From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Winter 1998 Volume 5, Issue 1

Final MQSA Rule Takes Effect April 28, 1999

The final Mammography Quality Standards Act (MQSA) regulations will become effective on April 28, 1999, 18 months after FDA published them in the *Federal Register.* On the effective date, the final regulations will replace the interim standards under which facilities have been operating since October 1994. Although most of the regulations are the same as, or merely clarify, the interim regulations, there are many modifications.

FDA is making every effort to educate the public and key target audiences well in advance of April 28, 1999, so they will have time to make changes that may be necessary to comply with the new requirements. The responsibility for complying with all MQSA requirements ultimately rests with the facility.

This issue of *Mammography Matters* presents major changes, as well as highlights, in the areas of personnel requirements and equipment standards. In future issues, reporting and recordkeeping, quality assurance, and other requirements of the final rule will be examined.

During the months prior to the final regulations taking effect, FDA will distribute guidance documents dealing with such areas as interpreting the regulations and preparing for the new round of inspections, provide materials and/or speakers at key professional meetings, and regularly update the MQSA-related information available on the Internet (http://www.fda.gov/cdrh/dmqrp.html).

Continued on page 4

Inspection Fee Update

As noted in the past two issues of *Mammography Matters,* MQSA inspection fees are going up to cover the increased costs of the inspection program. This increase is the first since the initiation of the inspection program three years ago in January 1995. FDA sent all facilities a letter dated January 22, 1998, alerting them of the new fee.

Effective February 13, 1998, the new fee for facilities with one unit will be $1,549 and $204 for each additional unit. The fee for a follow-up inspection, if necessary, is $878.

Any inspections conducted on or after February 13, 1998, are subject to the new fee. Government entities, whose costs are covered through appropriated funds, will continue to be exempt from fee payment. Eligible mobile mammography providers will continue to have the option of grouped inspections for a fee discount.

The total aggregate cost of the MQSA inspection program is estimated to be $12.8 million in FY 1998. Beyond the inflation increases that are to be expected over a three-year period, the increased inspection costs reflect the full-scale operation of a program that utilizes 250 State and FDA inspectors to inspect over 10,000 facilities annually.

FDA continues to evaluate the fee assessment procedures, as described in the January 14, 1998 *Federal Register* (FR).

What's Inside

From the Director . . .

Final regulations for MQSA will be effective April 28, 1999. It's never too early to prepare!

FDA developed the final regulations with advice from our National Mammography Quality Assurance Advisory Committee and input from about 1,800 members of the public who wrote over 8,000 comments to our proposed rule of April 3, 1996. Writing the final regulations was a difficult job, because we were concerned about weighing and balancing all the different points of view.

When you first look at the final rule, as published in the October 28, 1997 Federal Register, *it appears there are many more regulations. In fact, a significant part of the document covers public inquiries and clarifications of the broad terminology used in the interim regulations that was confusing.*

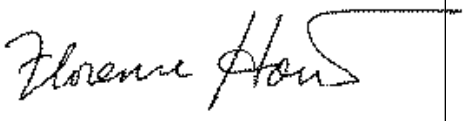
For example, the interim regulations require technologists to have "training" in mammography, but no content or amount was specified, which led to a lot of misunderstanding. FDA published guidance on what would count as training in October of 1994, but the interim regulations themselves still confused people. Thus, the final regulations codify "training" for technologists in terms of amount and required subject matter.

Another reason there appears to be more final than interim regulations is because quality control tests, previously

incorporated by reference to the American College of Radiology (ACR) manual, are now provided directly in the regulations. The ACR manual contains a lot of educational advice and recommendations that, when referenced by the interim regulations, became, at times, inappropriate as law. The final regulations recognize that the manual is an invaluable tool, but limits the scope of regulations on quality-control testing to a performance-based approach. This allows facilities to use a variety of methods to come up with the performance-specified result.

Lastly, some final regulations are new: infection control, consumer complaint mechanisms, breast implant imaging, and others. Over the next year, FDA will be highlighting all the facility final regulations to prepare you for April 28, 1999. This issue of Mammography Matters *details the new regulations for personnel and equipment.*

We will also be distributing our new inspection questions for the final regulations in early 1999 so you'll be familiar with the new inspection procedures. Please visit our website (www.fda.gov/cdrh/dmqrp.html) for more information. Thanks, again, for your commitment to your patients!



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MammographyMatters
Winter 1998

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

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

Mammography Matters
FDA/CDRH (HFZ-240)
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Back issues of *Mammography Matters* may be viewed on the Internet at www.fda.gov/cdrh/ dmqrp.html

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Facility Hotline

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

Don't Delay Reaccreditation

Make sure you check the expiration date on your FDA certificate and allow enough time for reaccreditation. Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during annual inspections that it continues to meet the MQSA quality standards.

Since it's unlawful to perform mammography with an expired FDA certificate, don't delay getting reaccredited. Start the process by contacting your accreditation body — the American College of Radiology (ACR) or the States of Arkansas, California, and Iowa — about eight months before your certificate is due to expire.

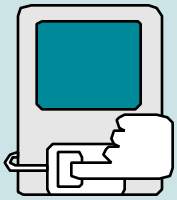
Remember, it's up to you to request an application from the accreditation body, complete it, return it, and pass reaccreditation in time for FDA to issue you a new certificate before your current one expires.

The accreditation body reviews the facility's equipment, personnel qualifications (interpreting physicians, radiologic technologists, and medical physicists), and practices. This includes personnel qualifications (continuing experience and training); the physicist's survey report of each x-ray unit used for mammography; the results of dosimetry evaluations, phantom images, and various other quality control tests from each unit; and clinical images from a number of patients.

If the review establishes that, in the judgment of the accreditation body, the facility meets the quality standards established under MQSA, then the facility will be reaccredited.

Facilities should not apply directly to FDA for certification. The accreditation body notifies FDA when a facility has successfully completed the reacceditation process. FDA then issues the facility a new three-year certificate. MM

Get the latest MQSA information.



Check it out on the Internet.

www.fda.gov/cdrh/dmqrp.html

(see page 8 for more information)

Final MQSA Rule

Continued from page 1

Personnel Requirements

The final rule, like the interim standards, stipulates requirements for interpreting physicians, radiologic technologists, and medical physicists. For each of these personnel categories, the final rule specifies initial qualifications, continuing experience, and continuing education requirements. The final rule also specifies ways for personnel who have become deficient in continuing experience and/or continuing education requirements to reestablish their qualifications.

The responsibility for complying with all MQSA requirements ultimately rests with the facility.

All personnel must have at least eight hours of training in the use of specific mammographic modalities (such as xeromammography, screen film, or digital mammography) before working independently in that modality. The continuing education requirements include completing at least six credit hours in each mammographic modality used.

The following section focuses on the major changes in the personnel requirements made in the final rule.

Interpreting Physicians

Initial qualifications: To qualify initially, interpreting physicians must have a state license to practice medicine and be *either* board certified in radiology or diagnostic radiology or have had three months of formal training in interpreting mammograms. This requirement is an increase of one month in the level of formal training necessary to qualify initially without board certification.

Additionally, the 40 hours of documented medical education previously required of interpreting physicians has been increased to 60 hours. The 60 hours must include at least eight hours of training in each modality used by the physician and all hours must be in Category I (topics directly related to the regulated areas of mammography). The requirement to interpret at least 240 mammography examinations has not increased, but the time period in which this must be done is now limited to the six-month period immediately prior to qualifying as an interpreting physician.

Exemptions to initial qualification requirements for interpreting physicians: Physicians who qualified under the interim regulations, prior to April 28, 1999, are exempt from the additional month of training required of non-board-certified physicians and the additional 20 hours of medical education in mammography. They must maintain their continuing experience and continuing medical education (CME) requirements (read 960 mammograms over a 24-month period and earn 15 CME credits over a 36-month period) to continue to interpret mammograms. Before they begin using a new modality, however, they will first have to obtain at least eight hours of training in its use.

The second exemption in the final rule applies to the requirement that physicians read 240 examinations during the six months immediately prior to qualifying as an interpreting physician. Physicians who became board certified at the first allowable time may do these interpretations in any six-month period during the last two years of their residency. This allows radiology residents to qualify if their mammography rotations are scheduled earlier than the final six months of the residency program.

Continuing education and continuing experience: The physician continuing education and experience requirements are unchanged with the exception that the continuing education credits now must be in Category I and must include at least six credits in each modality used by the physician.

Interpreting physicians who do not maintain the required continuing education and/or experience requirements must stop interpreting mammograms independently. To reestablish qualifications, physicians must meet the continuing experience requirements by interpreting or multi-reading at least 240 mammographic examinations or a sufficient number to bring their total up to 960 examinations for the prior 24 months (whichever is less) under the direct supervision of a qualified interpreting

physician. To reestablish the continuing education requirement, the physician must obtain a sufficient number of Category I training credits to bring their total to 15 in the previous 36 months before resuming independent interpretation.

Radiologic Technologists

Initial qualifications: Radiologic technologists must be licensed by a state or be certified in general radiography by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The primary change in the initial requirements is that at least 40 hours of training in mammography is now specifically required. The training must cover several specific topics and must include the performance of at least 25 examinations. *These initial education and experience requirements are waived for technologists who already qualify under the interim regs.* Additionally, all technologists must have eight hours of training in any new modality before working independently with that modality.

Continuing qualifications: A new continuing experience requirement has been added. All radiologic technologists must have conducted at least 200 examinations in the previous 24-month period. To meet the continuing education requirement, technologists must now include, as part of the required 15 continuing education units (CEU) in the past 36 months, at least six credits in each modality used.

Radiologic technologists who do not maintain their continuing experience requirements must perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming independent performance of mammography.

The final rule specifies initial qualifications, continuing experience, and continuing education requirements.

Medical Physicists

Initial qualifications: All medical physicists must be licensed or approved by a state or be certified by an FDA-approved body (the American Board of Radiology or the American Board of Medical Physics).

In addition, medical physicists must have a master's degree or higher in a physical science with at least 20 semester hours of college-level physics and 20 hours of training in conducting mammography surveys. They must also have completed surveys of at least one facility and 10 units (a unit may be resurveyed multiple times as part of this requirement, provided each survey is separated by 60 days) and eight hours of training in each new mammography modality before surveying that modality independently.

Alternative initial qualifications: The *alternative* initial qualifications can be used by medical physicists qualified under the interim regulations if they have kept all their necessary qualifications active. Such physicists are considered qualified if they have a bachelor's degree in a physical science with at least 10 semester hours of college-level physics, 40 contact hours of training in conducting mammography surveys, and experience surveying at least one facility, as well as at least 20 mammography units. They must also obtain eight hours of training in each new modality before independently surveying that modality.

Continuing qualifications: A continuing experience requirement has been added under which medical physicists must have surveyed at least two facilities and six units over 24 months. The continuing education requirement is unchanged.

Medical physicists who fail to maintain their qualifications must reestablish their continuing experience requirements under the direct supervision of a qualified medical physicist or obtain a sufficient number of continuing education units to bring their total to 15 in the previous three years before they can resume working independently.

MQSA Equipment Standards

The final rule's equipment standards, **most of which go into effect April 28, 1999,** are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

In response to concerns voiced by the public and the National Mammography Quality Assurance

Continued on page 6

Final MQSA Rule

Continued from page 5

Advisory Committee, FDA reduced the level of regulation originally proposed on equipment specifications. After a review of these comments, FDA reexamined the balance between the economic impact and the public health gains of each provision and decided to eliminate specifications related to source-to-image receptor distance, focal spot location, film processors, and several other items.

The final rule includes specific standards for the equipment as outlined below. In drafting the regulations, FDA relied heavily on the recommendations of groups such as the equipment focus groups convened by the American College of Radiology, with the support of the U.S. Centers for Disease Control and Prevention. FDA believes that most mammography equipment manufactured in recent years will meet many, if not all, of these requirements, but older equipment may have to be retrofitted or replaced.

Motion of the Tube-Image Receptor Assembly. Facilities must ensure that the tube-image receptor assembly is capable of being locked in any intended operating position within the range of its normal movements. The assembly should not undergo unintended motion once it is locked in any such position. The locking mechanism must not fail in the event of a power failure.

Image Receptor Sizes. Each screen-film mammography system must have, at a minimum, both an 18-by-24 cm and 24-by-30 cm image receptor and moving grids matched to each image receptor size provided with the system. Each system used for x-ray magnification procedures must be operable with the grid removed from between the source and the image receptor when the technologist is performing magnification procedures.

FDA believes that most mammography equipment manufactured in recent years will meet many, if not all, of these requirements.

Beam Limitation and Light Fields. Facilities must ensure that, in all systems, the x-ray field can extend to or beyond the edges of the image receptor. The intent is not to require that the collimator be adjustable, but that the collimator allow for complete coverage of the image receptor at all edges. For any system with a light beam that passes through the x-ray beam-limiting device, the light must have an average illumination of not less than 160 lux (15 foot-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

Magnification. The x-ray systems used for noninterventional problem-solving mammography must have x-ray magnification capability available to the user. These systems must be able to provide at least one magnification from within the range of 1.4 to 2.

Focal Spot Selection. Facilities must ensure that when more than one focal spot or target material is provided, the mammography systems must indicate, prior to exposure, which focal spot or target material has been selected. Similarly, when a selection is made by a system algorithm based on the exposure or on a test exposure, the system must display, after the exposure, the target material and/or focal spot actually used during the exposure.

Compression. Effective October 28, 2002, each mammography unit must have initial power-driven compression and fine adjustment compression controls operable from both sides of the patient.

Facilities' systems must be equipped with different-sized compression paddles that match the sizes of all full-field image receptors provided for the system. There are also requirements for the orientation of the compression paddle with respect to the breast support table and the chest wall edge of the image receptor.

Technique Factor Selection and Display. Manual selection of milliampere seconds (mAs) or at least one of its component parts (mA and/or time) must be available on each unit. The technique factors (peak tube potential in kVp and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure must be indicated before the exposure begins.

When automatic exposure controls (AEC) are in use, the technique factors set prior to the exposure must be indicated. And following AEC mode use, the system must indicate the actual kVp and mAs used during

the exposure. The mAs may be displayed as mA and time.

Automatic Exposure Control. Facilities must ensure that each screen-film mammography unit has an AEC mode that can be used in all equipment configurations provided on that unit (e.g., grid, nongrid, magnification, nonmagnification, and various target filter combinations). The positioning or selection of the AEC detector must permit flexibility in the placement of the detector under the target tissue.

Additionally, facilities must ensure that the size and available positions of the AEC detector are clearly indicated at the x-ray input surface of the breast compression paddle and that the system provides the means for the operator to vary the selected optical density from the normal (zero) setting.

X-Ray Film. Facilities performing screen-film mammography must use film that is designated for mammography by the film manufacturer.

Intensifying Screens. Facilities must use intensifying screens that have been specified by the manufacturer as appropriate for screen-film mammography. These screens must be used with film that is matched to the screen's spectral output as specified by the manufacturer. Facilities are responsible for matching the spectral output of the screen with the film; however, they are expected to use information provided by manufacturers rather than deriving the information independently.

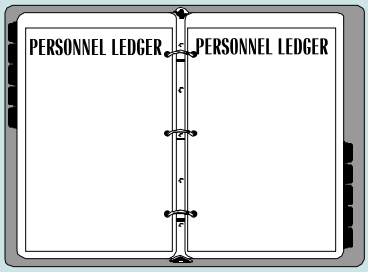
Film Processing Solutions. Facilities using film must use film processing solutions that meet, at least, the film manufacturer's minimum developing specifications.

Lighting. Facilities must provide special viewing lights for use by the interpreting physician during interpretation of mammograms. These "hot lights" must be capable of producing light levels greater than that provided by the standard viewbox to assist in the visualization of the darker areas of the image.

Film Masking Devices. Facilities must provide film masking devices that are capable of limiting the light from the viewbox to an area equal to or smaller than the exposed area of the film. Facilities using nonrectangular collimation must ensure suitable masking, and such devices must be available to the interpreting physicians. The general intent is for the masking to allow visualization of the complete image and to permit the reduction of the area to assist in visualizing smaller areas of interest on the image.

Any device that eliminates viewbox light not required for viewing and interpreting the image would meet this requirement. It need not be an expensive or elaborate system. This masking requirement applies to all sizes and shapes of images.

Are Your Personnel Records Up-To-Date?



Be Prepared for Your Inspection!
Avoid Being Out-of-Compliance.
Remember To Keep Your Records Current.

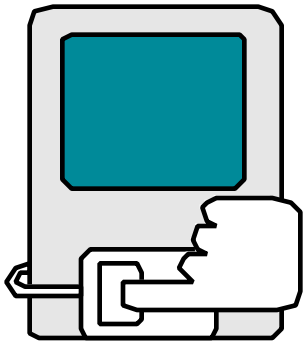
Examples of the kind of documentation facilities should maintain can be found in the Spring 1997 issue of *Mammography Matters*, page 5. Please note that FDA discontinued the classification system for continuing education training described on page 4 of that issue. Also see "What a Mammography Facility Should Do To Prepare for the MQSA Inspection," available on the Internet.

Find MQSA Information on the Internet

You can get the latest MQSA information by visiting the home page of FDA's Division of Mammography Quality and Radiation Programs (www.fda.gov/cdrh/dmqrp.html).

The MQSA website includes a number of documents you may review or download. For documents labeled "PDF Format," you will need to use Acrobat Reader from Adobe Systems. To access Acrobat, click on "PDF Reader" in the home page and follow directions.

Documents available on the website include a copy of the Final Regulations published in the *Federal Register*, a related guidebook *(Small Entity Compliance Guide)* that outlines changes from the Interim Regs, speaker's kit materials on the Final Regs, policy Q&As, the latest report from the General Accounting Office evaluating the MQSA program, back issues of *Mammography Matters*, and other useful information.



www.fda.gov/cdrh/dmqrp.html

Important Upcoming Website Documents

Keep checking the MQSA website for new items dealing with the final regulations. FDA expects to publish a draft Final Regulations Inspection Policy for public comment around September 1998. Also watch for Final Regulations Inspection Questions.

Errata Notice

Small Entity Compliance Guide, page 35, Section §900.12(e)(13), Infection Control

The first sentence in the Infection Control section of the *Small Entity Compliance Guide*, a companion document to the MQSA Final Regulations as published in the *Federal Register,* should be replaced with the following:

"Facilities must establish and comply with a system specifying procedures to be followed in cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials."

This document was distributed with the *Federal Register* and is also available on the DMQRP home page: http://www.fda.gov/cdrh/dmqrp.html.

What Your Data Can Reveal

This column provides useful suggestions for establishing and maintaining your medical audit system. (The suggestions presented here are not required by MQSA regulations.)

While facilities must collect and annually review outcome data on all women with positive mammograms, there is no requirement to do specific statistical analyses. However, your medical audit data can reveal key information for radiologists and technologists about their performance, where they are successful, and what needs improvement.

For example, it is extremely important for a facility to know the proportion of screening mammograms that are determined to be positive. Screening exams include the standard CC and MLO views of each breast performed on a woman with no current history of breast problems or changes.

Calculating and analyzing positive findings as determined by an individual interpreting physician, or for a subset of your client population, offer the opportunity to increase the quality of screening services you provide to your clients. Depending on the volume of mammograms done at your facility, you may want to calculate this statistic monthly (high-volume facilities), quarterly, or bi-annually.

Carole Chrvala, Ph.D., Chief of Clinical Research, Division of Mammography Quality and Radiation Programs

To calculate this proportion, determine the total number of screening mammograms completed during a specific period of time; determine the total number of positive mammograms on the basis of the radiologists' initial interpretations; and divide the number of findings by the total number of screenings.

A Simple Example

For example, interpreting physician A has interpreted 1,750 screening mammograms within the past 12 months. Of these, 13 were positive. If you divide 13 by 1,750, you find that 0.75% of physician A's exams were positive.

Now let's assume the total group of seven interpreting physicians at the facility (including physician A) have read 12,500 screening mammograms within the past year, with 188 positive findings. The facility rate of positive findings is 1.5%. In this example, physician A is 50% less likely than the entire group to interpret screening mammograms as positive.

A variety of factors can influence this ratio, including, but not limited to: (1) demographic and personal characteristics of the client population, (2) equipment characteristics, and (3) characteristics of each interpreting physician. As you gather and analyze your data, consider these factors, as well as any others you think may influence your statistics. This is true for the proportion of positive findings as well as other statistics to be addressed in subsequent columns.

Consider charting trend data to illustrate changes over time and facilitate problem-solving, if necessary. Remember: the interim and final regulations do not require any specific statistical analyses.

Future columns will focus on positive predictive value, specificity, sensitivity, as well as address in more detail the factors that can influence your outcomes data.

Q & A

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

Q In my files I have some old attestation forms previously provided by the American College of Radiology (ACR) for use in documenting that personnel requirements were met. Can I use these forms for the MQSA personnel requirements?

A It depends upon how old the forms are, as some of the ACR forms are obsolete. To determine if you can use a form from the ACR, or any other source, to attest to meeting MQSA personnel requirements, you should first confirm that the form includes the three required elements:

- space to record details about the training or experience being attested to, as we ask that you provide as many details on date, location, subject, etc. as you can remember;
- a statement recognizing the possible liability that can result from providing false information; and
- a space for the signature of the person who is attesting that he/she has met certain requirements.

Second, you should keep in mind that an individual can attest only to training and experience received prior to October 1, 1994. Thus, attestation is not acceptable for licenses or certificates or any alternatives to these (i.e., the training alternative to board certification for physicians) or to initial or continuing education and experience obtained after October 1, 1994. **Any form indicating that the individual is attesting to anything other than training and experience received before October 1, 1994, cannot be used.**

An example of an adequate attestation form was illustrated in *Mammography Matters* (Fall 1994, page 7), and the requirements that can be attested to were outlined in the Winter-Spring 1995 issue, page 7.

Q I have heard that radiologic technologists can "double count" their training credits to satisfy both the initial training and the continuing education requirements. How does it work?

A This "double counting" option applies *only* to technologists who met their initial requirements (prior to October 1, 1996) using the *experience* alternative. All of these technologists were required to meet the initial MQSA *training* requirement by October 1, 1996. As a result, these technologists had to be working to meet both their initial and continuing training requirements at the same time.

Consequently, a greater training burden was placed on this group of technologists than on those who first met their initial requirements through training and could focus solely on meeting the continuing education requirement. For example, the technologist who met the initial requirement on October 1, 1994, through training had to earn only the 15 continuing education units during the same 3-year period. In contrast, a technologist who had met the initial requirement on October 1, 1994, using the experience alternative, had to earn as many as 40 hours to meet the initial training requirement by October 1, 1996, and 15 more hours prior to October 1, 1997, to meet the continuing education requirement.

For that reason, FDA allows this group of technologists to count any part of the 40 hours earned after the date on which they satisfied the initial requirements using the experience alternative toward meeting both the initial training requirements and the continuing education requirements. For example, a technologist who had 20 hours of training in mammography on October 1, 1994, but was able to continue to work independently because she met the experience requirement, could maintain her qualifications after October 1, 1996, by receiving an additional 20 hours of training prior to that date. The additional 20 hours will also count toward her continuing education requirement.

Q & A *(continued)*

Q The medical physicist our facility employed to conduct the annual survey met the initial qualification requirements under MQSA by using the degree-training-experience option, but did not meet the October 27, 1997 deadline of being (1) certified in an FDA-approved speciality by an FDA-approved board, or (2) State licensed or State approved. Can our facility continue to use this person's services?

A No. The degree-training-experience option that medical physicists could use to meet the initial qualification requirement under MQSA expired on October 27, 1997. A mammography facility that continues to use the services of a medical physicist who is not certified or State licensed/approved *after* October 27, 1997, either for a consultation or for a new survey, will be cited for using unqualified personnel. This applies even when a medical physicist, who originally qualified through the degree-training-experience alternative, but does not now meet the requirements, was legally qualified to conduct annual mammography survey(s) *prior* to October 27, 1997.

Until the medical physicist meets the MQSA requirements, he/she may provide services to mammography facilities only under direct supervision.

This issue has been discussed in previous issues of *Mammography Matters* (see Summer 1996, page 7; Fall 1996, page 11; Winter 1997, page 5; Spring 1997, Editor's column; and Summer 1997, page 11).

The mention or illustration of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by FDA.

General MQSA Information

Submit requests for MQSA information to:

MQSA
c/o SciComm, Inc.
P.O. Box 30224
Bethesda, MD 20824-9998
Fax: 301-986-8015

Name and Address Changes:

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

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

Accreditation, Certification, and Commercial Products

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

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

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

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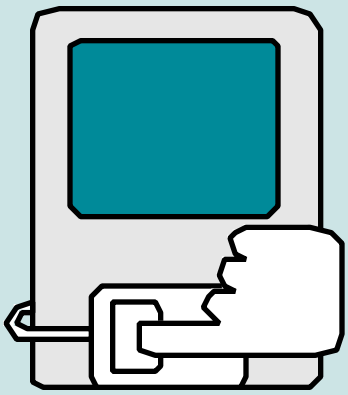
You can get the latest MQSA information by visiting the home page of FDA's Division of Mammography Quality and Radiation Programs (www.fda.gov/cdrh/dmqrp.html).

The MQSA website includes a number of documents you may review or download. For documents labeled "PDF Format," you will need to use Acrobat Reader. To access Acrobat, click on "PDF Reader" in the home page, and then click on "Instructions."



www.fda.gov/cdrh/dmqrp.html

Documents available on the website include a copy of the Final Regulations published in the *Federal Register*, a related guidebook *(Small Entity Compliance Guide)* that outlines changes from the Interim Regs, speaker's kit materials on the Final Regs, policy Q&As, the latest report from the General Accounting Office evaluating the MQSA program, back issues of *Mammography Matters*, and other useful information.

Important Upcoming Website Documents

Keep checking the MQSA website for new items dealing with the final regulations. FDA expects to publish a draft Final Regulations Inspection Policy for public comment around September 1998. Also watch for Final Regulations Inspection Questions.