Guidance for Industry and FDA

The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #8

Document issued on October 23, 2003

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

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 Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, 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/guidance/1232.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 1232 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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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) (Pub. L. 102-539). This guidance document updates previous guidance. Please note the following points, which are reflected in this update:

1. Delay in implementation of citations for mammography modality specific continuing education from April 28, 2004 to April 28, 2006
2. Inspection Fee changes
3. Newly approved alternative standards

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 the State or local authorities regarding their requirements.

Background

The Mammography Quality Standards Act was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally 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 the MQSA final regulations in the *Federal Register*. The final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance related to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: www.fda.gov/cdrh/mammography/robohelp/start.htm

This compliance guidance document serves to update the Policy Guidance Help System.

Guidance information is periodically updated. Individuals wishing to get automatic notification of such 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.

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/.

Mammography Modality Specific Continuing Education

Interpreting Physician Continuing Education

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

Interpreting Physician New Mammographic Modality Training

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

Medical Physicist Continuing Education

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide adequate documentation to their students.

Medical Physicist New Mammographic Modality Training

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

Radiologic Technologist Continuing Education

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

Radiologic Technologist New Mammographic Modality Training

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^-*+~~2004~~*-. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

Inspections Fees

Inspection Fee Consolidation

Discussion:
Due to the various ways mammographic machines were originally accredited and later certified, some inequitable billing situations have occurred. To address this, FDA has instituted an inspection fee consolidation policy ^+(inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them)^-. While this was originally designed for mobile facilities, it also applies to some stationary facilities. We believe that this policy will affect only a small percentage of mammographic facilities but will go a long way in correcting these billing problems. While everyone has his/her own idea of what a mammographic facility is or should be, it is important to remember that for MQSA purposes, a mammographic facility is defined by its MQSA certificate: one certificate equals one facility.

When you walk into a radiology department, you may intuitively think of it as an independent mammographic facility; however, it may actually be a small portion of a much larger operation with several mammographic machines at widely separated locations, covered by a single MQSA certificate. Remember, the consolidation policy refers to inspection fee billing issues only. Any changes to accreditation status must be handled between the facility and its Accreditation Body.

The three main factors determining the fee are:

1. Ownership of the mammographic x-ray units by a single entity,
2. The number of certificates, and
3. The number of mammographic x-ray units.

When two or more facilities (remember, one certificate equals one facility) are being considered for inspection fee consolidation, the number of "sites" must also be evaluated. "Site" refers to the relative location of the mammographic machines at the time of inspection. Multiple facilities located at one "site" may have their inspection fees consolidated, while those at multiple "sites" may not. Determining when two or more facilities qualify for the inspection fee consolidation will require the judgment of the inspector and should be based on the following guidance.

1. The two main factors to consider are the proximity of the mammographic x-ray units at the time of the inspection and that all the mammographic machines are owned by a single entity. Paper records for all the facilities (QA, QC, medical audit, and personnel records) must be available at the time and location of the inspection.
2. X-ray units that are close enough (usually in the same building or separated by no more than a block or two) to allow an inspector to examine the machines in a reasonable amount of time should be considered one "site."
3. Mobile units that can be brought together (possibly at the site of one or more stationary units), thereby allowing an inspector to examine the machines in a reasonable amount of

time, should be considered one "site" ^+for billing purposes^-. All processing must be done either centrally at the inspection site or on-board.

This policy is best illustrated by reviewing several representative examples. In all the cases below, it is assumed that the mammographic machines are owned by one entity.

Example 1 — You are inspecting a facility and find that they have a second mammographic unit under a different *+~~FDA~~*- ^+MQSA^- certificate number. The second unit is just down the hallway. In this case you can combine the inspections for billing purposes. The total charge will be *+~~$1549~~*- ^+$1,749^- (1 full fee) + $204 (1 additional unit fee).

Example 2 — You are inspecting *+~~a mobile company~~*- ^+an entity^- that owns 5 mobile mammography units and 2 stationary mammography units. Each of the 7 mammographic units *+~~have their~~*- ^+has its^- own *+~~FDA~~*- ^+MQSA^- certificate number. All mobile units have on-board processing. The 2 stationary units are located several miles apart. The owner is able to bring 2 of his mobile units to the same location as one of his stationary units. In this case you can combine these ^+three^- inspections for billing purposes. The total charge will be *+~~$1549~~*- ^+$1,749^- + $204 + $204. The remaining units ^+(3 mobile and 1 stationary)^- will be inspected at a later date or dates.

Example 3 — You are inspecting a large university with a total of 4 units, all under one certificate. Three of the mammographic units are in the same building and the other is located 5 miles away in a satellite location. The total charge will be *+~~$1549~~*- ^+$1,749^- + $204 + $204 + $204. While this would seem to be a contradiction of the definition of a single "site" (units separated by 5 miles), the overriding factor in this case is that all the units are covered by a single *+~~FDA~~*- ^+MQSA^- certificate. While this may seem "unfair" to other facilities, by law, this facility cannot be charged as if it were two separate facilities.

Example 4 — You are inspecting a mobile operator that has 2 mammographic units, each with its own *+~~FDA~~*- ^+MQSA^- certificate. Each of the units goes to 10 remote locations. The remote locations have their own processors. The mobile operator brings both mammographic units to one of the remote locations for the inspection. This example does not qualify for fee consolidation because all film processing is not done centrally or on-board the mobile units. Total charge will be *+~~$1549~~*- ^+$1,749^- + *+~~$1549~~*- ^+$1,749^-.

The preceding guidance and examples should answer many of your questions but cannot take into account all the possible situations you may encounter. If *+~~inspectors~~*- ^+inspectors^- have further questions or run into an unusual situation, they should contact the *+~~Inspector Help Desk via MPRIS Electronic Mail~~*- ^+Facility Hotline at 1-800-838-7715 or MQSAhotline@SSSI.net^-. The inspection software feature called Grouping Inspections for Billing should be used for this purpose. This software feature deals ONLY with fee consolidations. The inspection data should be entered in the usual manner. Each certificate-holding facility is to have its own data entered into its own inspection report. This will require you to input data common to the facilities into each of the inspection reports. For example, you will have to input the common data on the personnel, audits, QC, QA, and so on into all the inspection reports.

+~~Mammography Inspection Fees~~- ^+Inspection Fees^-

Discussion:

*+~~Effective February 13, 1998, the MQSA inspection fees for mammography facilities with one unit are $1,549 and $204 for each additional unit. For a follow-up inspection (if necessary), the fee is $878. The fees notice was published in the January 14, 1998, Federal Register (63 F.R. 2245). Any MQSA inspections conducted on or after February 13, 1998, are subject to these fees.~~
~~The total aggregate cost of the MQSA inspection program is estimated to be $12.8 million in 1998. The costs reflect the full-scale operation of an inspection program that utilizes 240 State and FDA inspectors to inspect 10,000 facilities annually. Included are the costs associated with the scientific, administrative, and data system support for the mammography inspection program.~~

~~Comments on the Fees~~

~~FDA hopes that this fee schedule will remain constant through FY 1999. However, the program will be assessed annually to determine the adequacy of the fee. As noted in the Federal Register notice, FDA continues to evaluate its fee assessment procedures and invites written comments from interested parties.~~

~~Facilities Subject to the Fees~~

~~Governmental entities continue to be exempt from fee payment, and eligible mobile mammography providers continue to have the option of grouped inspections for a fee discount.~~

~~Copies of the Federal Register (FR) Notices~~

~~We encourage you and other interested parties to access our Internet Homepage (http://www.fda.gov/cdrh/mammography) to view and download a copy of the FR notice. Otherwise, you may request a faxed copy of the FR Inspection Fee Notice by calling 1.800.899.0381. Or you may write to:~~

~~MQSA c/o SciComm, Inc.~~
~~P.O. Box 30224~~
~~Bethesda, MD 20824-9998~~*-
^+The MQSA inspection program is required by law to be fee-supported. Effective October 1, 2003, the MQSA inspection fees for mammography facilities with one unit are $1,749 and $204 for each additional unit. For a follow-up inspection (if necessary), the fee is $991. Included in the fee are the costs associated with the scientific, administrative, and data system support for the mammography inspection program. The fees notice was published in the September 4, 2003, Federal Register (68 F.R. 52589). Any MQSA inspections conducted on or after October 1, 2003, are subject to these fees.

The total aggregate cost of the MQSA inspection program is estimated to be $14.1 million in FY 2004. The costs reflect the full-scale operation of an inspection program that utilizes State and FDA inspectors to annually inspect mammography facilities. Included in the fee are the costs associated with the scientific, administrative, and data system support for the mammography inspection program.

Facilities in Certifying States should contact their State Certifying Agency to determine the fees that apply to them. FDA will continue to assess its $509 fee on facilities operating in approved Certifying States.

Comments on the Fees
The program is assessed annually to determine the adequacy of the fee. As noted in the Federal Register notice, FDA invites written comments from interested parties on its fee assessment procedures.

Facilities Subject to the Fees
Governmental entities continue to be exempt from fee payment, and eligible mobile mammography providers continue to have the option of grouped inspections for a fee discount.

Copies of the Federal Register (FR) Notice
We encourage you and other interested parties to access our Internet Homepage (http://www.fda.gov/cdrh/mammography) to view and download a copy of the FR notice.^-

Mobile Mammography Facility Inspection Fee Reduction Fact Sheet

Discussion:
*+~~The Mammography Quality Standards Act (MQSA) of 1992 requires the FDA to assess and collect fees from mammography facilities to cover the costs of annual inspections required by MQSA.~~
~~FDA has established the following fee structure under MQSA as explained in the January 14, 1998, Federal Register Notice (63 F.R. 2245).~~*-
~~Annual Inspection: $1,549 for the first mammography unit, plus $204 for each additional unit.~~
Providers with multiple mobile mammography units that are presently operating under two or more *+~~FDA~~*- ^+MQSA^- certificates have the option (for inspection purposes only) of combining their facilities in order to reduce their total inspection fee. The following conditions must be met to qualify for this reduction:

1. All mobile units use either on-board film processing or centralized processing at the site where inspection is to take place.
2. All quality control, personnel qualification, and medical records for all units in the group, and for all sites serviced by the mobile unit, are available at the time of the MQSA inspection.
3. All units must be available at the inspection site at the time of the MQSA inspection.

Those providers meeting the above conditions will be charged using the following equation:

Total Inspection Fee = *+~~$1549~~*- ^+$1,749^- +(n-1) x $204
where n = total number of units inspected

+~~We are not asking you to take any action now.~~- If you are the operator of multiple mobile units, please inform the inspector at the time of the initial appointment call. Arrange to have some or all of your mobile units at the inspection site to qualify for the fee reduction.

Newly Approved Alternative Standards

^+Separate Assessment of Findings for Each Breast

FDA approved this alternative standard July 3, 2003 for an indefinite period. It allows the interpreting physician to provide a separate assessment of findings for each breast in the medical report, without the need to also provide an overall assessment of findings. Therefore, the interpreting physician can choose between providing separate assessments under this alternative or providing an overall assessment for the examination under the original standard.

The original standard is 21 CFR 900.12(c)(1)(iv), which states:

21 CFR 900.12(c)(1): *Medical records and mammography reports*
(iv) Overall assessment of findings, classified in one of the following categories:

The approved alternative is:

21 CFR 900.12(c)(1): *Medical records and mammography reports*
(iv) A separate assessment findings for each breast, classified in one of the following categories:

When this alternative is used, the following conditions apply.

- A single medical report covering the assessment of both breasts will be sent to the referring physician (or to the patient if there is no referring physician;
- A single lay report will be sent to the patient, containing information based on the overall assessment for both breasts; and
- Even though separate assessments are made for each breast, the interpretation will count as only one examination towards meeting the MQSA experience requirements and will be billed as a single examination.

Correction Period When Components of the Selenia Full Field Digital Mammography System Fail Quality Control Tests

This alternative requirement was approved on August 21, 2003. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Selenia Full Field Digital Mammography System. The specified tests are equivalent to quality control tests for screen-film systems for which a 30 day correction period is already allowed. The alternative standard also divides into two groups the quality control tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, image acquisition must cease until the problem is corrected but image interpretation can continue. Similarly if the test failure is related to the interpretation of images, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The alternative was approved for an indefinite period.

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

> 21 CFR 900.12(e)(8): *Use of test results*
> (ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:
> (A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;

The approved alternative is:

> 21 CFR 900.12(e)(8): Use of test results.
> (ii) If the test results for the Selenia FFDM System fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken:
> (A) If any of the following quality control tests that evaluate the performance of the image acquisition components of the Selenia FFDM system produce results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed:
> (1) Evaluation of System Resolution
> (2) Breast Entrance Exposure and Average Glandular Dose
> (3) Phantom Image Quality Evaluation (Medical Physicist)
> (4) Phantom Image (Radiologic Technologist)

(5) Signal-to-Noise and Contrast-to-Noise Measurements
(6) Detector Flat-Field Calibration
(7) Compression
(8) Post-Move and Pre-Examination Tests for Mobile Selenia™ FFDM systems

(B) If any of the following quality control tests that evaluate the performance of a *diagnostic device used for mammographic image interpretation* (i.e. laser printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Clinical imaging can be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation:

(1) Phantom Image Quality Evaluation (Medical Physicist)
(2) Phantom Image (Radiologic Technologist)
(3) Softcopy Workstation QC
(4) Laser Printer Quality Control
(5) Dark Room Cleanliness
(6) Processor Quality Control
(7) Viewboxes and Viewing Conditions
(8) Darkroom Fog

(C) If any of the following quality control tests that evaluate the performance of *components <u>other</u> than the digital image receptor or the diagnostic devices used for mammographic image interpretation* produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation can be continued during this period:

(1) Mammographic Unit Assembly Evaluation
(2) Collimation Assessment
(3) Artifact Evaluation
(4) kVp Accuracy and Reproducibility
(5) Beam Quality Assessment – HVL Measurement
(6) Radiation Output Rate
(7) Viewbox Luminance and Room Illuminance
(8) Compression Thickness Indicator
(9) Visual Checklist
(10) Analysis of Fixer Retention in Film
(11) Repeat Analysis

Amendment to GE Senographe™ 2000D Full Field Digital Mammography (FFDM) system alternative standard originally approved on June 27, 2002.

The following amended alternative standard was approved on August 25, 2003 and became effective on the date of approval.

The amended standard replaces the specific reference to the GE Senographe™ 2000D FFDM system with a generic reference to an "FDA-approved GE" FFDM system. Like the original standard, it allows a 30 day period for corrective actions following the failure of specified quality control tests by an FDA-approved GE FFDM system. However, it divides into two groups the tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, the review of already acquired images can continue and when the test failure is related to the image review components only, images can continue to be acquired. Also, in approving the amended alternative standard, FDA stated that if GE introduces new FFDM systems having QC tests other than what is included in the original or amended standard, the subject amended alternative standard would not be applicable to such systems.

The original approved alternative standard is 21 CFR 900.12(e)(8)(ii), which states:

21 CFR 900.12(e)(8): *Use of test results.*

(ii) If the test results for the Senographe™ 2000D FFDM fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammograms are acquired using the Senographe™ 2000D FFDM system that failed any of the following tests:

(1) Monitor cleaning for the Acquisition Work Station (AWS)
(2) Flat Field Test
(3) CNR Test
(4) Phantom Image Quality Test for the AWS
(5) MTF Measurement
(6) AOP Mode and SNR Check
(7) Visual Check List
(8) Compression Force Test
(9) Average Glandular Dose
(10) Post-move, Pre-examination Tests for Mobile Senographe™ 2000D FFDM

(B) Before any further examinations are reviewed or any films are printed or processed using the component of the Senographe™ 2000D FFDM system that failed any of the following tests:

(1) Monitor cleaning for the Review Work Station (RWS)

(2) Viewing Conditions for the RWS (Radiologic Technologist's test)
(3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
(4) Phantom Image Quality Test for the RWS
(5) Phantom Image Quality Test for the Printer
(6) Viewbox and Viewing Conditions Test
(7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
(8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
(9) Printer QC

(C) Within 30 days of the test date for the following tests:
(1) Repeat Analysis
(2) Collimation Assessment
(3) Evaluation of Focal Spot Performance
(4) Exposure and mAs Reproducibility
(5) Artifact Evaluation; Flat Field Uniformity
(6) Monitor Calibration (Medical Physicist's test for the RWS)
(7) Analysis of the RWS Screen Uniformity
(8) kVp Accuracy and Reproducibility
(9) Beam Quality Assessment (Half-Value Layer Measurement)
(10) Radiation Output
(11) Mammographic Unit Assembly Evaluation

The approved amendment to this alternative is stated below:

21 CFR 900.12(e)(8): *Use of test results.*

For the image acquisition system

(i) If the test results for the image acquisition system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the image acquisition system that failed any of the following tests:

(1) Monitor cleaning for the acquisition work station (AWS)
(2) Flat Field Test
(3) CNR Test
(4) Phantom Image Quality Test for the AWS
(5) MTF Measurement
(6) AOP Mode and SNR Check
(7) Visual Check List
(8) Compression Force Test
(9) Average Glandular Dose
(10) Post-move, Pre-examination Tests for a mobile FDA-approved GE FFDM

(B) Before any further films of mammographic images are printed or processed using the component of the FDA-approved GE FFDM equipment that failed any of the following tests:

(1) Phantom Image Quality Test for the Printer
(2) Viewbox and Viewing Conditions Test
(3) Printer QC

(C) Within 30 days of the test date for the following tests:

(1) Repeat Analysis
(2) Collimation Assessment
(3) Evaluation of Focal Spot Performance
(4) Exposure and mAs Reproducibility
(5) Artifact Evaluation; Flat Field Uniformity
(6) kVp Accuracy and Reproducibility
(7) Beam Quality Assessment (Half-Value Layer Measurement)
(8) Radiation Output
(9) Mammographic Unit Assembly Evaluation

For the image display system

(ii) If the test results for the image display system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are reviewed or any films are printed or processed using the component of the image display system that failed any of the following tests:

(1) Monitor cleaning for the review workstation (RWS)
(2) Viewing Conditions for the RWS (Radiologic Technologist's test)
(3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
(4) Phantom Image Quality Test for the RWS
(5) Phantom Image Quality Test for the Printer
(6) Viewbox and Viewing Conditions Test
(7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
(8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
(9) Printer QC

(B) Within 30 days of the test date for the following tests:

(1) Monitor Calibration (Medical Physicist's test for the RWS)
(2) Analysis of the RWS Screen Uniformity.

No time limit has been placed on the period of approval for this alternative requirement.

Modifications in the Assessment Categories Used in Medical Reports

Two alternative requirements were approved on August 29, 2003. One of these adds a new assessment category for use in the reports of the mammography examinations and also adds clarifying language to the existing assessment categories. The second adds a reference to the possible need to obtain prior mammograms in order to make a final assessment. The alternatives were approved for an indefinite period.

The original standards are 21 CFR 900.12(c)(1)(iv) and (v), which state:

> 21 CFR 900.12(c)(1): *Medical records and mammography reports*
> …..
> (iv) Overall assessment of findings, classified in one of the following categories:
> (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
> (B) "Benign:" Also a negative assessment;
> (C) "Probably Benign:" Finding(s) has a high probability of being benign;
> (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
> (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:
> (v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and ….

The approved alternatives are:

> 21 CFR 900.12(c)(1): *Medical records and mammography reports*
> …..
> (iv) Overall assessment of findings, classified in one of the following categories:
> (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
> (B) "Benign Finding(s):" Also a negative assessment;
> (C) "Probably Benign Finding:" Initial short-interval follow-up suggested. Finding(s) has a high probability of being benign;
> (D) "Suspicious Abnormality:" Biopsy should be considered. Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

> (E) "Highly suggestive of malignancy:" Appropriate action should be taken. Finding(s) has a high probability of being malignant:
> (F) "Known Biopsy Proven Malignancy:" Appropriate action should be taken.
> (v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and ….

As was the case with the original standard, only the words in quotation marks are required to be included in the medical report when giving the assessment category or indicating that no final category can be assigned at the present time. The remaining language is intended to provide explanations of the categories in order to promote their consistent use. It is not required to be included in the medical report, although the interpreting physician may do so if he or she wishes.

Assessment category for "Post Procedure Mammograms for Marker Placement"

This alternative standard was approved on September 17, 2003. This approved assessment category can only be used for a post procedure mammogram to confirm the deployment and position of a breast tissue marker. The lay summary, which must be provided to the patient, must be specific to the procedure. If the facility makes this post procedure examination part of the interventional study instead of a separately charged examination, then it does not fall under MQSA and the approved alternative standard does not apply. The alternative was approved for an indefinite period

The original standard is 21 CFR 900.12(c)(1)(iv), which states:

21 CFR 900.12(c)(1): *Medical records and mammography reports*

(iv) Overall assessment of findings, classified in one of the following categories:
(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign:" Also a negative assessment;
(C) "Probably Benign:" Finding(s) has a high probability of being benign;
(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:
(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and...

The granted alternative is:
21 CFR 900.12(c)(1): *Medical records and mammography reports*

(iv) Overall assessment of findings, classified in one of the following categories:

(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign:" Also a negative assessment;
(C) "Probably Benign:" Finding(s) has a high probability of being benign;
(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:
(F) "Post Procedure Mammograms for Marker Placement"

(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and...^-