wandell, Editor

David Heffernan, Managing Editor

Marjorie MacDonald, Designer

Other contributors:
Anne Bowen, Kish Chakrabarti, Martha Pien, Orhan Suleiman

Facility Hotline

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

Medical Physicists at Work

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Different Regions, Similar Practices

Both medical physicists have been practicing for over 20 years—25 years for Martin and 23 for Pizzutiello. Martin's Los Angeles-based consulting group covers 250-275 mammography units per year, with Martin responsible for 100-125 of those. Supporting 20 full-service medical centers and 100 other clinics, she and her peers oversee more than just mammography equipment. "We provide complete medical physics services for all imaging modalities—radiographic, fluoroscopic, CT, MRI, angiography, digital imaging, and PACS." Martin travels extensively to support a practice that covers a 100-mile radius. Boise, Idaho also benefits from her solid experience, with Martin traveling there six times a year to provide mammography physics coverage.

On the other side of the country, Pizzutiello and other members of his consulting group serve roughly 120 facilities in upstate New York and surrounding regions. He counts on 2-3 days of travel per week in surveying about 70 mammography facilities per year and working with facilities that use all modalities of imaging with ionizing radiation—stereotactic breast biopsy systems, radiographic and fluoroscopic equipment, c-arm fluoroscopy units, special procedures laboratories, cardiac catheterization laboratories, and nuclear imaging systems. "We also work with ultrasound and MR imaging systems," Pizzutiello added.

A Dialogue with Mammography Matters

Mammography Matters asked our two interviewees to comment on various aspects of their work in ensuring the safety and effectiveness of mammography equipment. Their responses, presented in the Q & A format that follows, underscore the

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Meet our Medical Physicists

Bob Pizzutiello

B.S., Electrical Engineering
University of Rochester, May 1977

M.S., Electrical Engineering
University of Rochester, May 1978

American Board of Radiology
Therapeutic Radiological Physics (1982)

American Board of Medical Physics
Diagnostic Imaging Physics (1993)

Upstate Medical Physics, Inc.
Victor, NY

Years in Practice: 23

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critical role each plays in implementing MQSA regulations.

What are the most important things you check for in conducting surveys and unit reviews?

Pizzutiello first asks the technologists which screen-film combination, cassettes, and film processing they use. He wants to know if they have made any changes since his last visit, or if they have had problems with processor or phantom image QC testing. Pizzutiello then looks at their technique charts to see if they are consistent with his experience, given the screen-film, processing, and x-ray machine at their site.

"I've been working recently with clients to develop better technique charts for machines that have AEC (Automatic Exposure Control) systems that can automatically select the kVp and target-filter combination. After discussions at an NMQAAC meeting [Pizzutiello is a member of NMQAAC, the National Mammography Quality Assurance Advisory Committee], I worked with FDA to develop guidance on this subject.

"Some technique charts state 'Use the automatic mode,' but don't indicate the expected kVp and target-filter combination. And in some units, the fully automatic AEC mode develops a glitch and suddenly begins selecting sub-optimal kVp. More detailed technique charts would help technologists recognize when the fully automatic AEC mode might not be working optimally," Pizzutiello concluded.

Martin covers many of Pizzutiello's steps, but in a slightly different order. For example, she first reviews clinical images and phantom images with a staff technologist and, preferably, a radiologist. Martin then monitors for compliance with current and future equipment requirements established by MQSA regulations and state requirements. Next, she asks which screen-film system is in use and how it is decided if image quality is acceptable?

Martin then turns to processor maintenance, determining first if the maintenance program is current. She also checks if the processor is causing image quality problems, and if the chemicals are correct for the type of film being processed. Finally, Martin determines if technologists know how to use the equipment, assessing if they have been properly trained or need more training.

Describe what you look for when checking equipment.

In addition to the items she mentioned above—MQSA compliance and unit integrity—Martin checks to see if all of the options on the unit work correctly and if the unit will be able to meet the facility's clinical demands in the immediate future. Pizzutiello stressed that the first, most important things he checks are the facility personnel and their techniques—not the equipment. "Medical physicists first need to know how the equipment is used so they can be aware of what to look for when testing it."

That said, Pizzutiello observed that AEC systems present the most clinically significant problems in his experience with checking mammography units. Facilities can have a wide range of AEC capabilities, often with both 15-year-old and state-of-the-art designs in the same facility. "Ensuring the best possible performance for a single unit is as important as having consistent image quality among different units in a multi-unit facility," he said.

"I also compare each unit's performance with my experience of how well that model of x-ray unit is capable of performing under the best conditions. This helps me decide if I should recommend that a unit be serviced by a qualified engineer or if I need to work

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Meet our Medical Physicists

Melissa Martin

B.S., Engineering Technology
Oklahoma State University, May 1971

M.S., Medical Physics
UCLA, June 1975

American Board of Radiology
Radiological Physics (1979)

Therapy Physics, Inc.
Bellflower, CA

Years in Practice: 25

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with the staff to develop different techniques of using the equipment so that design limitations do not compromise image quality," Pizzutiello explained.

In addition to annual physics surveys, do you support facilities in other ways?

QC consultations, particularly on film processing performance, define much of the additional support Martin and Pizzutiello provide facilities. "We encourage our clients to call us when they are not sure what to do next. Very often, we find that technologists have developed excellent instincts about what to do, and consulting with us adds confidence to their assessment," Pizzutiello observed.

Martin noted other areas of support she provides facilities: immediate on-site evaluations for all new x-ray tube installations or AEC changes; image quality evaluation, as requested by a radiologist or technologist when a facility is preparing for accreditation reviews; consultations on possible new screen-film combinations; and equipment evaluations and recommendations for new equipment, as facilities prepare for compliance with the equipment requirements that go into effect in October 2002.

In addition to providing support to facilities in these areas, Pizzutiello conducts staff education programs at client facilities and frequently lectures at local, regional, and national mammography conferences for technologists, radiologists, and physicists.

What impact do the new requirements for Mammography Equipment Evaluations (MEE), Annual Physics Survey, and Timeliness of Corrective Actions have on mammography quality?

> New requirements for Mammography Equipment Evaluations "prevent significant changes in x-ray equipment or processing from compromising mammography image quality."
>
> — Bob Pizzutiello

The clearest impact is in improved image quality, both medical physicists agree. These requirements "prevent significant changes in x-ray equipment or processing from compromising mammography image quality," Pizzutiello observed. "To be sure," he continued, "the new requirements put a lot of pressure on mammography facility personnel, medical physicists, and service personnel. With good communication and emphasis on teamwork among all players, rapid response, and realistic expectations, the requirements for MEEs have moved all facilities a step closer to providing quality mammography services to every patient in the United States."

Martin concurred, noting the benefit derived from having the "force of MQSA regulations behind medical physicists recommendations." She added, "In many instances, facilities rely on our annual reports and evaluations to obtain new equipment or screen-films to achieve compliance." Martin noted occasions when it is difficult for a facility to comply with the 30-day limit for corrective action on an older unit. However, she added, absent this time limit, these same units would not be repaired at all in many instances.

Both interviewees noted the impact these requirements have had on their practices: more regularly scheduled visits to facilities as well as short-notice availability for consultation or immediate action. "No longer can the physicist be a nighttime phantom that no one sees or interacts with. We now know the technologists at each institution very well," Martin explained.

Can you project the impact of the new equipment requirements that take effect in October 2002 on your practice? On your client facilities?

Echoing his earlier AEC concerns, Pizzutiello said, "We are particularly focused on the new AEC requirements." He explained that many facilities use older mammography equipment that, although possibly purchased recently, was designed more than 10 years ago. Since then, film contrast has increased dramatically. Hence, a smaller change in the x-ray exposure incident on the image receptor now produces much larger changes in optical density than when these units were designed. Some AEC systems that could provide consistent optical density over a range of exposure conditions 10 years ago may not be able to achieve the same result with the newer films.

"We are now evaluating each unit we survey so that we can advise our clients whether or not the equipment will meet the new requirements. If not, we have to then assess if the unit can be 'tweaked' or optimized to

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Extended Cycle Processing

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

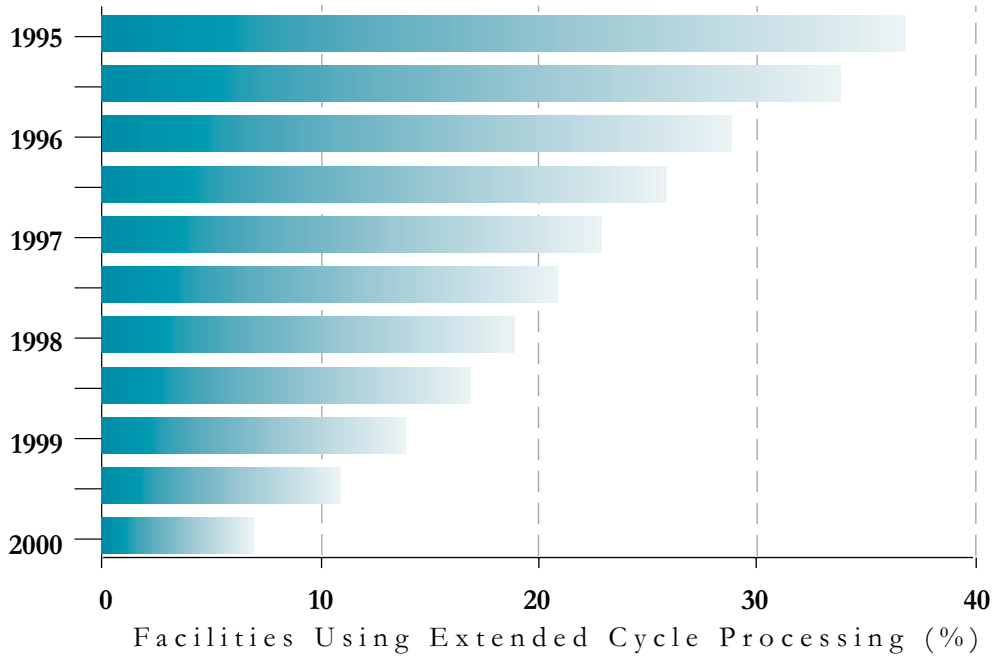
Extended cycle processing, once a popular means of film processing, is on the decline. Facilities use of this processing technique has fallen steadily over the past five years, with use decreasing from 37 percent of facilities in 1995 to only 7 percent this year. (Statistics gathered from inspections.)

Introduced in the late 1980s, extended cycle processing doubled the film development time of an automatic film processor but improved contrast in some mammography films. In addition to improving image quality in many types of film, the technique reduced patient's radiation dose. However, several disadvantages have compromised facilities' use of this processing technique. For example, extended cycle processing is not optimal for all mammography films, it may enhance artifacts, and it makes it more difficult to maintain processor control.

Today, most film manufacturers' mammography films are designed for standard cycle processing, rather than extended cycle processing. However, we suggest that you always verify whether the mammography film you use is designed for standard or extended cycle processing.

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

Percent of Mammography Facilities Using Extended Cycle Processing, 1995-2000.



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 How should facilities document performance of the required QC tests to comply with the regulations?

A Performance of the required QC tests must include clear and legible documentation. The documentation must include the dates when the tests were performed. For each test result that falls outside the action limits, the documentation must also include the date and corrective actions taken and their results. The data and results should be properly charted or tabulated. Facilities may consult any appropriate quality control manual for examples of charts and tables or establish their own format for documenting the test data and the results.

Q If a facility fails to have proper documentation for a personnel requirement, will the facility be cited for failure of the inspection question, "Required personnel documents available?"

A Yes. If the facility is unable to supply the inspector with all the appropriate documentation for any personnel qualifications during the time the inspector is at the facility, the inspector will answer the personnel question, "Required documents available?" with an "N" thereby generating a level 3 finding. Examples include: personnel who do not have any documentation showing they meet any one of their respective personnel requirements, personnel whose documents are not available at the facility but are claiming that they exist, and personnel who have incomplete documentation or whose documentation has been rejected by the inspector.

Q Our interpreting physicians send out reports and lay summaries under their own letterhead. Must the certified facility performing the examination be identified on the report and lay summary?

A Yes. While mammography reports and lay summaries may go out under letterheads other than that of the certified facility, the name of the certified facility performing the mammography examination must also be identified on the report and lay summary.

Q Must the radiologic technologist performing the mammogram be identified in the mammography report and lay summary?

A No. While the radiologic technologist must be identified on the mammographic images, the technologist does not have to be identified in either the mammography report or lay summary.

Q Does the lay summary have to be signed by the interpreting physician?

A No. While the mammography report must be signed by the interpreting physician, the lay summary does not have to be signed.

Q Does the lay summary have to have a final assessment category?

A No. While the lay summary will be based on the medical report's final assessment category, the summary does not have to include a final assessment category.

Q Do we have to provide lay summaries translated into different languages for our patients who cannot read English?

A Facilities are required to provide lay summaries of their mammography reports to all their patients. The content of the lay summary is left to the facility so that the summary may be customized to adequately convey information to the patient. While facilities are not required under MQSA to provide summaries in different languages, those facilities with sizable non-English reading populations should make reasonable efforts to accommodate these patients through the provision of appropriate foreign language summaries.

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Q&A

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Q Must a lay summary be provided to the patient if the images from an examination are re-read by a physician not associated with the facility where the examination was originally performed and interpreted (e.g., if the patient or health care provider requests a second opinion from another facility)?

A No, there is no requirement that a lay summary be provided to the patient when re-interpretations of images are done at a facility different from the facility that made the original interpretation. However, FDA strongly recommends that the second facility inform the patient requesting the second opinion of the results, especially when the second opinion differs from the initial results.

Medical Physicists at Work

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meet the requirements, or if it will simply become obsolete by these new standards," Pizzutiello reported.

Martin discussed what she is seeing in her practice, where 25 percent of the units her group covers will be replaced by 2002 to comply with the new requirements. "We are working very hard with our clients to coordinate our review of new equipment replacement units with their annual physics survey to minimize the financial impact," she explained. Martin is also concerned about facilities waiting until the last minute to replace equipment and not allowing adequate time for acceptance testing. To avoid this problem, she is encouraging her client facilities to purchase new equipment no later than the first quarter of 2002.

How do you keep up with changes in the MQSA regulations and guidance?

Both medical physicists note that they routinely visit the Mammography Program website (http://www.fda.gov/cdrh/mammography) and rely on the ListServ (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mail/listman.cfm,) to alert them to any changes in the regulations. In closing, Pizzutiello noted that he downloads the most current version of the Policy Guidance Help System (web version) to his notebook computer for easy reference.

In addition to her routine use of the Mammography Program website, Martin attends continuing education workshops to keep current with MQSA regulations. She also uses communication from ACR and contact with ACR personnel, state regulatory personnel, and MQSA inspectors to stay on top of the regulations.

Notice: NMQAAC Meets September 28

The National Mammography Quality Assurance Advisory Committee (NMQAAC), which provides advice and recommendations to FDA on mammography regulatory issues, is scheduled to meet Thursday, September 28, 2000, 9 a.m. to 6 p.m. at the Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Avenue, Gaithersburg, MD. The meeting will be open to the public.

The committee will discuss FDA oversight of the MQSA inspectors and inspections, the MQSA compliance guidance, and FDA's role under the MQSA in evaluating personnel competency. The committee will also receive updates on the status of accreditation and certification of full field digital mammography, use of small field digital mammography receptors for diagnostic examinations, States as Certifiers, and the Inspection Demonstration Project.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. For more information, contact Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850, 301-594-3332, or FDA's Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397.

Please call the Information Line for up-to-date information on this meeting.