From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Summer 1999 Volume 6, Issue 3

Radiologic Technologists: Dedicated to Patient Care and Meeting MQSA Challenges

Since the Mammography Quality Standards Act of 1992 was enacted, radiologic technologists in mammography facilities have played a significant role in the development and implementation of the final regulations. While FDA relies on the technologist community to provide insights on the world of the mammography department, this segment of facility professionals contributes much more than the scope of regulations in providing quality mammography services. As mammographers, radiologic technologists must combine their interpersonal skills with their technical expertise in providing quality images and patient care.

Education and qualifying examinations leading to American Registry of Radiologic Technologists (ARRT) certification and extensive experience distinguish the careers of Marty Custis, R.T. (R)(M), Louise Schloss, R.T (R)(M), and Pamela Sirois, R.T. (R)(M). These three women have earned certification in both diagnostic radiography and mammography.

As senior staff and administrators at their facilities, these professionals perform a broad range of duties. During our interviews, each technologist affirmed her personal dedication and that of her facility to provide their patients with the best possible health care. They gave generously of their time to offer readers a glimpse into their facilities, highlighting their priorities for patient care, while meeting the challenges presented by regulations, including MQSA.

Marty Custis reaches out to the community

A subsidiary of St. Mary's Center, the St. Mary's Breast Center is located on the medical center campus in Evansville, Indiana. "Our reputation as a dedicated patient-first facility has brought us many patients by word-of-mouth," says Marty Custis, R.T. (R)(M). "Patients also come to us by a large referring physician base from

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Guidance on Consumer Complaints and Patients with Breast Implants

MQSA final regulations cover some new areas that may be of particular interest to a patient/consumer. Taken from the Policy Guidance Help System found on the FDA/MQSA website, the following information addresses the consumer complaint mechanisms and the issue of performing mammographic examinations on patients with breast implants.

Consumer complaints

The regulations require facilities to establish a system for collecting and resolving "serious" consumer complaints. Also, facilities must maintain a record of each serious complaint for at least three years from the date the complaint was received.

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What's Inside

From the Director . . .

Radiologic technologists serve at the front line in the war against breast cancer. We commend these dedicated professionals first for their efforts on behalf of patients and for all they do to ensure that high-quality mammography services are uniformly available across the nation.

It's not an easy job. Meeting MQSA requirements means spending extra time keeping knowledge and skills current, as well as performing and documenting quality control and quality assurance procedures. And while some technologists may dislike regulatory paperwork, especially if it means taking time away from reassuring anxious patients or sharing their emotional highs and lows, we rarely see examples of complacency.

Every facility is different, of course, but it's usually the R.T.s who monitor processing, equipment, and reporting activities and deal with many issues related to inspections. Regardless of any particular facility's operation, the MQSA program owes a significant share of its success to the collective performance of these mammographers.

This issue of Mammography Matters *features a close-up look at three mammographers who exemplify their profession. We spotlight them as fine examples of dedicated professionals providing patients with high-quality service. Thank you all for your commitment to your patients and the MQSA program.*

Checklists and clar ifications

This issue also includes a checklist of items to keep in mind as you prepare

for your annual inspections. In addition to making sure your equipment is in good operating order, you want to be sure to assemble information for the inspection that is related to personnel qualifications, recordkeeping, reporting and tracking systems, quality assurance records, and standard operating procedures. This checklist comes from our new "Preparing for MQSA Inspections" document, which you can get on our website or through the CDRH Facts on Demand system (see page 4).

We've also issued amendments to the final rule (recently published in the Federal Register*) that include regulatory language covering new requirements brought about by passage of the Mammography Quality Standards Reauthorization Act in the fall of 1998. The amendments involve the MQSRA requirement of issuing lay language reports to all patients, as well as a few other points of clarification with the October 1997 final rule (see page 5).*

States as Cer tifiers

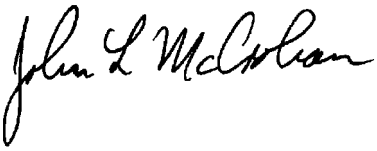
In August 1998, FDA implemented a States as Certifiers (SAC) Demonstration Project with the States of Iowa and Illinois. The project is scheduled for one year with an option for renewal. Both Iowa and Illinois will be renewed for year two (no additional States applied) and have the option of renewal for a third and final year under this demonstration program.

Regulations to implement the program on a nationwide basis are projected to go into effect around August 2001. Responsibilities delegated to the participating States include:

- *Issuance, renewal, suspension, and revocation of certificates to mammography facilities within the State;*
- *Annual facility inspections;*
- *All compliance actions for any inspection finding.*

As reported at the National Mammography Quality Assurance Advisory Committee (NMQAAC) meeting on July 12, Illinois and Iowa so far have met their responsibilities under the SAC project. Congratulations Illinois and Iowa!

Finally, don't forget to keep up with MQSA activities through our website at www.fda.gov/cdrh/dmqrp.html.



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MammographyMatters
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Mammography Matters is a quarterly publication of the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested organizations and individuals.

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

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Facility Hotline

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

FDA Clarifies Equipment Test Frequencies

Regarding equipment test frequencies, FDA's experience with MQSA inspections indicates that, under the interim regulations, some facilities interpreted the words "weekly," "quarterly," and "semi-annually" in ways different from that intended by FDA. To ensure a uniform application of the final regulations to all facilities, FDA will enforce the following interpretation of test frequencies starting October 1, 1999.

Weekly Phantom Image Test: Must be performed each week that clinical mammography examinations are conducted before performing examinations. However, the test need not be done on the same day each week.

Quarterly Tests: Must be performed 4 times a year. The 4 months that are chosen must be spaced 3 months apart (such as February, May, August, and November.) However, for any of the 4 selected months, each test may be performed on any day (not necessarily the same day) in the month.

Semi-annual Tests: Must be performed 2 times a year. The 2 months that are chosen must be spaced 6 months apart (such as January and July). However, for any of the 2 selected months, each test may be performed on any day (not necessarily the same day) in the month.

Coming Soon!

A new website for FDA's Mammography Program, featuring a search engine for policy information. You'll also be able to sign up for electronic newsletter notices.

Name and Address Changes

Each facility **must** notify its **Accreditation Body** of any changes or corrections in its mailing information, such as new contact person, change of address (including new usage of a P.O. Box), or change of facility name. If your mailing label code includes **ACR, SAR, SCA, SIA,** or **STX,** then this is your address as it appears in the official address files and you **must inform your Accreditation Body of any changes.**

Preparing for MQSA Inspections

The following brief exerpts from "Preparing for MQSA Inspections," a document FDA recently uploaded on its website, include some specific items that inspectors will be looking for when they come to inspect your facility.

The inspection process

The inspector will work with the facility to schedule the inspection so that any inconvenience to the facility's daily operations is limited. Normally the facility is provided with advance notice of at least five business days.

Inspections of facilities with a single x-ray unit/film processor are estimated to take approximately five hours, with one hour required to evaluate the equipment and the balance of the time being spent in review of the facility's procedures and records. To reduce disruption of the facility's activities, FDA suggests that the facility schedule a block of time for the evaluation of each x-ray unit/film processor. In addition, the facility should organize and consolidate the records the inspector will need to review and have them complete and readily available.

Upon arrival, the inspector will first meet with designated facility representatives to verify preliminary information and briefly outline the proposed inspection agenda. This time allows the facility to request any changes to the proposed schedule of testing and records reviews. After the inspection, the inspector will again meet with facility representatives for an exit interview to discuss the inspection findings and answer any questions facility personnel may have.

Specific inspection items

In addition to testing the facility's equipment, the inspector will look for specific information regarding personnel qualifications, recordkeeping, reporting and tracking systems, quality assurance records, and standard operating procedures. Specifically, the inspector will:

1. Confirm that the facility has a valid certificate prominently displayed in each patient waiting area.
2. Examine records for all personnel who have provided mammography services since the facility's last inspection. Note: These records must cover both permanent and temporary staff, as well as employee start, duration, and termination dates.
3. Perform equipment tests on each x-ray system used for regulated mammography activities. Note: this includes equipment being leased by, loaned to, or evaluated for purchase, as well as equipment owned by the facility. Assistance from facility personnel will be required. The inspector will also examine the records that are specific to each system.
4. Review the Quality Assurance and Quality Control Program.
5. Review the two most recent Medical Physicist's Survey Reports.
6. Examine evidence that all equipment, which is new to the facility or has been repaired or moved, has been evaluated by a qualified medical physicist before being placed in service.
7. Review selected patient medical records to ensure that they identify the interpreting physician, have an overall assessment, and that the appropriate records are being generated and maintained.
8. Review the facility's procedure for communicating results to both referring physicians and patients, as well as the facility's mechanism for providing quick response to cases requiring such action (if the assessment is "Suspicious" or "Highly suggestive of malignancy").
9. Review the facility's mammography medical audit and outcomes analysis program to ensure that it meets the requirements.
10. Look at other standard operating procedures to ensure that the regulations are being met.

If you do not have access to the Internet, you may order "Preparing for MQSA Inspections" from the CDRH Facts on Demand system at 1-800-899-0381 or 1-301-827-0111 using a touch-tone phone. The document number for this publication is 6400. At the first voice prompt, select 1 to access DSMA Facts; at the second voice prompt, select 2 and enter the document number, 6400. Continue to follow the voice prompts to complete your request.

Amendments to the Final Rule

The MQSA Reauthorization Act (MQSRA) signed into law on October 9, 1998, requires that all patients receive a summary of their mammography report written in lay terms. This requirement, effective April 28, 1999, superseded the corresponding requirement in the MQSA final regulations published on October 28, 1997.

As a result, FDA is proposing to amend the final regulations on this point, as well as several others, to make the wording of the October 1997 rule consistent with MQSRA. Since the law is a higher authority than the regulations, the amendments will not affect the patient lay summary requirement that is already in effect. **The amendments were added simply to enable all of the quality standards to be part of a single document instead of having to consult both the October 1997 final rule and MQSRA.**

On June 17, 1999, FDA published the new amendments in the form of both a "direct final rule" and a "proposed rule" that is a companion to the first. You may submit comments on the proposed rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rockville, MD 20857.

Unless substantial adverse comments are received before August 31, 1999, on issues other than the statutory requirement (which only Congress, not FDA, can change), the direct final rule amendments will become effective on November 1, 1999. However, as noted above, this November 1 date does not affect the date on which the requirements included in this amendment became effective. If substantial comments are received on issues under FDA's control, the direct final rule will be withdrawn and FDA will proceed with modifying the proposed rule in response to these comments. The modified proposed rule will be published later as final.

Besides the communication of results to patients, the following issues are covered in the amendments.

Review physician

MQSRA used the term "review physicians" to identify physicians used by the accreditation bodies to review the clinical images submitted by facilities. Since this review is a key factor in determining if a facility should be accredited and then certified, these physicians should meet qualifications beyond those needed to serve as interpreting physicians in mammography facilities. The amendment will change the final rule by adding the definition of "review physician" and changing all "clinical image reviewer" references to "review physician" in section 900.4(c).

To eliminate confusion between the "review physician" and the "reviewing interpreting physician," the latter will now be referred to as the "audit physician" in paragraph 900.12(f)(3).

Patient notification

The October 1997 final rule states that if FDA determines that any activity related to the provision of mammography at a facility presents a sufficiently serious health risk, the agency may require the facility to notify the patients, their physicians, and/or the public of actions that may be taken to reduce this risk. MQSRA specifically states that FDA has authority to require patient notification. The amendment brings the final rule into conformance with the wording in MQSRA on this point.

Other amendments

Two other amendments were published in the *Federal Register* (FR) on October 22, 1998, and April 14, 1999. The former corrects typographical errors, and the latter resolves a regulatory conflict regarding collimation. All these documents are available on our website.

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the tri-state area of Indiana, Kentucky, and Illinois."

A radiologic technologist since l971, Custis, who has worked in mammography exclusively since 1986, is the Center manager. "A mammographer at heart," she is one of the six facility technologists who together perform an average of 50 mammograms a day. All hold current ARRT mammography certification. Custis says she prefers to hire staff members who have the desire—and pride in the profession—to earn those credentials. In discussing the budget for continuing education, Custis makes clear she values staff development and believes in education for its own sake, not just in the fulfillment of various federal and state requirements.

Asked if there were significant changes in the Center's procedures as a result of the final MQSA regulations, Custis said, "just more dotting i's and crossing t's." As to reporting mammography exam results to patients, she says the Center provides "same-day service," meaning that the patients learn what their screening or diagnostic results are before leaving the facility. Also, the Center has been providing written reports to patients since l994, as a result of Indiana's requirement.

Appropriate and timely follow-up to suspicious or positive results is a high priority at St. Mary's Breast Center. "If a patient needs additional views or an ultrasound," Custis relates, "it's performed at the time of the mammogram, and the radiologist then speaks with each ultrasound patient. We tell the patient what we are seeing, what we see as her options, and what we recommend." Even with a recommendation for a 6-month follow-up, some patients opt for an immediate biopsy. She explains that, whether ultrasound or stereotactic, the biopsy is performed as soon as possible or at the patient's convenience.

Marty Custis, R.T. (R) (M)

Education and perserverance are the keys to reaching underserved women.

Her facility's process for consumer complaints has been in place "forever," well before MQSA required such a process. The facility's own quarterly survey, besides allowing reports of serious complaints, also covers courtesy, promptness, atmosphere, and effectiveness of education and explanation.

Patient care is always foremost in Custis's mind. The biggest challenge, she relates, is making mammography more accessible to the "poor and working women who are unable to come to the facility for any number of reasons." To reach them, St. Mary's Breast Center provides mammography services with its mobile van, reaching women near their homes or work.

The mobile unit has had "moderate success" in reaching women at their worksites. It has been less successful in reaching low-income women, even though those who qualify are provided free medical care. At a recent Community Health Center Health Fair, the mobile unit had scheduled 26 mammograms, but performed 30. More than half turned out to be walk-ins, which the van could handle because so many women cancelled due to last-minute conflicts.

"I believe education and perseverance are the keys to reaching this population." Custis notes with pride that St. Mary's is actively collaborating with local nonprofit organizations and newspapers to reach these underserved women. Because she likes to keep up with ways to improve outreach efforts, she will attend a regional meeting this fall, focusing on mobile mammography—not only to brush up on technical advances, but also to explore ways to increase participation of low-income women in mammography services.

Louise Schloss sees the whole picture in a rural setting

Louise Schloss, R.T. (R)(M) has supervised radiology at Benson Hospital for the past 10 years. The facility is located in the small town of Benson, Arizona, about 70 miles southeast of Tucson. "We are a 22-bed rural community, nonprofit hospital," says Schloss, "and have offered mammography services since 1993." Of the five technologists at the facility, Schloss is the only mammographer, and she performs five to eight mam-

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mograms a day on selected days of the week. Although shorthanded at present, she is hoping to replace a mammographer who recently left.

"We draw a large number of our patients from 'snow birds,' people who vacation here from about October to May." Some of these vacationers/winter residents don't always remember where or when they had their last mammogram. "We do our best to locate prior studies, and we usually do." In the spirit of MQSA, Schloss urges patients to retain copies of their exam reports and advises them of their rights to request their original mammograms.

When mammography was first offered in 1993, Benson Hospital reported mammograms with positive findings above the national average. Schloss attributes this number to the large population of seniors in this area, who either didn't drive or couldn't find someone to take them to Tucson for a screening mammogram. Lack of education about early detection was also a large factor. This is no longer the case.

Schloss and her colleagues participate in and search out special programs to reach new and larger segments of the population. This outreach includes addressing women's organizations, students and teachers at local schools, and staff gatherings at business sites.

The hospital serves a steadily increasing number of patients, partly because it has been addressing Congress's concern about access to mammography services for the medically underserved population. In addition to a Susan B. Komen Foundation grant to assist low-income patients, the hospital is able to charge for services on a sliding scale.

Although access may be broader when patients can self-refer, Benson Hospital does not accept self-referrals for mammograms, because, by Arizona law, a radiologist would have to serve as the primary care physician. With only two part-time interpreting physicians, the hospital is unable to provide this service. Consequently, to maintain patient access to mammography, one of the five local physicians has agreed to fulfill this role, providing health checkups, referring patients for their mammograms, and taking responsibility for follow-up care.

Since "Day 1," the patient pre-exam history questionaire has included breast implant questions to ensure that only mammographers with special training in imaging patients with breast implants conduct the exams. Schloss, the only mammographer at the facility, is qualified to provide this service.

Louise Schloss, R. T. (R) (M)

We've cried with patients and laughed with them. This makes the job so rewarding.

Although the MQSA final regulations now require facilities to provide results directly to all patients, Benson Hospital has always provided this service. In keeping with the spirit of the consumer complaint mechanism requirement of MQSA, the facility surveys patients about services the hospital provides. Benson Hospital finds this a useful tool on which to base changes toward improvements.

Schloss has also worked in larger facilities and finds she enjoys working in a smaller department. "Working here gives all of us a chance to get to know our patients and their families, and have a more personal relationship with them. We have been there for patients with bad news, as well as with patients waiting anxiously for test results. We have cried with them and laughed with them. This makes the job so rewarding."

The close involvement Schloss enjoys with the patients, the community, and with all members of the hospital staff contrasts with her more limited opportunities to communicate with fellow professionals and the regulating bodies. These obstacles are partially overcome through quarterly meetings of a rural hospital administrative network organization, the Arizona Imaging Forum. "Here," she says, "we share how each of us has dealt with inspections, certification, and equipment problems. This networking has helped us make sure that we are doing our best to comply with all federal and state regulations." In addition, Schloss and her colleagues keep up their contacts and continu-

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ing education units (CEUs) through the Arizona State Society of Radiological Technologists conferences and through readings and tests.

Still, she thinks there needs to be better communication among facilities, the ACR, and the FDA. As an example, she suggests that there be regional representatives from the ACR who would "be familiar with the problems of a particular area." She counts herself as fortunate in having the "ear of an [MQSA] inspector," one she can call and say, "I have a problem. What should I do?" Schloss related that, when the MQSA regulations were released, the inspector volunteered to meet with area mammographers and review the issues and answer questions.

Pamela Sirois welcomes MQSA's uniform standard for care

Pamela Sirois, R.T. (R)(M), has witnessed many transitions in the improvement of breast imaging in the 25 years she's worked at St. Joseph's Hospital (SJH) in Bangor, Maine. "Mammography was a small focus here at St. Joseph's in the early 1970s," says Sirois. "Over the years, we improved our mammography service from industrial film, vacuum packs, and xeromammography to screen-film. Now we're eager to jump into the digital mammography era."

When SJH developed the first free-standing breast center in northern New England in the mid-1980s, Sirois began working as a dedicated mammography technologist. The Regional Breast Care Center (RBCC) facility is affiliated with the hospital and serves the north-central Maine area. The facility is located in a Healthcare Park about one mile from the main 100-bed hospital. "Bangor is a small urban area of about 35,000, but a large portion of our patients are from rural communities. We provide breast imaging services for much of the Native American population of cental and downeast Maine, as well," Sirois reports.

Pamela Sirois, R.T. (R) (M)

Every facility wants to do a good job for its patients.

"Our facility provided 10,000 exams in 1998, including screening and diagnostic mammography, localizations, breast ultrasound, aspirations, and fine-needle biopsies. Some of the local breast surgeons use our Center for breast surgical consults, as well," she says.

As chief mammography technologist, Sirois works in tandem with all the other radiologic technologists providing patient services. Of the 50 mammograms the group averages daily, about 30 are screening procedures and 20 are diagnostic. She says that before every mammogram, the mammographer reviews the patient's history so that questions relating to breast surgery will prompt her to elicit other pertinent information, sometimes revealing the presence of breast implants. Beginning with the 1992 HCFA rules, her facility instituted reports to patients for screening results; RBCC now also provides diagnostic results to patients in a summary report.

Sirois states that Maine's very specific guidelines for mammography meant that implementation of MQSA did not change much in how the RBCC radiologic technologists conducted patient care. Despite "plenty of extra paperwork" under the new law, Sirois welcomed the uniform standard for care. "Every facility wants to do a good job for its patients," so in 1987 "our Center jumped in on the voluntary ACR Mammography Accreditation Program" to see how it was doing. Now the team at RBCC enjoys benchmarking on a daily basis—comparing "last time's films to see if we have done a better job [this year]." Film keeps improving, as do techniques for positioning, so the mammographers at RBCC continually try to "figure out how to get something better with each image."

Related to this quest for improvement, RBCC's clinical director looks for ways to evenly distribute funds to staff technologists for continuing education (CE). The occasional meeting where one can garner six or eight credits is supplemented by videos with post-tests. Sirois states that meeting the CE requirements is not that difficult, nor is finding seminars that stimulate interest in and

understanding of their rapidly changing profession. For example, another local hospital holds early morning multi-disciplinary breast conferences, and the staff recently attended one on genetic testing and breast cancer. Sirois and her colleagues also investigate new aspects of the profession through conferences sponsored by the Maine Society of Radiologic Technologists.

Continuing Medical Education (CME) hours are, of course, also required for interpreting physicians. Radiologists in the Bangor area, Sirois says, have an additional four sites for which they read, and those sites all have different inspection deadlines. It's Sirois's job to track down the interpreting physicians' CME information in time for the RBCC MQSA inspection. This task clearly requires tact and perseverance, because, as she relates, the physicians *know* they just provided *someone* with those details. Understanding the law and making sure the papers are in place are worth it to Sirois—for the sake of the patients and out of a quarter century of loyalty to St. Joseph's.

"I'm in charge of much of the pathology tracking and the outcome audits, and I compile the statistical reports," says Sirois. Although the state provided mammography software some time ago, until recently it hadn't "married well with the hospital's system." Now Sirois looks forward to the benefits of a streamlined statistics reporting system.

Sirois also credits the office staff for its help in tracking recalls and scheduling follow-up exams. "Our system utilizes a complete team effort," she says.

She offers some useful tips to other mammographers. "Anticipate patient and referring physician reaction to any changes you institute," she says. "Be far-sighted to minimize any perceived impact on patient comfort in relation to their previous experience. Take every advantage to interact and learn from other techs—one can always learn or share a technique or 'trick' for improvement. Be a model for a positioning class—I never learned more!"

RBCC learns from its patients, too. Through patient comment cards and occasional surveys, her facility has gleaned some easy-to-implement suggestions. RBCC has also developed the newly required MQSA consumer complaint mechanism to address serious patient complaints.

Sirois concludes with this observation: "Advances in the technology of breast imaging now allow all facilities to produce high-quality images. Much of the challenge continues to be reaching patients, both in encouraging them to have mammograms and in providing a friendly, caring, personalized experience. Our Center continues to focus on these challenges as we increase our number of patients served."

Guidance on Consumer Complaints and Patients with Breast Implants

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A "serious complaint" is defined as a report of a serious adverse event that significantly compromises clinical outcomes or one for which a facility fails to take appropriate corrective action in a timely manner. Examples of serious adverse events include: poor image quality, missed cancers, the use of personnel who do not meet regulatory requirements, and failure to send to the appropriate person(s) mammography reports or lay summaries within 30 days.

If a facility is unable to resolve a serious complaint to the consumer's satisfaction, the consumer may file the complaint with the facility's accreditation body. The facility must provide the consumer with adequate directions for filing the complaint with the accreditation body. Section 900.4(g), under accreditation body standards, established requirements for actions that accreditation bodies must take to resolve consumer complaints that have been referred to them. The final regulations do not prescribe any one particular method for accreditation bodies to use because FDA believes that flexibility will permit each accreditation body to establish a system that works best for the facilities it accredits and the patients they serve.

If the problem still can't be resolved, the accreditation body and/or the consumer may forward their serious complaint to FDA. Note that nothing in MQSA or the regulations precludes FDA or a State from investigating complaints.

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Q & A

The following questions and answers currently are in proposal stage under review and can be found in Compliance Guidance Document #2 on the MQSA website.

Q We use only one mammographic modality (screen-film) at our facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?

A Yes, if you are an interpreting physician or a radiologic technologist. FDA permits training in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each modality used by an interpreting physician or radiologic technologist. If screen-film is one, or the only, modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen.

In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given. The documentation must thus show that some of the 15 hours was related to film-screen mammography.

While facilities (and their personnel) will not have to provide documentation of mammographic modality specific continuing education until June 30, 2002, at the earliest, facilities can be cited for failure to meet this requirement after that date. Therefore, personnel should begin collecting such documentation as of 4/28/99. FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not breakdown the amount of credit issued by specific topic or mammographic modality. It is unlikely that this will change by the time of the implementation of the final regulations. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, it is strongly recommended that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend. If needed, these agendas will allow personnel to use the limited attestation policy to document the amount of CME/CEU in each mammographic modality.

Q Must the technologist complete the 40 hours of training prior to performing the 25 exams under direct supervision?

A No. The time spent performing the examinations can be part of the 40 hours of training (see next question).

Q What is an acceptable method for documenting the 40 contact hours of documented training specific to mammography?

A The training program or facility providing the training should provide a signed letter(s) or other document(s) on official letterhead indicating that the trainee acquired at least 40 hours of training specific to mammography. The letter(s) or document(s) should include the following:

1. that the training included breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants and, at least 8 hours in each mammographic modality used by the technologist during the training.
2. that the trainee performed at least 25 examinations under the direct supervision of a qualified radiologic technologist.
3. the inclusive dates during which time the training was given.
4. the name of the individual(s) supervising the performance of the 25 exams.

Q & A

5. signature of a responsible official of the facility or training program.

Training programs or facilities can include the actual time spent performing supervised examinations toward the 40 hour total. As guidance, however, no more than 12.5 hours of the required 40 should come from the performance of examinations. In those cases where training was obtained from more than one entity, each entity must provide its own letter documenting those areas that it covered. The total hours from all the letters must meet the requirement.

An example of acceptable documentation could read as follows:

OFFICIAL LETTERHEAD
During the dates [INCLUSIVE DATES], [NAME] received at least 40 contact hours of training specific to mammography, including breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants, and at least 8 hours in each mammographic modality used by the technologist during the training. The training included the performance of 25 examinations under the direct supervision of [NAME OF QUALIFIED SUPERVISOR(S)].
SIGNED BY RESPONSIBLE OFFICIAL

Q When is the earliest a facility can be cited for using a radiologic technologist who has failed to meet the continuing experience requirement and when does a radiologic technologist need to start keeping records documenting this requirement?

A A facility will not be cited for this requirement before June 30, 2001 and then only if the radiologic technologist has had at least 24 months since meeting his or her initial requirements.

The radiologic technologist could begin keeping records documenting continuing experience from June 30, 1999, or the date he or she completed his or her initial requirements, whichever is later. However, it is recommended that technologists currently in the field or their facilities begin keeping these records even before June 30, 1999. This will allow time to "work the bugs" out of their recording system and/or to identify situations in which workloads may have to be adjusted to meet the requirement before FDA begins citing facilities for failure to meet the requirement.

Guidance on Consumer Complaints and Patients with Breast Implants

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A third party may handle complaints for the facility if this approach is part of the facility's written Standard Operating Procedures (SOP) for handling complaints. However, the facility bears the ultimate responsibility for meeting the regulations related to the consumer complaint mechanism.

Breast implants

Facilities are not required to perform mammographic examinations of patients with breast implants. However, they are required to have a procedure in place for asking patients whether or not they have breast implants, even if the facility doesn't provide this service. So that patients are not inconvenienced, the facility may want to make this inquiry at the time the patient contacts them to schedule an appointment. But, this inquiry can be made at any time before the actual mammographic exam.

If the facility doesn't provide breast implant imaging, it may refer the patient to other facilities that have breast implant imaging expertise and provide such services. However, the final regulations do not require that this referral be made.

Because breast implant imaging techniques are evolving, MQSA allows facilities to use any implant displacement technique when imaging patients. FDA believes that it would be inappropriate at this time to limit, by regulation, this imaging to only one technique.

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