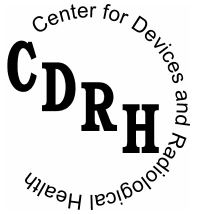
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #5; Guidance for Industry and FDA

Document issued on July 8, 2002

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



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 while deletions are shown by strikethroughs. Note: Questions and answers that are currently in the PGHS and are not being modified are not included in this document. For questions regarding the use or interpretation of this guidance contact Charles Finder at (301) 594-3332 or by email caf@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/mammography/pubs/1411.pdf, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, 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 1411 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #5

This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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Background

The Mammography Quality Standards Act was passed 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 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 referable 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/guidance-rev.html
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/

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). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

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.

Introduction to the PGHS

~~It is~~ We recommend~~ed~~ that you download the Policy Guidance Help System to run on your own computer. However, it is important to remember that the guidance is updated on a regular basis, so you should check FDA's Mammography website to make sure that you have the most current information. 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.

Welcome to the Policy Guidance Help System (PGHS).
~~The guidance presented here reflects FDA's current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L.102-539).~~ The Policy Guidance Help System is intended to provide useful information 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). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

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.

The system is organized as a series of books or main topics (see the Contents tab to the left). To view the list of topic titles in a specific book click on the "+" symbol or double-click on the book icon. To see the contents of a topic, simply click on its title.

The Index consists of a list of keywords associated with appropriate topics. Click on the Index tab on the left side of this screen to display the list of keywords. You may scroll through all the keywords or type in a keyword in the box at the top of this list. To see topics associated with a specific keyword, click on it and the relevant topics will appear in a box. To go to one of these topics, click on its topic title.

To search for any word in the system, click on the Search tab. Follow the "Find Setup Wizard" instructions to generate the list of words. Once the word list has been generated, follow the keyword procedures.
All pages have a "non-scrolling" area at the top of the page. This area may contain references to sections within the topics, such as "Questions" or "Key Words/Related Topics." These references are hyperlinked – that is, you can click on them to quickly go to that section. Because this area does not scroll, it allows you to easily navigate within topics.

Many of the pages begin with the regulatory citation related to the selected topic, followed by a discussion and/or a series of questions and answers offering guidance about how FDA will implement the regulations.

The topics conclude with a list of key words and related topics. Clicking on a **Keyword** will bring up a pop-up box from which you can choose to see another topic by clicking on it. If there is only one topic for the key word, you will go directly to that topic. Clicking on a **Related Topic** will take you directly to the related topic.

If you want to make the font size on the screen larger or smaller, choose "Options" from the top menu, then "Font," then highlight the desired font size.
If you have comments or questions about the Policy Guidance Help System, please submit them via e-mail to dmqrp@scicomm.com.

Accreditation and Certification Overview

900.11(a) General. After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in section 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

Discussion:

~~Accreditation and certification are two separate processes and both are required of mammography facilities under MQSA.~~ The Mammography Quality Standards Act (MQSA) requires that before ~~Before~~ a mammography facility can legally perform mammography, it must be certified. Before a facility can be certified, it must become accredited. To begin the process, it must first contact its ~~selected~~ accreditation body ~~(the ACR or the States of Arkansas, California, Iowa, or Texas)~~ and apply for accreditation.

Currently the FDA-approved accreditation bodies (AB) are:

American College of Radiology (ACR)
Mammography Accreditation Program
1-800-227-6440

Arkansas Department of Health
Division of Radiation Control and Emergency Management
1-501-661-2301

California Department of Health Services
Radiological Health Branch
1-916-322-6268

Iowa Department of Health
Bureau of Radiological Health
1-515-281-3478

Texas Department of Health
Bureau of Radiation Control
1-512-834-6688 extension 2246

Note: Under MQSA regulations, a facility located in a State approved by FDA as an AB may be accredited by the State or by the ACR. However, State law may require facilities to have State accreditation or State certification. State requirements are independent of MQSA. You may want to contact your State about their requirements.

The regulations require the AB to review a mammography facility's equipment, personnel (interpreting physicians, radiologic technologists, and medical physicists), and practices. The AB will accredit the facility if its review establishes that the mammography facility meets the quality standards established under MQSA.

Certification is a process separate from accreditation. It is administered by a Certifying Agency (FDA or an FDA-approved Certifying State). FDA will not certify facilities in approved Certifying States. Certifying States only certify facilities within their State borders. Currently the FDA-approved Certifying States are:

State of Illinois
Office of Radiation Safety
Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704
217-785-9974

State of Iowa
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street, Suite D
Des Moines, IA 50309
515-281-3478

Issuance of an MQSA certificate occurs after the AB notifies the Certifying Agency of the facility's accreditation. Only MQSA certified facilities can lawfully provide mammography services. The Centers for Medicare and Medicaid Services (CMS) will only reimburse for mammography performed at an MQSA certified facility.

Facilities Waiting for Receipt of their Provisional (6 month) MQSA Certificate (New Facilities)

When the AB accepts the facility's application for review, the AB will notify FDA or the Certifying State. The Certifying Agency will fax the facility an MQSA provisional certificate or a 45 day interim notice allowing it to begin performing mammography as soon as possible. The facility cannot perform mammography until it receives either of these documents. Facilities with questions about their accreditation/certification status should first contact their AB to see if their application has been accepted and if the Certifying Agency has been notified. If the facility still has not received its MQSA certificate or interim notice, the facility should contact FDA or the Certifying State. FDA may be contacted by fax at 1-410-290-6351 or by phone at 1-800-838-7715. Contact the Certifying State if your MQSA certificate is issued by the State.

During the six month provisional period, the facility must collect clinical images and other data needed for completion of the accreditation process (within the AB required timeframes) and adhere to all requirements of the AB. If the facility has not completed the accreditation process prior to the expiration of the provisional MQSA certificate, it must cease performing mammography or apply for and receive

reinstatement of the facility's MQSA certificate. Alternatively, a facility that meets certain criteria may qualify for a one-time **90-day extension** of the provisional MQSA certificate. Contact your AB for further information regarding reinstatement or a 90-day extension of the MQSA provisional certificate.

Facilities Waiting for Receipt of their Full (3 year), Reinstatement, or 90 Day Extension MQSA Certificates

Upon AB notification to FDA or the Certifying State that a facility has successfully completed the accreditation process, the Certifying Agency will mail the facility an original MQSA certificate. Because there may be a delay in receipt of the MQSA certificate, the AB may request the Certifying Agency to fax the facility a 45 day interim notice or photocopy of the MQSA certificate allowing continued mammography performance in cases where the facility's MQSA certificate has or is about to expire. Upon receipt of the interim notice or MQSA certificate, the facility may perform or continue to perform mammography. A facility that has questions about its accreditation status should contact its AB.

~~When the application has been accepted for review, the accreditation body will notify FDA, which will then send the facility a six-month provisional certificate. The facility must collect the clinical images and other data that will be needed for completion of the accreditation process and respond to all requirements of the accreditation body in a timely manner. If the facility has not completed the accreditation process prior to the expiration of the provisional certificate, it must cease performing mammography. A facility that has adhered to the accreditation body process timeframes may qualify for a 90-day extension of the provisional certificate.~~

~~A new facility whose application has been accepted by an accreditation body should receive its FDA certificate within 7 to 10 days after FDA has been notified. Prior to that, the facility will receive an Interim Notice within 2 to 3 business days. A facility that has not received its Interim Notice after 3 business days should notify the Mammography Quality Assurance Program by fax at 1-410-290-6351. The facility should prominently display this interim notice until it receives its FDA Mammography Facility Certificate. Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during its annual inspections that it continues to meet the MQSA quality standards.~~

Interested parties may find out which mammography facilities are certified as follows:

- The FDA MQSA Website (http://www.fda.gov/cdrh/mammography) has a link to "Listing of FDA Certified Mammography Facilities" that lists facilities by selected ~~s~~State or by specified three-digit zip code area. This information is updated weekly.
- The National Cancer Institute (NCI) ~~has~~ provides information regarding breast cancer and mammography, including a list of FDA-certified mammography facilities in a caller's area through their hotline: 1-800-4-CANCER (1-800-422-6237).
- A complete listing of all certified facilities may be ordered from the National Technical Information Service (NTIS) for a fee. The information is updated quarterly and is provided on 3-1/2" diskettes in ASCII format. Call 1-800-363-2068 or 1-703-605-6060 to order either a single disk (SUB 5286/Code D01) or a one-year subscription (SUB-5386).

Question 1: What are 45 day interim notices and interim accreditation and when are they used ~~Under what circumstances may FDA issue Interim Notices~~?

~~Facilities may call the FDA hotline to request assistance when they have not received a certificate or have other questions pertaining to certification, or they may contact their accreditation body with a similar request, and the accreditation body may contact FDA to request issuance of an interim notice. The following criteria will be used by FDA to determine whether an interim notice should be issued to a facility.~~

When a facility's MQSA certificate has expired or is about to expire, FDA or the Certifying State may, under certain conditions, issue a 45 day interim notice that allows the facility to continue to perform mammography. FDA or a Certifying State may issue ~~an~~ a 45 day ~~Interim Notice~~ interim notice to a mammography facility under the following ~~two sets of~~ circumstances:

1. REACCREDITATION COMPLETION DELAY: In cases where there has been a delay in the AB reaching a final reaccreditation decision, FDA or the Certifying State may issue a 45 day interim notice to a facility. This allows the facility to continue to perform mammography after its MQSA certificate has expired. Beginning in the summer of 2002, in order for a facility to be eligible to receive an interim notice, the facility must have been granted interim accreditation by its AB.

   A facility should submit its request for interim accreditation to its AB. The AB will apply its established criteria for interim accreditation and issue a decision regarding the request. If the interim accreditation request is approved by the AB, FDA or the Certifying State will be notified by the AB to fax the facility an interim notice. Upon receipt of the interim notice, the facility may perform or continue to perform mammography for up to 45 days. If full accreditation does not occur during this time period, contact the AB to discuss reinstatement. A facility whose interim notice has expired is considered no longer certified and must not perform mammography.

   If the AB does not grant the facility's request for interim accreditation, the facility may apply for reinstatement in accordance with its AB's policies. Once the current MQSA certificate and interim notice expire, a facility is considered no longer certified and must not perform mammography.

2. CERTIFICATE DELAY: If the AB has already made a positive accreditation decision, FDA or the Certifying State may fax the facility a copy of its MQSA certificate or issue an interim notice in order to allow the facility to perform mammography while awaiting receipt of the original MQSA certificate as described below.

   Facilities Waiting for Receipt of their Provisional (6 month) MQSA Certificate (New Facilities)

   When the AB accepts the facility's application for review, the AB will notify FDA or the Certifying State. The Certifying Agency will fax the facility an MQSA provisional certificate or a 45 day interim notice allowing it to begin performing mammography as soon as possible. The facility cannot perform mammography until it receives either of these documents. Facilities with questions about their accreditation/certification status should first contact their AB to see if their application has been accepted and if the Certifying Agency has been notified. If the facility still has not received its

MQSA certificate or interim notice, the facility should contact FDA or the Certifying State. FDA may be contacted by fax at 1-410-290-6351 or by phone at 1-800-838-7715. Contact the Certifying State if your MQSA certificate is issued by the State.

Facilities Waiting for Receipt of their Full (3 year), Reinstatement, or 90 Day Extension MQSA Certificates

Upon AB notification to FDA or the Certifying State that a facility has successfully completed the accreditation process, the Certifying Agency will mail the facility an original MQSA certificate. Because there may be a delay in receipt of the MQSA certificate, the AB may request the Certifying Agency to fax the facility a 45 day interim notice or photocopy of the MQSA certificate allowing continued mammography performance in cases where the facility's MQSA certificate has or is about to expire. Upon receipt of the interim notice or MQSA certificate, the facility may perform or continue to perform mammography. A facility that has questions about its accreditation status should contact its AB.

~~1) CERTIFICATE DELAY: There may be a delay in issuing or delivering a certificate to a facility that has met the requirements for a provisional or provisional reinstatement certificate, or has completed accreditation or reaccreditation and the facility's certificate has or is about to expire.~~

~~2) REACCREDITATION OR ACCREDITATION COMPLETION DELAY: There may be a delay in completing reaccreditation or accreditation beyond the expiration date of a facility's certificate for various reasons such as delay in completion of clinical image review. For a facility to be eligible to receive an interim notice, all of the following criteria should be met:~~

- ~~a) the facility has an expired or expiring three year FDA Mammography Facility Certificate, or the facility has an expired or expiring provisional certificate and accreditation is imminent;~~
- ~~b) the reaccrediting facility has applied for reaccreditation in a timely manner, i.e., at least six months prior to the expiration date of its certificate. Facilities receive ample notice from their AB's several months prior to expiration of their accreditation, that they should apply for reaccreditation. FDA considers six months prior to certificate expiration to be a minimum time frame that is adequate for reaccreditation;~~
- ~~c) the facility has adhered to the accreditation body process timeframes, i.e., submitted its clinical images and other information in time to complete normal review within the six-month accreditation/reaccreditation window; and~~
- ~~d) the delay should not otherwise be due to inappropriate facility activities.~~

Question 2: What should a facility do if its MQSA certificate expires before it is ~~accredited or~~ reaccredited?

If a facility's MQSA certificate expires before it has been ~~accredited or~~ reaccredited, it must immediately stop performing mammography or it may be subject to civil ~~monies~~ money penalties of up to $10,000 ~~per examination~~. Before the MQSA certificate expires, a facility should contact its accreditation body to discuss its options for continuing to perform mammography.

Question 3: Our group practice interprets mammograms sent to us by other facilities under a contractual arrangement. This is the only service that we provide in the mammography area. Does my group practice need an MQSA certificate to interpret mammograms?

No. Partial providers (groups such as yours that provide only part of the services required for mammography) are certified as part of a "system" for producing, processing, and interpreting mammograms. The provider of some component of the system that performs mammography must take the lead in obtaining an MQSA certificate.

FDA expects that, in most cases, the owner of an x-ray unit or units will apply for accreditation and receive an MQSA certificate. However, anyone interested in providing mammography services may apply for accreditation leading to an MQSA certificate. Under the facility accreditation process, partial providers, such as your group practice, are included in the required documentation provided to the accreditation body. The application for accreditation must show that all components of the system used to produce, process, and interpret mammograms meet MQSA requirements. These components do not have to be in the same location. If one or more of the facilities for which you ~~(or wish to)~~ interpret (or wish to interpret) mammograms is applying for accreditation and certification (or reaccreditation and recertification), your ~~responsibility~~ will need ~~be~~ to provide them with information documenting that the physicians in your group meet MQSA quality standards requirements for interpreting physicians.

When the MQSA certificate is issued or renewed, all such partial providers are covered as providing services through that facility. Each partial provider must meet the MQSA quality standards that apply to its part of the mammography process. Each partial provider must provide adequate documentation to the certificate holder that the quality standards are met. Any partial provider providing services for more than one MQSA certified facility will be covered separately under each facility's MQSA certificate. Conversely, if one of the facilities for which you interpret mammograms is not certified, it would be unlawful for that facility to continue to produce mammograms and for your group to interpret mammograms produced by them.

Your group practice could apply for accreditation and receive the MQSA certificate, as part of a system. In that case, your practice would be responsible for assuring not only that your practice meets MQSA quality standards for interpreting physicians, but also that the providers that produce and process the mammograms for your interpretation meet the quality standards that apply to them. Your practice would also be responsible for passing the review of clinical images from each facility that produces images for your interpretation, and for meeting the other requirements for accreditation. Finally, as an MQSA certificate holder, you would be responsible for paying an annual ~~FDA~~ MQSA inspection fee.

In summary, ~~it is~~ the MQSA certificate holder ~~who~~ is ultimately ~~will be held~~ responsible for assuring that all MQSA requirements are met.

Question 4: What should a facility do if it closes or decides that it will no longer provide mammography services?

Before a facility permanently stops performing mammography, it should do the following:

1. Inform its accreditation body that it will no longer be performing mammography;
2. Notify its State radiation control program;
3. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less than 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. The facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine if their requirements are more stringent. Note: Radiology practices and other medical facilities that still see patients but have permanently stopped performing mammography, may choose to keep the patients' medical records rather than transfer them to another facility (unless the patient requests such a transfer).

If option 3 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested and that former patients are made aware of that mechanism. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

Once the facility ceases operation, the MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.

Due to the fact that some facilities have not followed the above recommendations, FDA has received inquiries from patients complaining that their mammography facility has closed, that they were not informed, and that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that a facility that plans to stop performing mammography notify its Certifying Agency of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to:

FDA/CDRH/OHIP/DMQRP

Attention: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

Facilities certified by States may send the above information to:

State of Iowa

Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street, Suite D
Des Moines, IA 50309
515-281-3478

State of Illinois
Office of Radiation Safety
Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704
217-785-9974

Question 5: If a facility that fails to become accredited and certified continues to perform mammography, what penalties is it subject to? Can the facility be reimbursed by Medicare and insurance companies for mammography services?

Any facility that performs mammography without MQSA certification may be subject to civil money penalties of up to $10,000 per violation.
MQSA provides for civil money penalties for:

1) Failure to obtain an MQSA certificate as required;
2) Each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established; and
3) Each violation, or for each aiding and abetting in a violation of any provision of, or regulation promulgated under MQSA, by an owner, operator, or any employee of a facility required to have an MQSA certificate.

Facilities that are not MQSA certified cannot be reimbursed by the federal government for mammography services. CMS will not reimburse facilities for Medicare screening and diagnostic mammography examinations if they do not have an MQSA certificate, or if their MQSA certificate has expired, been suspended, or been revoked. The amount and frequency of reimbursement is governed by CMS regulations. FDA has provided an efficient system for CMS to confirm the certification status of all mammography facilities. CMS will share this information with insurance carriers, who are committed to reimburse only for lawfully performed mammography procedures.

Question 6: Since accreditation and certification are so closely linked, how will FDA or the Certifying State synchronize its certification period with a facility's accreditation period?

Certification is linked to the accreditation of the first mammography unit in a facility. The accreditation body notifies FDA or the Certifying State of a facility's first unit accreditation, which is for three years. FDA or the Certifying State issues an initial MQSA certificate that is effective on the date provided by the accreditation body and expires three years from that date.

Facilities that wish to continue to lawfully provide mammography services must be reaccredited before the initial MQSA certificate expires. Certificates that are issued following the initial MQSA certificate are effective for three years. The expiration date of the subsequent MQSA certificates is three years from the expiration date of the initial certification.

Question 7: By law, MQSA certificates must be prominently displayed in all facilities. Where should they be displayed?

An MQSA certificate should be displayed prominently where mammography patients can easily see it, such as the patient reception area. If a facility has more than one patient reception area, it may request an additional MQSA certificate for each reception area from FDA. All MQSA certificates issued to a facility will share that facility's unique 6-digit identification number. Contact the FDA MQSA Facility Hotline at 1-800-838-7715 to request additional MQSA certificates. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates.

Question 8: Are Spanish-language MQSA certificates available for facilities providing mammography services to a Spanish-speaking population?

Yes. FDA will issue an additional MQSA certificate translated into Spanish for those facilities serving a Spanish-speaking population. To obtain this additional MQSA certificate, contact the FDA MQSA Facility Hotline at 1-800-838-7715. The Spanish-language MQSA certificate and the English-language MQSA certificate should both be prominently displayed where they can be viewed by mammography patients. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates.

Question 9: Our facility has several patient waiting areas. Can I photocopy our facility MQSA certificate and place copies in each area?

While the Statute requires that the original MQSA certificate be prominently displayed, the photocopying of the MQSA certificate so that it may be displayed in additional areas is not prohibited. However, we recommend that facilities wishing to display their MQSA certificate in several different areas obtain additional MQSA certificates (at no charge) by contacting FDA at 1-800-838-7715 or writing to: FDA MQSA Program, P.O. Box 6057, Columbia, MD 21045~~-6057~~. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates. Facilities are reminded that, at a minimum, they must have the original MQSA certificate displayed even if they choose to display additional copies of the MQSA certificate. Mobile facilities must have at least one original MQSA certificate displayed whenever the mobile unit is performing mammography.

Question 104: We are a private radiology practice that applied for and became accredited and certified as a mammography facility. We do not own a mammography x-ray unit or employ a radiological technologist qualified to perform mammography. We had applied for accreditation using the x-ray unit and technologist from a certified mobile facility that visits our practice periodically. Do we have to be inspected

separately from the mobile facility and who is responsible for correcting any problems found?

If your facility and the mobile facility are both certified, you are both required to be inspected annually. Your facility and the mobile facility may, under certain circumstances, qualify under our Inspection Fee Consolidation policy, which could reduce your inspection fee cost. Regarding who is responsible for correction of problems, both facilities would be responsible for assuring that all aspects of mammography are in compliance prior to performing examinations on patients.

Appeal of Adverse Accreditation or Reaccreditation Decisions That Preclude Certification or Recertification

900.15(d)(3)(4)(5)(6): (d) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published in 42 CFR part 498.

(3) In accordance with the procedure set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP (Division of Mammography Quality and Radiation Programs).

(I) A facility must request reconsideration by DMQRP within 60 days of the accreditation body's adverse appeals decision, at the following address: Division of Mammography Quality and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, Attn: Facility Accreditation Review Committee.

(ii) The request for reconsideration shall include three copies of the following records:

(A) The accreditation body's original denial of accreditation.

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the basis for the facility's disagreement with the accreditation body's decision.

(iii) Will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Department of Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

Discussion:

A facility that has been denied accreditation is entitled to an appeal to the facility's accreditation body (AB). A facility should avail itself of the AB's appeal process before requesting reconsideration from the Food and Drug Administration (FDA).

If the facility cannot achieve satisfactory resolution of an adverse accreditation decision through its AB's appeal process, the facility may request reconsideration of that adverse decision by FDA through the Division of Mammography Quality and Radiation Programs (DMQRP).

NOTE: A facility cannot perform mammography services while an adverse accreditation decision is being appealed. For example, a facility that has been denied accreditation will receive a letter from the Certifying Agency notifying it that it must cease performing mammography. Once the facility receives that letter, it cannot perform mammography even if it is appealing the accreditation body's decision.

The appropriate procedure for requesting reconsideration of an adverse decision on accreditation ~~to DMQRP~~ is as follows:

APPEALS PROCEDURE

A facility should make its request for reconsideration to DMQRP, within 60 days of the AB's adverse appeals decision, at the following address:

~~Division of Mammography Quality and Radiation Programs (HFZ-240)~~
~~Center for Devices and Radiological Health~~
~~Food and Drug Administration~~
~~1350 Piccard Dr.~~
~~Rockville, MD 20850~~
~~Attn: Accreditation Body~~

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality and Radiation Programs
Attention: Accreditation and Certification Branch
Room 220, HFZ-240
1350 Piccard Drive
Rockville, MD 20850
Phone: (301) 594-3332
Fax: (301) 594-3306

The request for reconsideration should include 3 copies of the following records:

1. The AB's original denial of accreditation, including clinical or phantom image score sheets when applicable;
2. All information the facility submitted to the AB as part of the appeals process, including all original films submitted to the AB (additional copies of the films are not required);
3. A copy of the AB's adverse appeals decision including clinical or phantom image score sheets when applicable;
4. A statement of the bases for the facility's disagreement with the AB's decision.

The DMQRP will make a decision concerning the request for reconsideration within 60 days of receipt of all of the material specified above. The Division will provide the facility with written notification of its decision, and of the facility's options as a consequence of that decision.

A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing before the Departmental Appeals Board (DAB) of the Department of Health and Human Services. Copies of the applicable regulations (subpart D of 42 CFR part 498) for formal hearings will be supplied upon written request.

Application for a Provisional Certificate

900.11(b)(2)(i) and (ii): Provisional certificates.

(i) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.-C. 263b(c)(2) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

(ii) Following the agency's receipt of the accreditation body's decision that a facility has submitted the required information, FDA may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of section 900.11(b)(2)(i). A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90-day extension of the provisional certificate.

Discussion:

A facility that has applied for accreditation will be issued a provisional MQSA certificate by FDA or the Certifying State after the accreditation body has 1) reviewed the facility's initial application and 2) informed FDA or the Certifying State that it has accepted the facility's application. The provisional MQSA certificate ~~will~~ allows the facility to perform mammography lawfully for up to six months so it can complete the accreditation process. The facility cannot perform mammography until it receives its MQSA certificate or a 45 day interim notice.

During the six month provisional period, the facility must collect clinical images and other data needed for completion of the accreditation process (within the AB required timeframes) and adhere to all requirements of the AB. If the facility has not completed the accreditation process prior to the expiration of the provisional MQSA certificate, it must cease performing mammography or apply for and receive reinstatement of the facility's MQSA certificate. Alternatively, a facility that meets certain criteria may qualify for a one-time **90-day extension** of the provisional MQSA certificate. Contact your AB for further information regarding reinstatement or a 90-day extension of the MQSA certificate.

Facilities Waiting for Receipt of their Provisional (6 month) MQSA Certificate (New Facilities)

When the AB accepts the facility's application for review, the AB will notify FDA or the Certifying State. The Certifying Agency will fax the facility an MQSA provisional certificate or a 45 day interim notice allowing it to begin performing mammography as soon as possible. The facility cannot perform mammography until it receives either of these documents. Facilities with questions about their accreditation/certification status should first contact their AB to see if their application has been accepted and if the Certifying Agency has been notified. If the facility still has not received its MQSA certificate or interim notice, the facility should contact FDA or the Certifying State. FDA may be contacted by fax at 1-410-290-6351 or by phone at 1-800-838-7715. Contact the Certifying State if your MQSA certificate is issued by the State.

~~in order to obtain the clinical images needed to complete accreditation, as well as for the accreditation body to complete the necessary clinical image reviews.~~

~~Because this time period is limited and facilities cannot operate lawfully beyond the six-month period of provisional certification, it is essential that facilities promptly provide all required information, including clinical images, to the accreditation body so that the reviews required for accreditation can be completed. There are only limited circumstances under which a facility may receive additional time to complete the accreditation process.~~

Application for Extension of Provisional Certificate

900.11(b)(3)(i), (ii), (iii), and (iv): Extension of provisional certificate.

(i) To apply for a 90-day extension to a provisional certificate, a facility shall submit to its accreditation body, or other entity designated by FDA, a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

(ii) The accreditation body shall forward the request, with its recommendation, to FDA within 2 business days after receipt.

(iii) FDA may issue a 90-day extension for a provisional certificate upon determination that the extension meets the criteria set forth in 42 U.S.C. 263b(c)(2).

(iv) There can be no renewal of a provisional certificate beyond the 90-day extension.

Discussion:

A facility operating under a six-month provisional MQSA certificate (including a provisional reinstatement MQSA certificate) may be eligible for a single 90-day extension to its provisional MQSA certificate. (A facility operating under a three-year MQSA certificate is not eligible for a 90-day extension.)

If the accreditation process is not completed within the six-month provisional period, a facility may apply to FDA or the Certifying State, through its accreditation body, for a 90-day extension. To be eligible for a 90-day extension, a facility should have adhered to the accreditation body's schedule in submitting the necessary images and information (i.e., to have completed accreditation in the six month provisional period) and provide evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.
To apply for a 90-day extension, a facility should contact its accreditation body. Note: The MQSA Facility Hotline no longer answers questions related to 90-day extensions. Consult with the accreditation body on this issue.

The accreditation body will review the request and forward it, with its recommendation for or against the extension, to the FDA or the Certifying State for a decision. FDA or the Certifying State will then review the request and inform the facility and the accreditation body of its decision.

A facility that does not receive a 90-day extension must cease performing mammography when its provisional MQSA certificate expires, or when notified by FDA or the Certifying State that they are no longer certified based on the accreditation body's denial of accreditation ~~has been denied~~, whichever is first. Additionally, the facility should contact its accreditation body about how to resume the accreditation process.

Application to an Accreditation Body

900.11(b)(1)(i)(ii): Application.

(1) Certificates.

(i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity designated by FDA, the agency may issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

Discussion:

Facilities should not apply directly to FDA or the Certifying State for certification. To be ~~FDA~~ MQSA certified, a facility must first apply to, and become accredited by, an FDA-approved accreditation body. Currently these are:

- American College of Radiology (ACR)
  Mammography Accreditation Program
  1-800-227-6440

- Arkansas Department of Health
  Division of Radiation Control and Emergency Management
  1-501-661-2301

- California Department of Health Services
  Radiological Health Branch
  ~~1-916-323-2772~~ 1-916-322-6268

- Iowa Department of Health
  Bureau of Radiological Health
  1-515-281-3478

- Texas Department of Health
  Bureau of Radiation Control
  ~~1-512-281-3478~~ 1-512-834-6688 extension 2246

Currently, to ~~To~~ be accredited by the States of Arkansas, California, Iowa, or Texas a facility must be located in that accreditation body's respective State ~~state~~. Under MQSA regulations, a facility located in a ~~state~~ State approved by FDA as an accreditation body may be accredited by the State ~~state~~ or by the ACR. However, ~~state~~ State law may require ~~every facility~~ facilities to have ~~state~~ State accreditation or State ~~state~~ certification. These State ~~state~~ requirements are independent of MQSA, and facilities must

satisfy all such regulations in addition to MQSA requirements. You may want to contact your State about its requirements.

The accreditation body will notify FDA or the Certifying State after it has determined the initial accreditation application is acceptable or when a facility has ~~successfully completed its application for accreditation, or has~~ been accredited. The FDA or the Certifying State will then issue a six-month provisional, or a three-year MQSA certificate to the facility, as appropriate. The MQSA certificate must be displayed prominently where patients can easily see it, such as the patient reception area. A facility may not lawfully perform mammography unless it has received its MQSA certificate (or a 45-day Interim Notice to be displayed temporarily in lieu of an MQSA certificate.)

Accreditation and certification are ~~normally~~ valid for up to three years. Facilities must reaccredit prior to expiration of their MQSA certificates. Renewal MQSA certificates will be issued ~~automatically~~ upon completion of reaccreditation and notification of FDA or the Certifying State by the accreditation body. Facilities should allow at least six months for the reaccreditation process to be completed, since reaccreditation should be expected to take as long as initial accreditation. It is the responsibility of each facility to apply for and complete reaccreditation before its MQSA certificate expires. Failure to do so may result in the facility being uncertified and unable to lawfully perform mammography.

Question 1: Should mammography units that are used exclusively for special purposes other than screening or diagnostic mammography (localization, biopsy, specimen radiography, and/or research) be accredited under MQSA? Must a facility that limits its activities to these special purposes only be accredited and certified?

Not at this time. Although these procedures do involve radiography of the breast, special procedures are currently exempted from MQSA regulations.

Personnel who are not involved with screening or diagnostic mammography may also be excluded from the application for accreditation. However, an accredited and certified facility that also has a mammography unit dedicated to such special purpose usage must be prepared to provide the MQSA inspector with proper attestation that such equipment and personnel are used only for these special purposes, and are not used for screening or diagnostic mammography.

Note that any X-ray units or personnel involved even occasionally in routine screening or diagnostic mammography must meet the MQSA quality standards. These units must be included in the accreditation process and will be covered under the MQSA certificate.

Question 5: Since loaner, demonstration, and prototype mammography units are temporary, must these units be accredited? What steps should a facility take to ensure that it remains in compliance if they use these units for mammography?

A loaner, demonstration, or prototype mammography unit may be used for a limited time period before a facility is required to apply to have the unit(s) included under its accreditation. However, a facility should always contact its accreditation body before using such units on patients to determine whether such use is in accord with current policy.

Loaner units (placed in a facility while the facility's unit is undergoing in-house or off-site repair) should not be used for more than 30 days. This period may be extended upon written verification from a repair service that there is a legitimate cause for repairs to exceed 30 days with the concurrence of the accreditation body.

Demonstration units under consideration for purchase by a facility and prototype units that are being tested prior to marketing can be used for up to 90 days. However, a facility should contact its accrediting body and follow its requirements for accreditation, prior to use of any demonstration unit on patients. MQSA inspectors will need to see this documentation during any inspection.

If a facility wishes to continue use of such a unit after the specified time period is up, it should apply to its accreditation body to have the unit included under the facility's accreditation.

Note that the unit still must have passed a mammography equipment evaluation prior to patient use and each such unit will be tested by the MQSA inspector during the MQSA inspection, regardless of its accreditation or ownership status. The discussion above describes of the requirements to comply with MQSA; States may have more stringent requirements regarding the use of these systems.

Question 7: When a certified facility purchases a new mammography unit, what steps must the facility take ~~will the unit need to be accredited~~ before ~~it~~ the unit can be used for mammography?

~~Yes. All mammography units in an FDA certified facility must be accredited by an FDA approved accreditation body.~~ In an already certified facility, a newly installed unit can be used only after a mammography equipment evaluation has been conducted and the requirements of the accreditation body are satisfied. The facility must immediately contact its accreditation body and follow its guidelines for newly installed mammography units before use on patients. After the new unit meets all the specified requirements, it may be used to make the clinical images for review by the accreditation body.

Question 8: What are the requirements for accreditation and certification of mobile units? Can mobile units be accredited as additional units of a ~~fixed-site~~ stationary facility?

An x-ray unit may be deemed to be mobile if it is wheeled or located in a van or truck for the purpose of providing mammography service to various locations. Accreditation and certification requirements for mobile units are the same as the requirements for ~~fixed-site~~ stationary units. They must be accredited by an FDA-approved accreditation body.

Whether multiple mobile units or a mobile unit operated by a ~~fixed-site~~ stationary facility may be included under a single accreditation and MQSA certificate depends on the policy of the accreditation body. Currently, the ACR's policy is to accredit each mobile unit as a ~~unique~~ separate facility, with a unique ACR MAP number. Consequently FDA or the Certifying State certifies ACR accredited mobile units as ~~unique~~

separate facilities with unique FDA MQSA identification numbers, and each is issued its own MQSA certificate.

Other accreditation bodies may accredit multiple units or mobile units belonging to a ~~fixed-site~~ stationary facility as additional units. In this case there would be one identification number for the entire facility and an additional MQSA certificate (with the same ID number) would have to be requested for each mobile unit. Additional MQSA certificates may be requested by contacting the FDA MQSA Facility Hotline at 1-800-838-7715. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates.

Question 9: A facility moves or relocates and the address on its MQSA certificate is no longer correct. Is the MQSA certificate still valid?

Your MQSA certificate is still valid. However, when ~~When~~ a facility moves or relocates, it must notify its accreditation body. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. ~~Once those requirements are satisfied, the~~ The accreditation body will then inform FDA or the Certifying State of the facility's new address. FDA or the Certifying State will then issue a new MQSA certificate to the facility reflecting the new address. The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation. Any failures of a regulatory requirement found during the mammography equipment evaluation must be corrected before that piece of equipment is used for patient examinations.

Until the new MQSA certificate is received, the facility must prominently display its original MQSA certificate. The expiration date of the new MQSA certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new MQSA certificate arrives, the original MQSA certificate should not be displayed. The facility should file or destroy the original MQSA certificate after it receives the new MQSA certificate.

Question 10: The individual who signed the facility's application for accreditation resigns or retires and a replacement is named. Should the facility notify its accreditation body, ~~or~~ the FDA or the Certifying State regarding the change of a designated facility contact?

The facility should notify its accreditation body immediately. All official notifications from both the accreditation body and the FDA or the Certifying State are addressed to the designated facility contact. If the addressed individual is no longer associated with the facility, mail may be rejected by the facility's mail room and/or the post office.

Only the accreditation bodies have the authority to modify the facility mailing list. Therefore, a facility that fails to notify its accreditation body of this change may not receive ~~either~~ MQSA mailings~~,~~ (such as MQSA certificates and *Federal Register* notices) or mailings from its accreditation body.

Question 11: Is xeroradiography banned under MQSA?

No. The accreditation bodies will accredit facilities with xeromammography units that meet the dose limit and other accreditation requirements. However, some ~~states~~ States have banned or intend to ban xeroradiography for mammography.

Definition of Certificate

900.2(h) Certificate means the certificate described in section 900.11(a).

Discussion:

After October 1, 1994, all mammography facilities are required to have an MQSA certificate issued by FDA or the Certifying State ~~is required for lawful operation of all~~ to legally perform mammography ~~facilities~~. To obtain an MQSA certificate from FDA or the Certifying State, facilities are required to be accredited by an approved accreditation body or other entity, as designated by FDA, and to meet the quality standards as published in 900.12.

By law, ~~FDA~~ MQSA certificates must be prominently displayed ~~in all patient reception areas~~ where they can be viewed by mammography patients ~~examinees~~.

Question 1: Where does a facility with more than one patient/~~examinee~~ reception area display its certificate?

~~FDA~~ MQSA certification is facility based. Therefore, if a facility has more than one patient reception area, it may request an additional MQSA certificate for each reception area from FDA. All MQSA certificates issued to a facility will share that facility's unique 6-digit identification number. Contact the FDA MQSA Facility Hotline at 1-800-838-7715 to request ~~the~~ additional MQSA certificates. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates.

Question 2: Can a facility with a ~~large~~ Spanish-speaking population get a Spanish-language MQSA certificate?

FDA will issue an additional MQSA certificate translated into Spanish for those facilities serving a Spanish-speaking population for each patient reception area. The Spanish-language MQSA certificate(s) and the English-language MQSA certificate(s) must both be prominently displayed where they can be viewed by mammography ~~examinees~~ patients. Contact the FDA MQSA Facility Hotline at 1-800-838-7715 to request a Spanish-language MQSA certificate. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates.

Question 3: A facility has changed its name but has the same owner, personnel, and equipment. Is the MQSA certificate still valid even though the facility name is different?

Your MQSA certificate is still valid. However, ~~W~~when a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. ~~Once the facility has complied with the accreditation body's requirements, the~~ The accreditation body will then inform FDA or the Certifying State of the facility's new name. FDA or the Certifying State will then issue a new MQSA certificate to the facility.

Until the new MQSA certificate is received, the facility must prominently display its original MQSA certificate. The expiration date of the new MQSA certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new MQSA certificate arrives, the original MQSA certificate should not be displayed. The facility should file or destroy the original MQSA certificate after it receives the new MQSA certificate.

Question 4: A facility moves or relocates and the address on its certificate is no longer correct. Is the MQSA certificate still valid?

Your MQSA certificate is still valid. However, ~~W~~when a facility moves or relocates, it must notify its accreditation body. The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation. Any failures of a regulatory requirement found during the mammography equipment evaluation must be corrected before that piece of equipment is used for patient examinations. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. ~~Once those requirements are satisfied, the~~ The accreditation body will then inform FDA or the Certifying State of the facility's new address. FDA or the Certifying State will then issue a new MQSA certificate to the facility reflecting the new address.

Until the new MQSA certificate is received, the facility must prominently display its original MQSA certificate. The expiration date of the new MQSA certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new MQSA certificate arrives, the original MQSA certificate should not be displayed. The facility should file or destroy the original MQSA certificate after it receives the new MQSA certificate.

Question 5: What should a facility do if it closes or decides that it will no longer provide mammography services?

~~The facility should contact its accreditation body and inform it that the facility is no longer practicing mammography. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.~~ Before a facility permanently stops performing mammography, it should do the following:

1. Inform its accreditation body that it will no longer be performing mammography;
2. Notify its State radiation control program;
3. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or

health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less than 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. The facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine if their requirements are more stringent. Note: Radiology practices and other medical facilities that still see patients but have permanently stopped performing mammography, may choose to keep the patients' medical records rather than transfer them to another facility (unless the patient requests such a transfer).

If option 3 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested and that former patients are made aware of that mechanism. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

Once the facility ceases operation, the MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.

Due to the fact that some facilities have not followed the above recommendations, FDA has received inquiries from patients complaining that their mammography facility has closed, that they were not informed, and that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that a facility that plans to stop performing mammography notify its Certifying Agency of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to:

FDA/CDRH/OHIP/DMQRP

Attention: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

Facilities certified by States may send the above information to:

State of Iowa
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street, Suite D
Des Moines, IA 50309
515-281-3478

State of Illinois
Office of Radiation Safety
Department of Nuclear Safety

1035 Outer Park Drive
Springfield, IL 62704
217-785-9974

Question 6: Our facility has several patient waiting areas. Can I photocopy our facility MQSA certificate and place copies in each area?

While the Statute requires that the original MQSA certificate be prominently displayed, the photocopying of the MQSA certificate so that it may be displayed in additional areas is not prohibited. However, we recommend that facilities wishing to display their MQSA certificate in several different areas obtain additional MQSA certificates (at no charge) by contacting FDA at 1-800-838-7715 or writing to: FDA MQSA Program, P.O. Box 6057, Columbia, MD 21045~~-6057~~. Facilities with State-issued MQSA certificates should check with their Certifying State ~~agencies~~ for their policies regarding additional MQSA certificates. Facilities are reminded that, at a minimum, they must have the original MQSA certificate displayed even if they choose to display additional copies of the MQSA certificate. Mobile facilities must have at least one original MQSA certificate displayed whenever the mobile unit is performing mammography.

General Requirements for Accreditation and Certification

900.11(a) General. After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in section 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

Discussion:

Accreditation is a process administered by an FDA-approved "Accreditation Body," a private, nonprofit organization or state agency approved to accredit mammography facilities. Currently, the FDA-approved accreditation bodies are:

- American College of Radiology (ACR)
- State of Arkansas
- State of California
- State of Iowa
- State of Texas

The state accreditation bodies may accredit only those facilities that are located in their respective states. The accreditation body is charged with reviewing a mammography facility's equipment, personnel (interpreting physicians, radiologic technologists, and medical physicists), and practices. The materials reviewed include details of the qualifications of the personnel involved in mammography, a report of the physicist's survey of each X-ray unit used for mammography, the results of dosimetry evaluations of each unit, phantom images from each unit, results from various quality control (QC) tests on the mammography equipment (including the film processor), and clinical images from representative patients.

If the review establishes that, in the judgment of the accreditation body, the mammography facility personnel, equipment, and practices meet the quality standards established under MQSA, then the accreditation body will "accredit" the facility.

Certification is a separate process that is administered by FDA. FDA issues an MQSA certificate upon notification by an approved accreditation body that a mammography facility has been accredited by that body.

Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during its annual inspections that it continues to meet the MQSA quality standards.

Only FDA certified facilities can lawfully provide mammography services. The Health Care Financing Administration (HCFA) will reimburse only for the mammography performed at an FDA certified facility.

Question 1: What should a facility do if it closes or decides that it will no longer provide mammography services?

The facility should contact its accreditation body and inform it that the facility is no longer practicing mammography. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.

Question 2: If a facility that fails to become accredited and certified continues to perform mammography, what penalties is it subject to? Can the facility be reimbursed by Medicare and insurance companies for mammography services?

Any facility that performs mammography without FDA certification may be subject to civil money penalties of up to $10,000 per examination.

MQSA provides for civil money penalties not to exceed $10,000 for:

1) Failure to obtain a certificate as required;
2) Each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established; and
3) Each violation, or for each aiding and abetting in a violation of any provision of, or regulation promulgated under MQSA, by an owner, operator, or any employee of a facility required to have a certificate.

Facilities that are not FDA certified cannot be reimbursed by the federal government for mammography services. HCFA will not reimburse facilities for Medicare screening and diagnostic mammography examinations if they do not have an MQSA certificate, or if their certificate has expired, been suspended, or been revoked. The amount and frequency of reimbursement will still be governed by HCFA regulations. FDA has provided an efficient system for HCFA to confirm the certification status of all mammography facilities. HCFA will share this information with insurance carriers, who are committed to reimburse only for lawfully performed mammography procedures.

Question 3: Since accreditation and certification are so closely linked, how will FDA synchronize its certification period with a facility's accreditation period?

Certification is linked to the accreditation of the first mammography unit in a facility. The accreditation body notifies FDA of a facility's first unit accreditation, which is for three years. FDA issues an initial certificate that is effective on the date of notification by the accreditation body and which expires three years from that date.

Facilities that wish to continue to lawfully provide mammography services must be reaccredited before the initial certificate expires.

Certificates that are issued following the initial certificate are effective for three years. The expiration date of the subsequent certificates is three years from the expiration date of the initial certification.

Question 4: By law, FDA certificates must be prominently displayed in all facilities. Where should they be displayed?

An FDA certificate should be displayed prominently where mammography patients can easily see it, such as the patient reception area. If a facility has more than one patient reception area, it may request an additional certificate for each reception area from FDA. All certificates issued to a facility will share that facility's unique 6-digit identification number. Contact the FDA MQSA Facility Hotline at 1-800-838-7715 to request the additional certificates.

Question 5: Are Spanish-language certificates available for facilities providing mammography services to a large Spanish-speaking population?

Yes. FDA will issue an additional certificate translated into Spanish for those facilities serving a Spanish-speaking population. To obtain this additional certificate, contact the FDA MQSA Facility Hotline at 1-800-838-7715. The Spanish-language certificate and the English-language certificate should both be prominently displayed where they can be viewed by mammography patients.

Question 6: Our facility has several patient waiting areas. Can I photocopy our facility certificate and place copies in each area?

While the Statute requires that the original certificate be prominently displayed, the photocopying of the certificate so that it may be displayed in additional areas is not prohibited. However, we recommend that facilities wishing to display their MQSA certificate in several different areas obtain additional certificates (at no charge) by contacting FDA at 1-800-838-7715 or writing to: FDA MQSA Program, P.O. Box 6057, Columbia, MD 21045-6057. Facilities with State-issued MQSA certificates should check with their State agencies for their policies regarding additional certificates. Facilities are reminded that, at a minimum, they must have the original certificate displayed even if they choose to display additional copies of the certificate. Mobile facilities must have at least one original certificate displayed whenever the mobile unit is performing mammography.

Full Field Digital Mammography (FFDM) Certification

Discussion

Until accreditation bodies are prepared to accredit full field digital mammography (FFDM) units, FDA has implemented a process for extending the certification of an already certified screen-film facility to include FFDM units. Until otherwise notified by FDA, a facility with an FFDM unit will be exempt from the MQSA accreditation requirement but must request FDA to extend its screen-film certification to cover its FFDM unit. Requests for FFDM certification extension need to supply all the information listed in the document **MQSA Facility Certification Requirements For Use Of Full Field Digital Mammography (FFDM)** and should be forwarded to:

Dr. Kish Chakrabarti
Division of Mammography Quality and Radiation Programs
FDA/CDRH/OHIP
1350 Piccard Drive, HFZ-240, Room 230B
Rockville, MD 20850
Phone : 301-594-3332 or 3313
Fax : 301-594-3306

After a decision has been reached, you will receive either a Letter of Acceptance or a Letter of Denial for your FFDM unit(s). If you receive a Letter of Acceptance, your FFDM unit will be added to your certificate and you may begin to use it for clinical examinations. Your facility must maintain its accreditation status for at least one screen-film unit in order to maintain its certification status when utilizing an FFDM unit. Your facility is also subject to an annual onsite MQSA inspection of its FFDM unit at the same time its screen-film unit(s) is/are being inspected.

If you receive a Letter of Denial, we will work with you to resolve the problems preventing your acceptance.

Question 1: Does a facility have to have its FFDM unit accredited?

Until notified by the FDA, facilities with FFDM units are exempt from MQSA accreditation requirements. However, you must obtain FDA's extension of your MQSA screen film certification to cover the FFDM unit before you can use it clinically.

Question 2: What information will we need to provide in our request for FFDM certification extension?

You need to provide a list of all personnel who began working in (i.e., interpreting, performing, and surveying) the FFDM mammographic modality prior to April 28, 1999 (if any) as well as a list of personnel who began or will begin working in the FFDM mammographic modality after April 28, 1999. In addition,

you need to provide a satisfactory FFDM mammography equipment evaluation (including an evaluation of the Soft Copy Display system, if applicable) performed by a qualified medical physicist within 6 months prior to the date of your application.

You will also need to follow the manufacturer's guidelines for quality assurance and quality control tests as described by the manufacturer's manual. No later than 9 months after you begin clinical examinations using the FFDM unit, you must submit to the FDA the results of the tests performed during the first 6 months after beginning clinical FFDM examinations.

Question 3: How does a facility apply for FFDM certification extension?

Requests for FFDM certification extension need to supply all the information listed in the document **MQSA Facility Certification Requirements For Use Of Full Field Digital Mammography (FFDM)** and should be forwarded to:

Dr. Kish Chakrabarti
Division of Mammography Quality and Radiation Programs
FDA/CDRH/OHIP
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Rockville, MD 20850
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Question 4: What is FDA's FFDM review process?

Upon receipt of the completed FFDM package, FDA will review the documentation. If the application is complete and satisfactory, FDA grants an approval to the facility and sends a Letter of Acceptance. For an incomplete or unsatisfactory application, FDA will send a Letter of Denial or request additional information from the facility. FDA will then work with the facility and/or the medical physicist to resolve discrepancies and complete the application process.

Question 5: Does the FFDM unit have to be in the same location as the screen film unit?

The FFDM unit must be located within the same inspection jurisdiction as the certified screen film facility. In most cases, this means that the FFDM unit must be located in the same State as the certified screen film facility.

Question 6: Our FFDM unit is not at the same location as our screen film facility. Is our lead interpreting physician still responsible for the quality assurance program of the off-site FFDM unit?

Yes. The lead interpreting physician must oversee the quality assurance programs for both the screen film and off-site FFDM units.

Question 7: Which FFDM units have been approved by FDA?

FDA's Office of Device Evaluation has approved the following FFDM units for commercial use:
GE Senographe 2000D (approval date: 1/28/00)
Fischer Imaging SensoScan (approval date: 9/25/01)
Lorad Digital Breast Imager (approval date: 3/15/02)

Question 8: FDA has extended our certification to include our FFDM unit. Are there any special requirements we need to be aware of?

Once you receive FDA's Letter of Acceptance, you may lawfully begin using the FFDM unit for clinical examinations. However, you must meet the following conditions while using the FFDM unit:

1. Maintain accreditation status for at least one screen-film unit to which the FFDM unit is linked. During the annual onsite MQSA inspection, both the screen film facility and the FFDM unit will be evaluated.
2. Upon completion of the first semi-annual quality control tests, provide FDA with the results of the weekly, monthly, quarterly, and semi-annual quality control tests outlined in the manufacturer's quality control manual. The report must include the results of the required QC tests for the Soft Copy Display system.
3. Send quality control test results to FDA no later than nine months after starting clinical examinations using the FFDM unit.
4. Have the FFDM unit surveyed annually by an MQSA qualified medical physicist.

Question 9: What will happen when the accreditation bodies start to accredit FFDM units?

Once the accreditation bodies begin accrediting your specific model of FFDM unit, your facility will have to apply to and go through the AB's accreditation process, similar to what you would have to do for screen film units. During this transition period, your facility can continue to use the FFDM unit. Because of the different technologies used by FFDM unit manufacturers, the accreditation bodies may have to develop different programs for the different types of units. As a result, it is likely that not all FFDM unit types will be accredited at the same time. For example, if an AB implements a program to accredit the GE Senographe 2000D but not other types of units, then facilities having this GE unit have to get them accredited. Facilities having other types of FFDM units will not have to get them accredited until an accreditation process is implemented for their unit. However, the facility will be able to continue to use their unit under FDA's FFDM certification extension policy.

MQSA Facility Certification Requirements For Use Of Full Field Digital Mammography (FFDM)

1. Facility Status Information
a. Facility Name and FDA Facility ID Number
b. FDA Certificate Expiration Date
c. Current Accreditation Body for Screen-Film Unit(s)
d. Accreditation Expiration Date
e. Facility Contact Person for FFDM (if different from screen-film contact)
f. Contact Person's Title
g. Contact Person's Telephone, Fax, E-mail
h. Facility Address
i. Facility Owner

2. FFDM Unit Identification
a. Machine Manufacturer
b. Machine Model
c. Year of Manufacture
d. Serial Number

3. Digital Image Receptor Identification (if interchangeable)
a. Receptor Manufacturer
b. Receptor Model
c. Year of Manufacture
d. Serial Number (if applicable)

4. Identification of Printer for Hard Copy Output
a. Printer Manufacturer
b. Printer Model
c. Year of Manufacture
d. Serial Number

5. Monitor Identification (if soft copy display is available)
a. Monitor Manufacturer
b. Monitor Model
c. Year of Manufacture
d. Serial Number

6. Phantom Identification
a. Phantom Manufacturer
b. Phantom Model

7. Personnel Qualifications

a. Interpreting Physicians who are qualified to interpret hard and soft copy digital mammograms (See page 4)

b. Radiological Technologists who are qualified to perform digital mammography examinations and the manufacturer recommended quality assurance tests
(See page 5)

c. Medical Physicists who are qualified to perform equipment evaluations and/or surveys of digital mammography units including tests of the Soft Copy Display system (See page 6)

8. Report of Mammography Equipment Evaluation (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to request for use approval)

a. Statement that equipment performance, as required under the following sections of the MQSA final regulation 21 CFR 900.12(b), is met:

(1) Prohibited Equipment
(2) Specifically Designed for Mammography
(3) Motion of Tube-Image Receptor Assembly
(4)(iii) Removable Grid (if applicable to the FFDM system used)
(5) Beam Limitation and Light Fields
(6) Magnification
(7) Focal Spot Selection
(8) Compression
(9) Technique Factor Selection and Display (GE system may use AOP instead of AEC in this requirement)
(10) Automatic Exposure Control (GE system may use AOP instead of
AEC in this requirement)
(14) Lighting (if hard copy display is used for image evaluation)
(15) Film Masking Devices (if hard copy display is used for image evaluation)

b. The results of quality control tests as required under the following sections of the MQSA final regulations 21CFR 900.12(e):

(4)(iii) Compression Device Performance
(5)(i) Automatic Exposure Control Performance (if applicable to the FFDM system used)
(5)(ii) Kilovoltage Peak Accuracy and Reproducibility
(5)(iii) Focal Spot Condition
(5)(iv) Beam Quality and Half-Value Layer
(5)(v) Breast Entrance Air Kerma and AEC Reproducibility (if applicable to the FFDM system used)
(5)(vi) Dosimetry
(5)(vii) X-Ray Field/Light field/Image receptor/Compression paddle alignment
(5)(ix) System Artifacts
(5)(x) Radiation Output
(5)(xi) Decompression (or alternative standards allowed for these requirements)
(6) Quality Control Tests – Other Modalities (Facilities must perform all FFDM manufacturer recommended quality control tests including the medical physicist's tests for Soft Copy Display system)

c. The results of the phantom image quality tests, including a sample image

d. If any of the requirements in 8 a, b, or c are not met, submit documentation of successful corrective action
e. If any of the requirements in 8 a or b are not performed, explain why the requirement is not applicable
f. Date of the evaluation
g. Name and address of the physicist(s) who performed the evaluation

9. Manufacturer's Quality Control Program
a. Name of the Quality Control Manual
b. Year published
c. Revision number, if not the original
d. Printing number, if not the original

10. Signature

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DIGITAL MAMMOGRAMS

List the current interpreting physicians who:
(1) meet all the requirements of CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began interpreting digital mammograms prior to April 28, 1999.

List the current interpreting physicians who:
(1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began interpreting digital mammograms after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DIGITAL MAMMOGRAMS

List the current radiologic technologists who:
(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began performing digital mammography examinations prior to April 28, 1999.

List the current radiologic technologists who:
(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began performing digital mammography examinations after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

*Supporting documentation for these requirements will be checked during annual MQSA inspections.

PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM FFDM SURVEYS

List the current medical physicists who:
(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began performing equipment evaluations and/or surveys of digital mammography units prior to April 28, 1999

List the current medical physicists who:
(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began performing equipment evaluations and/or surveys of digital mammography units after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.

Signature (Lead Interpreting Physician) _____

Print Name_____

Date_____

Revocation of Accreditation

900.13(a) FDA action following revocation of accreditation. If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

Discussion:

When a facility's accreditation is revoked, its MQSA certificate should remain in effect unless the FDA or the Certifying State determines that the MQSA certificate shall no longer be in effect. If FDA or the Certifying State determines that the revocation of accreditation was justified, it may determine that the MQSA certificate is no longer in effect, that the facility should take corrective action, or that other action may be appropriate while the facility seeks reaccreditation.

Additional Mammography Review and Patient Notification

900.12(j)(1)(2): Additional mammography review and patient notification.

(1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If FDA determines that the quality of mammography performed by a facility, whether or not certified under Sec. 900.11, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, FDA may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as FDA may require.

Discussion:

Question 1: ~~Is an~~ How are additional mammography reviews (AMR) ~~used for the same purpose as~~ different from the reviews that are performed for accreditation, reaccreditation, or random clinical image review?

~~No.~~ AMRs ~~is~~ are performed in cases where FDA or the Certifying State has reason to believe that mammography quality has been compromised and may present a serious risk to human health. An example of such a circumstance ~~would~~ might be the detection of a Level 1 phantom image failure during an inspection. Accreditation bodies do not use the clinical image reviews (CIRs) performed during accreditation, re-accreditation, and random clinical image review to investigate possible problems at facilities. Accreditation bodies use these types of CIRs to evaluate the ongoing quality of mammography at all facilities.

Question 2: Who ~~is responsible for performing~~ can perform an AMR?

~~Either an~~ An FDA approved accreditation body or an entity approved by FDA ~~may be responsible for performing~~ can perform an AMR.

Question 4: Will the facility be responsible for patient/physician notification that may result following the AMR?

Yes. If the AMR indicates that ~~patient~~ notification of patients and physicians is ~~among the~~ necessary ~~corrective actions~~, the facility will be required to notify patients and physicians of the identified problems, consult with FDA or the Certifying State in developing the patient/physician notification, and ensure that the appropriate audience is reached. The facility may request the Certifying Agency to review its ~~has the right to have a~~ determination ~~about~~ that patient/physician notification is required ~~reviewed within the agency~~.

AMR General Guidance

Background

The Food and Drug Administration (FDA) developed this Additional Mammography Review (AMR) guidance to inform facilities of possible FDA actions ~~assist FDA officials in determining the appropriate agency response~~ when MQSA inspections show a Level 1 finding for phantom image testing or interpreting physician qualifications. A Level 1 finding represents a deviation from MQSA standards that may seriously compromise the quality of mammography services offered by the facility. FDA has determined that these specific Level 1 findings are indicators that serious quality problems may be present at the facility and require further evaluation. An assessment of the quality of mammograms produced by the facility should indicate whether the equipment problems that resulted in the Level 1 phantom image finding have affected clinical image quality. A Level 1 finding for the phantom image test exists when the score is less than 3 fibers, less than 2 speck groups, and/or less than 2 masses. Regarding interpreting physician qualifications, an assessment of mammograms and mammography reports may indicate whether failure to meet specific personnel standards has affected the quality of mammographic findings.

In addition to these ~~While this policy only identifies~~ two specific inspection findings, other problems ~~that~~ could result in FDA requiring AMR for a facility.~~, there may be other evidence or information that could convince FDA to require AMR. This~~ For example, evidence or information may ~~not~~ be obtained from ~~a routine MQSA inspection, but from another source, such as~~ the facility's accreditation body or patient or physician complaints that could convince FDA to require an AMR.

~~This guidance provides specific criteria to assist the agency in determining the appropriate type and scope of assessment that would be necessary, how and by whom the action should be conducted, and whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and/or accuracy of interpretation of mammograms may have been compromised.~~ In the case where serious quality problems are suspected at a facility ~~of Level 1 inspection findings~~, FDA may require that the facility undertake an investigation of the impact of these findings on the clinical images produced by the facility or ~~of~~ the interpretations rendered by the interpreting physician. If FDA determines that the problems rise to the level of a serious risk to human health, FDA may require the facility to undertake patient/physician notification.

~~This policy is effective April 28, 1999. when the authority to require a facility to undergo AMR is also effective.~~ This authority is stated as follows (21 C.F.R. Part 900.12(j)):

Additional mammography review and patient notification.

(1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or

their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified by FDA.

There are two specific types of AMR identified in this policy. These are AMR Conducted by the Facility (AMRF) and AMR Conducted by the Accreditation Body (AMRAB). Under AMRF, FDA would work with the facility to identify a qualified interpreting physician(s) who would perform the AMR. The physician(s) would be subject to FDA approval. Under AMRAB, the facility's accreditation body would be asked to conduct the AMR.

This policy does not prevent FDA from taking legal actions against facilities, in addition to AMR, where the use of an MQSA sanction may be necessary to compel a facility to comply with FDA regulatory requirements. As an example, FDA may issue a Directed Plan of Correction (DPC) to a facility to address serious problems at the facility. The DPC may require the facility to take specific corrective actions. ~~, in addition to specific corrective actions that the facility must take, that~~ FDA may require the facility to ~~undergo AMR and~~ notify patients and/or their referring physicians of facility problems, in the event the AMR indicates mammography quality problems are present that would justify such a notification.

Note: The interpreting physician(s) conducting the image review for AMRF or AMRAB should not have a relationship with the facility, conduct the review when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility. Before the facility's accreditation body (AB) conducts AMRAB, the AB may require reimbursement of their expenses for the AMRAB. In this case, the AB should notify the facility accordingly, including an estimate of the cost to conduct the AMRAB. The AB may also require payment prior to the start of the AMRAB.

~~***Phantom Image - Level 1 Findings***~~

~~**Criteria - Phantom Image**~~

~~**Procedure for AMR - Phantom Image**~~

~~**Follow up Actions by FDA with the Facility**~~

~~Criteria - Phantom Image~~

~~AMR Conducted by the Facility (AMRF)~~

~~If a facility has a Level 1 phantom image finding, but there is no other evidence of serious problems relating to image quality, then it may be asked to conduct AMRF. In the event that a facility refuses to conduct AMRF, FDA may refer the facility to their AB for AMRAB.~~

~~AMR Conducted by the Accreditation Body (AMRAB)~~

If a facility has a Level 1 phantom image finding or a Level 1 interpreting physician finding, ~~and there is other evidence of serious problems relating to image quality or it refuses to conduct AMRF, then~~ FDA may require the facility to undergo ~~AMRAB~~ an AMR. Because the AB already has procedures and personnel in place for performing AMRs, this generally will be the preferred method. However, if FDA considers it appropriate, it may propose an AMRF. The facility would then provide FDA with specific details as to how the AMR would be conducted, how the patient exams would be selected and the qualifications of the proposed interpreting physician (including the physician's specialized training in evaluating clinical image quality). If FDA does not approve the facility's proposal, the facility must undergo AMRAB.

Evaluation of Inspection Findings Leading to an AMR and Patient/Physician Notification

- All phantom image test results at Level 1 will be confirmed through a second review by the MQSA auditor or an FDA MQSA inspector (or by the State, if the State has a thorough phantom image quality assurance (QA) program in place). For those cases where there are no second reviewers in the FDA district or regional office, the Division of Mammography Quality and Radiation Programs (DMQRP) will provide the second review.
- After confirmation that a physician was not board certified and did not have initial training in mammography and/or never had a valid license or the license to practice medicine was revoked, FDA will evaluate the findings to determine whether an AMR is appropriate.
- After confirmation of the Level 1 finding(s), a Warning Letter may be sent to the facility.
- The Warning Letter should advise the facility that they are required to undergo an AMR, that they will be responsible for the cost of the AMR, and that further details (including whether an AMRF or AMRAB will be required) will follow in a letter from FDA and/or the AB. The type (AMRAB or AMRF) and scope of the AMR will be determined by FDA (usually after consultation with the facility's AB).
- If the results of the AMR indicate that the quality of mammographic images or interpretations at the facility represent a serious risk to human health, FDA may require the facility to undertake notification of patients and/or referring physicians.
- If the results of the AMR do not indicate a serious risk to human health, FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary.

~~Examples of types of other serious problems are listed below. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts (see note at end of Background section), FDA may require the facility to undergo AMRAB. FDA, in conjunction with the AB, would rely primarily on the following criteria, by themselves or in combination, to evaluate whether quality at the facility may be sufficiently impaired for FDA to require the facility to undergo AMRAB.~~

- ~~Level 1 finding for phantom image was not due to artifacts and failing phantom image raw score was less than 6.~~
- ~~Review of phantom images performed by the technologist for the weekly quality control (QC) testing for the time period back to the previous inspection demonstrates more than one Level 1 phantom image failure without corrective action.~~
- ~~Other Level 1, Level 2, and/or numerous Level 3 findings related to equipment QC testing are detected during the inspection.~~
- ~~Other indications of quality problems may be present at the facility (examples: prior or pending serious patient complaints to FDA or the State; Level 1 or Level 2 findings or numerous Level 3 findings related to equipment QC testing in the previous annual inspection).~~

~~Note: Serious complaint means a report of an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner. Each complaint should be evaluated carefully to assure that information in the complaint is valid.~~

- FDA determines that the facility would not be able to or is unwilling to undergo AMR conducted by the facility.

Procedure for AMR – Phantom Image
Evaluation of Inspection Findings and Other Information

1. All phantom image test results at Level 1 must be confirmed through a second review by the MQSA auditor or an FDA MQSA inspector (or by the State, if the State has a thorough phantom image quality assurance (QA) program in place). For those cases where there are no second reviewers in the district or regional office, the Division of Mammography Quality and Radiation Programs (DMQRP) could provide a second review.
2. The district should download the inspection reports (including the detail report containing all of the inspection data) to evaluate all the findings of the inspection. The district should contact DMQRP with their evaluation and determine whether the findings meet the criteria for AMRF or AMRAB. The district would also indicate what arrangements were being made to have a second evaluation of the Level 1 phantom images from the inspection, if not already done.
3. Level 1 finding only: If a facility inspection has a Level 1 finding for phantom image, the district should confirm that the Level 1 finding is correct. FDA should evaluate the findings, along with any other information, including complaints about clinical mammograms, to determine whether AMRF or AMRAB is appropriate.
4. Level 1 finding with other findings and/or complaints: In the event that the facility has a Level 1 finding for phantom image and there are other serious problems or complaints identified with this facility (see examples above), FDA may confer with the AB as to whether the AB should undertake AMRAB.
5. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB about implementation of the AMRAB. The district may send a Warning Letter to the facility which would indicate that the facility's AB has been asked to conduct AMRAB in response to the findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts, FDA may require the facility undergo AMRAB.

Follow-up Actions by FDA with the Facility

1. If the conditions are met for AMRF (i.e., there is no other evidence of serious problems relating to image quality), the district should send a Warning Letter to the facility. The letter would require that the facility conduct AMRF in response to the findings. The letter would also indicate that the facility would be responsible for the cost of the AMR.
2. If the facility agrees to conduct AMRF, the district would monitor the progress of the review until completion. The review of images under AMRF could be on-site at the facility or by mail.
3. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB as to whether the AB should undertake AMRAB. The district may send a Warning Letter to the facility that would indicate that FDA had asked the facility's AB to conduct AMRAB in response to the inspection findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have

inappropriate conflicts, FDA may require the facility to undergo AMRAB (see note regarding expenses for AMRAB in the background section).

4. a. For both AMRF and AMRAB, the review should cover a sample of mammographic examinations produced using the same equipment (x-ray system and processor) that was tested and found to fail phantom image evaluation during the inspection. The review should be retrospective and start with the last set of mammographic images produced prior to the inspection phantom image test and proceed backward to earlier examinations. The review should concentrate on examinations conducted as close as possible to the date and time of the inspection. The review should encompass the appropriate number of examinations needed to effectively evaluate the impact on mammographic quality of the image quality problems discovered through phantom image evaluation. The review should extend back to the most recent date when the facility's weekly QC phantom images did not show a Level 1 finding.
   b. If none of the facility's weekly QC phantom images showed a Level 1 finding without corrective action, then the review period should be from the date of inspection back to the date of the last QC phantom image.
   c. While the size of the sample will vary with the situation, the sample should probably be no smaller than ten percent of the examinations conducted in the time period selected for evaluation.
   d. In the event that the facility has not performed weekly QC phantom images, the review period could extend from the date of inspection back to the date of the last medical physicist survey (provided the physicist score was not the equivalent of a Level 1 finding).
   e. In the event that the facility has not performed weekly QC phantom images and the medical physicist survey showed either the equivalent of a Level 1 finding for the phantom image, as scored by the medical physicist, or the phantom image test was not done by the medical physicist, then the period for review could extend from the date of inspection back to the date of the previous inspection.

Note: The decision for the time period covered for the AMR should be based on public health considerations for the patients who were examined.

5. The AMR should consist of reviewing a sample of mammograms (or all of the mammograms, if appropriate) from the specified period and, depending on the results of the review, the review may be extended.
6. The review of images under AMRAB would be on-site at the facility or by mail, as determined by the facility's AB in consultation with FDA.
7. If the results of the AMRF or AMRAB indicate that the quality of mammographic images or interpretations at the facility represent a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). If appropriate, FDA may ask the facility to undertake notification of patients and/or referring physicians. If the facility does not agree or does not have the means to perform a patient notification (PN), FDA would consider other methods of initiating a PN.
8. The district and DMQRP should coordinate implementation and monitoring of the notification process.

9. If the results of the AMR do not indicate a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary. FDA might require the AB to perform continued close monitoring of this facility. In the case of AMRF, FDA may require the AB to perform its own AMR.

Interpreting Physician - Level 1 Findings

Criteria - Interpreting Physician

Procedure for AMR - Interpreting Physician

Follow-up Actions by FDA with the Facility

Criteria – Interpreting Physician

AMR Conducted by Facility (AMRF)

If a facility has a Level 1 finding for interpreting physician qualifications, with no other inspection findings for the physician or other significant evidence that the quality of interpretation of mammograms is compromised, then FDA may ask the facility to conduct AMRF. Currently, facilities may have a Level 1 finding for interpreting physician qualifications if the physician is neither board certified nor has the initial (two or three months) training in mammography and/or never had a valid license to practice medicine.

AMR Conducted by Accreditation Body (AMRAB)

If a facility has a Level 1 finding for interpreting physician qualifications and has other problems that may relate to the qualifications of the interpreting physician, then the facility may be asked to conduct AMRAB. Some examples of other problems could include complaints regarding the performance of the interpreting physician or other inspection findings relating to the physician's qualifications. In these cases, FDA, in conjunction with the AB, may evaluate whether quality at the facility may be sufficiently impaired for FDA to require that the facility undergo AMR by the facility's AB (AMRAB).

Note: An interpreting physician, who fails to meet the qualifications under the MQSA quality standards, may not continue to read and interpret mammograms independently until he or she has received the necessary training or experience to meet the qualifications.

Procedure for AMR – Interpreting Physician

Evaluation of Inspection Findings and Other Information

1. Level 1 finding only: If a physician was not board certified nor had initial training in mammography and/or never had a valid license to practice medicine, the district should confirm that the Level 1 finding is correct. FDA should evaluate the findings, along with any other information, including complaints about the physician, to determine whether AMRF or AMRAB is appropriate.
2. The district should download the inspection reports (including the detail report containing all of the inspection data) to evaluate all the findings of the inspection. The district should contact DMQRP with their evaluation and determine whether the findings meet the criteria for AMRF or AMRAB.
3. Level 1 finding with Level 2 findings and/or complaints: In the event that the facility has a Level 1 finding for a physician and there are other serious problems or complaints identified with this physician (examples could include Level 2 findings for initial and/or continuing qualifications or the AB or FDA has received serious complaints about the quality of the physician's interpretation

accuracy (i.e., missed cancers or incorrect interpretations)), FDA may confer with the AB as to whether the AB should undertake AMRAB.

4. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB about implementation of the AMRAB. The district may send a Warning Letter to the facility which would indicate that the facility's AB has been asked to conduct AMRAB in response to the findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts (see note regarding expenses for AMRAB in the background section), FDA may require the facility undergo AMRAB.

Note: Complaints may come from a facility, patient, inspector, or other source. If the AB suspects an interpretation problem may be present, due to complaints or other information, the AB should provide FDA with all the pertinent information in their possession. In the absence of any inspection findings regarding the physician, the AB will conduct follow-up for any complaints received according to its existing complaint procedures.

Follow-up Actions by FDA with the Facility

1. If the conditions are met for AMRF (i.e., there is no other evidence of serious problems (findings, complaints, etc.) relating to the physician), the district should send a Warning Letter to the facility. The letter would require that the facility conduct AMRF in response to the findings. The letter would also indicate that the facility would be responsible for the cost of the AMRF.
2. If the facility agrees to conduct AMRF, the district would monitor the progress of the review until completion. The review of images and reports under AMRF could be on-site at the facility or by mail.
3. If the facility does not agree to conduct AMRF or the conditions for AMRAB are met, FDA may confer with the AB as to whether the AB should undertake AMRAB. The district may send a Warning Letter to the facility that would indicate that FDA had asked the facility's AB to conduct AMRAB in response to the inspection findings. Also, in the event that the facility cannot obtain the services of an interpreting physician to perform the review, or all of the available physicians have inappropriate conflicts, FDA may require the facility to undergo AMRAB.
4. The AMR may encompass reinterpretation of all films or limit reinterpretation to a random sample of cases and could be either on-site or by mail. In either case, the facility should generate amended reports and notify appropriate physicians and patients of significant differences from original reports. While the size of the sample will vary with the situation, the sample should probably be no smaller than ten percent of the examinations conducted in the time period selected for evaluation.
5. If the results of the AMRF or AMRAB indicate that the interpretation of mammograms at the facility represent a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). If appropriate, FDA may ask the facility to undertake a patient notification (PN) of patients and/or referring physicians, where the initial interpretation may have been deficient. If the facility does not agree or does not have the means to perform a PN, FDA would consider other methods of initiating a PN.
6. The district and DMQRP should coordinate implementation and monitoring of the notification process.

7. ~~If the results of the AMR do not indicate a serious risk to human health, the entity performing the AMR should notify FDA (FDA would notify the AB in the case of AMRF). FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary. FDA might require the AB to perform continued close monitoring of this facility. In the case of AMRF, FDA may require the AB to perform its own AMR.~~

Approved Alternative Standards

Daily Processor QC Tests

Conducting the daily processor QC tests when the sensitometer is not available

This alternative standard was approved on October 18, 1999 and was made retroactive to April 28, 1999. The alternative to sensitometric-densitometric testing of processor performance can be used for a period of up to two weeks when the facility's sensitometer is unavailable. This alternative is based on evaluating a phantom image through measurements described in 21 CFR 900.12(e)(1) and (2).
The final regulation and its alternative standard are stated below:
21 CFR 900.12(e)(1) and (2) states that:

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within + 0.03 of the established operating level.

(ii) The mid-density shall be within +/- 0.15 of the established operating level.

(iii) The density difference shall be within +/- 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than +/- 0.20 from the established operating level.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).

(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than +/- 0.05 from the established operating level.

When using the alternative test, processor performance is considered satisfactory if:

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions.
2. The optical density of the film at the center of the phantom image changes no more than +/- 0.20 from the established operating level.
3. The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than +/-0.05 from the established operating level.

In addition:

4. To evaluate base + fog, an additional measurement of density must be made either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within + 0.03 of the established operating level.

This alternative test must be conducted “each day clinical films are processed, but before processing of clinical films.” All results must be recorded and charted. If processor performance fails to meet any part of the alternative test, the problem must be corrected before processing is resumed.

Continuous Display of Override Status

Continuous display of the override status for machines with decompression devices

This alternative standard was approved on June 22, 1999 and was made retroactive to April 28, 1999. It has no time limit.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(5)(xi) states that:

(xi) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

(A) An override capability to allow maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

The approved alternative standard to 21 CFR 900.12(e)(5)(xi)(B) allows facilities having machines equipped with automatic decompression devices that are never disabled to permanently place a label on the panel indicating that the unit must always be operated in the automatic decompression mode, in lieu of a continuous display of the automatic decompression override status required in 21 CFR 900.12(e)(5)(xi)(B). The wording of this label must be:

> "Unit always to be used in auto release mode. If auto release is overridden this status will not be displayed."

Weekly Phantom Image Test

Conducting the weekly phantom image test at facilities with intermittent mammography operation

This alternative standard was approved on May 24, 1999 and was made retroactive to April 28, 1999. It applies to facilities that do not conduct mammography every week. Rather, they may conduct mammography during some, but not all, weeks in a given month.
The final regulation and its alternative standard are stated below:
21 CFR 900.12(e)(2) states that:

(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using a FDA-approved phantom, at least weekly.

The approved alternative standard is:

(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, in each week that clinical mammography examinations are performed, prior to the performance of such examinations.

The alternative standard requires that if the number of weeks per month in which clinical mammography is performed increases or decreases, the frequency of the performance of the phantom image quality test must automatically undergo a corresponding increase or decrease. Because of this automatic adjustment to changing facility conditions, no time limit has been placed upon the period of approval.

Post Exposure Focal Spot Indication

Post exposure indication of the machine pre-selected focal spot and or target material

This alternative standard was approved on April 19, 1999, and became effective on April 28, 1999, for Senographe™ DMR GE machines.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(b)(7) states that:

(7) Focal spot selection.

(i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

The approved alternative is:

(7) Focal spot selection.

(i) When more than one focal spot and/or more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected focal spot and target material, and shall indicate, after the exposure, the focal spot and target material actually used during the exposure; or

(ii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall indicate, after the exposure, the target material and/or focal spot actually used during the exposure.

Under the approved alternative, an indication of the pre-exposure focal spot and target material would no longer be required when the pre-exposure target material and focal spot are set by a system algorithm based on exposure and the user has no control over that selection. In operating modes where the user has control of the pre-selected focal spot and/or target material, indication of the pre-selected values would still be required. In all cases, indication of the focal spot and/or target material actually used during the exposure would be required.

Manufacturer's software modification of the AEC

Manufacturer's software modification of the AEC

This alternative standard was approved on September 24, 2001. It has no time limit.
The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(10) states:

(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

The alternative applies to the specific situations described below, in which manufacturer's software modifications have been made to specific units. In such cases, an onsite mammography equipment evaluation performed by the medical physicist is not required. Instead, all that is required is oversight by the medical physicist.

The approved alternative standard states that for:

1. the modification of the AEC component of Senographe™ 700T or 800T mammography systems described in the GE Medical System's Field Modification Instruction (FMI) 11451, "Seno 700/800T Optical Density Optimization", and

2. the optimization of the AEC component of the Senographe™ DMR mammography systems described in the GE Medical System's FMI 11450, "DMR V1/V2/+ Optical Density Optimization".

Verification testing to demonstrate that the affected equipment meets the applicable standards must be carried out after these actions are completed. However, the verification testing may be performed under Medical Physicist Oversight. Medical Physicist Oversight means that the medical physicist is consulted as to whether an on-site visit is required or if other personnel can verify that the standards are met, with direction by telephone or printed material from the medical physicist as needed.

Conducting the Mammography Equipment Evaluation After a Software Upgrade Under Medical Physicist Oversight

Conducting the Mammography Equipment Evaluation After a Software Upgrade Under Medical Physicist Oversight

This alternative standard was approved on May 31, 2002. It defines the conditions under which the mammography equipment evaluations performed after some computer software upgrades may be performed either by a medical physicist on site or under the conditions of Medical Physicist Oversight. If these conditions are not met the mammography equipment evaluation after the upgrade must be performed by a medical physicist on site.

The original standard is contained within 21 CFR 900.12(e)(10).

> *(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.*

The approved alternative and the conditions for its use are:

> Software changes or upgrades are considered by FDA to be major repairs, thus the facility must have a mammography equipment evaluation performed after installation of such a change or upgrade. The mammography equipment evaluation must be performed and all failures to meet the applicable standards must be corrected before the affected equipment is used for patient examinations. The tests to be included in the mammography equipment evaluation must be specified by the manufacturer. The specified tests must be adequate for determining whether all of the standards of 21 CFR 900.12(b) and (e) that are applicable to the upgrade are met. If the tests included in the mammography equipment evaluation are all tests that are performed by the quality control technologist as part of the quality assurance program required by the manufacturer, then the mammography equipment evaluation may be conducted either during an onsite visit by a medical physicist or under Medical Physicist Oversight. If any of the necessary tests after the software upgrade are required to be performed by the medical physicist, the mammography equipment evaluation must be performed in its entirety by the medical physicist on site.

Additional conditions for using this alternative requirement in association with a software upgrade are that:

1. The manufacturer must notify FDA of its intention to install the upgrade. The notification must include a brief description of the upgrade, the model(s) of the units that will be upgraded, and a copy of the information to be provided to each facility describing the upgrade and the facility's post installation responsibilities. The manufacturer must receive confirmation from FDA that the upgrade is covered by the alternative requirement before beginning installation.
2. By the completion of each individual upgrade, the manufacturer must inform the facility in writing of its post installation responsibilities under the alternative requirement, which are that the facility must:
   - conduct a mammography equipment evaluation after installation of the upgrade, either during a medical physicist onsite visit or under Medical Physicist Oversight,
   - include in its mammography equipment evaluation the tests specified by the manufacturer,
   - perform the mammography equipment evaluation and correct all test failures before the affected equipment is used for patient examinations, and
   - keep records of the test results and follow-up actions in accordance with 21 CFR 900.12(d)(2).

Correction Period When Components of the Senographe™ 2000D Full Field Digital Mammography (FFDM) System Fail Quality Control Tests

This alternative standard was approved on June 27, 2002. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Senographe™ 2000D FFDM 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, 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. 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 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 mammographic images 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 mammographic images are reviewed or interpreted 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

Alternative Requirements

Alternative Requirements Overview

Discussion:

Question 1: What process is FDA ~~currently~~ following to ~~arrive at a decision~~ decide on a request for approval of an alternative requirement?

When a request is received, a staff member or members are assigned to review it to determine if it meets the criteria for approval established in 900.18(c). This individual or group may also consult with experts in other parts of FDA, with members of the National Mammography Quality Assurance Advisory Committee, and with FDA's Office of the Chief Counsel ~~General Council~~. The end result of this review is a recommendation to the Chief of the Accreditation and Certification ~~Mammography Standards~~ Branch that the request be accepted, rejected, or that more information be requested before a decision is made. If the Chief of the ~~Mammography Standards~~ Accreditation and Certification Branch agrees, the recommendation is sent to the Director of the Division of Mammography Quality and Radiation Programs for the final decision. The Branch Chief and/or the Division Director may also seek information from additional scientific or legal experts to aid in making their decisions.

Breast Implants

900.12(g)(1)(2): Mammographic procedure and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

Discussion:

Question 6: Is there a specific amount of training or number of mammograms of breast implant patients that the technologist must perform under direct supervision prior to performing these studies independently?

All radiologic technologists whose starting dates are after April 28, 1999 must have received some training in the imaging of patients with breast implants as part of the 40 hours of required initial training. No specific amount of breast implant imaging training or performance of a specific number of studies is required~~,~~ ~~however~~. Although there are no requirements referable to implant training for those radiologic technologists whose starting dates ~~under MQSA~~ are before the effective date of the final regulations (April 28, 1999), FDA recommends that all radiologic technologists have training specific to the imaging of patients with breast implants.

Consumer Complaints

900.12(h)(1)(2)(3)(4): Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints.

(2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received.

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

Discussion:

Question 6: What criteria ~~will~~ does FDA use to determine ~~that~~ if facilities meet the MQSA requirements for dealing with consumer complaints?

To meet the requirements for dealing with consumer complaints, facilities must provide written documentation that describes their system for recording, maintaining, and resolving patients' complaints. The documentation must include the instructions that are, or would be, provided to patients describing how to proceed with referral of serious unresolved complaints to the accreditation body. The documentation must also include the procedures that are, or would be used by the facility to report serious unresolved complaints to their accreditation body.

If the facility has received serious complaints after 4/28/99, it must be able to produce records indicating that they are following their system and are maintaining the serious complaint for 3 years.

Question 9: What is an example of an acceptable system for collecting and resolving consumer complaints?

The MQSA final regulations require facilities to have a written and documented standard operating procedure for responding to consumer complaints. The facility may select its own format. An example of an acceptable system for collecting and documenting the consumer complaint is described below:

1. The facility designates a facility contact person with whom consumers, the accreditation body, and FDA can interact regarding serious consumer complaints. The contact person and other health professionals at the facility develop a clear understanding of the definitions of "consumer," "adverse event," "serious adverse event," and "serious complaint" so all parties are knowledgeable about the requirements of the consumer complaint mechanism.
2. If the facility cannot resolve a complaint to the consumer's satisfaction, the facility provides the consumer with directions for filing serious complaints with the facility's accreditation body. These directions are to be provided in writing.
   The facility may wish to post a sign to explain how to file complaints. In this case, the facility could use messages such as, "We care about our patients. If you have comments and/or concerns, please direct them to (the name of the person in the facility who is responsible for complaints)."

This would be in addition to the name and address of the accreditation body, which is listed on the facility's MQSA certificate. The facility is required by law to post the MQSA certificate prominently in the facility.

3. The facility keeps documentation of the complaint on file for a period of three years from the date the complaint was received. The facility may develop a form to record, at a minimum, the following items concerning "serious complaints": name, address and telephone number of the person making the complaint; date of the complaint; date the serious adverse event occurred; precise description of the serious adverse event (including the name(s) of the individual(s) involved); how the complaint was resolved; and the date the complaint was resolved. This record can be either manual (written) or computerized, depending on the facility's preference.
4. The facility acknowledges the consumer's complaint, investigates the complaint, makes every effort to resolve the complaint, and responds to the individual filing the complaint within a reasonable time frame (these steps can usually be accomplished within 30 days).
5. The facility assures that the complaint and any information regarding the complaint or its followup will be shared only with those needed to resolve the complaint. In addition, facilities should design their complaint procedures to be responsive to the particular needs of the patients they serve. Patients or their representatives may complain in person or in writing.
6. The facility reports unresolved serious complaints to its accreditation body in a manner and timeframe specified by the body. The facility may wish to contact their accreditation body regarding this requirement. For easy reference, facilities may want to keep a separate listing of unresolved serious complaints, with the date of referral, summary and date of response, if any, from the accreditation body. (This would be in addition to the record described in number 3, above).

FDA suggests that facilities analyze the complaints to determine if persistent/recurrent problems exist and use this information to help improve their mammography services.

The primary responsibility for the consumer complaint mechanism is with the facility. However, for complaints that cannot be resolved at the facility, the consumer may choose to report the complaint to the accreditation body or the FDA.

Question 10: Does the complaint mechanism have to be posted?

No. The final regulations do not require facilities to post a sign describing how consumers can file complaints. The MQSA certificate includes the name and address of the facility's accreditation body, and filing a complaint with the accreditation body is the next step for consumers registering a complaint. The facility is required to post their MQSA certificate prominently within the view of patients.

The final regulations also require the facility to give consumers with serious unresolved complaints directions for filing such complaints with the facility's accreditation body.

While not required, FDA encourages facilities to post a sign informing their patients of the presence of its complaint mechanism. Facilities can use messages such as, "We care about our patients. If you have

comments, compliments, and/or concerns, please direct them to (the name of the person at the facility who is responsible for complaints)."

Additional suggestions for making patients aware of the complaint mechanism include: providing information about the complaint mechanism on the patient information sheet filled out before the exam, and requesting that patients complete a comment card following the mammography exam. FDA also encourages the facility to train its staff to be receptive to patient concerns so that the patient will feel comfortable in expressing those concerns.

States as Certifiers

Scope

Sec. 900.20 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart C of this part establishes procedures whereby a State can apply to become a FDA-approved certification agency to certify facilities within the State to perform mammography services. Subpart C of this part further establishes requirements and standards for State certification agencies to ensure that all mammography facilities under their jurisdiction are adequately and consistently evaluated for compliance with quality standards at least as stringent as the national quality standards established by FDA.

Application for approval as a certification agency

Sec. 900.21 Application for approval as a certification agency.

(a) Eligibility. State agencies may apply for approval as a certification agency if they have standards at least as stringent as those of Sec. 900.12, qualified personnel, adequate resources to carry out the States as Certifiers' responsibilities, and the authority to enter into a legal agreement with FDA to accept these responsibilities.

(b) Application for approval.

(1) An applicant seeking FDA approval as a certification agency shall inform the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, Rockville, MD 20850, marked Attn: States as Certifiers Coordinator, in writing, of its desire to be approved as a certification agency.

(2) Following receipt of the written request, FDA will provide the applicant with additional information to aid in the submission of an application for approval as a certification agency.

(3) The applicant shall furnish to FDA, at the address in paragraph (b)(1) of this section, three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant;

(ii) Detailed description of the mammography quality standards the applicant will require facilities to meet and, for those standards different from FDA's quality standards, information substantiating that they are at least as stringent as FDA standards under Sec. 900.12;

(iii) Detailed description of the applicant's review and decisionmaking process for facility certification, including:

(A) Policies and procedures for notifying facilities of certificate denials and expirations;

(B) Procedures for monitoring and enforcement of the correction of deficiencies by facilities;

(C) Policies and procedures for suspending or revoking a facility's certification;

(D) Policies and procedures that will ensure processing certificates within a timeframe approved by FDA;

(E) A description of the appeals process for facilities contesting adverse certification status decisions;

(F) Education, experience, and training requirements of the applicant's professional and supervisory staff;

(G) Description of the applicant's electronic data management and analysis system;

(H) Fee schedules;

(I) Statement of policies and procedures established to avoid conflict of interest;

(J) Description of the applicant's mechanism for handling facility inquiries and complaints;

(K) Description of a plan to ensure that certified mammography facilities will be inspected according to MQSA (42 U.S.C. 263b) and procedures and policies for notifying facilities of inspection deficiencies;

(L) Policies and procedures for monitoring and enforcing the correction of facility deficiencies discovered during inspections or by other means;

(M) Policies and procedures for additional mammography review and for requesting such reviews from accreditation bodies;

(N) Policies and procedures for patient notification;

(O) If a State has regulations that are more stringent than those of Sec. 900.12, an explanation of how adverse actions taken against a facility under the more stringent regulations will be distinguished from those taken under the requirements of Sec. 900.12; and

(P) Any other information that FDA identifies as necessary to make a determination on the approval of the State as a certification agency.

(c) Rulings on applications for approval.

(1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the certification standards the applicant will require facilities to meet are the quality standards published under subpart B of this part or at least as stringent as those of subpart B.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be corrected within a specified time period. If the deficiencies are not corrected to FDA's satisfaction within the specified time period, FDA may deny the application for approval as a certification agency.

(3) FDA shall notify the applicant whether the application has been approved or denied. The notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(d) Scope of authority. FDA may limit the scope of certification authority delegated to the State in accordance with MQSA.

Standards for certification agencies

Sec. 900.22 Standards for certification agencies.

The certification agency shall accept the following responsibilities in order to ensure quality mammography at the facilities it certifies and shall perform these responsibilities in a manner that ensures the integrity and impartiality of the certification agency's actions:

(a) Conflict of interest. The certification agency shall establish and implement measures that FDA has approved in accordance with Sec. 900.21(b) to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the certification agency's behalf.

(b) Certification and inspection responsibilities. Mammography facilities shall be certified and inspected in accordance with statutory and regulatory requirements that are at least as stringent as those of MQSA and this part.

(c) Compliance with quality standards. The scope, timeliness, disposition, and technical accuracy of completed inspections and related enforcement activities shall ensure compliance with facility quality standards required under Sec. 900.12.

(d) Enforcement actions.

(1) There shall be appropriate criteria and processes for the suspension and revocation of certificates.

(2) There shall be prompt investigation of and appropriate enforcement action for facilities performing mammography without certificates.

(e) Appeals. There shall be processes for facilities to appeal inspection findings, enforcement actions, and adverse certification decision or adverse accreditation decisions after exhausting appeals to the accreditation body.

(f) Additional mammography review. There shall be a process for the certification agency to request additional mammography review from accreditation bodies for issues related to mammography image quality and clinical practice. The certification agency should request additional mammography review only when it believes that mammography quality at a facility has been compromised and may present a serious risk to human health.

(g) Patient notification. There shall be processes for the certification agency to conduct, or cause to be conducted, patient notifications should the certification agency determine that mammography quality has been compromised to such an extent that it may present a serious risk to human health.

(h) Electronic data transmission. There shall be processes to ensure the timeliness and accuracy of electronic transmission of inspection data and facility certification status information in a format and timeframe determined by FDA.

(i) Changes to standards. A certification agency shall obtain FDA authorization for any changes it proposes to make in any standard that FDA has previously accepted under Sec. 900.21 before requiring facilities to comply with the changes as a condition of obtaining or maintaining certification.

Evaluation

Sec. 900.23 Evaluation.

FDA shall evaluate annually the performance of each certification agency. The evaluation shall include the use of performance indicators that address the adequacy of program performance in certification, inspection, and enforcement activities. FDA will also consider any additional information deemed relevant by FDA that has been provided by the certification body or other sources or has been required by FDA as part of its oversight mandate. The evaluation also shall include a review of any changes in the standards or procedures in the areas listed in Secs. 900.21(b) and 900.22 that have taken place since the original application or the last evaluation, whichever is most recent. The evaluation shall include a determination of whether there are major deficiencies in the certification agency's regulations or performance that, if not corrected, would warrant withdrawal of the approval of the certification agency under the provisions of Sec. 900.24, or minor deficiencies that would require corrective action.

Withdrawal of approval

Sec. 900.24 Withdrawal of approval.

If FDA determines, through the evaluation activities of Sec. 900.23, or through other means, that a certification agency is not in substantial compliance with this subpart, FDA may initiate the following actions:

(a) Major deficiencies. If, after providing notice and opportunity for corrective action, FDA determines that a certification agency has demonstrated willful disregard for public health, has committed fraud, has failed to

provide adequate resources for the program, has submitted material false statements to the agency, has failed to achieve the MQSA goals of quality mammography and access, or has performed or failed to perform a delegated function in a manner that may cause serious risk to human health, FDA may withdraw its approval of that certification agency. The certification agency shall notify, within a time period and in a manner approved by FDA, all facilities certified or seeking certification by it that it has been required to correct major deficiencies.

(1) FDA shall notify the certification agency of FDA's action and the grounds on which the approval was withdrawn.

(2) A certification agency that has lost its approval shall notify facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, that its approval has been withdrawn. Such notification shall be made within a timeframe and in a manner approved by FDA.

(b) Minor deficiencies. If FDA determines that a certification agency has demonstrated deficiencies in performing certification functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, including failure to follow the certification agency's own procedures and policies as approved by FDA, FDA shall notify the certification agency that it has a specified period of time to take particular corrective measures as directed by FDA or to submit to FDA for approval the certification agency's own plan of corrective action addressing the minor deficiencies. If the approved corrective actions are not being implemented satisfactorily or within the established schedule, FDA may place the agency on probationary status for a period of time determined by FDA, or may withdraw approval of the certification agency.

(1) If FDA places a certification agency on probationary status, the certification agency shall notify all facilities certified or seeking certification by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status shall remain in effect until such time as the certification agency can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems, or

(3) If FDA determines that a certification agency that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the certification agency. The certification agency shall notify all facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, of its loss of FDA approval, within a timeframe and in a manner approved by FDA.

(c) Transfer of records. A certification agency that has its approval withdrawn shall transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

Hearings and appeals

Sec. 900.25 Hearings and appeals.

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval of certification agencies or withdrawal of approval of certification agencies shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied certification is entitled to an appeals process from the certification agency. The appeals process shall be specified in writing by the certification agency and shall have been approved by FDA in accordance with Secs. 900.21 and 900.22.