*Contains Nonbinding Recommendations*

# Guidance for Industry, MQSA Inspectors, and FDA

# The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #11

**Document issued on August 12, 2005**

**This document modifies and updates guidance appearing in the Policy Guidance Help System**

The information collection provisions in this guidance have been approved under OMB control number 0910-0309. This approval expires 3/31/2007. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

For questions regarding this document contact Charles Finder at 301-594-3332 or by email at caf@cdrh.fda.gov.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**
**Division of Mammography Quality and Radiation Programs**
**Office of Communication, Education, and Radiation Programs**

# Preface

## Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For purposes of this document, additions to the Policy Guidance Help System (PGHS) are shown as highlighted text (^+Example^-) while deletions are shown by strikethroughs (*+~~Example~~*-). The symbols ^+, ^-, *+, and *- have been added to enable computerized text readers to identify the changes. Note: Questions and answers that are currently in the PGHS and are not being modified are not included in this document.

## Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/mammography/pubs/1569.pdf, or to receive this document by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number **1569** followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

# Guidance for Industry, MQSA Inspectors, and FDA Staff

# The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #11

***This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.***

## Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Public Law 102-539). This guidance document updates previous guidance and deals with the issue of mammographic modality specific continuing medical education (CME).

The MQSA final regulations, published on October 28, 1997, required continuing education for each of the three personnel categories in each mammographic modality used. The purpose of these regulations, which were developed with input from the National Mammography Quality Assurance Advisory Committee (NMQAAC), was to assure that personnel receive updated information on the new mammographic modality of Full Field Digital Mammography (FFDM). The first FFDM unit was not approved for commercial use by FDA until January 2000. Due to difficulties in obtaining continuing education credits specific to FFDM, over the years FDA delayed enforcement of these requirements twice. The current enforcement date is April 28, 2006. However, as the professional community has gained more experience with FFDM, the need for mammographic modality specific CME has come into question. NMQAAC revisited this issue and advised FDA that these

specific requirements are no longer necessary. The Institute of Medicine recommended that these requirements be deleted from the regulations. These groups concluded that the general requirement of obtaining 15 hours of continuing education in mammography every three years provides adequate assurance that personnel receive appropriate updated information about all mammographic modalities in a timely fashion. Until such time as FDA can proceed with the notice and comment process for deleting these regulations, FDA intends to delay their enforcement indefinitely. The general requirement of obtaining 15 hours of continuing education every three years in mammography or related topics is not under reconsideration and will not change. The purpose of this document is to inform the mammography community and make the necessary changes to the Policy Guidance Help System.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with its State or local authorities regarding their requirements.

# The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

# Background

MQSA was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that, in order to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification body. The authority to approve accreditation bodies, State certification bodies, and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published final regulations implementing the MQSA in the *Federal Register*.

In November 1998, FDA compiled all final FDA guidances related to MQSA and put them into a computerized searchable database called the Policy Guidance Help System (PGHS). The PGHS is available on the Internet at:
www.fda.gov/cdrh/mammography/robohelp/start.htm

FDA periodically updates the information in the PGHS and this document serves as a further update. Individuals wishing to receive automatic notification of future updates may subscribe to our E-mail ListServ by visiting http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

# Personnel

The discussion in the PGHS concerning several topics listed under the "Personnel" heading is being revised as follows:

## Personnel – Interpreting Physician – Interpreting Physician Continuing Education

**Citation:**
*900(a)(1)(ii)(B): All interpreting physicians shall maintain their qualifications by meeting the following requirement: Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.*

**Question 15: I'm an interpreting physician and use only one mammographic modality (screen-film) at my facility. Will I have to document six category I CME credits in screen-film mammography as part of the 15 general mammography CME credits?**
*+~~Yes. FDA permits education 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 mammographic modality used by an interpreting physician. If screen-film is one, or the only, mammographic modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen. Personnel should have begun collecting documentation of their mammographic modality specific continuing education as of April 28, 1999.~~

~~FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not break down the amount of credit issued by specific topic or mammographic modality. 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, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend in order to use the limited attestation policy to document the amount of CME/CEU earned in each mammographic modality.~~

~~Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.~~*-
^+No. Due to recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine, FDA intends to propose deleting the requirement for mammography modality specific continuing education and will delay enforcement of these requirements indefinitely.^-

***+~~Question 16: I use Full Field Digital Mammography (FFDM) at my facility. What records should I keep with respect to the mammographic modality continuing education requirement?~~**

~~If you clinically use FFDM, you need to begin to collect category I CME credits in that specific mammographic modality. You will need to demonstrate that you have acquired 6 credits in digital mammography within 36 months of your first having started using FFDM. If your category I CME certificates do not identify credits by mammographic modality, personnel can use the limited attestation policy to satisfy the requirement. FDA is extending this policy to allow personnel with CME certificates documenting the total number of credits, but not the specific mammographic modality covered by those credits, to attest that the required amount of CME in the specific mammographic modality has been obtained. In order to use the limited attestation policy, personnel are reminded that they need to retain, at the facility, the certificate stating the total number of credits awarded and an agenda or syllabus showing that the number of credits in the specific mammographic modality claimed could have been earned in the course. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present.~~

~~Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.~~*-

## Personnel – Interpreting Physician – Interpreting Physician New Mammographic Modality Training

**Citation:**

*900.12(a)(1)(ii)(C): Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.*

***+~~Question 10: What is the best way for personnel to document their mammography modality specific continuing education?~~**

~~The best way to document mammography modality specific continuing education is to have the education provider list the mammography modality credit hour "breakdown" on the CME/CEU certificate. Currently, most certificates do not provide such a "breakdown".~~

FDA strongly encourages CME/CEU providers to provide this "breakdown" information on their certificates. Facilities are reminded that they are held responsible for maintaining documentation of their personnel's mammography modality specific continuing education and should have begun collecting this documentation as of April 28, 1999. For those CME/CEU certificates that do not list the mammography modality credit hour "breakdown," personnel may verify meeting this continuing education requirement by providing the CME/CEU certificate, a signed attestation form, and the course agenda or syllabus (see limited attestation policy).

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.*-

## Personnel – Medical Physicist – Medical Physicist Continuing Education

**Citation:**
*900.12(a)(3)(iii)(A): Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.*

**Question 10: I'm a medical physicist and evaluate only one mammographic modality (screen-film). Will I have to document CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?**
*+Yes. 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. Your documentation must therefore show that some of the 15 hours were related to screen-film mammography. Personnel should have begun collecting documentation of their mammographic modality specific continuing education as of April 28, 1999.

FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not break down the amount of credit issued by specific topic or mammographic modality. 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, we strongly recommend that personnel keep the agendas (or

similar documents) of the courses or other educational activities they attend in order to use the limited attestation policy to document the amount of CME/CEU earned in each mammographic modality.

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.*-

^+No. Due to recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine, FDA intends to propose deleting the requirement for mammography modality specific continuing education and will delay enforcement of these requirements indefinitely.^-

***+Question 11: I evaluate Full Field Digital Mammography (FFDM) units. What records should I keep with respect to the mammographic modality continuing education requirement?**

If you evaluate FFDM, you need to begin to collect CME/CEU credits in that specific mammographic modality. You will need to demonstrate that you have acquired some credits in digital mammography within 36 months of your first having started using FFDM. If your CME/CEU certificates do not identify credits by mammographic modality, personnel can use the limited attestation policy to satisfy the requirement. FDA is extending this policy to allow personnel with CME/CEU certificates documenting the total number of credits, but not the specific mammographic modality covered by those credits, to attest that the required amount of CME/CEU in the specific mammographic modality has been obtained. In order to use the limited attestation policy, personnel are reminded that they need to retain, at the facility, the certificate stating the total number of credits awarded and an agenda or syllabus showing that the number of credits in the specific mammographic modality claimed could have been earned in the course. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present.

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide adequate documentation to their students.*-

## Personnel – Medical Physicist – Medical Physicist New Mammographic Modality Training

**Citation:**

*900.12(a)(3)(iii)(C): Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.*

***+Question 9: What is the best way for personnel to document their mammography modality specific continuing education?**

~~The best way to document mammography modality specific continuing education is to have the education provider list the mammography modality credit hour "breakdown" on the CME/CEU certificate. Currently, most certificates do not provide such a "breakdown". FDA strongly encourages CME/CEU providers to provide this "breakdown" information on their certificates. Facilities are reminded that they are held responsible for maintaining documentation of their personnel's mammography modality specific continuing education and should have begun collecting this documentation as of April 28, 1999. For those CME/CEU certificates that do not list the mammography modality credit hour "breakdown," personnel may verify meeting this continuing education requirement by providing the CME/CEU certificate, a signed attestation form, and the course agenda or syllabus (see limited attestation policy).~~

~~Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.~~

## Personnel – Radiologic Technologist – Radiologic Technologist Continuing Education

**Citation:**
*900.12(a)(2)(iii)(A) and (C): Continuing Education Requirements:*
*(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.*
*(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.*

**Question 11: I'm a radiologic technologist and use only one mammographic modality (screen-film) at my facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?**
*+~~Yes. FDA permits education 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 mammographic modality used by a radiologic technologist. If screen-film is one, or the only, mammographic modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen. Personnel should have begun collecting documentation of their mammographic modality specific continuing education as of April 28, 1999.~~

~~FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not break down the amount of credit issued by specific topic or mammographic modality. 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, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend in order to use the limited attestation policy to document the amount of CME/CEU earned in each mammographic modality.

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.*- ^+No. Due to recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine, FDA intends to propose deleting the requirement for mammography modality specific continuing education and will delay enforcement of these requirements indefinitely.^-

***+Question 12: I use Full Field Digital Mammography (FFDM) at my facility. What records should I keep with respect to the mammographic modality continuing education requirement?**

If you clinically use FFDM, you need to begin to collect CME/CEU credits in that specific mammographic modality. You will need to demonstrate that you have acquired 6 credits in digital mammography within 36 months of your first having started using FFDM. If your CME/CEU certificates do not identify credits by mammographic modality, personnel can use the limited attestation policy to satisfy the requirement. FDA is extending this policy to allow personnel with CME/CEU certificates documenting the total number of credits, but not the specific mammographic modality covered by those credits, to attest that the required amount of CME/CEU in the specific mammographic modality has been obtained. In order to use the limited attestation policy, personnel are reminded that they need to retain, at the facility, the certificate stating the total number of credits awarded and an agenda or syllabus showing that the number of credits in the specific mammographic modality claimed could have been earned in the course. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present.

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.*-

## Personnel – Radiologic Technologist – Radiologic Technologist New Mammographic Modality Training

**Citation:**

*900.12(a)(2)(iii)(E): Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for*

*which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.*

***+Question 11: What is the best way for personnel to document their mammography modality specific continuing education?**

The best way to document mammography modality specific continuing education is to have the education provider list the mammography modality credit hour "breakdown" on the CME/CEU certificate. Currently, most certificates do not provide such a "breakdown". FDA strongly encourages CME/CEU providers to provide this "breakdown" information on their certificates. Facilities are reminded that they are held responsible for maintaining documentation of their personnel's mammography modality specific continuing education and should have begun collecting this documentation as of April 28, 1999. For those CME/CEU certificates that do not list the mammography modality credit hour "breakdown," personnel may verify meeting this continuing education requirement by providing the CME/CEU certificate, a signed attestation form, and the course agenda or syllabus (see limited attestation policy).

Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2006. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.*-