Guidance for Industry and FDA Staff

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #10

Document issued on October 31, 2005

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

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

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

Preface

Public Comment

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

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

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/mammography, or you may either send a fax request to (301) 443-8818 to receive a hard copy of the document, or send an e-mail request to GWA@CDRH.FDA.GOV to request hard or electronic copy. Please use the document number **1554** to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #10

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

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). This guidance document updates previous guidance. Please note the following highlights, which are reflected in this update:

1. In order to simplify the Policy Guidance Help System (PGHS), a number of topics dealing with inspection issues are being deleted from the PGHS and will be incorporated into a separate Inspection Procedures Document. The Inspection Procedures Document will be made available on our Website at a future date.
2. Information regarding accreditation and certification extension of Full Field Digital Mammography (FFDM) units has been added.
3. Tables indicating acceptable uses for attestation for personnel requirements have been added.
4. The mechanism for physicists to obtain a "physicist credential letter" from FDA has been added.
5. Major repairs for FFDM units have been added to the tables describing physicist participation in mammography equipment evaluations.
6. The list of inspection questions has been updated.

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

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

The Least Burdensome Approach

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

Background

The Mammography Quality Standards Act was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification body. The authority to approve accreditation bodies, State certification bodies, and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The majority of the final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance related to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: www.fda.gov/cdrh/mammography/robohelp/start.htm

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

Guidance information is periodically updated. Individuals wishing to get automatic notification of such updates may subscribe to our E-mail ListServ by visiting http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

Introduction

This manual was last updated August 31, 2005.

We recommend 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 ListServ and following the directions there.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance by sending your inquiry to: MQSAhotline@SSSI.net.

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Welcome to the Policy Guidance Help System (PGHS).

The Policy Guidance Help System ^+(PGHS)^- 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~~*- ^+its^- 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 print the text in the right window pane, just highlight a word in that pane and print as usual.

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 ^+implements^- *+~~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 MQSAhotline@SSSI.net.

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:

The Mammography Quality Standards Act (MQSA) requires that before a mammography facility can legally perform mammography, it must be certified. Before a facility can be certified, it must ^+meet applicable MQSA requirements, including those established by its accreditation body^-*+~~become accredited~~*-. To begin the process, *+~~it~~*-^+the facility^- must first contact its accreditation body 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

^+Mammography Accreditation Program^-
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 ^+Public^- Health

^+Mammography Accreditation Program^-
Bureau of Radiological Health
1-515-281-3478

Texas Department of ^+State^- Health ^+Services^-

^+Mammography Accreditation Program^-
+~~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. 21 C.F.R. 900.4(a)(7).*+~~However,~~ *-State law may require facilities to ^+meet additional requirements^-*+~~have State accreditation or State certification~~*-. State requirements are independent of MQSA. You may want to contact your State about *+~~their~~*- ^+its^- 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. 21 C.F.R. 900.4.

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

^+State of South Carolina
Mammography Certification Program
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201
803-545-4400^-

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. 21 C.F.R. 900.11(b)(2), 42 U.S.C. 263b(c)(2). 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. 21 C.F.R. 900.11 (b), (c). 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.

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 State or by specified three-digit zip code area. This information is updated weekly.
- The National Cancer Institute (NCI) provides information regarding breast cancer and mammography, including a list of FDA-certified mammography facilities in a caller's area through ^+its^-*+~~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?

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 a 45 day interim notice to a mammography facility under the following 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~~*-^+In^- order for a facility to be eligible to receive an interim notice, the facility ^+needs to^- *+~~must~~*- have been granted interim accreditation by its AB. ^+Interim accreditation is a temporary accreditation granted by the AB. The AB may grant an interim accreditation for up to 45 days if additional time is needed to complete the reaccreditation process.^-

   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, ^+the AB will notify^- FDA or the Certifying State *+~~will be notified by the AB*~~ to fax the facility an interim notice ^+(an MQSA certificate is not issued in this situation)^-. 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, ^+the facility should^- 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.

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

If a facility's MQSA certificate expires before it has been reaccredited, it must immediately stop performing mammography or it may be subject to civil money penalties of up to $10,000 ^+per violation per day^-. 42 U.S.C. 263b(h)(3). Before the MQSA certificate expires, a facility should contact its accreditation body to discuss its options for continuing to perform mammography.

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 ^+per day^-.

MQSA (42 U.S.C. 263b(h)(3)) 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;
3) ^+Each failure to notify a patient of risk as required by the Secretary;^- and
4) 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. ^+The Centers for Medicare and Medicaid Services (CMS)^- *+~~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~~*- ^+provides CMS with^- an efficient system *+~~for CMS~~*- to confirm the certification status of all mammography facilities. CMS *+~~will share~~*- ^+shares^- 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 certificate*+~~s~~*- is three years from the expiration date of the ^+previous^- *+~~initial~~*- certification.

^+If an already certified facility acquires an additional unit, that unit will take on the facility's accreditation/certification expiration date once the unit is accredited.^-

Question 7: By law, MQSA certificates must be prominently displayed in all facilities (42 U.S.C. 263b(b)(1)(A)(iii)). 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 ^+at no charge^- for each reception area from FDA. ^+Mobile facilities must have at least one original MQSA certificate displayed whenever the mobile unit is performing mammography.^- 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 ^+at no charge^- 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 (42 U.S.C. 263b(b)(1)(A)(iii)), 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 ^+Hotline^-*+~~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 12: Now that FDA has approved *+~~an~~*- FFDM accreditation ^+bodies^-*+~~body~~*-, do we have to have our FFDM unit accredited?

If your State accreditation body or ACR has received FDA approval to accredit your specific model FFDM unit, then you must have your unit accredited by one of those bodies. If neither your State accreditation body nor ACR has received FDA approval to accredit your specific model FFDM unit, then you *+~~must~~*- ^+need to^- have FDA extend your *+~~film-screen~~*- ^+facility's^- certification to cover your FFDM unit before you can use it clinically.

Question 13: We have been using our FFDM unit under FDA's *+~~film-screen~~*- certification extension policy. Now that there is an accreditation body for our model FFDM unit, what do we need to do to have the unit accredited? We were keeping our old film-screen-unit just to be eligible for the certification extension policy. Do we still need to keep this film-screen unit?

Your facility must follow the accreditation body's procedures for accreditation of your model FFDM unit. 21 C.F.R. 900.11.The facility may continue to operate its FFDM unit under FDA's *+~~film-screen~~*- certification extension policy while it applies for and proceeds through the accreditation process. Once you have started the accreditation process, you no longer are required to keep your film-screen unit.

Question 14: We have been operating our FFDM unit under FDA's *+~~film-screen~~*- certification extension policy by linking our unit with a ^+certified^- *+~~film-screen~~*- facility at a different location. Now that an accreditation body has been

approved for our FFDM model unit, must we become accredited and certified as our own independent facility?

Yes. You *+~~must~~*- ^+need to^- become accredited and certified as your own independent facility. Once you have received your MQSA provisional certificate, you can sever your links with the ^+other certified^- *+~~film-screen~~*- facility.

Question 15: Which FFDM units can be accredited by which accreditation bodies?

+~~The General Electric 2000D FFDM unit can be accredited by the American College of Radiology as of February 15, 2003.~~- ^+ The American College of Radiology has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, Fischer SenoScan, Hologic/Lorad Selenia, and Siemens Mammomat Novation DR FFDM units.

The State of Iowa has been approved to accredit the General Electric Senographe 2000D and Hologic/Lorad Selenia FFDM units.

The State of Texas has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, Fischer SenoScan, and Hologic/Lorad Selenia FFDM units.^-

^+Question 16: A mammography facility has contacted our accreditation body (AB) and wants to switch from its current AB. What procedures should the ABs follow to ensure a smooth transition?

The following procedures should be followed to process a facility's request to change ABs.

1. When a facility notifies its current AB that it wants to change ABs, the current AB should make no change in the facility status until it has been notified that the new AB has received and accepted an application for accreditation from the facility.

2. Upon receipt and acceptance of an application for accreditation from a facility intending to change accreditation bodies, the new AB should notify by e-mail both FDA (and the State Certifying Agency where applicable) and the previous AB.

   Note 1: If a facility notifies the new AB that it wants to change its accreditation to it but does NOT send an acceptable application for accreditation, the new AB should not send any notification to either FDA (and the State Certifying Agency where applicable) or the previous AB and should not make any changes to its database.

   Note 2: Prior to transmitting updates to the facility's accreditation history, the new AB should review the history in FDA's certification/accreditation support system (CASS) database and avoid reusing unit #s (unless the update pertains to an existing unit). This ensures retention of unit accreditation history of all units accredited by both AB's.

3. Upon receipt of the AB's notification, FDA will switch the facility's affiliation in the CASS database so that CASS will only accept data for the facility from the new body, and not accept data from the previous AB.

4. To preclude FDA from receiving a status change report before the facility affiliation is manually changed, both ABs should wait two business days after the notification of acceptance of an application before transmitting updated facility records to FDA. The previous AB need not transmit any further records for the facility. The new AB should only transmit additional records when there is a change in the facility's status.

Change of accreditation body subsequent to denial or expiration of accreditation:

A facility that has been denied accreditation, or has allowed its accreditation to lapse, may have to provisionally reinstate before it can continue performing mammography. Provisional reinstatement involves submission and completion of a corrective action plan that is acceptable to the AB, and in some cases FDA or the State Certifying Agency. Corrective action plan requirements are no less stringent for a facility that decides to change ABs while seeking provisional reinstatement. The new AB should request the facility provide a complete accreditation and certification history when applying for provisional reinstatement. It is essential that the new AB be fully aware of the issues that made provisional reinstatement necessary.

In such cases, in addition to the accreditation history provided by the facility, the new AB should contact the previous AB by e-mail, with a copy to the FDA accreditation liaison officer (and State Certifying Agency where applicable), and request a complete history of the facility's prior accreditation or attempts at accreditation. The previous AB should provide such history, including pertinent information about any failure or revocation of accreditation.

The new AB, in consultation with FDA through the AB liaison officer (or State Certifying Agency where applicable), when appropriate, should then request a corrective action plan from the facility in accordance with the AB's policies.

Accreditation body of record:

When switching ABs, which AB is the facility's AB of record may be ambiguous if the change is not made subsequent to a denial or expiration of accreditation. The facility's full certificate will usually remain in effect until it expires. The full certificate is predicated upon accreditation by the previous accreditation body. Unless such accreditation was revoked for cause, FDA would not usually make a determination that a facility's certificate should be terminated.

However, once the CASS affiliation has been changed, only the new AB is able to change facility status information in CASS. It is therefore incumbent on the new AB to ensure that FDA (and the State Certifying Agency, where applicable) is notified of any

change in the accreditation status of the facility. This includes submitting or having the facility submit a request for an interim notice when necessary, and determining when such a notice is appropriate in accordance with the FDA's (or the State Certifying Agency's) and the AB's policy. When a facility has not completed renewal of accreditation before its certificate has expired, and the issuance of an interim notice is not appropriate, the new AB should make a determination concerning provisional reinstatement of the facility in accordance with its policies.^-

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

Citation:

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 procedures 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) DMQRP 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 Departmental 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 ^+that was informed by its Certifying Agency that it must cease performing mammography^- 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 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:

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 Reinstatement of Accreditation ^+and Certification^-

Citation:

900.11(c)(1)(2)(3)(4): (c) Reinstatement policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.

(1) Unless prohibited from reinstatement under section 900.11(c)(4), a facility applying for reinstatement shall:

(i) Contact an FDA-approved accreditation body or other entity designated by FDA to determine the requirements for reapplication for accreditation;

(ii) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

(A) Name and address of the facility under which it was previously provisionally certified or certified;

(B) Name of previous owner/lessor;

(C) FDA facility identification number assigned to the facility under its previous certification; and

(D) Expiration date of the most recent FDA provisional certificate or certificate; and

(iii) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity designated by FDA, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

(2) FDA may issue a provisional certificate to the facility if:

(i) The *accreditation body or other entity designated by FDA notifies the agency that the facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and*

(ii) FDA determines that the facility has taken sufficient corrective action since the lapse of, denial of renewal, or revocation of its previous certificate.

(3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

(4) If a facility's certificate was revoked on the basis of an act described in 42 U.S.C. 263b(i)(1), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

Application to an Accreditation Body

Citation:

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 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
  ^+Mammography Accreditation Program^-
  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 ^+Public^- Health
  ^+Mammography Accreditation Program^-
  Bureau of Radiological Health
  1-515-281-3478
- Texas Department of ^+State^- Health ^+Services^-
  ^+Mammography Accreditation Program^-
  +~~Bureau of Radiation Control~~-
  1-512-834-6688 extension 2246

+~~Currently to be accredited by the~~- ^+The^- States of Arkansas, *+~~California,*-~~ Iowa, *+~~or~~*- ^+and^- Texas ^+accredit facilities located within their respective States^-*+~~a~~

~~facility must be located in that accreditation body's respective State~~*-. Under MQSA regulations, a facility located in a State approved by FDA as an accreditation body may be accredited by the State or by the ACR. 21 C.F.R. 900.4(a)(7).*+~~However,~~ *-State law may require facilities to ^+meet additional requirements^-*+~~have State accreditation or State certification~~*-. These State requirements are independent of MQSA, and facilities must^+, for State purposes^- satisfy all such regulations in addition to MQSA requirements. *+~~You~~*-^+The facility^- may want to contact *+~~your~~*-^+the^- 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 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. 42 U.S.C. 263b(b)(1)(A)(iii). 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 valid for up to three years. Facilities must reaccredit prior to expiration of their MQSA certificates. Renewal MQSA certificates will be issued 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: ^+Must mammography units that are used exclusively for special interventional purposes (localization, biopsy, or specimen radiography) be accredited? Must a facility that performs mammography only for such special purposes be accredited and certified?*- *+~~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. 21 C.F.R. 900.2(aa)(1).

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~~*- ^+should inform^- *+~~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. ^+In some cases, inspectors may have to examine facility records to verify this.^-

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. 21 C.F.R. 900.11.

Question 5: Since loaner, demonstration, and *+~~prototype~~*- ^+investigational^- 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~~*-^+it uses^- these units for mammography?

A loaner*+~~,~~*- ^+or^- 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. 21 C.F.R. 900.12(e)(10).

^+Investigational units are those being used prior to receiving FDA approval for marketing and are being used in accordance with FDA's investigational device exemption regulations. As such they are exempt from MQSA regulations and do not have to be accredited or certified.^- 21 C.F.R. 900.2(aa)(2).

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 before the unit can be used for mammography?

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. 21 C.F.R. 900.12(e)(10), 900.4(e).The facility *+~~must~~*- ^+needs to^- 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 ^+on patients and^- to make the clinical images ^+needed*- 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 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 stationary units. They must be accredited by an FDA-approved accreditation body. 21 C.F.R. 900.11.

Whether multiple mobile units or a mobile unit operated by a 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 separate facility, with a unique ACR MAP number. Consequently FDA or the Certifying State certifies ACR accredited mobile units as separate facilities with unique FDA MQSA identification numbers, and each is issued its own MQSA certificate.~~

~~Other accreditation bodies may accredit multiple units or~~*- ^+If the AB accredits^- mobile units belonging to a stationary facility as additional units ^+of that facility, then^- *+~~. In this case~~*- there would be one identification number for the entire facility and an additional MQSA certificate (with the same ID number) ^+may^- *+~~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.

Definition of Certificate

Citation:

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 to legally perform mammography. 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. 21 C.F.R. 900.11(a).

By law, MQSA certificates must be prominently displayed where they can be viewed by mammography patients. 42 U.S.C. 263b(b)(1)(A)(iii).

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

MQSA certification is facility based. Therefore, if a facility has more than one patient~~*+/examinee*-~~ reception area, it may request an additional MQSA certificate ^+at no charge^- for each reception area from FDA. ^+Mobile facilities must have at least one original MQSA certificate displayed whenever the mobile unit is performing mammography.^- 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 2: Can a facility with a large Spanish-speaking population get a Spanish-language MQSA certificate?

FDA will issue an additional MQSA certificate ^+at no charge^- translated into Spanish for those facilities serving a Spanish-speaking population for each patient~~*+/examinee*-~~ reception area. The Spanish-language MQSA certificate(s) and the English-language MQSA certificate(s) *+~~must~~*- ^+should^- both be prominently displayed where they can be viewed by mammography 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 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 (42 U.S.C. 263b(b)(1)(A)(iii)), 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 ^+Hotline^-*+~~Program~~*-, P.O. Box 6057, Columbia, MD 21045-6057. Facilities with State-issued MQSA certificates should check with their Certifying State 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.

Full Field Digital Mammography (FFDM) Certification ^+Extension Program^-

Discussion

Until an accreditation body has been approved to accredit your specific model full field digital mammography (FFDM) unit, FDA will continue its process for extending the certification of an already certified *+~~screen-film~~*- facility to include these specific model FFDM units. Until otherwise notified by FDA, a facility with an FFDM unit (that does not have a corresponding approved accreditation body) will be exempt from the MQSA accreditation requirement but must request FDA to extend its *+~~screen-film~~*- ^+current^- certification to cover its ^+unaccredited^- FFDM unit. Requests for FFDM certification extension need to *+~~supply~~*- ^+include^- 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~~- ^+FFDM Certification Extension Program^-
Division of Mammography Quality and Radiation Programs

+~~FDA/CDRH/OHIP~~- ^+FDA/CDRH/OCER^-
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~~*- ^+mammography^- unit in order to maintain its certification status when utilizing an FFDM unit. 21 C.F.R. 900.11(a). Your facility is also subject to an annual onsite MQSA inspection of its FFDM unit at the same time its *+~~screen-film~~*- ^+accredited^- 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?

If your State accreditation body or ACR has received FDA approval to accredit your specific model FFDM unit, then you must have your unit accredited by one of those bodies ^+to qualify for certification^-. 21 C.F.R. 900.11(a). If neither your State accreditation body nor ACR has received FDA approval to accredit your specific model FFDM unit, then you ^+need to ask^- *+~~must have~~*- FDA ^+to^- extend your *+~~film-screen~~*- ^+current^- certification to cover your FFDM unit before you can use it clinically.

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

Requests for FFDM certification extension need to *+~~supply~~*- ^+ include^- 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~~- ^+FFDM Certification Extension Program^-
Division of Mammography Quality and Radiation Programs
+~~FDA/CDRH/OHIP~~- ^+FDA/CDRH/OCER^-
1350 Piccard Drive, HFZ-240*+~~, Room 230B~~*-
Rockville, MD 20850
Phone : 301-594-3332 *+~~or 3313~~*-
Fax : 301-594-3306

Question 5: Does the FFDM unit have to be in the same location as the *+~~screen film unit~~ *- ^+certified facility^-?

The FFDM unit *+~~must~~*- ^+needs to^- be located within the same inspection jurisdiction as the certified *+~~screen film~~*- facility. In most cases, this means that the FFDM unit *+~~must~~*- ^+needs to^- 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~~*- ^+certified^- 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 ^+certified facility^- *+~~screen film~~*- and off-site FFDM units. 21 C.F.R. 900.2(x).

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~~*- ^+SenoScan^-(approval date: 9/25/01)

Lorad Digital Breast Imager (approval date: 3/15/02)

Hologic/Lorad Selenia FFDM System (approval date: 10/02/02)

^+GE Senographe DS (approval date: 02/19/04)

Siemens Mammomat Novation DR (approval date: 08/20/04)^-

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, ^+the extension is contingent upon you meeting^- *+~~you must meet~~*- the following conditions while using the FFDM unit:

1. Maintain accreditation status for at least one *+~~screen film~~*- ^+mammography^- unit to which the FFDM unit is linked. During the annual onsite MQSA inspection*+~~, both~~*- ^+of^- the ^+certified^- *+~~screen film~~*- facility^+, all units, including this^- *+~~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~~*- ^+needs to^- 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: Which FFDM units can be accredited by which accreditation bodies?

*+~~Answer: The General Electric 2000D FFDM unit can be accredited by the American College of Radiology as of February 15, 2003~~^+ The American College of Radiology has been approved to accredit the General Electric Senographe 2000D, General Electric

Senographe DS, Fischer SenoScan, Hologic/Lorad Selenia, and Siemens Mammomat Novation DR FFDM units.

The State of Iowa has been approved to accredit the General Electric Senographe 2000D and Hologic/Lorad Selenia FFDM units.

The State of Texas has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, Fischer SenoScan, and Hologic/Lorad Selenia FFDM units.^-

Question 10: We have been using our FFDM unit under FDA's *+~~film-screen~~*- certification extension policy. Now that there is an accreditation body for our model FFDM unit, what do we need to do to have the unit accredited? We were keeping our old *+~~film-screen~~*- ^+accredited^- unit just to be eligible for the certification extension policy. Do we still need to keep this ^+old accredited^- *+~~film-screen~~*- unit?

Your facility must follow the accreditation body's procedures for accreditation of your model FFDM unit. 21 C.F.R. 900.11. The facility may continue to operate its FFDM unit under FDA's *+~~film-screen~~*- certification extension policy while it applies for and proceeds through the accreditation process. Once you have started the accreditation process, you no longer are required to keep your ^+old accredited^- *+~~film-screen~~*- unit.

Question 11: We have been operating our FFDM unit under FDA's *+~~film-screen~~*- certification extension policy by linking our unit with a *+~~film-screen~~*- ^+certified^- facility at a different location. Now that an accreditation body has been approved for our FFDM model unit, must we become accredited and certified as our own independent facility?

Yes. You *+~~must~~*- ^+need to^- become accredited and certified as your own independent facility. Once you have received your MQSA provisional certificate, you can sever your links with the ^+other certified^- *+~~film-screen~~*- facility.

^+Question 13: What actions must we take before we begin using our FFDM unit on patients?

The answer is outlined below and depends on whether there is an accreditation body that accredits your FFDM unit and whether you are adding the FFDM unit to an already-certified facility.

1. If your facility is already certified AND there isn't an approved accreditation body (AB) for your FFDM unit then you need to request that FDA extend your certification to cover the FFDM unit. Additional details are outlined in questions 2-4. You cannot use this FFDM unit on patients until you receive a Letter of Acceptance from the FDA.
2. If your facility is already certified AND there is an approved AB for your FFDM unit then you may begin examining patients with the new unit ONLY AFTER the medical physicist indicates that the Mammography Equipment Evaluation (MEE)

has passed AND the facility has sent the complete application for the new unit (with the MEE results) to the AB. Once approved, the AB will notify the FDA (or State Certifying Agency) within two business days that an accreditation application has been accepted for the new unit. You are not required to wait for a response from the AB to begin clinical use of the new unit since you are already operating with a current MQSA certificate. However, the Centers for Medicare and Medicaid Services (CMS) will not reimburse for examinations performed on an FFDM unit until the FDA has received notification that you have applied for accreditation of your new FFDM unit. In order to ensure appropriate reimbursement, we recommend that MQSA-certified facilities do the following before using their new FFDM unit to examine patients:
Fax or send the application materials with the MEE results to the accreditation body as soon as possible, and after three business days, contact the accreditation body to confirm that the new unit information was sent to the FDA.

3. If you are not already certified AND there is an approved accreditation body for your FFDM unit then you must follow and satisfactorily complete all the AB's procedures for accrediting that unit. 21 C.F.R. 900.11. Because your facility is not already certified, you CANNOT use the unit to examine patients until you receive your MQSA certificate or interim notice from the FDA or the State Certifying Agency. 21 C.F.R. 900.11.
4. If you are not already certified AND there isn't an approved AB for your FFDM unit then you need to either obtain accreditation and certification for a different mammography unit OR become linked to an already certified facility. You can then proceed with Step 1.^-

MQSA Facility Certification Requirements For Use Of Full Field Digital Mammography (FFDM) ^+Systems^-

Requirements

1. Facility Status Information

a. Facility Name and FDA Facility ID Number
b. FDA Certificate Expiration Date
c. Current Accreditation Body for Screen-Film ^+or FFDM^- 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

Additional Mammography Review and Patient Notification

Citation:

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. Such notification will occur within a timeframe and in a manner specified by FDA.

Discussion:

Question 4: Will the facility be responsible for patient/*+~~patient~~*-^+physician^- notification that may result following the AMR?
Yes. If the AMR indicates that notification of patients and physicians is necessary, the ^+FDA or certifying State will require^- 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. 21 C.F.R. 900.12(j), 900.22(g). The facility may request the Certifying Agency to review *+~~to review~~*- its determination that patient/physician notification is required.

AMR General Guidance

Background

The Food and Drug Administration (FDA) developed this Additional Mammography Review (AMR) guidance to inform facilities of possible FDA actions 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 two specific inspection findings, other problems could result in FDA requiring AMR for a facility. For example, evidence or information may be obtained

from a *+~~the~~*- facility's accreditation body or patient or physician complaints that could convince FDA to require an AMR. In the case where serious quality problems are suspected at a facility, 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~~*- ^+significant^- risk to human health, FDA may require the facility to undertake patient/physician notification.

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.*~~*-^+ *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. Such notification will 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~~*- ^+works^- with the facility to identify a qualified interpreting physician(s) *+~~who would~~*- ^+to^- perform the AMR. The physician(s) *+~~would be~~*- ^+is^-subject to FDA approval. Under AMRAB, the facility's accreditation body *+~~would be~~*- ^+is^-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. 42 U.S.C. 263b(h)(1)(A). FDA may require the facility to 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~~*- ^+its^- 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.

If a facility has a Level 1 phantom image finding or a Level 1 interpreting physician finding, FDA may require the facility to undergo 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.

Evaluations 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 ^+available^-*+~~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 ^+or Untitled^- Letter may be sent to the facility.
- The Warning ^+or Untitled^- Letter should advise the facility that *+~~they are~~*- ^+it is^- required to undergo an AMR, that *+~~they~~*- ^+it^- 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~~*- ^+significant^- 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~~*- ^+significant^- risk to human health, FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary.

*+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*~~

Modifications in the Assessment Categories Used in Medical Reports

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

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

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

.....

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

an assessment and reasons why no assessment can be made shall be stated by the interpreting physician;
and .....

The approved alternatives are:

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

.....

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

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

Consumer Complaints

Citation:

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 2: If a facility is unable to resolve a consumer's "serious complaint," how is the complaint then handled?

If a facility is unable to resolve a serious complaint to the consumer's satisfaction, the consumer may file the complaint with the facility's accreditation body. The consumer should be able to obtain adequate directions from the facility for filing serious complaints with the accreditation body. Section 900.4(g), under accreditation body standards, established requirements for actions that accreditation bodies must take to resolve consumer complaints that have been referred to them. The final regulations do not prescribe any one particular method for accreditation bodies to use because FDA believes that flexibility will permit each accreditation body to establish a system that works best for the facilities it accredits and the patients *+~~they serve~~*- ^+it serves^-. The accreditation body and/or a consumer may forward a serious complaint to the FDA ^+or the State Certifying Agency^-. FDA notes that nothing in the MQSA or the regulations precludes FDA^+, the State Certifying Agency,^- or a State from investigating complaints.

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 ^+or the State Certifying Agency^- 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. 42 U.S.C. 263b(b)(1)(A)(iii).

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~~*- ^+its^- 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~~*-.

Certificate

Citation:

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

Discussion:

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

MQSA certification is facility based. Therefore, if a facility has more than one patient*+~~/examinee~~*- reception area, it may request an additional MQSA certificate for each reception area from FDA ^+at no charge^-. ^+Mobile facilities must have at least one original MQSA certificate displayed whenever the mobile unit is performing mammography.^- 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 2: Can a facility with a large Spanish-speaking population get a Spanish-language MQSA certificate?*+.*-

FDA will issue an additional MQSA certificate ^+at no charge^- translated into Spanish for those facilities serving a Spanish-speaking population for each patient*+~~/examinee~~*- reception area. The Spanish-language MQSA certificate(s) and the English-language MQSA certificate(s) *+~~must~~*- ^+should^- both be prominently displayed where they can be viewed by mammography 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 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 (42 U.S.C. 263b(b)(1)(A)(iii)), 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 ^+Hotline^-*+~~Program~~*-, P.O. Box 6057, Columbia, MD 21045-6057. Facilities with State-issued MQSA certificates should check with their Certifying State 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.

^+Contact Configuration^-

^+Contact configuration refers to all mammographic imaging procedures where the breast is in direct contact with the patient support surface of the cassette holder (bucky).^-

Direct Supervision of RTs and MPs

Citation:

900.2(o)(2): Direct Supervision means that: During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

Discussion:

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the radiological technologist or physicist being supervised are corrected before patients are irradiated or harm is done to the patient.

Question 3: What does it mean to be under the direct supervision of a qualified medical physicist?

For the physics survey and/or mammography equipment evaluation, direct supervision means that *+~~the supervisor (if the supervision is done after 4/28/99,~~*- the supervising medical physicist must have qualified under the Master's or higher pathway, 21 C.F.R. 900.12(a)(3)(i)(B)(3) *+~~) is~~*- ^and be^- present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

Furthermore, when conducting a physics survey, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued. 21 C.F.R. 900.12(e)(9).

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.

Question 6: In a radiology training program with a mammography curriculum, would the facility be *+~~in~~*- non-compliant for letting student technologists show competency in performing mammography on live patients?

No. As long as the facility is MQSA certified, there is nothing in the MQSA or FDA's regulations that will interfere with training in mammography. Student technologists can receive classroom and practical training in a variety of ways. Student technologists who do not yet meet the requirements established under MQSA may perform actual examinations as part of the training so long as another technologist who does meet the MQSA requirements is present in the room to supervise (i.e. direct supervision) and, if necessary, corrects the student in the conduct of the examination. 21 C.F.R. 900.12(a)(2)(ii).

Question 7*+~~.~~*-^+:^- Do general supervisors of radiologic technologists or medical physicists have to meet any requirements under MQSA?

No. There are no requirements for general supervisory duties under the regulations. However, if a general supervisor, in addition to his/her general supervisory duties, also performs or directly supervises mammographic examinations or physics surveys, he/she must meet the appropriate requirements. 21 C.F.R. 900.12(a), (e)(9). (Note: the term "general supervisor," as used in this question, should not be confused with the other guidance referring to direct supervision).

+~~Supplementary Remark: Since October 1, 1994, there is no requirement that the interpreting physician observe each radiologic technologist perform a mammographic examination once a month.~~-

Mammographic Modality

Citation:

900.2(z) Mammographic Modality means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and xeromammography.

Discussion:

Question 4: Is Full Field Digital Mammography (FFDM) considered a mammographic modality?

Yes. FFDM is a technology for radiography of the breast and, therefore, is a mammographic modality. Until *+~~fairly recently~~*-^+January 2000^-, FFDM was classified as an investigational use of mammography and thus was exempted from the MQSA requirements. 21 C.F.R. 900.2(aa)(2). However, FFDM units produced by a growing number of manufacturers have *+~~now~~*-^+since^- been approved by FDA for commercial distribution. Such approved units are subject to the MQSA requirements. However, those FFDM units that are not yet cleared for commercial distribution are still viewed as investigational units and continue to be exempt from the MQSA requirements.

Quality Control Technologist

Citation:

900.2(pp) Quality control technologist means an individual meeting the requirements of section 900.12(a)(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

Discussion:

Question 1: What is the training requirement for a QC technologist working with digital units?

The QC technologist at a facility using a^+n^- FFDM unit must be a qualified radiologic technologist who also meets the training requirement for performing FFDM examinations. 21 C.F.R. 900.12(a)(2)(ii)(C), (iii)(E).

Verification Test

+~~This test(s) is~~- ^+Test^- performed after a mammography unit has been adjusted, changed, ^+moved,^- or repaired to show that the unit is within appropriate action limits.

Automatic Exposure Control (AEC) Performance Testing – Annual Physics Survey and Mammography Equipment Evaluation

Citation:

900.12(e)(5)(i)(A)(B)(C): Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) Automatic exposure control performance.

(A) The AEC shall be capable of maintaining film optical density within ±0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ±0.30 of the average under phototimed conditions can be produced.

(B) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within ±0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(C) The optical density of the film in the center of the phantom image shall not be less than 1.20.

900.12(b)(10)(i),(ii)(A)(B),(iii): Automatic Exposure Control.

(i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

Discussion:

Question 2: Can we continue to use technique charts *+~~after 10/28/2002*-~~?

Yes. Facilities should continue to develop and use technique charts for their clinical exams, especially for AEC modes where kVp and other technique factors must be selected by the technologist. The only place where the words “technique chart” appear in the regulations is in the annual AEC performance test requirement. This regulation places a restriction on the use of a specific factor of the technique chart, the density control setting, when the medical physicist is performing the AEC test *+~~after October 28, 2002~~*-. *+~~After that date, the~~*-^+The^- medical physicist may not adjust the density control setting while performing the AEC test in the 2 to 6 cm range. In other words, the medical physicist may not use the density control setting to compensate for inadequate

performance of the AEC. When performing this test, the medical physicist may use a technique chart to adjust other factors such as kVp, filter, anode track or AEC mode to the extent such factors are used clinically. If the AEC performance test fails, the medical physicist may create a temporary technique chart that includes the appropriate density settings (in addition to the other technique factors). This temporary technique chart may then be used by the facility for up to 30 days, or until the problem has been corrected and the equipment passes the AEC performance test, whichever comes first.

When the AEC is functioning properly, the radiologic technologist shouldn't need to adjust the density control setting while imaging patients who are in the 2 to 6 cm range. If the radiologic technologist needs to continually adjust the density control to achieve films of adequate density, the AEC may need adjustment and the medical physicist should be consulted.

The regulations do not restrict the use of technique charts by radiologic technologists. While a properly functioning AEC should reduce the need to use the density setting component of a technique chart, radiologic technologists may use these charts to change the density control settings whenever they believe it appropriate during the performance of clinical mammographic examinations. In addition, the regulations do not preclude the use of the manual mode and under that scenario, the use of technique charts is essential.

Question 3: During the annual physics survey, how must the medical physicist test AEC performance and what action limits apply?

Due to the proliferation of mammography units with multiple AEC modes, testing of AEC performance has become more complex in recent years. When units had only one AEC detector, a single AEC mode, and a single target-filter combination, testing was relatively straightforward. That is no longer the case for most units. The following guidance is designed to help medical physicists adequately test a unit's AEC performance without over-testing the unit.

During the annual physics survey, the physicist can limit testing of AEC performance to the contact configuration. To fulfill MQSA requirements, all AEC detectors (that can be individually selected by the operator) and all AEC modes used clinically over the 2 to 6 cm range in the contact configuration must be tested. While there are several ways to do the test, medical physicists who use the following guidance will have fulfilled this requirement. Note: Facilities that do not clinically use their AEC in the 2 to 6 cm range (only use manual techniques) must still test the AEC to ensure that at least one AEC mode for each available AEC detector meets the regulatory requirements.

In order to minimize sources of variability, the physicist should use a single cassette (or same cassette type), film from the same emulsion batch, and the same processing conditions throughout Steps 1 and 2 below (see question # 6 below).

Step 1: Determine the Mean Optical Density (MOD)

A) For an AEC detector used in the contact configuration, perform three exposures using 2, 4, and 6 cm thicknesses of a homogeneous material. The exposures are to be performed using an AEC mode clinically used at each of the thicknesses. For example, if a facility typically uses fixed kVp mode at 2 cm, fixed mA mode at 4 cm and OPDOSE mode at 6 cm, then the medical physicist

should use these same modes at those thicknesses when conducting the AEC performance test. Note: Even if a facility clinically uses more than one AEC mode at a particular thickness, no more than one of the AEC modes should be tested at each thickness to establish the MOD. For example, if a facility clinically uses both the fixed kVp and the AOP CONTRAST modes at 2 cm, the medical physicist should use the more commonly used of these modes to determine the MOD.

B) Measure the optical density of the images obtained at 2, 4 and 6 cm (total of three images) and average them. This is your MOD.

Step 2: Determine if the AEC detector used in Step 1 is within the regulatory action limit of +/- 0.15 OD of the MOD *+~~(+/- 0.30 OD if done before 10/28/2002)*~~

A) Check to see that all three of the optical densities obtained in Step 1B are within the action limit when compared to the MOD

B) If ALL three ODs are within the action limit AND no other AEC modes are clinically used in the 2 to 6 cm range, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See question #5 for additional guidance on testing multiple AEC detectors).

C) If ALL three ODs are within the action limit AND the facility clinically uses an additional AEC mode(s) in the 2 to 6 cm range (other than the ones used to originally establish the MOD), the facility must test the additional AEC modes. The medical physicist needs to test EACH additional AEC mode(s) at any ONE clinically used thickness in the 2 to 6 cm range. If the OD(s) is within the action limit when compared to the MOD, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See question #5 for additional guidance on testing multiple AEC detectors).

The medical physicist does not have to test the other clinically used equipment configurations during the annual physics survey, but will have to test these configurations whenever a mammography equipment evaluation involving the AEC is performed.

Question 4: During the mammography equipment evaluation, must the medical physicist test the AEC performance in all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?

During a mammography equipment evaluation, the AEC must be operable in all equipment configurations (contact, magnification, and various image receptor sizes) used clinically by the facility. The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. Compliance with this requirement may be demonstrated by any of the following three methods:

1. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density (OD) over the 2 to 6 cm range within the action limit of +/- 0.15 OD *+~~(+/- 0.30 OD if done before October 28, 2002)~~*- of the MOD (See question 3 for additional guidance).

AND

Confirming AEC performance in all other clinically used configurations. This can be done by demonstrating that the AEC meets the density and reproducibility limits established by the manufacturer for those other configurations.

Note: Method #1 can be used only in those cases where the manufacturer has established AEC performance standards for the non-contact configurations provided.

2. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density over the 2 to 6 cm range within the action limit of +/- 0.15 OD *+~~(+/- 0.30 OD if done before October 28, 2002)~~*- of the MOD.

AND

Confirming AEC performance in all other clinically used configurations. This can be done by comparing the contact configuration MOD with measurements obtained using the 4 cm thick phantom in the other configurations used clinically at the facility. When results across different configurations are compared, the facility may use the action limit of +/- 0.30 OD *+~~even after October 28, 2002~~*-.

3. Confirming AEC performance by demonstrating that the AEC maintains the MOD within +/- 0.15 OD *+~~(+/- 0.30 OD if done before October 28, 2002)~~*- in all configurations used clinically by the facility. The action limit applies only within each specific configuration tested and does not apply to data collected across the different configurations.

+~~Because of conflicting recommendations that existed in the professional community regarding measurement of AEC performance during mammography equipment evaluations, facilities-~~ ^+Note: During mammography equipment evaluations, facilities^- that measure^+~~d~~*- AEC performance only in the contact configuration *+~~before October 28, 2002 will not be cited for failure to measure AEC performance for all clinically used configurations. However, those that continue this practice after October 28, 2002*-~~ will be subject to citation. 21 C.F.R. 900.12(b)(10)

Question 5: Must medical physicists test <u>all</u> AEC detectors for AEC performance in mammography units with multiple AEC detectors and can the testing procedures be modified if the detectors are <u>in the same cassette holder</u> (bucky)?

The general principle is that all AEC detectors must be tested. What is considered adequate testing will depend on the arrangement of the AEC detectors in the mammography unit.

1. Where a mammography unit has different AEC detectors in the different size cassette holders (buckys), each detector must be tested separately as described above in questions #3 or #4.

2. Where a mammography unit has more than one AEC detector in a single cassette holder (bucky), the physicist must test all the individually selectable AEC detectors and may test the detectors using either of the following methods:

   i. All detectors as described above in questions #3 or #4, OR;
   ii. One detector as described above in questions #3 or #4 AND comparing the OD obtained at 4 cm from each of the other detectors to the MOD obtained from the first detector. When results across different detectors are compared, the medical physicist may use the action limit of +/- 0.30 OD *+~~even after October 28, 2002~~*-

3. Where a mammography unit has multiple AEC detectors that are not individually selectable by the operator, the AEC can be tested as if it was a single detector. An example of such a system is one with three fixed detectors in which the system automatically chooses which detector will be active during the exposure. Similarly, a large field detector that automatically selects its active area needs to be tested only as a single detector. However, a system with three fixed detectors, each of which can be selected individually by the operator, needs to have all three detectors tested as described in section #2 above. Please note that a detector that can be moved to different positions by the operator is still considered a single detector and needs to be tested at only one of those positions.

Question 8: The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an annual test for AEC performance using 2, 4, and 6 centimeter thicknesses of a homogeneous material. If a unit is used clinically at combinations of kVp and filtration that include thicknesses outside the 2 to 6 cm range, must it meet the AEC performance requirements at the thicknesses where it operates and must it be tested at those technique factors under the annual quality control requirements? What about AEC performance testing during a mammography equipment evaluation?

During the annual physics survey, the unit is not required to meet the AEC performance action limit outside the 2 to 6 cm range and the medical physicist is not required to test the AEC using thicknesses outside this range. However, we recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2 to 6 cm range, FDA recommends that a technique chart be developed showing appropriate technique factors (kVp, AEC mode, target/filter, and density control setting) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD *+~~(+/- 0.30 OD if done before October 28, 2002)~~*- of the MOD under AEC testing conditions can be produced.

During the mammography equipment evaluation (as defined in 900.12(e)(10)), the medical physicist must evaluate the AEC in all clinically used configurations (See Question 4). Section 900.12(e)(10) requires that the AEC meet the requirements of 900.12(b) and (e). Under 900.12(b)(10), the AEC is required to be "operable" under "configurations provided." The term "operable," means the AEC must meet the

performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. FDA also recommends that in addition to the required testing in the 2 to 6 cm range, the unit also be tested in all configurations at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2 to 6 cm range, FDA recommends that a technique chart be developed showing appropriate technique factors (kVp, AEC mode, target/filter, and density control setting) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD *+~~(+/- 0.30 OD if done before October 28, 2002)~~*- of the MOD under AEC testing conditions can be produced.

Application of Compression

Citation:

900.12(b)(8)(i)(A)(B): (i) Application of compression. Effective October 28, 2002, each system shall provide:

(A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(B) Fine adjustment compression controls operable from both sides of the patient.

Discussion:

Question 1: A facility's x-ray units have compression devices operated by a single foot control on each unit. Does the foot control meet both the "hands-free" requirement and the "operable from both sides" requirement, even if each unit only has one foot control? Must the facility purchase a second control for each in order to meet the "operable from either side" requirement?

The system described may meet the regulations, but individual evaluation is necessary. The foot control does meet the "hands-free" portion of the requirement. If the single foot control is operable from both sides of the patient, then it would meet the full requirement. However, if the control is permanently mounted so that an operator can activate it from only one location, then it would not meet the requirement, therefore requiring that an additional "hands-free" control be incorporated into the system. Note that the "fine adjustment control" is not required to be a "hands free" device. Any method of activation, including a "foot control" could be used as the "fine adjustment compression control" required by this section. If there are additional questions, the facility should consult with its medical physicist *+~~before the October 28, 2002, deadline~~*-.

Question 2: ^+Must all mammography units have power driven compression ^- *+~~Is power driven compression required once the final regulations go into effect on April 28, 1999?~~*-

^+Yes.^- *+~~No. Power driven compression will not be required until October 28, 2002.~~*-

Question 3: With machines such as the GE 500T and 600T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement?

Yes. After receiving input from the National Mammography Quality Assurance Advisory Committee, comments from the public, and performing its own evaluation, FDA has determined that, with proper use, fine compression can be achieved with GE 500T and 600T units by tapping the foot pedal. While FDA recognizes that fine compression can be achieved using these mammography units, the specifics of the compression device require the technologist to pay additional attention during the application of compression. Where this causes clinical problems, facilities may want to consider modifying the compression device to allow for more consistent operator control. Facilities wishing to modify their units may try contacting third-party vendors offering such modifications for more information. Before a facility decides to modify the compression device, the facility should assure itself that the unit meets all the other ^+equipment^- *+~~new~~*- requirements *+~~(AEC performance, maximum compression force, focal spot condition and radiation output) that go into effect on October 28, 2002~~*-.

Question 5: When I perform the semiannual compression QC test, our unit's initial power drive provides an initial compression force of 37 pounds^+. However^- *+~~however~~*-, it cannot maintain that force. The force decreases to less than 25 pounds in approximately 1 second. How long does the initial power drive have to maintain a force of at least 25 pounds?

+~~If the initial power drive is the sole means of providing compression for this mammographic unit, the unit must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations (see Question 4 above), the unit must be repaired, modified or replaced.~~-

+~~If the unit also has fine adjustment control (required on all units as of October 28, 2002), the~~- ^+The^- initial power drive must maintain a compression force of at least 25 pounds for ^+ the length of time it usually takes the radiologic technologist to either complete an average exposure OR^- *+~~the length of time it usually takes the radiologic technologist to~~*- engage the fine adjustment control. *+~~The~~*- ^+If the^- fine adjustment control ^+is engaged then it^- must *+~~then~~*- maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and ^+needs to^- be repaired, modified or replaced. 21 C.F.R. 900.12(e)(4)(iii). If the unit passes this test, but still loses compression force during clinical examinations (see Question 4 above), the unit must be repaired, modified or replaced.

General Equipment Requirement

Citation:

900.12(b)(2): General. All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to 1010.2 of this chapter as meeting the applicable requirements of §1020.30 and 1020.31 of this chapter in effect at the date of manufacture.

Discussion:

Question 3: At the time of the inspection, a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 21 CFR 900.12(b) (3-10). Must the unit immediately be taken out of service?

No. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 21 CFR 900.12(e) if it is to be used on patients and the facility remains subject to *+~~possible~~*- citation ^+for having a mammographic unit that did not meet one or more of the 21 CFR 900.12(b) requirements at the time of the inspection^-.

~~*+Question 4: Before 10/28/02, a facility learns (through a QC test, annual physics survey, mammography equipment evaluation or MQSA inspection) that one of its mammography units will not meet the new equipment requirements that go into effect on 10/28/02. Must the facility take the unit out of service as of 10/28/02?~~

~~No. The requirement to have the unit adjusted, modified, or replaced does not apply until a facility QC test, annual physics survey, mammography equipment evaluation or MQSA inspection that occurs after the 10/28/02 effective date, documents that the unit does not comply with the new requirements. For example, during the physicist's annual survey performed in July 2002 (prior to the 10/28/02 effective date of the new requirements), the focal spot does not pass the resolution test but does meet the focal spot dimension requirement. That unit will not have to be adjusted, modified, or replaced until it fails the resolution test the next time it is performed after 10/28/02 (usually during the next annual survey). While the unit may stay in service for the time period described above, FDA strongly recommends that the facility use this time to have the unit adjusted, modified or replaced. Once the unit is documented as non-compliant, the regulatory time limits for completion of repairs apply.*-~~

Image Receptor Sizes

Citation:

900.12(b)(4)(i),(ii),(iii): Image receptor sizes.

(i) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

(ii) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptors.

Discussion:

Question 1: How many cassette/image receptor (IR) sizes must the facility have for each x-ray unit?

As a minimum requirement, the facility must have at least one 18 x 24 cm cassette and one 24 x 30 cm cassette for each ^+film-screen^- mammography x-ray unit in the facility and each of these must be capable of properly functioning with their respective units. The facility may use additional sizes if desired.

Question 2: How many moving grid sizes must facilities have for each x-ray unit?

Facilities must have on hand at least one 18 x 24 cm and one 24 x 30 cm moving grid mechanism for each ^+film-screen^- mammography x-ray unit in the facility. In addition, if the facility uses image receptor sizes other than the 18 x 24 and the 24 x 30 sizes, the facility must have moving grid mechanisms matched to each of these additional sizes. Each of these must be capable of properly functioning with their respective units. Note that a single, large grid assembly that is capable of accepting multiple sized cassettes is not sufficient to meet this requirement. The reason for not allowing the use of the single large grid assembly is the problem such an assembly causes when trying to adequately position small-breasted patients.

Question 5: We perform magnification using only the 18 X 24 cm image receptor. Do we have to show that all our other image receptor sizes also meet the magnification requirements?

No. However, ^+the facility is reminded that for^- each image receptor size used ^+clinically^- for magnification ^+, the system^- must meet the ^+following three^- requirements^+:

- 900.12(b)(4)(iii) - system capable of operating with the grid removed from between the source and the image receptor
- 900.12(b)(6)(ii) - system provides at least one magnification from the range of 1.4 to 2.0
- 900.12(e)(5)(iii) - system resolution

If the facility performs magnification using multiple sizes of image receptors, then it must meet the requirements with each size receptor used for magnification.

+~~of 900.12(b)(4)(iii), 900.12(b)(6)(ii), and 900.12(e)(5)(iii). Two of these [900.12(b)(4)(iii) requiring such systems to be capable of operating with the grid removed from between the source and the image receptor and 900.12(b)(6)(ii) requiring the system to provide at least one magnification from the range of 1.4 to 2.0] can be considered to be image receptor size dependent. That means that if the facility only performs magnification with one image receptor size, the requirements need be met for only that size image receptor. If the facility performs magnification using multiple sizes of image receptors, then it must meet the requirements with each size receptor used for magnification. The third requirement relating to the system resolution under 900.12(e)(5)(iii) is not usually significantly affected by image receptor size.-~~

Question 6: Our mammography unit has a single image receptor holder that can accommodate both the 24 X 30 cm and 18 X 24 cm image receptors, but has only one size grid. Is that acceptable?

No. Each ^+film-screen^- mammography system must be equipped to allow operation with both referenced image receptor sizes AND be provided with moving grids matched to each image receptor size provided with the system. Having a system equipped with only a single size moving grid, even if the device is capable of accepting both size cassettes, would not meet the requirements.

Intensifying Screens

Citation:

900.12(b)(12): Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

Discussion:

Question 1: How can the facility establish the match between the film and the screen output?

The facility is responsible for matching the sensitivity of the film with the spectral output of the screen. Examples of acceptable ^+matching^- methods *+~~to establish compliance~~*- would be to provide documentation from the screen and/or film manufacturer, such as advertising material or specific literature, that clearly identifies the appropriateness of the combination or specifies the screen output and the film sensitivity showing a match between them. Otherwise, the facility should independently show that matching has been established. Facility personnel should contact their medical physicist for additional advice and assistance, if necessary.

Magnification

Citation:

900.12(b)(6)(i),(ii): Magnification.

(i) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

Discussion:

Question 3: In 21 CFR 900.12(b)(6)(i) what does the phrase "available for use by the operator" mean?

X-ray systems used for noninterventional problem-solving mammography *+~~x-ray systems~~*- are required to have the capability for magnification "available for use by the operator^+.^- *+~~," meaning~~*- ^+This means^- that any necessary magnification devices ^+or attachments^- must be present ^+so that the operator can perform^- *+~~with such units to allow operator access to, and to facilitate the use of,~~*- magnification procedures. The decision on whether to use *+~~the~~*- magnification still rests with the facility.

Question 4: We are a screening facility that schedules only asymptomatic patients for mammography. Our equipment cannot perform magnification. Are we permitted to perform additional views on patients who unexpectedly report an abnormality or area of concern at the time of the study or who have an abnormality detected during the screening mammogram, or must we refer such patients to another facility that has magnification capabilities?

If an abnormality or area of concern is unexpectedly reported (for example, by the patient) at the time of the examination or detected on a screening mammogram, facilities are permitted to perform additional views during this examination, that, in their *+~~judgement~~*- ^+judgment^-, may help clarify and further characterize the finding (as benign or malignant) or eliminate it as normal overlapping parenchymal structures. Such additional views may include, for example, repeat standard views, spot compression, rolled, or exaggerated views. If, however, the facility decides that a magnification view is necessary for the work-up of the case, but does not have this capability, the patient should be referred to a facility that does have magnification capability.

Facilities should have guidelines for adequately addressing such situations that unexpectedly arise at the time of the study, within their standard operating procedures. Please note that this guidance applies only to those situations in which facilities become aware of unexpected abnormalities or areas of concern, either reported at the time of the study or detected on a screening mammogram. Facilities without magnification capability should not knowingly schedule patients requiring noninterventional problem solving mammographic procedures.

Prohibited Equipment

Citation:

900.12(b)(1): Regulations published under §1020.30, 1020.31, and 900.12(e) of this chapter that are relevant to equipment performance should also be consulted for a more complete understanding of the equipment performance requirements. (1) Prohibited

equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in 1020.31(f)(3) of this chapter.

Discussion:

Question 1: Must mammography units that are used exclusively for special interventional purposes (localization, biopsy, ^+or^- specimen radiography*+~~,~~ ~~and/or research~~*-) be accredited? Must a facility that performs mammography only for such special purposes be accredited and certified?

^+Not at this time. Although these special procedures do involve radiography of the breast, they are currently exempted from MQSA regulations. 21 C.F.R. 900.2(aa)(1).

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 should inform the MQSA inspector that the unit and personnel are used only for these special purposes, and are not used for screening or diagnostic mammography. In some cases, inspectors may have to examine facility records to verify this.

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. 21 C.F.R. 900.11.^-

*+~~Accreditation of such units is not required at this time. Although these procedures do involve radiography of the breast, they currently are excluded from MQSA regulation.~~

~~Therefore, a mammography unit that is used exclusively for special purposes need not be included in the accreditation application. Similarly, personnel who are involved only with such special purpose mammography may also be excluded from the accreditation application.~~
~~However, an accredited and certified facility that has a mammography unit dedicated solely to these special purpose uses must be prepared to provide the MQSA inspector with proper attestation or documentation that such equipment and personnel are used only for these special purposes.~~

~~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 covered under the MQSA certificate.~~ *-

Centers for Medicare and Medicaid Services (CMS) (formerly HCFA) ^+Reimbursement As It Relates to MQSA Certification^- *+~~Process versus MQSA Accreditation & Certification Process~~*-

Discussion:

Question 1: How does *+~~the*-~~ CMS (formerly HCFA) ^+reimbursement relate to MQSA certification?^- *+~~process relate to the certification and accreditation process~~?*-

^+As long as a facility has a valid MQSA certificate and meets MQSA quality standards, CMS will reimburse it for Medicare-covered screening and diagnostic mammography examinations. CMS also accepts MQSA inspections in lieu of conducting its own inspections.^- *+~~CMS (HCFA) has revised its regulations so that since October 1, 1994, a facility that meets the MQSA quality standards has been considered as meeting the CMS (HCFA) requirements related to quality. CMS (HCFA) also accepts MQSA inspections in lieu of conducting its own inspections. Thus, as long as a facility has a certificate under MQSA, CMS (HCFA) will reimburse it for Medicare-covered screening and diagnostic mammography examinations.~~*- CMS *+~~(HCFA)~~*- will not reimburse facilities that do not have an MQSA certificate. The amount and frequency of reimbursement will still be governed by *+~~the~~*- CMS *+~~(HCFA)~~*- regulations and facilities will still need to use their CMS *+~~(HCFA)~~*- provider number.

To receive reimbursement from CMS *+~~(HCFA)~~*-, the facility *+~~must~~*- ^+needs to^- also submit the FDA or Certifying State facility ID number as it appears on its certificate to CMS *+~~(HCFA)~~*- with its request for reimbursement.

~~*+Inspection*-~~ ^+Inspector Guidance^-

^+Guidance that previously appeared in this section has been moved. Guidance dealing exclusively with instructions to inspectors has been incorporated into the Inspection Procedures Document. Guidance applicable to both inspectors and facilities has been moved to the appropriate topic specific section in the PGHS.^-

~~*+Inspection*-~~ ^+Inspector Guidance^- – General

Confirmation Notice [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Facilities Comments Concerning Their Inspection [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

^+Closed^- Facilities That *+~~Have Closed But*-~~ Are Still Certified ^+Inspector Instructions^-[DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

~~*+Facility*-~~ ^+FDA^- Employer Identification Number [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Governmental Entity

Discussion:

^+Facilities determined by FDA to be governmental entities are exempt from paying FDA-imposed MQSA inspection fees. Facilities in SAC States may still be responsible for paying any SAC-imposed fees.^- A governmental entity is a mammography facility that meets either of the following criteria:

1. The facility is operated by any federal department, state, district, territory, possession, federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. ^+In addition, (1) the entire salary of all on-site personnel of the mammography facility is directly paid by a particular form of government as listed above; (2) all of the facility's mammography equipment is owned, rented by, or leased by a particular form of government as listed above; and (3) the facility's ultimate authority to make day-to-day decisions concerning the management and operation of the mammography facility comes from a particular form of government as listed above. If the facility meets these criteria, FDA will consider the facility to be a governmental entity. The facility should also list the particular form of government on the Governmental Entity Declaration form (Form 3422) in the space provided.^-

or

2. The facility provides services under the ^+Centers for Disease Control and Prevention (CDC) grant supporting the^- Breast and Cervical Cancer *+~~mortality*-~~ ^+Mortality^- Prevention Act of 1990, and at least 50% of the mammography screening examinations provided during the preceding 12 months were funded under *+~~the~~*-^this^- statute. ^+Other breast cancer or mammography programs/grants are not recognized under the governmental entity exemption. For example, a facility that provides mammography services under the Medicare/Medicaid program does not qualify as a governmental entity, unless it meets the governmental entity criteria described above.^-

A Governmental Entity Declaration, FDA Form 3422, is included with each invoice for MQSA inspection services. A facility that believes that it qualifies as a governmental entity must complete this Declaration, have it signed by the facility's Chief Financial Officer or Chief Operating Officer (or equivalent responsible person), and return it to FDA.

^+Any questions or concerns about billing and collection procedures may be addressed to Billing Inquiries c/o MQSA Hotline, P.O. Box 6057 Columbia, MD 21045-6057, 1-800-838-7715 or e-mail at MQSAhotline@SSSI.net.^-

Governmental Entity Declaration Forms

Discussion:

A Governmental Entity Declaration, FDA Form 3422, is included with each invoice for MQSA inspection services.

A facility that believes that it qualifies as a governmental entity *+~~must~~*- ^+needs to^- complete this Declaration, have it signed by the facility's Chief Financial Officer or Chief Operating Officer (or equivalent responsible person), and return it to:

MQSA Government Entity Declaration
+~~FDA Mammography Quality Assurance Program~~-^+MQSA Hotline^-
P.O. Box 6057
Columbia, MD 21045-6057

FDA will review each declaration to determine if a facility qualifies as a governmental entity. ^+Facilities determined by FDA to be governmental entities are exempt from paying FDA-imposed MQSA inspection fees. Facilities in SAC States may still be responsible for paying any SAC-imposed fees.^-

~~*+Identify*-~~ Accompanying Individuals ^+on Inspections^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

^+Inspection Types^- ~~*+Independent Audit Inspections and Joint Inspections*-~~ [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Inspection Citation Levels

Discussion:

Question 1: What do the various inspection citation levels mean?

When FDA designed the MQSA inspection program, we realized that some inspection ^+observations^- *+~~findings~~*- would have a greater impact on the quality of mammography than others. For this reason, FDA adopted different levels of severity (or significance) for inspection ^+observations^- *+~~findings~~*-.

There are three possible levels of ^+observations^- *+~~findings~~*- resulting from an MQSA inspection. They range from Level 1 (representing the most serious noncompliances with MQSA standards) to Level 3 (representing minor deviations from MQSA standards).

A Level 1 ^+observation^- *+~~finding~~*- indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

A Level 2 ^+observation^- *+~~finding~~*- indicates that the facility's performance is generally acceptable. However, the inspector did find one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility.

A Level 3 ^+observation^- *+~~finding~~*- indicates that the facility's performance is generally satisfactory. However, the inspection did show one or more minor deviations from MQSA standards.

If there are no ^+observations^- *+~~findings~~*-, the inspection report will note " ^+All Items in Compliance^- *+~~No Findings~~*-."

If any ^+observations^- *+~~findings~~*- have not been corrected or have recurred since a facility's last MQSA inspection, they are identified as "Repeat *+~~Findings~~*-."

~~*+Inspection of Facilities with Provisional Reinstatement of Certification*-~~ ^+Timing of Routine Annual Facility Inspections^-

Discussion:

~~*+Initially, DMQRP gave priority to inspecting fully certified facilities. This is because provisionally certified facilities would be undergoing accreditation and associated~~

~~corrective action with their accreditation body. Provisional facilities failing accreditation were required to close.~~

~~Since our initial inspection priority determination, the question has arisen as to whether reinstated facilities, although provisionally certified, should have a higher priority for inspection since they have failed accreditation at least once. After discussion, the FDA has determined that provisionally reinstated facilities should have the same priority for inspection as fully certified facilities since there is evidence that they were not practicing high enough quality mammography to pass previous accreditation.*~~

^+Question 1: When should a facility be inspected?

In most cases, a facility gets its 6 month provisional certificate and then goes on to get its full 3 year certificate. This facility should be inspected within 10-14 months of its initial provisional certification date and then every 10-14 months from its most recent inspection.

The timing of an inspection of a facility that has undergone provisional reinstatement or has lost its certification for some period of time depends on a number of factors and can best be illustrated using the following examples.

1. A facility gets its 6 month provisional certificate, fails to get fully accredited and is granted a provisional reinstatement within one month following the expiration date of its provisional certificate. This facility should be inspected within 10-14 months of its initial provisional certification date. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline at 1-800-838-7715 or MQSAhotline@SSSI.net.
2. A fully certified facility fails to become reaccredited and is granted provisional reinstatement within a month following the expiration date of its full certificate. This facility should be inspected within 10-14 months of its most recent inspection. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline.
3. A provisionally certified facility voluntarily returns its certificate because it stops doing mammography. Within a month, circumstances change and the facility asks for and is granted provisional reinstatement. This facility should be inspected within 10-14 months of its initial provisional certification date. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be determined on a case by case basis and the inspector should contact the Facility Hotline.
4. A fully certified facility voluntarily returns its certificate because it stops doing mammography. Within a month, circumstances change and the facility asks for and is granted provisional reinstatement. This facility should be inspected within 10-14 months of its most recent inspection. If the facility has been without a certificate for more than a month, the timing of the inspection needs to be

determined on a case by case basis and the inspector should contact the Facility Hotline.

Inspectors should note that the above deals only with routine annual inspections and that any facility may be inspected at any time for cause. The above also does not deal with the situation where a facility has ceased performing mammography but still retains an active certificate. These facilities should be inspected within 10-14 months of their most recent inspection (or in the case of a new facility within 10-14 months of its initial provisional certification date) even though they might not currently be performing mammography.^-

Inspection Elements Common to Multiple Facilities [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Inspections of Certified Facilities Currently Not Performing Mammography

Discussion:

Question 1: Should a certified facility that is not currently performing mammography be inspected?

Yes. In keeping with the intent of the regulations, once a facility is certified, that facility must maintain its certified status by:

- having an annual physics survey performed ^+(and mammography equipment evaluations, when applicable)^-,
- undergoing periodic audits and reviews by *+~~their~~*- ^+its^- accreditation body,
- permitting an annual MQSA inspection,
- paying an inspection fee, and
- correcting any deficiencies found during inspections.

Should a certified facility choose not to meet these requirements, it must relinquish its certified status. This means the facility must notify its accreditation body and the FDA (Facility Hotline Number: (800) 838-7715, ^+MQSAhotline@SSSI.net^-, Address: *+~~FDA —~~*-MQSA ^+Hotline^-, P.O. Box 6057, Columbia, MD 21045-6057) ^+or the Certifying State^- as soon as possible. Once the facility's certified status has been relinquished, it cannot display the MQSA certificate and cannot lawfully perform mammography.

Should the facility decide to perform mammography services in the future, it must proceed through the accreditation process again. 21 C.F.R. 900.11.

Laptop Failure During an Inspection [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Letters from Approved Certifying Boards [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

^+Responding to FDA after Inspections with Adverse Observations^- *+~~Letters with Inspection Report and Facility Comments~~*- [moved to the Inspection/Report section]

Discussion:

Facilities need to understand how to respond if they have received ^+an adverse observation(s) during their inspection^- *+~~multiple levels of findings*~~. Facilities need to respond ^+in writing to any inspections with higher than a Level 3 observation.^- *+~~to any inspections with Level 1 and/or 2 violations in writing (Level 1 and repeated Level 2 after FDA has sent the facility a letter; for Level 2 and repeated Level 3 findings, the facility must respond within 30 days after they receive their inspection results).*~~ ^+For repeated Level 1, Level 1 and repeated Level 2 observations, the facility should respond within 15 working days after it receives its inspection results. For Level 2 and repeated Level 3 observations, the facility should respond within 30 working days after it receives its inspection results.^- Non-repeated Level 3 ^+observations^- *+~~findings*~~ do not need to be addressed in writing. However, these ^+observations^- *+~~findings*~~ must be corrected and these corrections would normally be checked during the next annual inspection. ^+Inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.^- The inspector should make sure that facility personnel understand what they should do and/or what will happen after the inspection is over.

Corrective Action Communication:

For any facility inspection, the inspector should give facility personnel two separate documents:

1. ^+A cover letter entitled "Important Information about Your MQSA Inspection" (with the appropriate section checked off by the inspector);^- *+~~One of six different cover letters (the letters were developed for the maximum level of finding during an inspection);*~~
2. The post-inspection report (MQSA Facility Inspection Report).

These documents, along with verbal instructions, should be issued to the appropriate personnel at the facility. Inspectors are strongly encouraged to attempt to discuss the ^+observations^- *+~~findings*~~ with the most responsible official available at the time of the inspection. The inspector should also ^+explain how to submit the facility^- *+~~attempt to make sure that facility personnel understand that they should submit their~~*- response to the appropriate FDA district (or regional) office ^+(or State Certifying Agency where applicable)^-, with the State radiation control office receiving a copy. The inspector might also mention that the facility response to the inspection ^+observations^- *+~~findings*~~ should ^+not^- be sent to the ^+Division of Mammography Quality and Radiation Programs (DMQRP) address in Rockville, Maryland or the^- FDA ^+Facility Hotline^- address in Columbia^+, Maryland^-. ^+These addresses^- *+~~That address~~*- should only be used if the facility intends to comment on the inspection process in general. ^+Inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.^-

~~***+Facility Comments:***~~

^+Facility Comments/Questions about Inspections^-

Facilities should *+~~be instructed only to~~*- ^+only^- use the Facility Hotline number (1-800-838-7715) for general comments about the inspection process and general MQSA

questions, not to ask *+~~inspection-specific*-~~ questions ^+about a specific inspection^-. If personnel at a facility have *+~~inspection-specific~~*- questions *+~~relevant to an upcoming or*-~~ ^+about a^- recent ^+or upcoming^- inspection, they should contact the MQSA Inspector who conducted ^+or will conduct^-the inspection, or the State radiation control office. If the inspector ^+or State radiation control office^- cannot answer the questions, the FDA district office^+, DMQRP or State Certifying Agency^- *+~~or DMQRP~~*- should be contacted.

^+Facility Responsibility Regarding Inspection Observation(s) Follow-up^-

+~~Mammography Facility Inspections and Individual Responsibility~~-

Discussion:

~~*+The following policy is what the FDA Districts adhere to for compliance activities.~~

~~Issue:~~

~~The identification of those individuals responsible for violations is a critical part of the inspection. Responsibility must be determined to permit administrative judgment on whom to charge in compliance proceedings and to whom to send official agency correspondence.~~

~~Policy:~~

~~For inspections performed under the Mammography Quality Standards Act (MQSA), the*-~~ ^+With regard to inspection observations the^- most responsible individual *+~~connected with the violation(s)~~*- is ^+the person at the facility who^- *+~~that individual associated with the facility that~~*- has the duty and power to make major decisions regarding corrective action and general operations. Major decisions can include the power to approve the purchase of expensive equipment (e.g., a new x-ray system), hire and fire personnel (e.g., interpreting physicians, ^+radiologic^- technologists, or medical physicists), and order as well as assure the implementation of significant quality assurance changes at the facility.

As an example, the *+~~chairman~~*- ^+chairperson^- of a radiology department at a facility may report to a medical director or an administrator. However, if the *+~~chairman~~*- ^+chairperson^- of the department has the power to make the types of decisions mentioned above, the *+~~chairman~~*- ^+chairperson^- is considered the most responsible individual connected with the ^+observation^-*+~~violation~~*-. In this particular example, if serious *+~~noncompliances~~*-^+observations^- were ^+made^- *+~~found~~*- (listed in Attachment D of Compliance Program 7382.014, Mammography Facility Inspections, under level 1), ^+the FDA District could address a Warning Letter *+~~would be addressed~~*- to the *+~~chairman~~*- ^+chairperson^- of the department. The FDA District could also send copies of the Warning Letter *+~~should always be sent~~*- to the addressee's superior (e.g. medical director) and to the highest known official in the organization (e.g. administrator or chief executive officer).

For MQSA inspections, the name and title recorded in the block for "responsible individual for compliance" would be the most responsible individual connected with the

^+observation^_ *+~~violation~~*- as described above. However, the inspection record must also include the name, title, and address of the highest official in the corporation, firm, facility, or organization; this information should be identified in the Remarks section of the Compliance Contact Data screen.

Highest Official for Facility – *+~~If there are*-~~ ^+There may be^- additional people who should get copies of the Warning Letters (i.e., the corporation president or hospital administrator might get a copy of the Warning Letter sent to the chief of radiology). In those facilities where the most responsible individual for mammography, as defined above, is different than the highest official in the corporation, organization or facility, please indicate the name, title, and mailing address of this individual(s) in the Remarks section of the Compliance Contact Data screen in the inspection software.

~~*+MQSA Inspector*-~~ Identification Card^+s^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Noting Change Within a Facility [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

***+~~Policy for~~*- Retention of MQSA Inspection Test Films [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]**

***+~~Use of Claimed or C~~*-^+Claimed Items – Use During Inspections^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]**

~~*+Use of Remarks Section*-~~ ^+Remarks Section – What to Include^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

~~*+When You Find a Facility Using an Expired Certificate*-~~^+ Expired Certificates Found During an Inspection^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Automatic Densitometers and Saving Data

Discussion:
Issue:
Inspectors are finding situations in which individuals ^+that monitor processor performance^- *+~~carrying out processor monitoring~~*- with an automatic densitometer are on occasion forgetting to press the "save" button. *+~~When~~*- ^+As a result, when^- they print out their processor charts later, there are gaps in those charts.

Policy:
This would be ^+an inspection observation^- *+~~a inspection finding~~*- just as is the case when an individual doing the test manually forgets to record the data on the chart, unless the facility had recorded the density on another form or on the film. If the facility has no record that the test was done on that day, the facility has no evidence that the test was done and ^+the inspector^- should *+~~be cited~~*- ^+cite this^-. The level of the

^+observation^- *+~~finding~~*- would depend upon how often the facility did not save the required data.

Charting of Quality Control Test Results

Discussion:

Question 1: Under the final regulations, must facilities chart the data for quality control tests, such a processor sensitometry or phantom image evaluation?

No. While facilities are required to keep records for the required QC tests, facilities are not required to record the data on charts or graphs. However, we believe that charting/graphing of *+~~these~~*- test data provides a valuable tool for the facility to monitor trends associated with the data and to take corrective action prior to equipment performance exceeding regulatory action limits. The use of charts/graphs will also serve to expedite the inspection process *+~~resulting in significant savings in facility time and resources~~*-.

Darkroom Blacklight [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Daylight System Inspection Issues [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

+~~Facility Use of a~~- Cracked Breast Phantom ^+ - Facility Use^-

Discussion:

~~*+Issue:~~

~~It has come to FDA's attention that some facilities are using cracked or broken phantoms for performing the weekly Phantom Image Quality Control (QC) test, while using a borrowed phantom to get through the accreditation process. This practice raised the following issue.~~

~~Should this practice be allowed and, if not, what should inspectors do when encountering such a situation? It is assumed that the crack or break is visible on the image and interferes with the scoring of the phantom (simulates masses, fibers or specks, and/or obscures one or more of the test objects).~~

~~Crack(s) in the breast phantom which a facility uses to perform their weekly Phantom Image QC test may affect the validity of the phantom QC test results. The use of a cracked or broken phantom that interferes with the scoring of the phantom image is clearly not consistent with performing QC testing properly. However, the inspection procedures do not have a particular item or question which relates directly to facility use of a cracked or broken phantom for their QC testing. Therefore, FDA requests all inspectors to incorporate the following policy into their MQSA inspections.~~

~~Policy: *-~~

When a facility is using a cracked or broken breast phantom that *+~~interferes with the scoring of the phantom image~~*- ^+interferes with the scoring of the phantom image

(simulates masses, fibers or specks, and/or obscures one or more of the test objects)^- for *+~~their~~*- ^+its^_ Phantom Image QC testing, the inspection question "C/A documented?", which is located on the 3.9.2 Phantom Image QC screen of the inspection software, should be answered "No" (since the use of such a phantom constitutes an uncorrected problem) and an explanation of the citation should be placed in the printable Remarks section for this screen. The facility should be advised to acquire a *+~~new*-~~ ^+defect-free^- phantom.

+~~Note: If the facility is using an older version of the ACR-approved phantom, they should contact the vendor where it was purchased to replace it with a current phantom.-~~

Phantom Modifications [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

+~~Preset~~- Scanning Densitometers ^+with Preset Steps^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Processing When Sensitometric Limits Are Out-of-Control

Question 1: Under what conditions, if any, can a facility lawfully process mammograms ^+if they don't have a sensitometer^-*+~~when the film processor determinants are outside the sensitometric action limits*-~~?

Discussion:

***+~~Issue:~~**

~~It has been brought to FDA's attention that some facilities may be processing mammograms when their processor QC test results in determinants which are outside the sensitometric action limits. The justification given for such action has, in some cases, been based on the results of the facility's own phantom image tests. In other cases, references were made to an article in the Summer 1995 issue of Mammography Matters. The purpose of this policy is to clarify misunderstandings regarding such practices.~~

***~~Guidance:*-~~**

^+ The facility may use the optical density measurements (BD, contrast, and B+F) from a phantom image test in place of the normal daily processor QC tests ONLY when the facility's sensitometer is unavailable (for example, it has been sent in for repair) and for no longer than two weeks. During this use, the facility must follow the procedures of the approved alternative requirement entitled "Conducting the Daily Processor QC Tests When the Sensitometer is not Available". The use of phantom image measurements of BD, contrast, and B+F as a substitute for processor QC tests is not permitted under any other conditions than those described in the alternative requirement.^-

*+~~FDA emphasizes that the daily use of the optical density measurements (BD, contrast, and B+F) from a phantom image test may be allowed for a limited period of time only under extreme cases where need is demonstrated and it is not a permanent substitute for daily sensitometry QC testing.~~

~~To use phantom image measurements of BD, contrast, and B+F as a substitute for processor QC tests when the processor determinants are known to be outside sensitometric action limits is not allowed under any conditions.~~

~~**Supplemental Information:**~~

~~Some confusion may have arisen from an article in the "Technical Corner" of the Summer 1995 issue of Mammography Matters. The article states that only under extenuating circumstances, such as when a facility's sensitometer breaks, cannot be repaired immediately and a back-up sensitometer is not readily available, may the facility lawfully operate for a limited time if a daily phantom image test is performed and it verifies that the background density (BD), contrast, and the base plus fog (B+F) values are "...within the control limits for the phantom quality control measurements ...," and that "acceptable (phantom) image scores will not be an acceptable substitute" for daily sensitometry QC testing.*~~

~~*+QC Tracking of Clinically Used Film~~

~~**Discussion:**~~

~~**Question 1: If a facility uses more than one type of film clinically, must the facility perform QC testing on each type of film?**~~

~~If more than one type of film is used clinically for conventional mammography, the facility is only required to perform QC testing with one type of film. For processor QC, we recommend that the fastest film should be used.*~~

Repeat Analysis of the JCAHO Inspection

Discussion:

~~*+During MQSA inspections of Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) accredited hospitals, you may encounter the following situation regarding the mammographic repeat analysis. Under JCAHO*-~~ ^+Under 1995 Joint Commission on the Accreditation of Healthcare Organizations (JCAHO)^- requirements, the repeat analysis *+~~is*-~~ ^+was^- to be performed on the basis of each individual technologist, rather than being based on the entire facility as is the *+~~present*-~~ MQSA standard. *+~~FDA has determined that the*-~~ JCAHO ^+has since modified its standards to allow the analysis to be performed on a facility basis.^- *+~~system is substantially equivalent to the MQSA standard (as long as the analysis is performed at least quarterly) and therefore meets the MQSA requirement.~~

~~A question then arises as to whether*-~~ ^+Whether^-the analysis ^+is^- *+~~can be*-~~ performed after the facility or the individual technologist has examined 250 mammogram patients ^+is^- ~~*+. This can be~~*- left up to the facility, but in all circumstances, the analysis must be performed at least quarterly in order to remain in compliance with MQSA. 21 C.F.R. 900.12(e)(3)(ii).

+~~Should Facilities Get Their Sensitometers Calibrated~~- ^+Sensitometer Calibration^-

It is not a requirement that facilities have their sensitometers calibrated, however it is recommended that they comply with the recommendations of the manufacturer or the facility's accreditation body.

Additional Information for Level 1 and ^+Level^- 2 Noncompliances [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Advice to Facilities Regarding Corrective Actions [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Advice to a Facility Following a Serious Citation [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Corrected Before Inspection (CBI) Policy [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Documentation and Other Issues Related to Inspection ^+Observations^- *+~~Findings~~*- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Inspection Findings Disputed By Facilities [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

~~***-Inspection Findings Disputed By Facilities***~~

~~**Discussion:**~~

~~In some cases, the facility may disagree with the inspector's findings. The following guidance pertains to these situations.~~

~~Note that when a facility has been cited as the result of an MQSA inspection, regardless of whether it is a Level 1, 2 or 3 finding, the facility has the right to disagree with the inspection findings.~~

~~**Level 1 and Level 2 Findings**~~

~~For Level 1 (Warning Letter) and Level 2 findings, the facility is required to submit a written response to the finding(s). Please follow the following steps for these situations.~~

~~1. When a facility notifies the FDA district office in writing of a disagreement with the findings from an inspection, the district should obtain facility information about the disagreement and contact the State and/or inspector to assess what the inspector found.~~

~~2. If it is determined that the inspector was incorrect:~~
~~a) The inspector should download the inspection record, correct the inspection data, and upload the corrected inspection record within 10 days after being informed of the need for correction. A new MQSA Facility Inspection Report should be printed and submitted by FAX or mail to the FDA district office.~~
~~b) The FDA district office should respond to the facility by letter (a phone call is optional) with regard to the disputed finding(s), indicating that FDA agrees with the facility, and that the inspection data for this area has been modified to reflect~~

the correction(s). The revised MQSA Facility Inspection Report should be included with the letter to the facility. FDA should contact the facility by letter within 30 days after notification by the facility of the disagreement with the inspection findings.

Note: The facility should not be informed of any changes before the revised inspection data has been uploaded to MPRIS.

3. The inspector is believed to be correct:

a) If the matter pertains to a disagreement regarding policy, the FDA district office should contact DMQRP, via e-mail, regarding the dispute. Facts concerning the disputed findings should be included with this E-mail.

b) If the matter pertains to a disagreement regarding facts or data for the inspection, the FDA district office should resolve the disagreement by contacting the facility and the State. The district office may contact DMQRP for additional guidance, when needed.

c) If the inspector is found to be in error, then follow 2a and 2b above.

d) If the inspector is correct, the district office should send a letter to the facility indicating that FDA supports the findings of the inspection and that the facility has a responsibility to correct the problems found. In those cases where contact has been made with DMQRP regarding the inspection, this should be stated in the letter to the facility. If a Warning Letter was sent and the disagreement arose from the letter, the response back to the facility should reiterate the intent of the FDA to take action should the facility fail to comply with MQSA.

Level 3 Findings

Level 3 findings are the least severe and do not require a response by the facility. However, many facilities will respond to these findings by letter to either the State or FDA. If the facility disputes a Level 3 finding, then the steps listed above should be followed.

Inspection Errors Discovered by FDA or the State

Inspection records containing errors need to be corrected, regardless of whether the finding(s) was disputed by the facility. In cases where errors are found by the FDA or the State, rather than the facility, the inspector should 1) correct the inspection record, 2) print the report, 3) upload the revised record to MPRIS, and 4) mail or FAX the report to the facility along with either a note or letter from the State explaining that a correction of the report was necessary. The State or the inspector may also call the facility about the correction, as long as the revised report is mailed before or after the call.

Letters with Inspection Report and Facility Comments

Discussion:

Facilities need to understand how to respond if they have received multiple levels of findings. Facilities need to respond to any inspections with Level 1 and/or 2 violations in writing (Level 1 and repeated Level 2 after FDA has sent the facility a letter; for Level 2

~~and repeated Level 3 findings, the facility must respond within 30 days after they receive their inspection results). Non-repeated Level 3 findings do not need to be addressed in writing. However, these findings must be corrected and these corrections would normally be checked during the next annual inspection. The inspector should make sure that facility personnel understand what they should do and/or what will happen after the inspection is over.~~

~~**Corrective Action Communication:**~~

~~For any facility inspection, the inspector should give facility personnel two separate documents:~~

~~1. One of six different cover letters (the letters were developed for the maximum level of finding during an inspection);~~

~~2. The post-inspection report (MQSA Facility Inspection Report).~~

~~These documents, along with verbal instructions, should be issued to the appropriate personnel at the facility. Inspectors are strongly encouraged to attempt to discuss the findings with the most responsible official available at the time of the inspection. The inspector should also attempt to make sure that facility personnel understand that they should submit their response to the appropriate FDA district (or regional) office, with the State radiation control office receiving a copy. The inspector might also mention that the facility response to the inspection findings should not be sent to the FDA address in Columbia. That address should only be used if the facility intends to comment on the inspection process in general.~~

~~**Facility Comments:**~~

~~Facilities should be instructed only to use the Facility Hotline number (1-800-838-7715) for general comments about the inspection process and general MQSA questions, not to ask inspection-specific questions. If personnel at a facility have inspection-specific questions relevant to an upcoming or recent inspection, they should contact the MQSA Inspector who conducted the inspection, or the State radiation control office. If the inspector cannot answer the questions, the FDA district office or DMQRP should be contacted.*-~~

Recording State vs. MQSA Requirements

Discussion:

FDA understands that it is both more efficient for inspectors and less disruptive for facilities when the State and MQSA inspections are performed ^+together^-*+~~back-to-back~~*-. However, it is important that inspectors take special care in communicating with facility personnel regarding which ^+observations^- *+~~findings~~*- are State requirements versus MQSA requirements. This means that inspectors should clearly state when a citation is a State noncompliance and when a citation is an MQSA ^+noncompliance^-*+~~finding~~*-.

Additionally, State noncompliances should not be listed on the MQSA Facility Inspection Report (including the printed Remarks sections), in the inspection cover letters, or any

other documents created for the MQSA inspection program. All State noncompliances should be placed on the appropriate State forms, documents, or letters to the facility.

Situations ^+Without^- *+~~That Do Not Have~~*- Corresponding Questions in the Software [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

+~~Additional~~- Processor *+~~Guidance~~*- ^+Conditions and the STEP Test^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Control Film Used for STEP [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Processing Cycle and the STEP Test

Discussion:

The proliferation of cycle times used in mammography *+~~today*~~ has made the distinction between standard processing and extended processing confusing. This has resulted in uncertainty in recording the type of processing cycle for some systems. *+ ~~used in the field. The purpose of this memo is to clarify the situation and present a uniform definition for the processing cycle to be used with the S.T.E.P test.~~*-

Currently, the "standard" processing cycle which refers to a nominal cycle time of 90 seconds can have a range of 88s – 150s (which corresponds to 24s – ~35s development time), depending on the developer temperature. Likewise, the "extended" processing cycle can have a nominal cycle time in the range 170s – ~240s (43s – ~55s development time).

Furthermore, although the *+~~S.T.E.P.*~~ ^+STEP^-test is an evaluation of the processing conditions regardless of the type of film used ^+by the facility^-, the fact that some mammography films are designed to gain most of their speed increase at about 32s development time compared to their gain at a fully extended cycle (~55s development time) has created a tendency in such situations to refer to this as extended processing and record it as such in conjunction with the *+~~S.T.E.P.*~~ ^+STEP^- test, even though this falls within the standard cycle time range.

+~~Reference~~- ^+Processor Performance Testing^- Information for Facilities - the STEP Test

Discussion:

^+The following guidance is designed to help a facility or a group of facilities set up a processor performance testing process similar to FDA's STEP test. Facilities may use this procedure to check whether they are consistently processing their mammography film according to the manufacturer's recommendations.^-

Identification of a Standard Reference Film Processor

First, a processor must be identified which is known to be operating according to the film manufacturer's recommendations. The local film representative may be able to assist in the identification of such a ^+processor^- *+~~facility~~*-.

Sensitometer, Densitometer and Film

Since there currently is no national standard for light sensitometry, any 21-step commercial light sensitometer is adequate. The film used for the test should be the same film used clinically for mammography. The comparison between the Standard Reference Film Processor and the tested processor should use the same sensitometer, densitometer and the same test film obtained from the same box.

Processing Speed

To calculate processing speed, ^+determine^- the speed density *+~~is determined~~*-. Speed density is the density equal to the base plus fog density plus 1.00. A sensitometric step number (speed step) corresponding to the speed density is interpolated from the sensitometric curve of the film.

Processing Speed is then calculated using the following formula:

$$\text{Processing Speed} = 100 \times 10^{(Sr - So) \times 0.15}$$

Where:
Speed density = 1.0 + (B+F)
S = speed step, the sensitometer step number corresponding to the speed density,
So = Observed speed step for the tested processor, and
Sr = Reference speed step when the film is processed according to the film manufacturer's recommendations.

Suggested Guidance

If there is no difference between So and Sr, then the processing speed is 100 for standard processing. Extended cycle processing speed is measured relative to standard cycle processing, and the appropriate processing speed is in the 130 – 140 range. STEP action limits are based on a 20% difference in processing speed, and corresponds to a nominal 2.2 degree Celsius (4.0 degree Fahrenheit) developer temperature difference. For a more detailed discussion, please refer to the article by Suleiman et. al., "Automatic Film Processing: Analysis of 9 Years of Observations" (Radiology 1992; 185:25-28).

If ^+you follow the guidance above and you don’t see an improvement, contact your medical physicist or FDA’s Facility Hotline (1-800-838-7715) for further assistance.^- *+~~the above specific actions have been conducted, and a documented improvement in processing has not been shown, then FDA should be consulted to determine if the facility's actions are to be considered adequate.~~*-

***+~~STEP~~*- ^+Sensitometer^- Field Calibration Protocol ^+for Inspectors^- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]**

***+~~STEP~~*- Reference Number ^+for STEP – Entering into Laptop^- *+~~and Discussing Specific STEP Test Result Values with the Facility~~*- [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]**

When the STEP Test Fails -- Actions By Facilities

Discussion:

Question 1: When facilities are cited for the STEP test, what ^+corrective^- actions by the facility are deemed adequate?

First, if the STEP test fails, the ^+inspector should repeat the^- test *+~~should be repeated*-~~ for verification. *+~~Since failing~~*- ^+If the^- STEP ^+test fails again,^- *+~~is a Level 2 non-compliance, it~~*-the facility will need to respond*+~~requires a facility response within 30 days*-~~ to FDA ^+or the Certifying State Agency^-. Any subsequent action by the facility that results in a documented improvement in *+~~their~~*- ^+its^- processing will be considered ^+an^- adequate ^+response^-. ^+The facility may use the process described in **Reference Information for Facilities – the STEP Test** found elsewhere in the PGHS to determine whether the processing speed has returned to acceptable limits.^-

The following tests should not be done by the inspector, but are rather the responsibility of the facility.

Known Chemistry-Processor

If adhering to film manufacturer's written recommendations, i.e., known processor, known chemistry, and correct developer temperature, then each of the critical parameters needs to be verified. Usually this will be performed by a technical representative or the medical physicist.

1. Accuracy of the developer temperature using an accurate thermometer.
2. Accuracy of the development time.
3. Correct replenishment rates.

Hybrid Chemistry-Processor System

If the chemistry-processor system consists of a hybrid system (i.e., manufacturer A's processor, manufacturer B's chemistry, and manufacturer C's film), and there is no available film manufacturer guidance ^+addressing this hybrid situation^-, then manufacturer C's film needs to be sensitometrically equivalent to manufacturer C's film when the film is developed according to manufacturer C's recommended processing condition.

Equivalent Performance

The facility can demonstrate "equivalent film performance" for *+~~their~~*- ^+its^- chemistry-processing system by comparing sensitometric curves. These curves must be generated with the facility's mammography film developed in the (1) facility's processor, and (2) in a chemistry-processor system known to be operating according to the film manufacturer's specifications. The same sensitometer and densitometer must be used for this comparison. 21 C.F.R. 900.12(e)(1).

It is critical that the films used to compare the different processors be from the same emulsion batch, not simply the same type of film.

Extension of the 14 Month Limit ^+for the Medical Physicist Survey^-

Discussion:

Policy:

When there is an extenuating circumstance(s), such as an impending move, which makes it impractical to have the annual physicist's survey performed within a 14-month time period, facilities should contact their State ^+inspector, State Certifying Agency,^- or the FDA District Office (whichever conducts their annual inspections) and request permission to defer the current survey until after the move has been completed, or until the extenuating circumstance(s) is no longer applicable.

The facility *+~~must~~*- ^+needs to^- explain, in writing, the reason for the request and establish a reasonable schedule showing the date by which the deferred physics survey will be completed. The State ^+inspector, State Certifying Agency,^- or FDA, based on the facility's history and circumstances, may at their discretion, approve a delay for such cases. If needed, States may consult with the FDA on a case-by-case basis.

When the State ^+inspector, State Certifying Agency,^- or the ^+FDA^- district office approves a delay for the annual physicist survey and the MQSA inspection is conducted before the approved delay is over, then the inspector should enter an ^+N/A^- *+~~"X"*~~ (^+N/A^- *+~~"X"*~~ denotes not applicable) as the answer to the question SURVEY REPORT AVAILABLE: and record the reason *+~~for this~~*- in the printable Remarks for the SURVEY REPORT section. The facility should be instructed to send a copy of the report to the inspector once the physicist survey is performed. The inspector will then need to evaluate the survey report, edit the inspection record (answer the physics survey questions), and re-upload the inspection data to DMQRP^+, and send the facility a revised facility inspection report.^-

*+~~Background~~:

~~The Statute and the regulations require that a physicist's survey be performed annually. As a matter of policy, FDA has allowed facilities up to 14 months between the date of the MQSA inspection and the most recent physicist's survey to meet this requirement. While this policy has worked reasonably well in most cases, possible situations may exist in which adhering to this policy would place an undue burden on a facility.~~

~~One such situation is when a facility plans to move to a new location on a date that either coincides with or slightly exceeds 14 months from the date of their most recent physics survey. Requiring a physics survey before such an impending move, simply to meet the annual requirement for the limited time period before the facility moves, would not serve the intent of the regulation. Remember that the facility will be required by their accreditation body to have a physics survey after the move. If exceptions were allowed to the 14-month policy to permit facilities to defer the physicist's survey until they have moved to the new address, an unnecessary burden would be lifted from these facilities. FDA reviewed the situation described above and has issued the above policy.*-~~

+~~Medical Physicist~~- Artifact Test for Daylight Processing Systems [MOVED TO QC SECTION]

Discussion:

This guidance should assist medical physicists who survey facilities that have daylight system processors for mammography.

In a normal darkroom setting, this test involves feeding two films at two different orientations into the processor (one film along the long dimension and another film along the short dimension). In ^+the daylight processor^- *+~~this~~*- case, using a large cassette and the same enclosure that the facility uses for loading the magazines:
a) Load a small (18 x 24 cm) film in the cassette so that its long dimension is parallel to the long dimension of the cassette, follow the recommended normal artifact test procedure to expose the film, and place the cassette in the daylight system for processing.
b) After the film has been processed, load another small film transversely in the same large cassette so as to occupy only half the cassette. Expose the new film by following the rest of the steps in the recommended procedures for the artifact test, and place the cassette in the daylight system to process the new film.

Artifact analysis on the two films can then be done in the same manner as for manually loaded cassettes.

+~~Medical Physicist Evaluation of~~- QC Testing ^+ Evaluation by Medical Physicist – Separate Reports^-

Discussion:

Some medical physicists include their evaluation of the tests conducted by the QC technologist *+~~to be~~*- in a separate document or addendum to the survey report, rather than ^+in the report itself.^- *+~~using a specified form or format.~~*- This practice is acceptable.

+~~Medical Physicist Survey –~~- kVp Values Used During ^+Medical Physicist Survey^- Testing

Discussion:

The term "kVp normally used clinically" should be considered as synonymous with the terms "clinical kVp" or "typical kVp."

^+In cases where the kVp is selected by the operator, we^- *+~~We~~*- have required the physicists to perform some tests at the kVp normally used clinically at the facility (except for surveys^+ ^-that are done before the facility has established that value, such as *+~~surveys*-~~ ^+mammography equipment evaluations^- of new units *+~~in new facilities~~*-). 21 C.F.R. 900.12(e)(5)(ii), (e)(9). *+~~We have also allowed a latitude of +/- 1 kVp for this clinical kVp versus the~~*- ^+The^- kVp used in the survey^+/mammography equipment evaluation^- tests of reproducibility (both for kVp and AEC performance), HVL, dose, and phantom image evaluation (i.e., for all inspection questions where "the kVp used clinically," appears.) ^+must not exceed +/- 1 kVp from the clinical kVp.^- For example, if the clinical kVp was 26, the test could be done at 25 kVp, 26 kVp, or 27

kVp. Likewise, fractional kVp values could be rounded off to the nearest integer without citing a noncompliance.

Note: There may be cases where the technique factors that the facility was using at the time of the survey^+/mammography equipment evaluation^- are different from the ones in use at the time of the inspection. In such cases, the technique factors in use at the time of the survey^+/mammography equipment evaluation^- should be applied.

For the kVp accuracy test and the kVp tracking portion of the AEC performance test, only the values used clinically at the facility need to be tested, up to a maximum of 3 values. If only 1 or 2 kVp's are used, only those kVp's need to be tested). If three or more kVp's are used, only three of those used need to be tested. *+~~Also, in the case of kVp tracking portion of the AEC performance test, if only 1 value of kVp is used clinically, the test only needs to include that kVp.*-~~

~~*+Medical Physicist*-~~ ^+Validity of the kVp(s) Used in^- Mammography Equipment Evaluation Testing *+~~Report~~*-

Discussion:

If the medical physicist survey report *+~~(which you review as part of an MQSA inspection) is*-~~ ^+contains^- a mammography equipment evaluation for a new x-ray unit ~~*+(i.e., the unit's first survey)*-~~, be aware that, at the time of the ^+mammography equipment evaluation^- *+~~survey~~*-, the physicist may not have known the exact kVp that the facility would be using for imaging the average breast. By the time of your inspection, the facility will probably have established this typical clinical value and it may differ from the value(s) the physicist used during the ^+mammography equipment evaluation^- *+~~acceptance testing~~*-.

During the mammography equipment evaluation testing, if the physicist used a kVp that is different from what the facility is now using as the "average clinical kVp," *+~~DO NOT cite~~*- the facility ^+should not be cited^- for survey report inspection questions which ask "Done at the kVp normally used clinically?" as long as the kVp(s) that was tested is within the usual range of kVp's used for mammography of an average breast.

Multiple Dates for the Medical Physicist Survey

Discussion:

If the survey is conducted over a period of time, all dates of the individual parts should be indicated. The survey date that the inspector should enter in the laptop should be the date that corresponds to the date that the last required test is completed. The date of the survey corresponds to the date of the last test, not the date on the written report provided to the facility. If any individual part is more than 14 months old at the time of the inspection, ^+the inspector should enter the date of that part as the date of the survey and the facility would be^- *+~~then the facility should get~~*- cited for having an overdue survey.

Signature on Survey Report

Discussion:

Question 1: Can a medical physicist sign-off on a physics survey ^+or mammography equipment evaluation (MEE)^- done by a surrogate if the medical physicist was not present during the survey ^+or (MEE)^-?

No. The qualified physicist (*+~~if the supervision is done after 4/28/99,~~*- the supervising medical physicist must have qualified under the Master's or higher pathway, 21 C.F.R. 900.12(a)(3)(i)(B)(3)) would have to be present during the survey ^+or MEE^- and, at a minimum, provide direct supervision over his/her surrogate (supervisee). Direct supervision means that the qualified medical physicist (supervisor) is present to observe and correct, as needed, the performance of the supervisee. 21 C.F.R. 900.12(o)(2). This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

Furthermore, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued.

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.

The supervisor must sign the survey report. 21 C.F.R. 900.12(e)(9)(v).The qualifications of the supervising medical physicist will be checked during the inspection. The names of all those being supervised must also be identified in the report. 21 C.F.R. 900.12(e)(9)(v).

Equipment Measurements Which Result in Borderline Values [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Phantom Images Exposed in a Fully Automatic Mode ^+– Assigning a kVp^- ~~*+, if that is the Clinically-used Technique*-~~ [TITLE CHANGE ONLY]

***+~~Poorly Aligned~~*- Intensifying Screens ^+with Poor Alignment^-**

Discussion:

Intensifying screens which had been poorly aligned with the chest wall edge of the cassette during the *+~~installation~~*- ^+manufacturing^- process may result in an image with a narrow low-density strip along the chest wall edge of the film (since there is no intensifying screen underlying this area). DMQRP has confirmed that the industry allows manufacturers a "tolerance" in screen-cassette alignment that may result in such a strip on the edge of the film. This low-density strip may simulate the appearance of the compression paddle being visible on the film and could lead to the inspector inappropriately citing the facility for compression paddle misalignment.

The strip is most visible on your alignment test film but can also be seen below the phantom on the phantom image films, once its presence is recognized. Once you are aware of this poor screen-cassette alignment as a possible cause for a narrow low-density strip on the chest wall edge of an image, it will usually be clear to you that it is not a

compression paddle misalignment problem. Please take care not to "misread" an image which was produced with a poor screen-cassette problem and then cite it as ^+compression paddle misalignment^- *+~~such~~*-.

There is not a question in the inspection procedures that addresses this issue. Since any tissue which is at the chest wall on a mammogram will not be imaged, many interpreting physicians will find this poor alignment undesirable. FDA suggests that if you observe a poor screen-cassette alignment, you note it in the Printable Remarks Section and discuss it with the facility. It will then be up to the facility to decide what action to take.

Reloading Cassettes During an Inspection [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

~~*+Systematic*-~~ ^+Systemic^- Errors [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Use of Equipment and *+~~Level 1*-~~ ^+Citation of^- Noncompliances [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

^+Dose Calculations^- Using BR12 Rather than the RMI 156 Phantom *+~~for Dose Calculations~~*- [MOVED TO QC SECTION]

Discussion:

The dose tables used for the calculation of average glandular dose are based on a phantom that represents a patient with a compressed breast thickness of 4.2 cm and with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue *+~~in composition~~*-. While BR12 is manufactured to represent this tissue composition, it is commercially available *+~~only~~*- in whole ^+or half^- centimeter *+~~thickness~~*- ^+thicknesses^-. If a medical physicist is using this material to determine the dose, the physicist must use a thickness equal to or larger than 4.2 cm to assure that the x-ray system passes this test. 21 C.F.R. 900.12(e)(5)(vi).

MQSA Inspector's Questions

Discussion:

Following are the questions that MQSA inspectors will address during the course of the annual inspection.

Mammography Quality Standards Act (MQSA)
~~*+V 3.2*-~~ Inspection Questions under the Final Regulations

^+**1.0 Inspection Information**
- 1.1 Name and Address
- 1.2 Equipment Registration

2.0 Facility Inspection Download
3.0 Facility Inspections
3.0 Facility Inspections – List

3.0 Facility Inspections – Facility
- (Certificate) Expiration Date mm/dd/yyyy
- (Certificate) Displayed (y/n)
- Operating with a valid* certificate? (y/n)
- (Facility) Name
- (Facility) ID
- (Facility) CFN
- (Facility) EIN
- Facility Category (check one)
  - Non Federal
  - Federal (Air Force, Army, Bureau of Prisons, Indian Health Service, Navy, VA)
- Facility Type *(check one from pop-up list)*

3.0 Facility Inspections - Address
- (Number & street, city, state, & zip code)
- Address changes (*double click to access new screen*)

3.0 Facility Inspections - Inspection
- Inspector Name & ID #
- Date (of inspection) mm/dd/yyyy
- Accomplishing District
- Inspection Time *(hours)*
  - On-site (time spent at the facility)
  - Other (pre-and post activities)
- Travel Time *(hours)*
- Annual Inspection Type** *(check one)*
  - Basic
  - Joint Audit
  - Mentored
  - Accompanying Inspector (if joint or mentored is checked)
- Regulation Enforcement (Interim, Final)
- Software Version

3.1 Aliases

3.2 Additional Sites *(name & address info, if applicable)*

3.3 Contacts
- 3.3.1 Facility Accreditation Contact
- 3.3.2 Facility Inspection Contact
- 3.3.3 Compliance Contact
- 3.3.4 Billing Contact
- 3.3.5 Inspection Report Contact

3.4 Related Equipment

3.5 Units - List (unit number, room, status & other info)

3.5 Units – Information
- (X-Ray unit) Number
- (X-Ray unit) Room name or number
- Serial Number

X-ray unit still in use? (No/Evaluate Records Only/Temporarily out of Service/Yes)*
Manufacturer
Model
AB Model
Manufacture Date - (mm/dd/yyyy)
Is the unit mobile (van, truck,..)? (y/n)
Image Receptor (IR) Type (Film-Screen/Xeromam./Digital)
If D is pre-filled, then:
Display Method (Monitor/Laser film/Other)

3.5 Units - Screen-Film

Film Manufacturer (pop-up list)
Film Type (pop-up list)
Screen Manufacturer (pop-up list)
Screen Type (pop-up list)

3.5 Units – Evaluation

X-Ray unit designed for mammography? (y/n)
Does x-ray system include the following? (y/n)
- Image Receptors for 2 sizes?
- Moving Grids for 2 sizes?
- Compression Paddles for 2 sizes?
- Post exp. display in AEC mode for focal spot?
- Post exp. display in AEC mode for target material)?

X-Ray unit accredited? (y/n/pending/x)
[in this list, "x" refers to "N/A or not applicable"
Is this a new* unit? (y/n/x)
Mammo equipment evaluation *(by m. phy.)* done? (y/n/x)

3.5.1 Collimation Assessment

Source to Image Distance (SID) (cm) --.-
Source to Patient Support Distance (SPSD) (cm) --.-
X-ray field/IR misalignment
Left (cm) --.-
Right (cm) --.-
Nipple (cm) --.-
Chest wall] (cm) --.-
IR/Paddle alignment
Is paddle image on the film? (y/n)
Compression paddle/IR chest wall edge (cm) --.-

3.5.2 Dose Estimate - Technique Factors

Target/filter (Mo/Mo, Mo/Rh, Other)
Focal Spot to Patient Support (same as SPSD) (cm) --.-
Mode (**A**uto [mAs, kVp, or full] / **M**anual)
(Pre-Exposure) **SETTINGS** *(if indicated)*
kVp -- mAs ---- Time--- Density (setting) –

3.5.2 Dose Estimate – Cassette Variability*

MDH

	C.ID	mAs	Exp. (mR)	Exp. Time (ms)
Cassette#1	----	-----	-----	----
Cassette#2	----	-----	-----	----
Cassette#3	----	-----	-----	----

3.5.2 Dose Estimate – Reproducibility

(exposure) # 1

mAs (post exp) ----

Exposure (mR) ----

Pulse duration (millisec) ----

(*Program will ask for above data entries for 3 or 9 additional times*)

3.5.2 Dose Estimate – Beam Quality (HVL)

Setttings

kVp *(copied from the Technique Factors screen)*

mAs ----

		Exposure Values (mR)
0.0	mmAl	----
0.1	mmAl	----
0.2	mmAl	----
0.3	mmAl	----
0.4	mmAl	----
0.5	mmAl	----

3.5.2 Dose Estimate – Summary Results

ESE ----

COV ----

Beam Quality (HVL) ----

Mean Glandular Dose (MGD)

3.5.3 Phantom Image Quality Evaluation

	Image #1	**Image #2**
Background density (0-4.00)	----	----
# of Fibers (x.x)	----	----
# of Fiber Artifacts (0 or 1)	----	----
# of Speck Groups (integer)	----	----
# of Specks in last group (integer)	----	----
# of Speck Artifacts (integer from 0 to 6)	----	----
# of Masses (x.x)	----	----
# of Mass Artifacts (0 or 1)	----	----

Net Scores	Compliance		
0.0	0.0	Fibers	p/f
0.0	0.0	Specks	p/f
0.0	0.0	Masses	p/f

3.6 Processors - List (status, number, room, site, model)

3.6 Processors – Information

Processor

Status (Evaluate all, Hold, Evaluate records only)

Number ------

Room name or number-------
Site *(if applicable, select from list)*
Type (Primary, Back-up)
Manufacturer (pop-up list)
Model (pop-up list)
Developer
Manufacturer (pop-up list)
Type (pop-up list)
Processing Cycle (Standard, Extended) *[check one]*

3.6 Processors – Evaluation

Processor equip. evaluation (by medical physicist) done? (y/n/x)

3.6 Processors - STEP Test

Ref. Step # xx.y
Base+Fog y.zz
Strip 1 (entries below repeated for strips 2, 3, & 4)
Lower step number (integer) --
Lower step density (x.xx) ----
Higher Step number (integer) --
Higher Step density (x.xx) ---
(STEP Test Result)
Processing Speed (PS) ---- (pass/fail)

3.7 Darkrooms – List (status, room, site)

3.7 Darkrooms – Information

Status (Evaluate all, Hold, Evaluate records only)
Room name or number -------
Site Name (if applicable, or defaults to facility) ----

3.7 Darkrooms – Evaluation

Border Visible? (y/n)
Unfogged Area O.D. y.zz
Fogged Area O.D. y.zz
Fog Density (FD)(calculated) y.zz

3.8 Quality Assurance (QA) Program

3.8 QA Program – Sites (Evaluation status & name)

3.8 QA Program – Evaluation

Do the QA records include the following? (y/n)
- QA Personnel Assigned? (y/n)
(lead I.P., QC technologist, med. physicist)
- Technique Tables/Charts? (y/n)
- Written S.O.P.'s for QC tests? (y/n)
(with acceptable limits for each)
S.O.P. for infection control?
(handling blood & other infectious materials)
S.O.P. for handling consumer complaints?

3.9 Quality Control

3.9.1 Processor Performance QC – Processor List

3.9.1 Processor Performance QC – Evaluation

Processor QC Records
Worst/Sampling Month/Yr. mm/yyyy
days processed mammograms (in worst mo.) dd
of processing days without recorded data dd
Calculated % for not recording
# of consecutive processing days (cd) missed
# of days/yr. operated out-of-limits(ool)
C/A (before further clinical use) Documented? (y/n/x)

3.9.1 Processor Performance QC – Evaluation

Fixer retention QC adequate (y/n)
- Done at the required frequency? (y/n)
- C/A (30 days) Documented? (y/n/x)

3.9.2 Phantom Image QC

3.9.2 Phantom Image QC – Unit List

3.9.2 Phantom Image QC – Evaluation

Number of operating weeks missing xx
(in worst consecutive 12-week period)
C/A (before further exams) documented? (y/n/x)
(for failing image score, background density or contrast)

Other phan. QC records/test conditions adeq?(y/n)
Image taken at clinical (±1kVp) setting?
BD > or = 1.20

For mobile units (van, truck,..):
Performance verification after each move? (y/n)

3.9.3 Compression QC

3.9.3 Compression QC – Unit List

3.9.3 Compression QC – Evaluation

Compression QC adequate? (y/n)
- Done at the required frequency? (y/n)
- C/A (before further exams) Documented? (y/n/x))

3.9.4 Repeat Analysis QC

3.9.4 Repeat Analysis QC – Site List

3.9.4 Repeat Analysis QC - Evaluation

Repeat Analysis QC adequate? (y/n)
- Done at the required frequency?
- Evaluation done (y/n)
(cause of repeats determined for changes> ±2%)
- C/A (30 days) Documented? (y/n/x)

3.9.5 Screen-Film Contact QC

3.9.5 Screen-Film Contact QC – Site List

3.9.5 Screen-Film Contact QC - Evaluation

Screen-Film Contact QC adequate? (y/n)
- Done at the required frequency? (y/n)
- All mammography cassettes in use tested? (y/n)
- 40-Mesh copper test tool used? (y/n)

- C/A (before further exams) Documented? (y/n/x)

3.9.6 Darkroom Fog QC – Darkroom/Site List

3.9.6 Darkroom Fog QC - Evaluation

Darkroom Fog QC adequate? (y/n)
- Done at the required frequency?
- Background Density > or = 1.20? (y/n/x)
- C/A (before further exams) Documented? (y/n/x)

3.9.7 Digital Mammography QC – Unit List

3.9.7 Digital Mammography QC - Evaluation

Manufacturer recommended QC procedures followed? (y/n)
If "Monitor" only was checked for display mode:
Monitor QC done per manufacturer's recomm.? (y/n)
If "Laser film" or "Other" was checked for the display mode, then:
Manufacturer recommended procedures used? (y/n)

3.10 Survey Report – Unit List

3.10 Survey Report - Information

Survey report available? (y/n/x)
Date of previous survey (mm/dd/yyyy)
Date of current survey (mm/dd/yyyy)
Survey conducted or supervised by -----
Dose value (mrad) reported ----
C/A taken before resuming clinical use? (y/n)
Action Taken (if called for in Report)?(y/n/x)
Rules conducted under *(Interim/Final)*
Survey Complete (y/n): *[determined by program]*

3.10.1 Survey Report Part 1 - Results

Overall Survey Complete: *[determined by program]*
Part 1 Complete: *[determined by program]*

3.10.1 Survey Report Part 1 - Evaluation

Focal Spot Size/Resolution Measurement (y/n)
- Done for all clinically used focal spots?
- Numerical results given?

AEC Performance
- Reproducibility (mAs) (y/n)
- Numerical results given?
- Performance Capability (y/n)
- Done for 2, 4, and 6 cm at typical kVp(s)?
- Numerical results given?

Dose (including entrance air kerma reprod.)(y/n)
- Exposure & HVL at same clinical kVp?(y/n/u)
- RMI156 or equivalent phantom? (y/n/u)
- Numerical results given?

Phantom Image (y/n)
- Done at the kVp normally used clinically?
- RMI156/equivalent phantom? (y/n/u)

- 3 object scores given?
Artifact Evaluation (y/n)
QC Tests - New Modality (if applicable) (y/n/x)

3.10.2 Survey Report Part 2 - Results

Overall Survey Complete: *[determined by program]*
Part 2 Complete: *[determined by program]*

3.10.2 Survey Report Part 2 – Evaluation

Pass/fail list (y/n)
Recommendations for failed items (y/n/x)
Physicist's Evaluation of Tech's QC Tests (y/n)
- Processor QC? [for each processor]
- Phantom image? [for each x-ray unit]
- Repeat analysis?
- Analysis of fixer retention? [for each processor]
- Darkroom fog? [for each darkroom]
- Screen-film contact? [for all cassettes]
- Compression? [for each x-ray unit]
Collimation (y/n)
- X-Ray Field - Light Field (y/n/x)
- X-Ray Field - Image Receptor Alignment
- Compression Device Edge Alignment
kVp Accuracy (y/n)
- Done at these 3 clinical kVps?
- Numerical results given?
kVp Reproducibility (y/n)
- Done at the kVp most commonly used clinically?
- Numerical results given?
Beam Quality (HVL) Measurement (y/n)
- Done at the kVp most commonly used clinically?
- Numerical results given?
Uniformity of Screen Speed (y/n)
- Numerical results given?
Radiation Output (y/n)
Decompression (y/n)

3.11 Personnel (list of status & names of all personnel)

3.11.1 Interpreting Physicians - List

3.11.1 Interpreting Physicians – Information

Status (Evaluate, Hold)
Name xxx [FIRST, M.I., LAST]
UPIN
Lead interpreting physician ( )

3.11.1 Interpreting Physicians – Evaluation

Rules qualifying under (interim, final)

If you selected the interim rules:
Initial qualifications under interim rules met? (prior to 4/28/99) (y/n)
- Licensed?

- Certified or 2 months training?
- 40 CME hours
- Initial experience adequate? (240 exams/6 months)

If you selected the final rules:

Initial qualifications met? (y/n)
- Licensed?
- Certified or 3 months training?
- 60 category I CME hours?
- Initial experience adequate? (240 exams/6 months)

Date completed initial requirements mm/dd/yyyy
New modality training (8 hrs.) (if applicable) (y/n/x)
Continuing experience

Continuing experience adequate? (y/n/x)
(960 exams/24 months) If "n", then:
Number of exams in 24 months yyy

Continuing education

CME credits adequate? *(15/36 m)* (y/n/x)
If "n", then:
Number of CME's in 36 months zzz

3.11.2 Technologists - List

3.11.2 Technologists - Information

Status (Evaluate, Hold)
Name yyy [FIRST, M.I., LAST]

3.11.2 Technologists - Evaluation

Rules qualifying under (interim, final)

If you selected the interim rules:

Initial qualifications under interim rules met?(y/n) *[prior to 4/28/99]*
- Licensed or certified
- Training specific to mammography

If you checked the final rules:

Initial qualifications met? (y/n)
- Licensed OR Certified? (y/n)
- 40 supervised hours of training adequate? (y/n/c) *[Includes subject training &25 supervised exams*]

Date completed initial requirements mm/dd/yyyy
New modality training (8 hrs.) (if applicable) (y/n/x)
Continuing experience adequate? (y/n/x)
[200 exams/24months]
Continuing education
CEU credits adequate? (15/36 months) (y/n/x)
If "n", then :
Number of CEU's in 36 months xxx

3.11.3 Medical Physicists - List

3.11.3 Medical Physicists - Information

Status (Evaluate, Hold)
Name yyy [FIRST, M.I., LAST]

3.11.3 Medical Physicists - Evaluation

Degree qualifying under *(Masters/higher, Bachelors, None)*
If you selected "Masters (or higher)":
Initial qualifications met? (y/n)
- Certified or state licensed/approved? (y/n)
- Masters degree in a physical science? (y/n)
[w/20 semester hours in physics]
- 20 contact hours of training in surveys? (y/n)
- Experience in conducting surveys? (y/n)
[1 facility & 10 units]
If you selected "Bachelors":
Alternative initial qualif. met before 4/28/99? (y/n)
- Certified or state licensed/approved? (y/n)
- Bachelor's degree in a physical science? (y/n)
[w/10 semester hours in physics]
- 40 contact hrs. training in surveys? (y/n)
[after Bachelors]
- Experience in conducting surveys? (y/n)
[after Bachelors, 1 facility & 20 units]
If you selected "None", the program will answer "n" to all the questions above
Date completed initial requirements mm/dd/yyyy
New modality training (8 hrs) (if applicable) (y/n/x)
Continuing experience adequate? (y/n/x) *[2 facilities & 6 units/24months)]*
Continuing Education
CME Credits/year adequate? (15/36 months) (y/n/x) *If "n", then :*
Number of CME's in 36 months xxx

3.11.4 Summary - Evaluation

For all personnel categories:
Required documents available? (y/n/x)

3.12 Medical Records – Site List

3.12 Medical Records – Evaluation

System (to communicate results) adequate? (y/n)
System to provide medical reports in 30 days? (y/n)
[to referring health care providers and or self-referred patients]
System to provide lay summaries in 30 days? (y/n)
[to all patients]
System to communicate serious cases ASAP? (y/n)
[Serious: suspicious or highly suggestive cases]

Random written reports

Number of random written reports reviewed ----
Number with assessment* categories ----
Number with qualified interpreting physician identification

3.13 Medical Audit and Outcome Analysis – Site List

3.13 Medical Audit and Outcome Analysis – Evaluation

- ALL positive mammograms entered in system? (y/n/x)

- Biopsy results present (or attempt to get) (y/n/x)
- Is there a designated audit (reviewing) interpreting physician? (y/n/x)
- Analysis done annually? (y/n/x)
- Done separately for each individual? (y/n/x)
- Done for the facility as a whole? (y/n/x)^-

~~*+~~

1. ~~**Equipment Registration** – for entering calibration data regarding inspection equipment.~~

-

~~**2.0 Facility Inspection Download** – for importing, prior to an inspection, any existing facility information from FDA's database.~~

-

~~**3.0 Facility Inspections**~~

~~**List** *(of facilities with inspections downloaded for view, edit, or new)*~~

~~**Facility**~~

~~**Address** ***(info about current facility address)***~~

~~**Inspection**~~

-

~~**3.0 Facility Inspections - Facility**~~

~~*(Certificate)* **expiration date** (mm/dd/yyyy)~~

~~*(Certificate)* **Displayed? (y/n)**~~

~~**Operating with a valid certificate? (y/n)**~~

-

~~*(Facility)* **Identification**~~

~~**Name ----- ID # ----- CFN # ----- EIN # -----**~~

-

~~**Facility Category**~~

~~Non Federal~~

~~Federal *(check one)*~~

~~Air Force~~
~~Army~~
~~Bureau of Prisons~~
~~Indian Health Service~~
~~Navy~~
~~VA~~

-

~~**Facility Type** *(check one)*~~

~~Breast Clinic~~

~~Health Agency~~

- Hospital – Radiology Dept.
- Hospital – Non Radiology Dept.
- Mobil Unit
- Multiple Specialty Practice
- Other
    - Private Practice – Internal Medicine
    - Private Practice – OB GYN
    - Private Practice – Radiology
    - Private Practice – Surgery
    - Private Practice – Other

3.0 Facility Inspections - Inspection

Inspector Name & ID # -----
Date *(of inspection)* m/dd/yyyy
Accomplishing *(FDA)* **District** -----
Inspection Time (on-site & other) (hours) xx.x
Travel Time (hours) xx.x

Annual Inspection Type

- Basic
- Joint Audit
- Mentored

Accompanying Inspector -----
(only for joint Audit and Mentored)

Regulation Enforcement (Interim, Final) -----
Software Version: -----

3.1 Aliases – other names by which the facility may be known
3.2 Additional Sites – other sites where the facility provides mammography services

3.3 Contacts

- 3.3.1 Facility Accreditation Contact
- 3.3.2 Facility Inspection Contact

3.3.3 Compliance Contact

3.3.4 Billing Contact

3.4 Related Equipment – for updating inspection equipment calibration data

3.5 Units – List *(if more than one)*

Unit #

Room Name or number

X-ray unit still in use *(Use Status)*

Manufacturer

Model

Image Receptor Type

3.5 Units - Information

X Ray unit # -----

(pre-filled with data supplied by the accreditation body)

X Ray Unit Room Name or Number -----

Serial Number -----

X-ray unit still in use *(evaluation status)***? (y/n/t/r)**

["t" for "temporarily out of service", "r" for "evaluate records only"]. If "t" or "r":
(Date) **Removed from service (mm/dd/yyyy)**

Manufacturer *(Code)* -----

Model *(Code)* -----

Manufacture Date - **(mm/dd/yyyy)**

Is the unit mobile (van, truck,..)? (y/n)

Image Receptor (IR) Type *(pre-filled)* **(F/X/D)**

[**F**: Film/screen, **X**: Xeromammograhy, **D**: Digital] ***If the answer is D, then:***

Display Method (M/L/O)
[**M**onitor/**L**aser film/**O**ther] *allows multiple options*

3.5 Units - Evaluation

X-Ray unit designed for mammography? (y/n)

Does x-ray system include the following? (y/n)

- Image Receptors for 2 sizes? (y/n)
- Moving Grids for 2 sizes? (y/n)
- Compression Paddles for 2 sizes? (y/n)
- Post-Exposure Display in AEC mode for focal spot? (y/n/x)

- Post-Exposure Display in AEC mode for target material? (y/n/x)

X-Ray unit accredited? *[p: pending, x: not applicable]* **(y/n/p/x)**

Is this a new* unit? *[* New: in clinical use for less than a year]* **(y/n)**

Mammo Equip. Evaluation *(by medical physicist)* **Done ?** (y/n/x)

3.5 Units - Screen-Film *(info)*

Film Manufacturer *(Code)* -----

Film Type *(Code)* -----

Screen Manufacturer *(Code)* -----

Screen Type *(Code)* -----

3.5.1 Collimation Assessment

Source to Image Distance (SID) (cm) --.

Source to Patient Support Distance (SPSD) (cm) --.

X-ray field /IR Misalignment [l/r/n] (cm) --.
(3 separate fields for: left, right, nipple)

X-ray field /IR Misalignment [chest wall] (cm) --.

IR/Paddle alignment

Is paddle image on the film? (y/n)

Compression paddle / chest wall edge of IR (cm) --.

3.5.2 Dose Estimate

Technique Factors

Target/filter (Mo/Mo, Mo/Rh, Other) ----

Focal Spot to Patient Support (cm) --.

Mode (**A**uto [mAs, kVp, or full] /**M**anual) ----

Pre-Exposure SETTINGS *(if indicated)*

kVp --- mAs --- Time --- Density *(setting)* ---

Cassette Variability

Exposure Exposure Time

C. ID mAs (mR) (ms)

Cassette # 1 ---- ---- ---- ---

Cassette # 2 ---- ---- ---- ---

Cassette # 3 ---- ---- ---- ---

Beam Quality (HVL)

Setttings

KVp ----

mAs ----

Exposure Values (mR) *(measured)*

0.0 mmAl ----
0.1 mmAl ----
0.2 mmAl ----
0.3 mmAl ----
0.4 mmAl ----
0.5 mmAl ----

Summary Results

ESE (mR) ----

C.O.V. *(reproducibility)* ----

Beam Quality (HVL) (mmAl) ----

Mean Glandular Dose (MGD) (mRad) ----

3.5.3 Phantom Image Quality Evaluation

Image #1

Background Density (0.0-4.0) x.xx

# of Fibers (0-6) x

# of Fiber Artifacts (0 or 1) x

# of Speck Groups (integer, 0-5) x

# of Specks in last group (integer, 2-6) x

# of Speck Artifacts (integer, 0-6) x

# of Masses (0-5) x

# of Mass Artifacts (0 or 1) x

Net Scores Compliance

Fibers --- pass/fail

Specks --- pass/fail

Masses --- pass/fail

If image # 1 passes, the test is completed. Otherwise, the same data for image # 2 must be entered.

3.6 Processors

List *(if more than one)*

Information

Processor

Status (Evaluate all, Hold, Evaluate records only) ------

Number -------

Room name or number -------

Site -------

Type (Primary, Back-up) ----

Manufacturer *(Code)* ----

Model *(Code)* ----

Developer

Manufacturer *(Code)* ----

Type *(Code)* ----

Processing Cycle (Standard, Extended) ----

Evaluation *(STEP Test)*

Ref. Step # xx.y

Base+Fog y.zz

Lower Step # Lower Step Den. Higher Step # Higher Step Den.

Strip 1 xx -.-- xx+1 -.--

Strip 2 xx -.-- xx+1 -.--

Strip 3 xx -.-- xx+1 -.--

Strip 4 xx -.-- xx+1 -.--

Test Result (Processing Speed) = ---- (pass/fail)

3.7 Darkrooms

List *(if more than one)*

Information

Status (Evaluate all, Hold, Evaluate records only) ------

Room name or number -------

Site Name -------

Evaluation

Border Visible? (y/n)

Unfogged Area O.D. y.zz

Fogged Area O.D. y.zz

Fog Density *(calculated)* y.zz

3.8 Quality Assurance Program

Sites – defaults to facility's name if there are no additional sites

Evaluate (double click next to site's name to evaluate) ------

Site *(name)* ------

Do the QA records include the following? (y/n)

- QA Personnel Assigned (lead I.P., QC tech., med. physicist)? (y/n)

- Technique Tables/Charts? (y/n)

- Written S.O.P.'s for QC tests (with acceptable limits for each)? (y/n)

- S.O.P. for infection control? (y/n)

- S.O.P. for handling consumer complaints? (y/n)

3.9 Quality Control

3.9.1 Processor Performance QC

Processors *(list)*

Type *(primary or back-up)* ----

Number ----

Room Name ----

Manufacturer ----

Model ----

Site ----

Evaluation

Processor QC Records

Worst/Sampling Month/Yr. mm/yyyy

days processed mammograms (in worst mo.) dd

of processing days without recorded data(#) dd

Calculated % for not recording *(# not recorded/# processed)* ---

# of consecutive processing days missed (12 months. 2 different mo. ok) dd

# of days/yr. operated out-of-limits [MD, DD:+-0.15. B+F: 0.03] dd

C/A Documented? (y/n/x)

Fixer Retention QC adequate? *(quarterly)* (y/n)
- Done at the required frequency? (y/n)
- C/A (30 days) Documented? (y/n/x)

3.9.2 Phantom Image QC *(weekly)*
Units (list - excluding units not in use since previous inspection)
Number ----
Room name or number ----
Manufacturer ----
Model ----
Mobile ----
Image receptor type ----

Evaluation
- **Number of operating weeks missing** xx
(in worst consecutive 12-week period)
- **C/A** (before further exams) **documented?** *(score, BD, contrast)* (y/n/x)
- **Other phantom QC records/test conditions adequate?** (y/n)

- Image taken at clinical (±1kVp) setting? (y/n)
- BD > or = 1.20 (y/n)

For mobile units (van, truck,..):
Performance verification after each move? (y/n)

3.9.3 Compression QC adequate? *(semi-annually)* (y/n)
(list of units as in phantom image QC)
- Done at the required frequency? (y/n)
- C/A (before further exams) Documented? (y/n/x)

1. **Repeat Analysis QC adequate?** *(quarterly)* (y/n)

(list of sites to evaluate -if applicable- as in QA records)
- Done at the required frequency? (y/n)
- Evaluation done (cause of repeats determined for changes > 2%)? (y/n)
- C/A (30 days) Documented (when a given repeat % changes by > 2%)? (y/n/x)

3.9.5 Screen-Film Contact QC adequate? *(semi-annually)* (y/n)
(list of sites to evaluate -if applicable- as in QA records)
- Done at the required frequency? (y/n)
- All mammography cassettes in use tested? (y/n)
- 40 Mesh copper test tool used? (y/n)
- C/A (before further exams) Documented? (y/n/x)

3.9.6 Darkroom Fog QC adequate? *(semi-annually)* (y/n)
(list of darkrooms to evaluate as in QA records)
- Done at the required frequency? (y/n)
- Background Density > or = 1.20? (y/n/x)
- C/A (before further exams) Documented? (y/n/x)

3.9.7 Digital Mammography QC
Manufacturer recommended QC procedures followed? (y/n)
If "Monitor" only was checked for display mode:
- Monitor QC done per manufacturer's recommendation? (y/n)
If "Laser film" or "Other" was checked for the display mode, then:
- **Manufacturer recommended procedures used? (y/n)**

3.10 Medical Physicist's Survey
List *(of all units except those not in use since the previous inspection)*

Information
Survey report available? (y/n/x)
Date of previous survey (mm/dd/yy)
Date of current survey (mm/dd/yy)
Survey conducted or supervised by -----
Action taken (if called for in Report)? (y/n/x)

Overall Evaluation
Rules conducted under *(Interim - for surveys < 4/28/99, Final - otherwise)* -----
Survey Complete? ***(computed answer)*** **(y/n)**
(answer would be "yes" only if all items in parts 1 and 2 below are answered "yes")

3.10.1 Survey Report Part 1

Part 1 Complete? *(computed answer)* **(y/n)**

Focal Spot Size/Resolution Measurement (y/n)

- Done for all clinically used focal spots? (y/n)
- Numerical results given? (y/n)

AEC Performance

- Reproducibility (mAs) **(y/n)**

- Numerical results given? (y/n)

- Performance Capability (y/n)

- Done for 2, 4, and 6 cm at typical kVp(s)? (y/n)
- Numerical results given? (y/n)

Dose (including entrance air kerma reproducibility) **(y/n)**

- Exposure & HVL at same clinical kVp? (y/n/u)
- RMI156 or equivalent phantom? (y/n/u)
- Numerical results given? (y/n)

Phantom Image (y/n)

- Done at the kVp normally used clinically? (y/n)
- RMI156/equivalent phantom? (y/n/u)
- 3 object scores given? (y/n)

Artifact Evaluation (y/n)

QC Tests - New Modalities (if applicable) **(y/n/x)**

3.10.2 Survey Report Part 2

Part 2 Complete? *(computed answer)* **(y/n)**

Pass/fail list (y/n)

Recommendations for failed items (y/n/x)

Physicist's Evaluation of Technologist's QC Tests (y/n)

- Processor QC? [for each processor] (y/n)
- Phantom image? [for each x-ray unit] (y/n)
- Repeat analysis? (y/n)
- Analysis of fixer retention? [for each processor] (y/n)
- Darkroom fog? [for each darkroom] (y/n)

- Screen film contact? [for all cassettes] (y/n)
- Compression? [for each x-ray unit] (y/n)

Collimation (y/n)

X-Ray Field Light Field (y/n/x)
X-Ray Field Image Receptor Alignment (y/n)
Compression Device Edge Alignment (y/n)

kVp Accuracy (y/n)

- Done at these 3 clinical kVps? (y/n)
(lowest measurable, most often used, highest available)
- Numerical results given? (y/n)

kVp Reproducibility (y/n)

- Done at the kVp most commonly used clinically? (y/n)
- Numerical results given? (y/n)

Beam Quality (HVL) Measurement (y/n)

- Done at the kVp most commonly used clinically? (y/n)
- Numerical results given? (y/n)

Uniformity of Screen Speed [for all cassettes used] **(y/n)**

- Numerical results given? (y/n)

Radiation Output (y/n)

Decompression (y/n/x)

3.11 Personnel

List

Status (Evaluate, Hold)
Type (Interpreting Physician, Technologist, Medical Physicist)
Last Name
First Name
Middle Initial
Full name

3.11.1 Interpreting Physicians

List *(if more than one)*

Information

Status (Evaluate, Hold)

Lead interpreting physician [ ] *one only may be checked*

Name xxx [FIRST, M.I., LAST] (caps, separate fields)

UPIN

Evaluation

Rules qualifying under (interim, final) *[select one]*

If you selected the interim rules:

Initial qualifications under interim rules met? (prior to 4/28/99) **(y/n)**

- Licensed? (y/n)
- Certified or 2 months training? (y/n)
- 40 CME hours (y/n)
- Initial experience adequate? (240 exams/6 months) (y/n)

If you selected the final rules:

Initial qualifications met? (y/n)

- Licensed? (y/n)
- Certified or 3 months training? (y/n)
- 60 category I CME hours? (y/n)
- Initial experience adequate? (240 exams/6 months) (y/n)

Date completed initial requirements mm/dd/yyyy

New modality training (8 hours) **(if applicable)** (y/n/x)

Continuing experience

Continuing experience adequate? (960 exams/24 months) (y/n/x)

If "n", then:

Number of exams in 24 months yyy

Continuing education

CME credits adequate? (15/36 m) (y/n/x)

If "n", then

- Number of CME's in 36 months – zzz

-

3.11.2 Technologists

List *(if more than one)*

Information

Status (Evaluate, Hold)

Name yyy [FIRST, M.I., LAST] (caps, separate fields)

-

Evaluation

Rules qualifying under (interim, final) *[select one]*

-

If you selected the interim rules:

Initial qualifications under interim rules met? (prior to 4/28/99) **(y/n)**

- Licensed or certified – (y/n)

- Training specific to mammography – (y/n)

-

If you checked the final rules:

Initial qualifications met? – (y/n)

– Licensed OR Certified? – (y/n)

- 40 supervised hours of training adequate? – (y/n)

-

Date completed initial requirements – mm/dd/yyyy

- **New modality training** (8 hrs.) **(if applicable)** – (y/n/x)

- **Continuing experience adequate**? [200 exams/24months] – (y/n/x)

-

Continuing education

CEU credits adequate? (15/36 months) – (y/n/x)

If "n", then :

Number of CEU's in 36 months – xxx

-

3.11.3 Medical Physicists

List *(if more than one)*

Information

Status (Evaluate, Hold)

Name zzz [FIRST, M.I., LAST] (caps, separate fields)

-

Evaluation

Degree qualifying under (Masters or higher, Bachelors, None) *[select one]*

If you selected "Masters (or higher)":

Initial qualifications met? (y/n)

- Certified or state licensed/approved? (y/n)
- Masters degree in a physical science? [w/20 sem. hrs. in physics] (y/n)
- 20 contact hours of training in surveys? (y/n)
- Experience in conducting surveys? (1facility & 10 units) (y/n)

If you selected "Bachelors":

Alternative initial qualifications met before 4/28/99? (y/n)

- Certified or state licensed/approved? (y/n)
- Bachelor's degree in a physical science [w/10 sem. hrs in physics] (y/n)
(physical science: physics, chemistry, engineering, radiation science)
- 40 contact hrs. training in surveys (after Bachelors) (y/n)
- Experience in conducting surveys (after Bachelors) (1facility & 20 units) (y/n)

Date completed initial requirements mm/dd/yyyy

New modality training (8 hours) **(if applicable)** (y/n/x)

Continuing experience adequate? (2 facilities & 6 units/24months) (y/n/x)

Continuing Education

CME Credits/year adequate? (15/36 months) (y/n/x)

If "n", then :

Number of CME's in 36 months *xxx*

3.11.4 Personnel – Summary

Evaluation

For all personnel categories:

Required documents available? (y/n/x)

3.12 Medical Records

Site List (if applicable)

Evaluation

System (to communicate results) adequate? (y/n)

System to provide medical reports within 30 days? (y/n)

(to referring health care providers and or self-referred patients)

System to provide lay summaries within 30 days? (y/n)

(to all patients)

System to communicate serious cases ASAP? (y/n)

(Serious: suspicious or highly suggestive cases)

Random written reports

Number of random written reports reviewed ----

Number with assessment categories ----

(Assessment categories: negative, benign, probably benign, suspicious, highly suggestive of malignancy, incomplete: need additional imaging evaluation)

Number with qualified interpreting physician identification ----

3.13 Medical Audit and Outcome Analysis

Site List (if applicable)

Evaluation

- ALL positive mammograms entered in system? (y/n/x)

- Biopsy results present (or attempt to get) (y/n/x)

- Is there a designated reviewing interpreting physician? (y/n/x)

The next 3 questions will not result in citations until 4/28/2001

- Analysis done annually? (y/n/x)

- Done separately for each individual? (y/n/x)

- Done for the facility as a whole? (y/n/x)*

Audit Interpreting Physician

Citation:

900.12(f)(3): Audit interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be

responsible for documenting the results and for notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.

Discussion:

Question 1: Does the FDA require that the interpreting physician who reviews the medical outcomes audit data also be responsible for overall facility quality assurance?

No. The *+~~final~~*- regulations ^+do not require that the audit and lead interpreting physicians be the same person.^- *+~~permit a facility to designate a person other than the lead interpreting physician as responsible for reviewing the medical outcomes audit data.~~*-

Question 2: Why is the data analyzed for the aggregate and then for each interpreting physician?

Aggregate medical outcomes audit data provide a picture of how the facility is detecting breast cancer among its patients. Individual analyses are *+~~also~~*- important to identify interpreting physicians who have results that are very different from the aggregate.

Question 3: How long must a facility maintain the medical outcomes audit data on positive mammograms, including the associated surgical and/or pathology reports?

For the purpose of MQSA, the medical outcomes audit (including the associated surgical and/or pathology reports) is considered part of a facility's internal quality assurance program. Therefore, the data should be maintained according to the quality assurance requirements. The applicable section of the regulations state that the *+~~records*-~~ ^+analyses^- must be kept until the test has been performed two additional times at the required frequency. 21 C.F.R. 900.12(d)(2). Since the audit analyses are required to be conducted at least once every 12 months, the audit ^+analyses^- *+~~data~~*- should be kept for an additional 24 consecutive months following the analysis. ^+If the facility has obtained actual pathology reports, those should be maintained until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements.^- However, State laws may define the data as part of a patient's or facility's medical records, and may have more stringent requirements for the retention of this data. A facility may want to check with the State regarding its requirements.

Question 4: Must the lead and audit physician(s) be listed as interpreting physician(s) at the facility?

Yes. The lead and audit physician(s) must be ^+qualified interpreting physicians and must also be^- listed as interpreting physician(s) at the facility so that their qualifications can be evaluated at the time of the inspection. 21 C.F.R. 900.12(f)(3), 900.2(u).This does not require that the physician(s) actually interpret ^+mammographic^- examinations at *+~~the*-~~ ^+that specific^- facility.

Frequency of Medical Outcomes Audit Analysis

Citation:

900.12(f)(2): Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

Discussion:

Question 1: Should a facility perform an audit analysis more frequently than once per year?

+~~Under the interim regulations, facilities were required to have a system to track their positive mammograms but the frequency of audit analysis was not specified. Under the final regulations, a facility must continue to~~- ^+Facilities must^- track their positive mammograms and perform a medical outcomes audit analysis at least once per year. However, facilities may review their audit data at more frequent intervals if they believe it would be beneficial for their practice.

Medical Outcomes Audit General Requirement [Merge Entire Section With Medical Outcomes Audit Program]

Citation:

900.12(f)(1): General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

Discussion:

Question 1: What are the MQSA requirements for a medical audit and outcome analysis recordkeeping system?

Each facility must have a system to track positive mammograms and a process to correlate the findings with biopsy results. Positive mammograms are those with final assessment categories of "Suspicious" or "Highly suggestive of malignancy."

^+The basic elements of a mammography medical audit system are: (1) a definition of positive mammograms requiring follow-up, (2) a method to follow-up positive mammograms, (3) a system to attempt to collect pathology results for all biopsies performed, (4) methods to correlate pathology results with the final assessment category indicated by the interpreting physicians, (5) a method to include any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility, and (6) review of medical outcomes audit data for the aggregate of interpreting physicians as well as each individual interpreting physician at least once every 12 months.^-

MQSA leaves it up to each facility to develop or use a tracking system that works best for them. This system must include a set of procedures to track mammograms, determine whether biopsies were done on the patient, determine (at a minimum) whether the biopsy specimen was benign or malignant, and report this information back to the interpreting physician. The system may be manual or computerized.

An adequate follow-up system is one that has potential to obtain pathology information on all patients with positive mammograms. If a facility enters all positive mammograms into a log, but does not gather pathology information of all these patients, the facility is said to have a mechanism of tracking positive mammograms but not an adequate follow-up system.

The system can be shared with other facilities. It can be part of the system of a state, university, private company, or other institution that tracks results. *+~~Private companies can be hired to track results also.~~*- Shared systems are allowed as long as the feedback to each facility is provided to the interpreting physician so that he/she can judge the accuracy of the interpretation.

Question 2: What criteria will FDA use to determine that facilities meet the MQSA requirements for the medical outcomes audit program?

For facilities that have had positive examinations, the medical outcomes audit program requirements can be met by demonstrating to the MQSA inspector that the facility has obtained, or attempted to obtain, pathology results for *+~~their~~*- ^+its^- positive cases (and cases of breast cancer among patients imaged at the facility that subsequently became known to the facility) and has performed appropriate analyses annually. The *+~~reviewing*-~~ ^+audit^- interpreting physician(s) *+~~must~~*- ^+needs to^-be identified.

For facilities that have not had positive examinations, the medical outcomes audit program requirements can be met by providing written documentation describing how the facility's medical audit system would follow-up on positive cases (and any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility), would correlate pathology results with the interpreting physician's findings and would perform appropriate analyses annually. The *+~~reviewing*-~~ ^+audit^- interpreting physician(s) *+~~must~~*- ^+needs to^-be identified. ^+An example of such a facility is a screening facility that classifies all problematic mammograms as “Incomplete, Need additional imaging evaluation” and sends those patients to a diagnostic center for further evaluation. Because the screening facility never classifies a patient as positive, the

facility does not have any patients that require tracking and has no patients to include in its audit.^-

Question 3: What statistical outcome data and biopsy results should facilities collect?

Beyond the requirement that each facility must have a system for collecting outcome information, FDA has not established specific requirements for statistical data collection. ^+However, some statistics that may be useful to the facility are the percent of exams interpreted as positive that have a positive pathology report, and the percent of exams interpreted as positive that do not have a positive pathology report.^- *+~~At a minimum,~~*- ^+With respect to biopsy results^- facilities *+~~should*-~~ ^+must attempt to^- collect biopsy data on whether the tissue sample is benign or malignant. Additional information, such as staging and size of tumors, would permit a facility to better evaluate its success in early detection of breast cancer. Facilities can refer to radiology journals for information regarding recommendations for the collection of biopsy data.
This information should be given periodically to the interpreting physicians so that they can learn from biopsy results and correlate biopsy results with their interpretations.

Question 4: What records for medical audit and outcome analysis will the MQSA inspector want to review during the annual inspection?

The inspector will ask a facility to document answers to the following questions:

(1) Are ALL positive mammograms entered in the system?
(2) Are biopsy results present or was there a documented attempt to obtain them?
(3) Is there a designated *+~~reviewing~~*- ^+audit^-interpreting physician?

+~~The following questions will not result in citations until 4/28/2001.~~-
(4) Is the analysis done annually?
(5) Is the analysis done separately for each individual?
(6) Is the analysis done for the facility as a whole?

Question 5: Which mammograms must be included in the medical outcomes audit system?

A facility must conduct follow-up for all patients with mammograms interpreted as "Suspicious" or "Highly suggestive of malignancy" *+~~and those recommended to have a biopsy~~*-. A facility is not required to follow-up other cases such as those recommended for short-term follow-up or ultrasound, or cases that are in the assessment category of "Incomplete, Need additional imaging evaluation", however, the facility may choose to follow these patients.

Question 9: Our radiology practice consists of several separately certified mammographic facilities. Is it permissible to combine our medical outcomes audit for all our facilities, or must it be broken down for each facility?

The regulations require that each certified facility establish a system to perform a medical outcomes audit analysis for that facility. The mechanics of data collection and analysis do

not have to be performed by the individual facility, but may be accomplished by combining the resources of several facilities, pathology registries, or other sources. However, the medical outcomes analysis must be facility specific and must be analyzed (both individually and collectively) for all interpreting physicians at that facility. If physicians read at more than one facility, they may find it beneficial to collectively analyze the data for all the facilities where the physicians interpret. However, this global analysis would not satisfy the requirement that the analysis be facility specific.

^+Note: Under the conditions specified by an approved alternative standard, certain mobile facilities may combine their medical audits and can be exempt from the facility specific requirement. (see approved alternative standard)^-

Question 10: Must a facility establish a "system" to identify their false negative examinations?

+~~Answer:~~- No. However, if the facility becomes aware of a false negative examination, *+~~they are~~*- ^+it is^- required to review the mammographic examinations in question and try to obtain surgical and/or pathology information. These cases must be included in the medical audit analyses.

Medical Outcomes Audit Program [MERGED WITH MEDICAL OUTCOMES AUDIT PROGRAM]

Citation:

900.12(f): Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

Discussion:

~~*+Question 1: What are the basic elements of a mammography medical outcomes audit system?~~

~~The basic elements of a mammography medical audit system are: (1) a definition of positive mammograms requiring follow-up, (2) a method to follow-up positive mammograms, (3) a system to attempt to collect pathology results for all biopsies performed, (4) methods to correlate pathology results with the final assessment category indicated by the interpreting physicians, (5) a method to include any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility, and (6) review of medical outcomes audit data for the aggregate of interpreting physicians as well as each individual interpreting physician at least once every 12 months.~~ *-

Question *+~~2~~*-^+17^-: Is a facility required to purchase and use a computerized system to conduct the follow-up of positive mammograms and correlation with pathology reports?

No. A computerized tracking and follow-up system for follow-up of positive mammograms is not required under the MQSA final regulations. Paper or patient log systems can be used to conduct the required follow-up.

Question *+~~3~~*-^+18^-: Is a particular staff person required to conduct the follow-up for positive mammograms?

No. The regulations do not designate a specific staff person to conduct the follow-up for positive mammograms. The facility may specify that the *+~~reviewing~~*- ^+audit^- interpreting physician conduct the follow-up, but this is not required under the MQSA final regulations. The facility may designate a single individual to take the lead on patient follow-up, and also identify a back-up person to conduct the follow-up during the designated lead person's absence. However, the lead interpreting physician is responsible for the facility's quality assurance program, which includes the mammography medical outcomes audit. 21 C.F.R. 900.2(x).

~~*+Question 4: Do the final regulations require specific calculations for the medical outcomes audit?~~

~~No. The final regulations do not require any specific calculations. However, some statistics that may be useful to the facility are the percent of exams interpreted as positive that have a positive pathology report, and the percent of exams interpreted as positive that do not have a positive pathology report.*-~~

Question *+~~5~~*-^+19^-: Where can a facility obtain more information about medical outcomes audit programs?

A facility may obtain additional information about medical outcomes audit programs from a variety of sources, including the medical literature*+~~,~~*- ^+and^- the latest ACR Illustrated Breast Image Reporting and Data System Manual~~*+, the Agency for Health Care Policy and Research's Publication No. 95-0632 Quality Determinants of Mammography (may be obtained by calling the AHCPR Publications Clearinghouse at 1-800-358-9295, or by writing to P.O. Box 8547, Silver Spring, MD 20907), and selected issues of the FDA's Mammography Matters (beginning with Volume 4, Issue 2)~~ *-. Be aware that non-FDA publications may suggest analyses and use definitions that are different from those required by the regulations^+.^-

Communication of Results to Patients

Citation:

900.12(c)(2)(i),(ii): Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are ``Suspicious'' or ``Highly suggestive of malignancy,'' the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

Discussion:

Question 1: What constitutes an acceptable system for notifying patients of examination results?

Facilities must provide a summary of the results of the mammographic examination written in lay terms to all patients within 30 days (patients who do not have a health care provider must also receive the mammographic report within 30 days). Furthermore, when the mammography report assessment is "Suspicious" or, "Highly suggestive of malignancy," the lay summary results and recommended course of action must be communicated as soon as possible. FDA believes that communication of suspicious or highly suggestive results can ordinarily be accomplished within five working days. One way to achieve this is through direct verbal communication with the patient; however, this does not obviate the need to also send written communication within 30 days. In the case of exams where the assessment is "Incomplete, Need additional imaging evaluation" FDA recommends that facilities communicate this (verbally or in writing) to the patient as soon as possible so as to avoid delays in patient work-up. FDA's concern is that an effective communication system exists. The details of such a system are left to the facility and should be individualized to address the facility's specific situation. A system that works well for one facility and its patients may not work well for another. *+~~Some examples of sample lay summary letters can be found in the Agency for Health Care Policy and Research's Publication No. 95-0632, Quality Determinants of Mammography, pages 44-50 (may be obtained from the AHCPR Publications Clearinghouse by calling 1-800-358-9295 or writing P.O. Box 8547, Silver Spring, MD 20907).~~*- One example of an acceptable system for patient communication would be through the use of the U.S. mail. Confirmation of the receipt of these results would not be required.

Contents of Records and Reports

Citation:

900.12(c)(1)(i),(ii),(iii),(iv)(A)(B)(C)(D)(E),(v),(vi): Medical records and mammography reports — (1) Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

(i) The name of the patient and an additional patient identifier;

(ii) Date of examination;

(iii) The name of the interpreting physician who interpreted the mammogram;

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

(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall he explained);

(B) "Benign:" Also a negative assessment;

(C) "Probably Benign:" Finding(s) has a high probability of being benign;

(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;

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

(vi) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

Discussion:

Question 3: What categories must be shown on mammography reports for final assessments of findings?

Only one of the following final assessment categories must appear on the mammography report: "Negative," "Benign," "Probably benign," "Suspicious," "Highly suggestive of malignancy," or "Incomplete: Need additional imaging evaluation." Furthermore, the report must contain recommendations for additional action(s), when appropriate. ^+Also see Approved Alternative Standards^-

Question 5: Is it necessary to include an assessment code (e.g. 0, 1, 2, 3, 4, 5 or N, B, P, S, M, A), in addition to the assessment category, on all mammography reports? Is there a specific reporting format required?

The answer to both questions is "No." In order to promote consistency and clarity in the interpretation of mammograms, the final regulations require that each mammographic report include an overall final assessment of the mammography examination, classified into one of the following six categories: Negative, Benign, Probably Benign, Suspicious, Highly Suggestive of Malignancy, and Incomplete: Need additional imaging evaluation. While the final assessment findings must not vary from these categories and must be stated as written above, limited flexibility is allowed for further description as long as it doesn't change the meaning of the category. The following are considered equivalent to the wording listed in the final regulations and are acceptable final overall assessments.

Negative
Negative Mammogram

Benign

Benign Finding, Benign Findings, Benign Abnormality, Benign Abnormalities, Benign Mammogram

Probably Benign

Probably Benign Finding, Probably Benign Findings, Probably Benign Abnormality, Probably Benign Abnormalities, Probably Benign- Short Interval Follow-up Suggested, Probably Benign Finding - Short Interval Follow-up Suggested, Probably Benign Mammogram

Suspicious

Suspicious Finding, Suspicious Findings, Suspicious Abnormality, Suspicious Abnormalities, Suspicious for Malignancy, Suspicious of Malignancy, Suspicious Abnormality - Biopsy Should Be Considered, Suspicious Finding - Biopsy Should Be Considered, Suspicious Mammogram

Highly Suggestive of Malignancy

Highly Suggestive for Malignancy, Highly Suggestive of Malignancy - Appropriate Action Should Be Taken

Incomplete: Need Additional Imaging Evaluation

Incomplete: Needs Additional Imaging Evaluation, Incomplete: Additional Imaging Evaluation Needed, Incomplete: Need Additional Imaging Evaluation- Comparison with Prior Studies, ^+ Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison, Incomplete: Need prior mammograms for comparison^- ,Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only Incomplete BIRADS assessment category), Incomplete Mammogram: Need Additional Imaging Evaluation

^+Known Biopsy Proven Malignancy

Known Biopsy Proven Cancer, Known Malignancy, Known Cancer^-

^+Post Procedure Mammograms for Marker Placement^-

There is no requirement that any specific assessment code be assigned to these assessments. Also, there is no specific reporting format required for the report, apart from the requirement that an overall assessment category be included within it.

^+Also see Approved Alternative Standards^-

Question 15: We provide assessment categories for each breast (or for each lesion) of the examination. Do we still have to provide one overall assessment category for the entire examination?

Yes. While individual assessments for each breast (or for each lesion), along with recommendations for *+~~their~~^- management, may be included in the report, one overall assessment category for the entire mammographic examination is required ^+unless the Approved Alternative Standard is applied^-. It should be based on the assessment category of the more suspicious breast (or lesion).

^+Question 17: Under new Centers for Medicare and Medicaid Services (CMS) guidelines, we can now charge for screening and diagnostic exams done on the same patient on the same day. Can we combine the two exams into one report or must we issue two separate reports?

The facility has the option of issuing either separate or combined reports. If two reports are issued, each must contain its own overall final assessment. The facility can report both exams on the "same piece of paper."

If the facility decides to issue a single combined report, the facility needs to be aware of the following:

1. A single combined report must contain a single overall final assessment.
2. The combined report should make it clear to the referring physician that it is combining the results of the screening and diagnostic studies. This is also important if questions ever arise about whether the exams were billed correctly.
3. Issuing a single report with a single final assessment may skew the facility's medical audit results.
4. Though some computerized reporting systems may consider this a single exam (rather than two), FDA would still allow facilities to count both exams toward meeting the continuing experience requirement.^-

^+Question 18: The American College of Radiology Breast Imaging Reporting and Data System (BIRADS) suggests that facilities subdivide the "Suspicious" assessment category into one of three subcategories (4A-Low Suspicion for Malignancy, 4B-Intermediate Suspicion for Malignancy, and 4C-Moderate Concern but not Classic for Malignancy). Can facility reports use these subcategories instead of the "Suspicious" assessment category?

No. While the facility has the option of using one of the three subcategories in addition to a final assessment of "Suspicious", it cannot use the subcategories instead of the "Suspicious" assessment category on the mammography report.^-

Mammographic Image Identification

Citation:

900.12(c)(5)(i),(ii),(iii),(iv),(v),(vi),(vii): Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(i) Name of patient and an additional patient identifier.

(ii) Date of examination.

(iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with 900.3(b) or 900.4(a)(8) shall be used to identify view and laterality.

(iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(v) Technologist identification.

(vi) Cassette/screen identification.

(vii) Mammography unit identification, if there is more than one unit in the facility.

Discussion:

Question 1: Do I have to label all my films with the mAs, kVp, compressed breast thickness or compression force used?

No. The *+~~final~~*- regulations do not require that mammographic images be labeled with mAs, kVp, compression force or compressed breast thickness. However, a facility has the option to include this information on the film if *_~~they believe it~~*- ^+it believes the information is^- beneficial.

Recordkeeping

Citation:

900.12(c)(4)(i),(ii): Recordkeeping. Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or healthcare provider of the patient or to the patient directly.

Discussion:

Question 2: Before a facility permanently stops performing mammography, what actions should it take to avoid future MQSA problems and how should it deal with retention of mammographic medical records?

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 *+~~that~~*- ^+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 the option in number 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 been receiving *+~~inquiries~~*- ^+complaints^- 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 the facility notify us of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to:
+~~FDA/CDRH/OHIP/DMQRP~~- ^+FDA/CDRH/OCER/DMQRP^-

Attention: Closed Facility Notification of Records Retention

1350 Piccard Drive, HFZ-240

Rockville, MD 20850

Facilities certified by States (currently Iowa^+, Illinois, or South Carolina^- *+~~or Illinois~~*-) may send the above information to:
Iowa:

Bureau of Radiological Health

Iowa Department of Public Health

401 SW 7th Street, Suite D

Des Moines, IA 50309
Or call 515-281-3478

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

^+South Carolina
Mammography Certification Program
Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201
Or call 803-545-4400^-

Question 3: What documentation should I get when a patient, or an individual acting on behalf of the patient, or the patient's physician requests the release of the patient's records? How long should I keep the documentation?

Facilities should request that patients, physicians, or individuals acting on behalf of patients sign a release form, or submit a written release request; however, if the facility chooses to accept oral transfer requests, a notation should be made in a log. Other documentation may also be possible. ^+Facilities must keep this documentation for the same 5/10 years as they are required to keep the original records.^- Facilities should check to see if State or local laws related to release of records require additional documentation.

Transfer of Records

Citation:

900.12(c)(4)(ii),(iii): Each facility that performs mammograms:

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

(iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.

Discussion:

Question 1: What should a facility do if a patient (or someone acting on her behalf) requests permanent or temporary transfer of mammograms and/or reports? Who

should pay for it? What recourse does the patient have if the facility overcharges for the transfer or refuses to cooperate?

The facility must transfer the original mammograms and copies of the patient's reports to the patient's designated recipient upon such written request by the patient (or someone acting on her behalf). Facilities should be aware that the Federal Law pertaining to transfer of original mammograms supersedes any conflicting State or Local requirements. The mammograms and reports may be sent to a medical institution, a health care provider, or to the patient. If the designated recipient is not available, the facility should work with the patient (or someone acting on her behalf) to designate an alternate destination. The facility may charge ^+the patient^- a fee for this service but it must not derive a financial profit from it. If the facility overcharges for the transfer or refuses to transfer the records, the patient ^+should complain to the facility. If that doesn't resolve the issue, the patient should notify the facility's AB. If that still doesn't resolve the issue the patient^- may inform the FDA via the Facility Hotline at 1-800-838-7715 or by writing to the following address: *+~~FDA,~~*- ^+MQSA Hotline,^- P.O. Box 6057, Columbia MD 21045-6057. ^+Patients in Certifying States should contact their State Certifying Agency directly.^-

Question 2: What documentation should I get when a patient, or an individual acting on the behalf of the patient, or the patient's physician requests the release of the patient's records? How long should I keep the documentation?

Facilities should request that patients, physicians, or individuals acting on behalf of patients sign a release form, or submit a written release request; however, if the facility chooses to accept oral transfer requests, a notation should be made in a log. Other documentation may also be possible. ^+Facilities must keep this documentation for the same 5/10 years as they are required to keep the original records.^- Facilities should check to see if State or local laws related to release of records require additional documentation.

Preparing for MQSA Inspections

Discussion:

The complete text of the document, "Preparing for MQSA Inspections," is available on the Guidance page of FDA's Mammography Website.

You may also obtain it by fax from the CDRH Facts on Demand at 1 800 899 0381 or 301 827 0111 using a touch tone telephone. At the first voice prompt press "1" to enter the system, at second voice prompt press "1" to obtain documents, then enter the document number, "6400." Follow the remaining voice prompts to complete your request. Longer documents may be sent after normal business hours.

Acceptable Subject Areas for the Continuing Education and Initial Training Requirements

Applicable Citations:

^+900.12(a)(1)(i)(B)(2) [OR] Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section.^-

900.12(a)(1)(i)(C): The interpreting physician shall have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution.

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

900.12(a)(1)(ii)(D): Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

900.12(a)(1)(iv)(B): Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

900.12(a)(2)(ii)(A)(B) and (C): Mammography requirements. All mammographic examinations shall be performed by radiologic technologists who meet the following mammography requirements: Have, prior to April 28, 1999 qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

(B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and

(C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams, and

900.12(a)(2)(iii)(A) and (C): Continuing Education Requirements:

(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

900.12(a)(2)(iii)(B): Continuing education requirements. (B) Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the course is taught multiple times during the previous 36 months.

900.12(a)(2)(iii)(D): Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

900.12(a)(3)(i)(B)(2): Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.

^+ *900.12(a)(3)(ii)(B)(2) Forty contact hours of documented specialized training in conducting surveys of mammography facilities.*^-

900.12(a)(3)(iii)(A): Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall

include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

900.12(a)(3)(iv)(A): Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows: (A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

Discussion:

All continuing education credits (category I for interpreting physician) related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography, will be acceptable toward meeting the continuing education requirement.

Initial training must be in topics directly related to the regulated areas of mammography ^+as specified in the regulations above^-.

Question 1: Are there specific subject areas that are acceptable for continuing medical education and others that are not acceptable?

Except for credits in each mammographic modality used, FDA does not require specific subject areas for continuing medical education in mammography. All continuing education units related to the diagnosis or treatment of breast disease or to other areas that will aid facility personnel in improving the quality of mammography, may be acceptable toward meeting the continuing education requirement.

Question 2: What information items must a training/CME/CEU certificate contain before it is considered acceptable documentation toward meeting an initial or continuing requirement?

Regardless of the variety of formats used by training providers, each certificate must, at a minimum, contain the following 5 items of information in order to comply with the regulations. Some or all of the items listed below can be filled-in by the recipient of the training/CME/CEU, if done on a certificate provided by the training/CME/CEU provider.

1. Identification of the training/CME/CEU provider

- This usually will be the name of a teaching institution, educational or professional society, private training organization, or medical facility.
- *+~~If a signature block (identification of an individual representative of the training/CME/CEU provider) appears on the certificate, it must be filled in,~~

~~otherwise the certificate is considered incomplete and therefore unacceptable. However, certificates without any signature block are acceptable.*-~~ ^+ While identification of an individual representative of the training/CME/CEU provider is not required, if such identification is not present AND a clearly defined space for such identification is provided and is not filled in by hand or other means, the certificate will be considered incomplete and unacceptable.^-

2. Name of the person receiving the training/CME/CEU
3. Date(s) the training/CME/CEU was provided
    - If the training provided occurred over a long period, e.g., the dates indicated on the certificate extend over months or years, the number of credits within the 36 month counting period applicable to the current inspection must be identified on the certificate or in accompanying documents.
4. Training/CME/CEU subjects(s)
    - Initial training must be in the subjects required by the regulations for the applicable personnel group (interpreting physician, radiologic technologist or medical physicist).
    - Continuing education must be in initial training subjects or other subjects related to the diagnosis or treatment of breast disease, or other areas that will aid facility personnel in improving the quality of mammography.
    - If the certificate is not specific as to subject matter, facility personnel may be able to *+~~use~~*- ^+attest to meeting this portion of the requirement. See^- "Attestation ^+ - Acceptable Uses for Personnel Requirements"^- *+~~For Continuing Education After October 1 1994" as described in the Policy Guidance Help System~~.
5. Number of training/CME/CEU credits awarded
    - Interpreting physician credits must be identified as Category I (unless being used for initial new mammographic modality training).
    - If the certificate indicates the person may "claim up to "X" credits" in acceptable training/CME/CEU subjects, the inspector should assume "X" credits were awarded, unless the certificate indicates that fewer credits were actually earned.

Inspector Instructions:

The inspector will NOT have to review the individual lectures or topics within a course if the certificate documenting the program clearly indicates it is in one of the areas listed ^+in question 1^- above. The inspector should apply the total number of CME/CEU listed on the certificate ^+(category I for interpreting physicians)^- toward the continuing education requirement.

Example 1:

If the program certificate states the person was granted 15 CME/CEU for a program or course entitled, "Update in Mammography", "Update of Breast Cancer", "New Technologies in the Evaluation of Breast Disease", "Interventional Mammography",

"Breast Imaging", or "MRI or Ultrasound of the Breast", that certificate should be accepted as meeting the continuing education requirement.

Example 2:

If the 15 CME/CEU course was entitled "Update in MRI" or "Developments in Ultrasound", the inspector should ask the facility for further documentation (a course brochure or outline should be sufficient) to determine how much of the course could be considered breast related.

Attestation Form

ATTESTATION REGARDING REQUIREMENTS OF THE MAMMOGRAPHY QUALITY STANDARDS ACT

Attestation must include as much of the following information as possible:

Name of the institution/facility where the applicable training or mammography reading/interpreting, or other activity, took place; name of the course(s) or training (where applicable); the attendance, reading/interpreting, or other activity dates; and the supervising/responsible person (where applicable) for the institution/facility.

Please provide these details in the space below. Attach additional sheets if necessary.

I, _____, attest that, to the best of my knowledge and my belief, the following information provided in this declaration is true and correct. I understand that FDA may request additional information to substantiate the statements made in this declaration:

_____
_____
_____
_____
_____
_____
_____
_____
_____

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 the MQSA, or both.

_____

+~~Attestor's~~-^+Attester's^- Signature and Title

_____

Date signed

Facility Name: _____

Facility Address: _____

(including zip code) _____

_____

Facility ID Number (from the facility's MQSA certificate: _____

Attestation^+ - Acceptable Uses for Personnel Requirements^- *+~~For Continuing Education After October 1 1994~~*-

Applicable Citations:

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

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

900.12(a)(1)(iv)(B): Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

900.12(a)(2)(iii)(A) and (C): Continuing Education Requirements:

(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

900.12(a)(2)(iii)(D): Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

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

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

900.12(a)(3)(iv)(A): Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows: (A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

Discussion:

^+Attestation – Table of Use

Interpreting Physician

Requirement	Is Attestation Acceptable?
State License	Never
Board Certification (ABR, AOBR, or RCPSC)	Never
Formal Training (2 months-interim regs)(3 months-final regs)	Never
Initial Medical Education (40 hours-interim regs)	Yes, if education completed before 10/1/94
Initial Experience (240)(any 6 month period-interim regs)	Yes, if experience completed before 10/1/94
Initial Mammographic Modality Specific Training (8 hours)	Yes, for training in the mammographic modality if completed before 10/1/94 or for experience with investigational units (no time period limitation)
Continuing Experience (960/24 months)	Never
Continuing Education (15 Cat I/36 months)	Limited*
Continuing Mammographic Modality Specific Education (6 Cat I/36 months)	Limited*
Requalification-Experience	Never
Requalification-Education	Limited*

Radiological Technologist

Requirement	Is Attestation Acceptable?
State Licensure	Never
Board Certification (ARRT or ARCRT)	Never
Initial Training (~40 hours-interim regs)	Yes, if training completed before 10/1/94
Initial Mammography Modality Specific training (8 hours)	Yes, for training in the mammographic modality if completed before 10/1/94 or for experience with investigational units (no time period limitation)
Continuing Experience (200/24 months)	Never
Continuing Education (15 CME/36 months)	Limited*
Continuing Mammographic Modality Specific Education (6 CME/36 months)	Limited*

Requalification-Experience	Never
Requalification-Education	Limited*

Medical Physicists

Requirement	Is Attestation Acceptable?
State Licensure or Approval	Never
Board Certification (ABR or ABMP)	Never
Degree in a physical science (Master's pathway)(Bachelor's pathway)	Never
Initial physics education (20 semester hours-Master)(10 semester hours-Bachelor)	Never
Survey Training (20 contact hours-Master)(40 contact hours-Bachelor)	Yes, if training completed before 10/1/94
Initial Experience (1 facility-10 units-Master)(1 facility-20 units-Bachelor)	Yes, if experience completed before 10/1/94
Initial Mammography Modality Specific training (8 hours)	Yes, for training in the mammographic modality if completed before 10/1/94 or for experience with investigational units (no time period limitation)
Continuing Experience (2 facilities-6 units/24 months)	Never
Continuing Education (15 CME/36 months)	Limited*
Continuing Mammographic Modality Specific Education (>1 CME/36 months)	Limited*
Requalification-Experience	Never
Requalification-Education	Limited*

*Limited Attestation Policy^-

FDA will continue to accept a limited form of attestation in certain cases where the following conditions exist:

(1) The documentation (certificate) lacks specific reference that the education was in topics directly related to the regulated areas in mammography or the documentation does not specify the specific mammography modality(ies) credit hours included. Education directly related to achieving quality mammography (e.g., anatomy of the breast, positioning, interpretation of mammographic examinations, quality assurance procedures, stereotactic techniques, breast ultrasound, needle localization) is acceptable toward meeting the continuing education requirement. Education in an area not covered by the regulations (e.g., stereotactic techniques, breast ultrasound, needle localization) shall not be accepted toward meeting the requirements for initial training.

(2) It is possible for conference attendees to earn education credits in topics not directly related to the regulated areas in mammography at that education event

(e.g., angiography, pediatric radiography, orthopedic radiography) or in which more than one mammographic modality was included.

In order to attest when these conditions apply, the interpreting physician, radiologic technologist, and medical physicist will need to provide:

(1) A letter, certificate or other documentation from the education provider identifying the total number of credits actually earned at the conference, and

(2) Documentation (for example, conference agendas) showing the total number of hours of education offered at the conference which were in topics directly related to the regulated areas in mammography and/or in a specific mammographic modality.

Facility personnel can then attest to the mammography education and/or mammography modality specific credits earned at the education event. However, the education credits attested to may not exceed the total number of credits identified in items 1 or 2 above.

In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present.

^+Attestation can also be used by facility personnel who had experience working with an FFDM unit(s) when the unit on which they gained that experience was in its investigational stage (prior to receiving FDA approval for commercial use). Such individuals are considered to have met the 8 hour initial mammographic modality training requirement for FFDM units by virtue of this experience. Personnel may either attest or provide documentation of that experience in order to be recognized as having met the 8 hour requirement. Personnel whose experience was with a non-investigational FFDM unit (one that had previously been approved by FDA for commercial use) must document 8 hours of training and cannot use experience to meet this requirement.^-

FDA's "Attestation Regarding Requirements of the Mammography Quality Standards Act" form (**ATTESTATION FORM**), or a form with similar elements or equivalent, shall be used for ^+these purposes^- *+~~this purpose~~*-.

~~Question 1: Under the interim regulations, personnel were allowed to attest to training, education, or experience that was earned before October 1, 1994. Under FDA's final regulations, will this still be allowed? What about attestation for training or experience earned between October 1, 1994 and April 28, 1999?~~

~~In general, personnel may continue to attest to training, education, and experience earned before October 1, 1994, except for the 3-month training alternative to board certification for physicians. Attestation also may not be acceptable for board certification, licensure, or State approvals. FDA generally does not intend to accept attestation for training, education, or experience obtained after October 1, 1994, including training, education, and experience for personnel qualifying after April 28, 1999.~~

~~Question 2: Are there any exceptions for attestation for education or training earned after October 1, 1994?~~

FDA may continue to accept a limited form of attestation beyond October 1, 1994, in situations where the education or training provider does not specifically document that the education or training offered at a meeting, or other educational opportunity, was in mammography. For example, to use continuing medical education (CME) or continuing education units (CEU), the interpreting physician, radiologic technologist, or medical physicist should provide:

(1) Documentation from the CME/CEU provider of the total number of CME/CEU he or she earned at the meeting.

(2) Documentation (for example, meeting agendas) showing the number of hours he or she could have earned in mammography at the meeting.

If an individual provides such documentation, FDA may then accept attestation (using FDA's recommended form or a form with similar elements) to the number of CME/CEU in mammography he or she actually earned at the meeting. The above policy applies only in cases where there are opportunities to earn CME/CEU in several fields at the same event. If the meeting or other educational opportunity is limited to mammography, then all that would be needed is documentation from the provider of the number of CME/CEU earned. This limited form of attestation also may be accepted for continuing medical education requirements for other subjects related to breast disease. *-

***+Attestation for Training Credits Earned for the Initial Training Requirement after October 1, 1994**

Applicable Citations:

900.12(a)(1)(i)(C): The interpreting physician shall have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution.

900.12(a)(2)(ii)(A): Mammography requirements. All mammographic examinations shall be performed by radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to: (A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants.

900.12(a)(3)(i)(B)(2): Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.

Discussion:

FDA will continue to accept a limited form of attestation in certain cases where the following conditions exist:

(1) The documentation for a training event lacks specific reference that the training was in topics directly related to the regulated areas in mammography. This includes any training directly related to achieving quality mammography (e.g., anatomy of the breast, positioning, interpretation of mammographic examinations, quality assurance procedures). Training in an area not covered by the regulations shall not be accepted as meeting the requirements for initial training (e.g., stereotactic techniques, breast ultrasound, needle localization).

(2) It is possible for conference attendees to earn training credits in different subject areas at that training event (e.g., angiography, pediatric radiography, orthopedic radiography, and mammography).

In order to attest when these conditions apply, the interpreting physician, radiologic technologist, and medical physicist will need to provide:

(1) A letter, certificate or other documentation from the training provider identifying the total number of credits actually earned at the conference, and

(2) Documentation (for example, conference agendas) showing the total number of hours of training offered at the conference which were in topics directly related to the regulated areas in mammography.

Facility personnel can then attest to the mammography training credits earned at the training event. However, the training credits attested to may not exceed the total number of credits identified in items 1 or 2 above.

When the certificate identifies only the total number of training credits earned at the conference and it is not clear that all of the training hours were in topics directly related to the regulated areas in mammography, the inspector will need to review the conference agenda to calculate the total training credits which can be applied to the MQSA initial training requirement. The inspector must compare the number of attested hours to the total number of agenda hours that are applicable toward the initial training requirement. This ensures the attested hours do not exceed the number of applicable agenda hours.

FDA's "Attestation Regarding Requirements of the Mammography Quality Standards Act" form (ATTESTATION FORM), or a form with similar elements or equivalent, shall be used for this purpose.

Question 1: Under the interim regulations, personnel were allowed to attest to training, education, or experience that was earned before October 1, 1994. Under FDA's final regulations, will this still be allowed? What about attestation for training or experience earned between October 1, 1994 and April 28, 1999?

In general, personnel may continue to attest to training, education, and experience earned before October 1, 1994, except for the 3-month training alternative to board certification for physicians. Attestation also may not be acceptable for board certification, licensure, or State approvals. FDA generally does not intend to accept attestation for training, education, or experience obtained after October 1, 1994, including training, education, and experience for personnel qualifying after April 28, 1999.

~~**Question 2: Are there any exceptions for attestation for education or training earned after October 1, 1994?**~~

~~FDA may continue to accept a limited form of attestation beyond October 1, 1994, in situations where the education or training provider does not specifically document that the education or training offered at a meeting, or other educational opportunity, was in mammography. For example, to use continuing medical education (CME) or continuing education units (CEU), the interpreting physician, radiologic technologist, or medical physicist should provide:~~

~~1. Documentation from the CME/CEU provider of the total number of CME/CEU he or she earned at the meeting.~~

~~2. Documentation (for example, meeting agendas) showing the number of hours he or she could have earned in mammography at the meeting.~~

~~If an individual provides such documentation, FDA may then accept attestation (using FDA's recommended form or a form with similar elements) to the number of CME/CEU in mammography he or she actually earned at the meeting. The above policy applies only in cases where there are opportunities to earn CME/CEU in several fields at the same event. If the meeting or other educational opportunity is limited to mammography, then all that would be needed is documentation from the provider of the number of CME/CEU earned. This limited form of attestation also may be accepted for continuing medical education requirements for other subjects related to breast disease. *~~

General Personnel

900.12(a): Personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

Discussion

Question 6: At the time of the inspection, the sole interpreting physician, radiologic technologist, and/or medical physicist at a facility is found to not meet one of their requirements. Must the person and the facility immediately stop practicing mammography?

If personnel fail to meet a requirement, the facility will be cited. The actions that the facility and the persons involved must or should take will be dependent on the specific circumstances that exist at the facility. For example, if the radiologic technologist fails to meet a requirement, the technologist can continue to perform mammography under the direct supervision of the interpreting physician (as long as the physician meets the technologist qualifications). If the physician fails to meet a requirement, he/she must stop interpreting mammograms independently; however, the facility can continue to perform mammography with the studies being interpreted by a different interpreting physician at a later time. Under no circumstance can the interval between performing and providing the results of the examination exceed 30 days. If the medical physicist fails a requirement, the facility will be cited but can continue to perform and interpret mammograms.

Because the consequences of having a facility cease performing mammography services, even for a short time, can be so detrimental to patient access and patient care, the inspector must take special actions in such cases. If both the interpreting physician and radiologic technologist fail to meet their requirements or other conditions exist that would cause shut down of the facility's operations, the inspector should immediately contact the FDA ^+Hotline^- *+~~Inspector Helpdesk~~*- for further instructions. In those cases where FDA determines that there is not an immediate risk to human health, the facility can continue to use the personnel for a limited time so that the problem(s) can be corrected without adversely affecting patient care ^+and access^-.

^+Question 11: Do general supervisors of mammography technologists, medical physicists, or interpreting physicians have to meet any requirements under MQSA?

No. There are no requirements for general supervisory duties under the regulations. However, if a general supervisor, in addition to his/her general supervisory duties, also performs or directly supervises one of the three tasks outlined in the regulations (perform mammography, read and interpret images, or conduct on-site physics surveys), he/she must meet the appropriate requirements for the tasks he/she performs or directly supervises and their records must be retained for the facility's annual MQSA inspection.

Question 12: Under MQSA regulations must an interpreting physician be present during the performance of a "diagnostic" mammogram?

No. For personnel purposes, the regulations do not differentiate "screening" from "diagnostic" and do not require that an interpreting physician be physically present for either type of exam. However, facilities should check with their third party payers and local standards of care to see if they require or recommend that a physician be present.^-

Retention of Personnel Records

Citation:

900.12(a)(4) Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

Question 2: Do ^+general^- supervisors of mammography technologists, medical physicists, or interpreting physicians have to meet any requirements under MQSA?

No, there are no requirements for ^+general^- supervisory duties under the *+~~final~~*- regulations. However, if a ^+general^- supervisor, in addition to his/her ^+general^- supervisory duties, also performs ^+or directly supervises^- one of the three tasks outlined in the regulations (perform mammography, read and interpret images, or conduct on site physics surveys), he/she must meet the appropriate requirements for the tasks

he/she performs ^+or directly supervises^- and *+~~their~~*- records must be retained for the facility's annual MQSA inspection.

Inspector Instructions: [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Starting Dates

Applicable Citations:

*+~~900.12(a)(1)(ii)(A)(B): All interpreting physicians shall maintain their qualifications by meeting the following requirement:~~

~~(A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.~~

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

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

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~~900.12(a)(2)(iv)(A): Continuing experience requirements. (A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the~~

~~*inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.*~~

~~*900.12(a)(3)(iii)(A)(B): Continuing qualifications*~~

~~*(A) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 13 units in a 36-month period, even if the course is taught multiple times during the 36 months.*~~

~~*(B) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(3)(i) and (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.*~~

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

Question 1: ^+How is an individual's starting date determined?^- *+~~Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?*~~

+~~Yes, the~~- ^+The^- date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

The starting date for evaluating continuing experience for interpreting physicians has been either October 1, 1994, or the date on which someone initially qualifies, whichever is later. For radiologic technologists and medical physicists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later.

The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists has been either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

Question 2: Does *+~~the date on which personnel initially qualify to work independently ever change,~~*- ^+an individual's starting date ever change^- due to personnel taking time off after they qualify or if they re-qualify when they are found to be deficient for either continuing experience or continuing education?

No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 4: Under the *+~~final~~*- regulations, if less than 24 months have passed since an interpreting physician^+'s^-, radiologic technologist^+'s^-, or medical physicist^+'s starting date^- *+~~has initially qualified to work independently~~*-, will they still be evaluated for continuing experience during an inspection? What about continuing medical education if less than 36 months have passed since ^+the starting date^- *+~~initial qualification~~*-?

If less than 24 months have passed since ^+an individual's starting date^- *+~~personnel have initially qualified~~*-, insufficient time has passed to cite the facility during an inspection for any failure of these personnel to meet continuing experience requirements. Similarly, in the case of *+~~the~~*- continuing medical education, inspectors cannot cite the facility for failure of these personnel until 36 months have passed since the individual^+'s starting date^- *+~~initially qualified~~*-. However, inspectors will try to draw the attention of facilities to situations in which it appears that personnel will not be likely to fulfill continuing education and experience requirements in a timely manner.

~~*+CEU/CME Exceptions Due to Terrorist Attacks~~

~~Discussion:~~

~~Since the terrorist attacks of September 11, our country has been dealing with their direct and indirect effects. All of us must adjust to the "new reality." The Mammography Quality Standards Act (MQSA) program is no exception. While only a relatively few mammography facilities were directly impacted by the attacks, the entire radiological community has been affected.~~

~~The Food and Drug Administration (FDA) is working with the American College of Radiology to help facilities in the immediate vicinity of New York's World Trade Center maintain their accreditation and certification. Additionally, FDA is aware that some~~

~~mammography facility personnel have been unable, or will be unable for some period of time, to attend some continuing education (CME/CEU) programs due to program cancellations or inability to travel to the meetings.~~

~~If a facility is scheduled for an inspection and has personnel who fail to meet the CME/CEU requirement due to the terrorist attacks, it should:~~

1. ~~Inform the MQSA inspector at the time of scheduling the inspection.~~
2. ~~At the time of the inspection, provide verification that the personnel were scheduled to obtain the CME/CEU but were unable to attend as a consequence of the terrorist attacks. This verification may include copies of program registrations, travel/reservation arrangements, cancellation letters, or other similar documents.~~

~~At the time of the inspection, provide a written explanation of how the facility plans for the personnel to obtain the balance of the required CME/CEU as soon as reasonably possible.~~

~~If the above materials are provided, the facility should not be cited for failure of the CME/CEU requirement.~~ ***-**

Interpreting Physician Overview

Discussion:

In order to independently interpret mammograms, one must qualify as an interpreting physician. To do this, one must have either qualified as an interpreting physician under the interim regulations prior to April 28, 1999, OR after April 28, 1999, have documented all of the following requirements:

1. Have a valid State license to practice medicine.
2. Be Board Certified in Diagnostic Radiology by an FDA-approved body or have 3 months of formal training in mammography.
3. Have 60 category I CME credits in mammography with at least 15 obtained in the 3 years immediately prior to qualifying as an interpreting physician.
4. Have interpreted, under direct supervision, *+~~the~~*- ^+240^- mammographic examinations *+~~from 240 patients~~*- in the 6 months immediately prior to qualifying as an interpreting physician OR if the physician passed *+~~their~~*- ^+his/her^-certifying board in diagnostic radiology at the first allowable time the 6 month period could have been anytime in the last two years of the residency program. See Sample Residency Letter – Interim Regulations and Sample Residency Letter – Final Regulations.

After meeting all the initial requirements, ALL interpreting physicians must:

1. Maintain continuing education (15 category I CME's/36 months).

2. Maintain continuing experience (960 examinations/24months).

3. Physicians failing to maintain the continuing requirements must requalify prior to performing independent mammographic interpretation.
(a) Continuing education: Must bring total up to 15 CME's/3 years.
(b) Continuing experience: Interpret 240 examinations under direct supervision or interpret a sufficient number, under direct supervision, to bring total to 960/24 months, whichever is less.

4. Maintain a valid State license to practice medicine.

All interpreting physicians shall participate in quality assurance activities as described in 900.12(d)(1)(ii).

Each mammographic facility shall designate one interpreting physician to be the lead interpreting physician, who is responsible for ensuring that the facility's quality assurance program meets the requirements of 900.12(d-f). 21 C.F.R. 900.2(x).

Each mammographic facility shall also designate at least one interpreting physician to be the *+~~reviewing~~*- ^+audit^- interpreting physician(s)), who is/are responsible for analyzing the medical outcomes audit. The reviewing interpreting physician may or may not be the lead interpreting physician. 21 C.F.R. 900.12(f)(3).

Physicians in training may work at facilities as long as they are under the direct supervision of a qualified interpreting physician.

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Interpreting Physician Qualification Worksheet	
This worksheet may be used by facilities to help ensure that their personnel meet all applicable requirements prior to providing mammography services.	
Initial Qualifications Met Before 4/28/99 (INTERIM)	Initial Qualifications Met After 4/28/99 (FINAL)
Need: ___ Valid license (any State)	Need: ___ Valid license (any State)
Need one of the following: ___ ABR, AOBR, or RCPSC ___ Two months of training	Need one of the following: ___ ABR, AOBR, or RCPSC ___ Three months of training
Need: ___ 40 hours CMEs (attestation allowed if CMEs obtained prior to 10/1/94)	Need: ___ 60 hours Category 1 CMEs of which 15 were earned in the past three years
Need: ___ 240 patient exams in any 6 month period (attestation allowed if the exams were completed prior to 10/1/94)	Need one of the following: ___ 240 patient exams in prior 6 month period ___ Certified at first allowable time & 240 patient exams in the last two years of residency
START DATE _____ (The later of 10/1/94 or date the last initial qualification was completed)	
___ 8 hours initial training in additional mammographic modality used (if applicable) DATE COMPLETED_____	
Continuing Qualifications	
All of the following: ___ 960 patient exams in the 24 months prior to the current date (applicable 24 months after start date) ___ 15 Category I CMEs in the 36 months prior to the current date (applicable 36 months after start date)	

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Acceptable Documents for Interpreting Physicians

Discussion:

The table below summarizes the types of documentation that interpreting physicians may use to document their initial qualifications, as well as their continuing requirements and requalification requirements, prior to MQSA and under the interim and final regulations.

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State License	1. State license/copy with expiration date 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy with expiration date 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy with expiration date 2. Confirming letter from State licensing board 3. Pocket card/copy of license
Board Certification (ABR, AOBR, or RCPSC)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Confirming letter from ACR 4. Listing in ABMS directory	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Confirming letter from ACR 4. Listing in ABMS directory	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Confirming letter from ACR 4. Listing in ABMS directory
Formal Training (2 months-interim regs) (3 months-final regs)	1. Letters or other documents from US or Canadian residency programs 2. Documentation of formal mammography training courses 3. Category I CME certificates	1. Letters or other documents from US or Canadian residency programs 2. Documentation of formal mammography training courses 3. Category I CME certificates	1. Letters or other documents from US or Canadian residency programs 2. Documentation of formal mammography training courses 3. Category I CME certificates
Initial Medical Education (40 hours-interim regs) (60 hours/15 in last 3 years-final regs)	1. Attestation 2. Letter from residency program 3. CME certificates 4. Letter or other document confirming in-house or formal training	1. Letter from residency program 2. CME certificates 3. Letter or other document confirming in-house or formal training	1. Letter from residency program 2. ^+Category I^- CME certificates 3. Letter or other document confirming in-house or formal training (Category I)
Initial Experience (240) (any 6 month period-interim regs) (last 6 month vs 6 month in last 2 years of residency-final regs)	1. Attestation 2. Letter or other document from residency or training program or mammography facility	1. Letter or other document from residency or training program or mammography facility – done under direct supervision	1. Letter or other document from residency or training program or mammography facility – done under direct supervision
Initial Mammographic Modality Specific Training-8 hours-final regs	1. Attestation for training or experience with investigational units 2. Mammography Modality Specific CME certificates (Category I or II) 3. CME certificates (Category I or II) plus agenda, course outline or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography Modality Specific CME certificates (Category I or II) 3. CME certificates (Category I or II) plus agenda, course outline or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. ^+Attestation for experience with investigational units^- 2. Mammography Modality Specific CME certificates (Category I or II) 3. CME certificates (Category I or II) plus agenda, course outline or syllabus 4. Confirming letters from CME granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses
Continuing Experience (960/24 months)	N/A	1. *+~~Letter, table, facility logs or other documentation from residency or training program or mammography facility~~*-^+N/A^-	1. Letter, table, facility logs or other documentation from residency or training program or mammography facility
Continuing Education (15 CME/36 months-interim regs) (15 Category I CME/36 months-final regs)	N/A	~~1.~~ *+~~CME certificates (Category I or II)~~ ~~2. Confirming letters from CME granting organizations~~ 3. ~~Letters, certificates or~~	1. CME certificates (Category I) 2. Confirming letters from CME granting organizations

		~~other documents from manufacturers' training courses~~*-^+N/A^-	
Continuing Mammographic Modality Specific Education-final regs ^+(Enforcement delayed indefinitely)^-	N/A	~~1.~~ *+~~Mammography Modality Specific CME certificates (Category I or II)~~ ~~2. CME certificates (Category I or II) plus agenda, course outline or syllabus~~ ~~3. Confirming letters from CME granting organizations~~ 4. ~~Letters, certificates or other documents from manufacturers' or other formal training courses~~*-^+N/A^-	1. Mammography Modality Specific CME certificates (Category I) 2. CME certificates (Category I) plus agenda, course outline or syllabus 3. Confirming letters from CME granting organizations
Requalification-Experience–done under direct supervision	N/A	1. *+~~Letter, table, facility logs or other documentation from residency or training program or mammography facility~~*-^+N/A^-	1. Letter, table, facility logs or other documentation from residency or training program or mammography facility
Requalification- Education	N/A	~~1.~~ *+~~CME certificates (Category I or II)~~ 2. ~~Confirming letters from CME granting organizations~~*-^+N/A^-	1. CME certificates (Category I) 2. Confirming letters from CME granting organizations

Interpreting Physician Certification

Citation:

900.12(a)(1)(i)(B)(1): The interpreting physician shall be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography.

^+Question 1: FDA-approved interpreting physician certification boards have started issuing certificates that have an expiration date. If an interpreting physician allows his board certification to expire, must he or she obtain recertification to continue interpreting mammograms?

No. With respect to the requirement in 21 CFR 900.12(a)(1)(i)(B)(1), FDA has always considered board certification to be an initial requirement that does not expire. FDA will accept an expired certificate as meeting this requirement.^-

Interpreting Physician Continuing Education

Citation:

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

include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

Any of the following options may be used to determine if the continuing education requirement has been met:

Option 1: The inspector counts back 36 months from the date of the inspection and includes all applicable continuing education credits received by each individual during that 36-month period. For example, if the inspection is conducted on November 10, 1999, the relevant continuing education credits for each person would be those earned from November 10, 1996, to November 10, 1999.

Option 2: The inspector counts back 36 months from the end of the full calendar quarter immediately preceding the inspection date and includes all applicable continuing education credits received by each individual during that 36-month period. For the inspection date of November 10, 1999, the relevant continuing education credits for each person would be those earned from October 1, 1996, through September 30, 1999.

Option 3: Inspectors may also count back 36 months from any date between the inspection date and the end of the previous full calendar quarter, and count the applicable continuing education received by each individual during that period towards meeting the continuing education requirement.
FDA recommends that the facility try to consistently use the same option for all interpreting physicians providing services to it. However, this is not required.

Copies of certificates earned or other documentation from the training provider will suffice for the continuing education qualification. FDA will continue to accept a limited form of attestation for CME received after October 1, 1994 in certain cases.

Question 1: Tumor boards are meetings in which cases of cancer or possible cancer are discussed by groups of physicians who may represent several specialties. In the case of possible breast cancer, mammograms may be reviewed during the discussion but the bulk of the time may be spent in discussing other issues such as follow-up actions. May interpreting physicians count their tumor board attendance time towards meeting the MQSA continuing medical education requirements? If so, how much credit should be given?

^+The first consideration is that the tumor board have category I status. 21 C.F.R. 900.2(g). In that case,^- FDA will accept any time at tumor boards devoted to the discussion of any aspect of a case of breast cancer or possible breast cancer or any other abnormal condition of the breast as counting towards meeting the continuing medical education requirement for interpreting physicians under MQSA. Documentation *+~~must~~*- ^+needs to^-be provided from the director/chairperson/organizer of the boards

instead of from the interpreting physician him or herself. Tumor boards also consider other cancer cases as well and time spent on those would not count towards the MQSA requirements. When calculating the amount of credit that should be given, the following example may be used as guidance: If an interpreting physician attended 20 hours of tumor board meetings and an estimated 20 per cent of those 20 hours was spent on breast related cases, the interpreting physician may be credited with the equivalent of 4 CME towards the continuing requirement.

Question 4: ^+How is an individual's starting date for beginning to meet the MQSA continuing requirements determined?^- *+~~Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?*-~~

+~~Yes, the~~- ^+The^- date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

The starting date for evaluating continuing experience and continuing education for interpreting physicians has been either October 1, 1994 or the date on which someone initially qualifies, whichever is later.

~~***+Question 6: After April 28, 1999, interpreting physicians must earn category I continuing medical education (CME). If a facility is inspected one year after this date, will all 15 of a physician's CME credits that were earned in the previous 36 months have to be category I?**~~

~~No. Any CME credits prior to April 28, 1999 may be either category I or II. Credits earned after April 28, 1999 must be category I. Category II credits earned prior to April 28, 1999 can be counted toward the required 15 credits as long as they were obtained within the 36-month period as measured back from the date of the current inspection.*-~~

Question 7: Does the *+~~date on which physicians initially qualify to work independently ever change,~~*- ^+starting date ever change^- due to physicians taking time off after they qualify or if they re-qualify when they are found to be deficient for either continuing experience or continuing education?

No. If physicians take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 8: Under the *+~~final~~*- regulations, if less than 36 months have passed since an interpreting physician^+'s starting date^- &+~~initially qualified to work~~

~~independently~~*-, will they still be evaluated for continuing education during an inspection?

If less than 36 months have passed since a physician^+'s starting date^- *+~~initially qualified~~*-, insufficient time has passed to cite the facility during an inspection for any failure of this physician to meet the continuing education requirements. However, inspectors will try to draw the attention of facilities to situations in which it appears that personnel will not be likely to fulfill continuing education requirements in a timely manner.

Question 10: Are there specific areas that are acceptable for continuing medical education *+~~and others that are not acceptable~~*-?

Except for credits in each mammographic modality used, FDA does not require specific subject areas for continuing medical education. All continuing education units related to the diagnosis or treatment of breast disease or to other areas that will aid facility personnel in improving the quality of mammography, may be acceptable toward meeting the continuing education requirement. ^+Because of the external pressures affecting mammography facilities that have caused facility closures and a decrease in the number of personnel performing mammography, topics such as medical malpractice and mammography billing and reimbursement are becoming increasingly important to the continued viability of many mammography facilities. Because of this, CME/CEU mammography training that addresses these areas may be accepted toward meeting the MQSA CME/CEU requirement. However, the number of hours devoted to these topics should not constitute a majority of the 15 hour requirement.^-

Question 12: If interpreting physicians do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

Physicians who have not worked in mammography for some period of time after meeting the initial requirements *+~~may*-~~ need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing education requirements. While under direct supervision, these personnel *+~~should*-~~ ^+must^- obtain the necessary continuing experience and CME to requalify before resuming independent work in mammography. 21 C.F.R. 900.12(a)(1)(iv). A facility may be cited during an inspection if such physicians work without supervision prior to obtaining sufficient hours of CME and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriated requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME/CEU, the facility may be cited for these problems.

Question 13: Under FDA's interim regulations, when physicians were found deficient for not having at least 15 mammography CME in the previous 36 months, they were given up to 90 days to obtain this education while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued *+~~after~~*-^+under^- FDA's final regulations *+~~take effect on April 28, 1999~~*-?

No^+.^- ~~*+, FDA does not intend to apply this policy after April 28, 1999. Also, any part of the 90-day period that might extend beyond April 28, 1999 will terminate on April 28, 1999.*-~~

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Interpreting Physician Continuing Experience

Citation:

900.12(a)(1)(ii)(A): All interpreting physicians shall maintain their qualifications by meeting the following requirement: Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

Any of the following options may be used to determine if the interpreting physician's continuing experience requirement has been met:

Option 1: The inspector counts back 24 months from the date of the inspection. For example, if the inspection is conducted on November 10, 1999, the relevant time period would be determined by counting back 24 months from November 10, 1999, to November 10, 1997. *+~~The facility may choose this option if the records for all interpreting physicians are updated to the inspection date.~~*-

Option 2: The inspector counts back 24 months from the end of the previous full calendar quarter immediately preceding the inspection date. For the inspection date of November 10, 1999, the relevant time period would be determined by counting back from the end of the previous calendar quarter, i.e., September 30, 1999, *+~~for the said case~~*- to October 1, 1997.

Option 3: The inspector may also count 24 months from any date between the inspection date and the end of the previous full calendar quarter. This could be the

case if the facility's records are updated to such a date, i.e., between September 30, 1999, and November 10, 1999, in the above example.
FDA recommends that the facility try to consistently use the same dating option for all interpreting physicians and other personnel providing services to it. However, this is not required.

It is important for interpreting physicians who interpret at multiple facilities to update all facilities on the number of mammograms interpreted at other sites to ensure that their recorded experience is complete and accurate. Since the interpreting physician will not know more than a few days in advance when a facility for which he/she interprets will be inspected, updates should occur frequently (at least quarterly).

Physicians may document continuing experience by obtaining a letter, table, or printout from each facility, signed by a responsible facility official, stating that he/she has interpreted a given number of mammograms at the facility in a given time period. Alternatively, signed copies of facility logs could be provided.

Question 1: ^+How is an individual's starting date for beginning to meet the MQSA continuing requirements determined?^- *+~~Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?*~~

+~~Yes, the~~- ^+The^- date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

The starting date for evaluating continuing experience and continuing education for interpreting physicians has been either October 1, 1994 or the date on which someone initially qualifies, whichever is later.

Question 3: Does the ^+starting date ever change^- *+~~date on which personnel initially qualify to work independently ever change,~~*- due to personnel taking time off after they qualify or if they re-qualify when they are found to be deficient for either continuing experience or continuing education?

No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 4: Under the *+~~final~~*- regulations, if less than 24 months have passed since an interpreting physician^+'s starting date^- *+~~has initially qualified to work independently,~~*- will he/she still be evaluated for continuing experience during an inspection?

If less than 24 months have passed since the interpreting physician^+'s starting date^-*+~~initially qualified~~*-, insufficient time has passed to cite the facility during an inspection for any failure of this physician to meet the continuing experience requirements. However, inspectors will try to draw the attention of facilities to situations in which it appears that personnel will not be likely to fulfill continuing experience requirements in a timely manner.

Question 6: If interpreting physicians do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

Physicians who have not worked in mammography for some period of time after meeting the initial requirements *+~~may~~*- need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing medical education (CME) requirements. While under direct supervision, these physicians *+~~should*-~~ ^+need to^-obtain the necessary continuing experience and CME to requalify before resuming independent work in mammography. 21 C.F.R. 900.12(a)(1)(iv). A facility may be cited during an inspection if such physicians work without supervision prior to obtaining sufficient hours of CME and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriate requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME, the facility may be cited for these problems.

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Interpreting Physician Exemption from Initial Requirements

Citation:

900.12(a)(1)(iii)(A): Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.

Discussion:

Question 1: An interpreting physician has been practicing under FDA's interim regulations and met all of the initial and continuing requirements under those regulations. Will he or she have to go back and get additional mammography

training to meet the requirements after April 28, 1999*+~~, the effective date for the new regulations~~*-?

No, the interpreting physician will not have to obtain additional initial training to continue reading and interpreting mammograms after April 28, 1999. However, after April 28, 1999, if the physician wants to begin reading and interpreting mammograms produced by a mammographic modality (such as digital mammography) in which he or she has not been trained, the physician will need to get at least 8 hours of training in the new mammographic modality. 21 C.F.R. 900.12(a)(1)(ii)(C). For continuing medical education, only category I may be counted toward meeting the requirement after April 28, 1999 *+~~and at least six credits must be obtained in each mammographic modality used by the interpreting physician in his or her practice~~*-. 21 C.F.R. 900.12(a)(1)(ii)(B).

Interpreting Physician Initial Experience

Citation:

900.12(a)(1)(i)(D): The interpreting physician shall have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

Discussion:

Question 1: What does it mean for a physician to be under the direct supervision of a qualified interpreting physician? Does the supervising physician have to sit next to the physician being supervised when he or she reads and interprets the film? Whose name goes on the report, the supervising physician or the physician being supervised?

The supervising physician need not be present during the initial reading and interpretation. Direct supervision for an interpreting physician means that during the joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised. ^+The supervising physician must review and, if necessary, correct the final interpretation before it is given to the patient or referring physician.^- 21 C.F.R. 900.2(o)(1). Since a qualified interpreting physician must sign each mammography report, the name of the supervising interpreting physician must be on the report as the interpreting physician. ^+The facility has the option of including on the report, the name of the physician being supervised.^-

Interpreting Physician Initial *+~~Training*-~~ ^+Medical Education^- 60 hours of CME

Citation:

900.12(a)(1)(i)(C): The interpreting physician shall have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the 3 years immediately prior to the

date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution.

Discussion:

Category I means medical educational activities that have been designated as category I by the Accreditation Council for Continuing Medical Education (ACCME), ^+the Accreditation Council for Graduate Medical Education (ACGME),^- the American Osteopathic Association (AOA), a state medical society, or an equivalent organization as cited in section 900.2(g). Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I.

Copies of certificates earned or other documentation from the training provider will suffice for the initial training qualification. If documentation is not available, proper attestation will be acceptable for records dated up to October 1, 1994. FDA will continue to accept a limited form of attestation for CME received after October 1, 1994, in certain cases. ^+(see Attestation - Acceptable Uses for Personnel Requirements)^-

Question 1: Tumor boards are meetings in which cases of cancer or possible cancer are discussed by groups of physicians who may represent several specialties. In the case of possible breast cancer, mammograms may be reviewed during the discussion but the bulk of the time may be spent in discussing other issues such as follow-up actions. May interpreting physicians count their tumor board attendance time towards meeting the initial MQSA *+~~training~~*- requirements? If so, how much credit should be given?

^+The first consideration is that the tumor board have category I status. 21 C.F.R. 900.2(g). In that case,^- FDA will accept any time at tumor boards devoted to the discussion of any aspect of a case of breast cancer or possible breast cancer or any other abnormal condition of the breast as counting towards meeting the initial medical education requirement for interpreting physicians under MQSA. Documentation *+~~must~~*- ^+needs to^-be provided from the director/chairperson/organizer of the boards instead of from the interpreting physician him or herself. Tumor boards also consider other cancer cases as well and time spent on those would not count towards the MQSA requirements. When calculating the amount of credit that should be given, the following example may be used as guidance: If an interpreting physician attended 20 hours of tumor board meetings and an estimated 20 per cent of those 20 hours was spent on breast related cases, the interpreting physician may be credited with the equivalent of 4 CME towards the initial requirement.

Interpreting Physician New Mammographic Modality Training

Citation:

900.12(a)(1)(ii)(C): Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the

interpreting physician shall have at least 8 hours of training in the new mammographic modality.

Discussion:

Copies of certificates earned or other documentation from the training provider will suffice for the new mammographic modality training. FDA will continue to accept a limited form of attestation for CME received after October 1, 1994, in certain cases.

Question 1: There is a *+~~new~~*- requirement for 8 hours of training for any new mammographic modality before an interpreting physician may begin independently interpreting mammograms produced by this new mammographic modality. If the physician did not have this training during residency, would it have to be category I continuing education? What about applications training from the manufacturer of the new mammographic modality?

The initial eight hours training in the new mammographic modality does not have to be category I training. FDA *+~~intends to accept~~*- ^+accepts^- applications training from the manufacturer in the new mammographic modality. Other examples of training in the new mammographic modality could include manufacturer's instruction materials, residency training, or special training courses.

Question 2: What are examples of *+~~new~~*- mammographic modalities? What types of training would be acceptable as training in new mammographic modalities?

The term mammographic modality refers to a technology for radiography of the breast. 21 C.F.R. 900.2(z). Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is ^+full field^- digital mammography ^+(FFDM)^-. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in ^+FFDM^- *+~~digital mammography~~*-, if they are to begin providing services or interpretations using this ^+mammographic^- modality after April 28, 1999. However, if those personnel gained their experience using investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution) *+~~started using this modality before April 28, 1999*-~~, they are considered to have met the 8 hour requirement.

New ^+mammographic^- modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer. For interpreting physicians, this does not have to be category I continuing medical education.

Question 3: Some personnel may receive some training in full-field digital mammography as part of their initial qualifications. In addition to counting toward their initial requirements, can this training also be applied to the 8-hour *+~~new*-~~ ^+mammographic^- modality training requirement?

Yes. They may use this training in digital mammography to count toward the 8-hour *+~~new~~*- ^+mammographic^- modality training.

Question 4: Some personnel may receive continuing medical education (CME/CEU) in full-field digital mammography as part of the CME/CEU requirement. Can they also use this toward meeting the initial 8-hour *+~~new*-~~ ^+mammographic^- modality training requirement?

Yes. They may use this CME/CEU in full-field digital mammography to count toward the eight hour *+~~new~~*- ^+mammographic^- modality training.

Question 5: ^+Can experience obtained using investigational Full Field Digital Mammography (FFDM) units count toward the 8 hour mammographic modality training requirement?^- *+~~Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the interpreting physician began interpreting~~ Full Field Digital Mammography ~~(FFDM) images?*-~~

Yes. Interpreting physicians who began interpreting FFDM images ^+on investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution)^- *+~~before April 28, 1999, the effective date of the final regulations~~*-, are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these interpreting physicians must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM interpretations were performed. An example of acceptable documentation would be a letter from an appropriate official at the facility where the interpretations were performed. For more information, see acceptable documents for interpreting physicians in the PGHS.

Interpreting physicians who begin working with ^+non-investigational^- FFDM ^+units^- after April 28, 1999 must document that they had 8 hours of training in that mammographic modality before independently interpreting FFDM examinations. Interpreting physicians must document this training using the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information see, acceptable documents for interpreting physicians in the Policy Guidance Help System (PGHS).

Reestablishing the Interpreting Physician Continuing Education Requirement

Citation:

900.12(a)(1)(iv)(B): Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

Discussion:

Requalification does not affect or change the date on which such individuals met their initial qualification requirements, therefore, the starting dates on which such individuals must meet their continuing requirements remains the same.

Copies of certificates earned or other documentation from the training provider will suffice for reestablishing the continuing education requirement. If documentation is not available, proper attestation will be acceptable for records dated up to October 1, 1994. FDA will continue to accept a limited form of attestation for CME received after October 1, 1994 in certain cases. ^+(see Attestation - Acceptable Uses for Personnel Requirements)^-

Question 1: Under FDA's interim regulations, when personnel were found deficient for not having at least 15 continuing medical education (CME) credits or units in the previous 36 months, they were given up to 90 days to obtain this training while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued *+~~after~~*-^+under^- FDA's final regulations *+~~take effect on April 28, 1999~~*-?

No^+.^- ~~*+, FDA does not intend to apply this policy after April 28, 1999. Also, any part of a 90-day extension period that might have extended beyond April 28, 1999 will terminate on April 28, 1999.*-~~

Inspector Instructions: **[DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]**

Medical Physicist Overview

Discussion:

In order to independently conduct surveys of mammography facilities and provide oversight of a facility's ^+equipment-related^- quality assurance program, one must qualify as a medical physicist. 21 C.F.R. 900.12(a)(3).

Because the duties of the medical physicist encompass more than just the physics survey, FDA expects the facility to be able to call on the services of the medical physicist throughout the year. Therefore, the facility must be able to identify *+~~their~~*- ^+its^- qualified medical physicist at the time of the MQSA inspection or *+~~they~~*- ^+it^- will be subject to citation. 21 C.F.R. 900.12(a)(3).

To qualify under the initial qualifications of the *+~~final~~*- regulations, a medical physicist must document all of the following requirements:

1. Be State licensed or approved or have certification.
2. Have a master's degree or higher in a physical science with no less than 20 semester hours in physics.
3. Have 20 contact hours of specialized training in conducting mammography facility surveys.
4. Have the experience of conducting surveys of at least l mammography facility and a total of at least 10 mammography units.

OR

To qualify under the alternative initial qualifications of the *+~~final~~*- regulations, a medical physicist must document all of the following requirements:

1. Have qualified as a medical physicist under the interim regulations and maintained active status of any licensure**,** approval**,** or certification required under the interim regulations.
2. Prior to April 28, 1999 have:
    a. A bachelor's degree or higher in a physical science with no less than 10 semester hours in physics.
    b. Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,
    c. Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.

Having once met the initial qualifications, all medical physicists (whether they initially qualified under the interim or final regulations) must meet the continuing qualifications:

1. Continuing education (15 CEU's/36 months).
2. Continuing experience (2 facilities and 6 units/24 months).
3. Maintain a valid State license, State approval, or certification.

Medical physicists failing to maintain the continuing requirements must requalify prior to independently conducting surveys of mammography facilities.

1. Continuing education: Must bring total up to 15 CEU's/3 years.
2. Continuing experience: Must bring total up to 2 facilities and 6 units/24 months under direct supervision.

^+

Medical Physicist Qualification Worksheet	
This worksheet may be used by facilities to help ensure that their personnel meet all applicable requirements prior to providing mammography services.	
Initial Qualifications (FINAL)	Alternative Initial Qualifications (FINAL)
Need one of the following: ___ ABR or ABMP certification ___ State licensed ___ State approved	Obtained one of the following before 4/28/99 and maintained it: ___ ABR or ABMP certification ___ State licensed ___ State approved
Need all of the following: ___ Masters degree or higher with no less than 20 semester hours in physics, in: Physics Chemistry Engineering Radiation Science (including Health Physics or Medical Physics) ___ 20 contact hours of training in surveys ___ Surveys of one facility and 10 mammography units (under direct supervision	Need all of the following: ___ Bachelors degree or higher (obtained prior to 4/28/99) with no less than 10 semester hours in physics, in: Physics Chemistry Engineering Radiation Science (including Health Physics or Medical Physics) ___ 40 contact hours of training in surveys ___ Surveys of one facility and 20 mammography units (training and surveys

after 4/28/99)	completed after degree and prior to 4/28/99)
START DATE _____ (The later of 10/1/94 or date the last initial qualification was completed)	
___ 8 hours initial training in additional mammographic modality used (if applicable) DATE COMPLETED_____	
Continuing Qualifications	
All of the following: ___ Surveys of two facilities and 6 units in the 24 months prior to the current date (applicable 24 months after start date) ___ 15 CMEs in the 36 months prior to the current date (applicable 36 months after start date)	

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^+Medical Physicist Approval Letter^-

^+Upon request, FDA's Division of Mammography Quality and Radiation Programs (DMQRP) will review a medical physicist's credentials to determine whether or not the physicist meets the initial requirements under the MQSA regulations. After the review, DMQRP will send the physicist a letter identifying the initial requirements that he or she meets. The physicist can then provide this letter to the mammography facilities he or she serves. The information identified in this letter will be accepted by the MQSA inspector as adequate evidence that the cited initial requirements are met. Consequently, the physicist will not need to provide facilities with copies of the more detailed credentials that he or she sent to us for evaluation.

This service can be particularly valuable for medical physicists who serve many facilities because it reduces the amount of paperwork that they have to provide to each of their facilities. Physicists who are uncertain about whether or not they meet the initial requirements may use this service for getting their questions related to the initial requirements answered.

We stress, however, that the decision to utilize this service is entirely yours. If you choose not to use this service, our inspectors will continue to evaluate your detailed credentials during their annual inspections of the mammography facilities you serve.

Should you be interested in using this service, the following "Questions and Answers" contain additional details on the submission of your credentials that will be necessary for review.

1. Must all medical physicists send documentation of their credentials to FDA headquarters for review by the mammography program?

No, only those wishing to obtain FDA’s medical physicist approval letter. While we are willing to provide this review as a service, whether you use the service is up to you. If you wish, you may continue to have all of your credentials reviewed during the annual inspection of the mammography facilities you serve.

2. What would be the advantage of sending my credentials to the FDA headquarters for review?

We see two possible benefits for you. First, if you are in doubt about whether you meet any of the initial requirements, this is an opportunity to get an answer from FDA. Second,

after the review, a letter signed by the Director of FDA's Division of Mammography Quality and Radiation Programs, will identify the initial requirements that you have met. This letter can be given to the facilities you serve in place of the documents related to those initial requirements that you presently provide to them for evaluation and credentialing purposes. This will reduce the volume of material that has to be given to the facility.

3. Will this review cover all of my MQSA personnel requirements?

No, it will be limited to the initial requirements. Your compliance with the continuing requirements will continue to be reviewed during the facility's annual MQSA inspection. Any requalification for these requirements also will be monitored by the inspectors and the FDA district offices. If you have a State approval or license that has to be renewed regularly, that credential will be reviewed during inspections and not at FDA headquarters.

4. What documents should I send to FDA headquarters for review?

Please refer to the **acceptable documentation table** in the Medical Physicist section of the PGHS for a detailed listing of appropriate documentation for the different requirements. Two questions in particular have been raised previously about this documentation. They are:

- **A. Must I provide a transcript or some similarly detailed document from my school to show that I have the required semester hours of physics or that my degree is in an acceptable field or both?**

  If you send us a copy of your diploma and it clearly states that your degree is in physics or any of its specialties, such as medical or health physics, we will accept that as sufficient proof that (1) your degree is in an acceptable field and (2) you have the required hours of physics.

  If the copy of your diploma shows that your degree is in one of the other fields (chemistry, engineering, radiation science) accepted in the regulations, this will be sufficient proof that your degree is acceptable. However, we will also need a transcript or other college document to determine whether you have sufficient hours of physics.

  If the copy of your diploma does not indicate the field of your degree or indicates a field other than those identified in the regulations, we will need a transcript to determine whether you have sufficient hours in physics and a statement from the degree granting institution, (or the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by one of the professional certifying bodies approved by FDA) that your degree can be considered to be in a "physical science," as defined in the regulations.

- **B. Can I attest to any requirements?**

  You can attest to contact hours of training in mammography surveys received and surveys performed before October 1, 1994. In addition, a sole owner of a physics consulting business can attest to surveys that he or she performed between October 1, 1994 and April 28, 1999. These attestations should be on a FDA-recommended form or one with the same elements. It should include as many details as you can remember.

NOTE: It is expected that if you can remember you did "x" number of surveys, you should also be able to remember the locations, although perhaps not the exact dates.

5. How long will it take FDA to perform this review?
We will perform a review as promptly as possible, but the actual time will depend on available staff time, the number of requests received, and the period of time in which we receive them. It will also depend on you. If your initial submission does not support a conclusion that you meet a particular requirement and you have to provide more material, this will obviously take more time.

6. What if one of my facilities is inspected while I am waiting to get my review back?
Until you receive the letter from us indicating that you have met the requirements **AND** you have provided a copy of the letter to the facility, our inspectors will determine whether you meet the initial requirements based on the documents you have provided to the facility.

7. What if this assessment of whether or not I meet the initial requirements disagrees with an earlier inspection finding?
In general, we do not plan on revisiting past inspection decisions. The letter you receive from us is intended for use during future inspections and will be accepted by MQSA inspectors.

8. How does FDA's letter relate to the State approval letter that I already have?
If you have a letter or other document from a State indicating that it has approved you for MQSA work, that letter will be sufficient proof that you meet the State approval option of the **requirement to be board-certified or State-licensed or State-approved.** It will not, however, address whether you meet all the initial MQSA requirements. Only the letter from FDA (or if you choose not to participate in this review service, the inspector's evaluation during an inspection) covers all the initial requirements.

9. Where do I send my credentials for review?
Mail them to the following address:
DHHS/PHS/FDA/CDRH
Office of Communication, Education, and Radiation Programs
Division of Mammography Quality and Radiation Programs, HFZ-240
1350 Piccard Drive
Rockville, MD 20850
OR
You may fax the information to us at: 1-301-594-3306
In either case, mark them:
ATTN: Medical Physicist Credentials^-

Acceptable Documents for Medical Physicists

Discussion:

The table below summarizes the types of documentation that medical physicists may use to document their initial qualifications, as well as their continuing requirements and requalification requirements, prior to MQSA and under the interim and final regulations.

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99

State Licensure or Approval	1. ^+Original/copy of^- State license or approval~~/~~copy with expiration date 2. Confirming letter from State licensing board 3. *+~~FDA Approval Letter~~*-	1. ^+Original/copy of^- State license or approval~~/~~copy with expiration date 2. Confirming letter from State licensing board 3. *+~~FDA Approval Letter~~*-	1. ^+Original/copy of^- State license or approval~~/~~copy with expiration date 2. Confirming letter from State licensing board 3. *+~~FDA Approval Letter~~*-
Board Certification (ABR or ABMP)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR 5. *+~~FDA Approval Letter~~*-	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR 5. *+~~FDA Approval Letter~~*-	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR 5. *+~~FDA Approval Letter~~*-
Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway)	1. Original/copy of diploma 2. Confirming letter from college or university 3. FDA Approval Letter	1. Original/copy of diploma 2. Confirming letter from college or university 3. FDA Approval Letter	1. Original/copy of diploma 2. Confirming letter from college or university 3. FDA Approval Letter
Initial physics education-final regs (20 semester hours-Master) (10 semester hours-Bachelor)	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics 4. FDA Approval Letter	1. College or university transcripts 2. Confirming letter from college or university 3. Master or Bachelor degree specifically in physics 4. FDA Approval Letter	1. College or university transcripts 2. Confirming letter from college or university 3. Master degree specifically in physics 4. FDA Approval Letter
Survey Training-final regs (20 contact hours-Master) (40 contact hours-Bachelor)	1. Attestation 2. Letter or other document from training program 3. CME/CEU certificates 4. Letter or other document confirming in-house or formal training 5. Training gained performing surveys 6. FDA Approval Letter	1. Letter or other document from training program 2. CME/CEU certificates 3. Letter or other document confirming in-house or formal training 4. Training gained performing surveys 5. FDA Approval Letter	1. Letter or other document from training program 2. CME/CEU certificates 3. Letter or other document confirming in-house or formal training 4. Training gained performing supervised surveys 5. FDA Approval Letter
Initial Experience-final regs (1 facility-10 units-Master) (1 facility-20 units-Bachelor)	1. Attestation 2. Copy or coversheet of survey 3. Letter from facility or listing from company providing the physics survey services documenting performance of survey done 4. FDA Approval Letter	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done 3. FDA Approval Letter	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision 3. FDA Approval Letter
Initial Mammography Modality Specific training-8 hours-final regs	1. Attestation for training or experience with investigational units 2. Mammography Modality Specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course	1. Attestation for experience with investigational units 2. Mammography Modality Specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course	1. ^+Attestation for experience with investigational units^- 2. Mammography Modality Specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course

		outline or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	outline or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	outline or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses
Continuing Experience (2 facilities-6 units/24 months-final regs	N/A		N/A	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done
Continuing Education (15 CME/36 months)	N/A		1. *+~~CME/CEU certificates~~ 2. ~~Confirming letters from CME/CEU granting organizations~~ 3. ~~Letters, certificates or other documents from manufacturers' or other formal training courses~~*-^+N/A^-	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates or other documents from manufacturers' or other formal training courses
Continuing Mammographic Modality Specific Education-final regs^+(Enforcement delayed indefinitely)^-	N/A		1. *+~~Mammography Modality Specific CME/CEU certificates~~ 2. ~~CME/CEU certificates plus agenda, course outline or syllabus~~ 3. ~~Confirming letters from CME/CEU granting organizations~~ 4. ~~Letters, certificates or other documents from manufacturers' or other formal training courses~~*-^+N/A^-	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates *+(*-plus agenda, course outline or syllabus 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses
Requalification-Experience–final regs–done under direct supervision	N/A		N/A	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision
Requalification- Education	N/A		1. *-~~CME/CEU certificates~~ 2. ~~Confirming letters from CME/CEU granting organizations~~ 3. ~~Letters, certificates or other documents from~~	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates or other documents from manufacturers' or other

~~manufacturers' or other formal training courses~~*-^+N/A^-

formal training courses

Medical Physicist Alternative Initial Qualifications

Citation:

900.12(a)(3)(ii)(A)(B)(1)(2)(3):

(A) Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

(B): Prior to the April 28, 1999 have:

1. A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,

2. Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,

3. Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

Discussion:

The FDA recognizes medical physicists certified with specialties in diagnostic radiological physics or radiological physics by the American Board of Radiology (ABR) or with a specialty in diagnostic imaging physics from the American Board of Medical Physics (ABMP).

A medical physicist who is state licensed or state approved in one State is qualified to conduct surveys in any other State under MQSA. However, MQSA permits States to have more stringent requirements than the MQSA standards. If the second state has regulations, policies, guidelines, or some other means based on regulatory authority that allows it to regulate medical physicists, then, under state law, the medical physicist must meet *+~~their~~*- ^+its^- requirements in order to practice. It can require the physicist to have its approval to practice within its borders in addition to meeting one of the options under MQSA. The physicist would still be qualified under MQSA, but physicists lacking such approval *+would*- ^+could^- be cited under the state regulations.

Attestation is not acceptable for ^+ academic degrees, state^- licenses^+, state approvals,^- or ^+board^- certification.

According to section 900.2(ll) Physical Science means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

Copies of certificates earned or other documentation from the training provider will suffice for the initial training qualification. If documentation is not available, proper

attestation will be acceptable for records dated up to October 1, 1994. FDA will continue to accept a limited form of attestation for CME received after October 1, 1994, in certain cases.^+(see Attestation - Acceptable Uses for Personnel Requirements)^-

When converting semester hours to CME's, an academic semester hour should be considered equal to 10 class hours and thus 10 continuing education credits. This 10 to 1 ratio is useful when you have to combine academic credit and continuing education units to determine if a requirement is met. However, if the facility can document that it took a different number of class hours than 10 (e.g., 12, 14, etc.) to earn 1 semester hour of credit, then the actual number of class hours should be used in making the conversion.

Question 1: A physicist was performing facility surveys prior to April 28, 1999, with a bachelor's degree in ^+a physical science as defined by FDA^- *+~~physics~~*-. His or her State approval is still current after April 28, 1999. Is this degree acceptable as meeting the alternative initial requirement?

Yes. The degree would be acceptable as meeting part of the initial qualifications. ^+The physicist would need to document the degree in a way that also identifies the field of study. If the degree is in physics, FDA assumes that the physicist has earned at least 10 semester hours of physics without requiring further documentation. However, if the degree is in one of the other physical science fields, the physicist has to provide documentation showing that he or she has at least 10 semester hours of physics.^- The physicist *+~~would~~*- also need^+s^- to document that he or she has the experience of conducting surveys on at least 20 mammography units and one complete facility survey (including the evaluation of technologist quality control records). In addition, the physicist must have 40 contact hours of documented specialized training in conducting surveys of mammography facilities.

Question 2: A State-approved medical physicist *+~~and~~*- has been conducting medical physicist surveys under the interim regulations. He or she has well over 40 contact hours of documented specialized training in conducting surveys of mammography facilities and has performed dozens of facility surveys. However, the physicist does not have a physical science degree and will obtain a bachelor's degree in physics by April 28, 1999. Will his or her survey experience count?

No. The experience and survey training must be met after fulfilling the degree requirement for those physicists expecting to qualify with a bachelor's degree.

Question 8: I have a degree in a physical science obtained at a non-US institution. Is that acceptable toward meeting the degree requirement?

A degree from a non-US institution is acceptable if the physicist can provide information showing that his or her foreign degree is accepted by an accredited US institution, the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by one of the professional certifying bodies approved by FDA. *+~~In cases where acceptance of a foreign degree by either an accredited US institution or by one of the FDA-approved professional certifying bodies can not be provided, FDA will evaluate such degrees on a case-by-case basis.~~*-

Medical Physicist Continuing Education

Citation:

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

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

Copies of certificates earned or other documentation from the training provider will suffice for the continuing education qualification. FDA will continue to accept a limited form of attestation for CME received after October 1, 1994, in certain cases.

Any of the following options may be used to determine if the continuing education requirement has been met:

Option 1: The inspector counts back 36 months from the date of the inspection and includes all applicable continuing education credits received by each individual during that 36-month period. For example, if the inspection is conducted on November 10, 1999, the relevant continuing education credits for each person would be those earned from November 10, 1996, to November 10, 1999.

Option 2. The inspector counts back 36 months from the end of the full calendar quarter immediately preceding the inspection date and includes all applicable continuing education credits received by each individual during that 36-month period. For the inspection date of November 10, 1999, the relevant continuing education credits for each person would be those earned from October 1, 1996, through September 30, 1999.

Option 3: Additionally, if the facility so chooses, inspectors may also count back 36 months from any date between the inspection date and the end of the previous full calendar quarter, and count the applicable continuing education received by

each individual during that period towards meeting the continuing education requirement.
FDA recommends that the facility try to consistently use the same option for all personnel providing services to it. However, this is not required.

Medical physicists may receive credit for presenting courses/lectures and/or reading/writing articles/papers for journals as long as the articles/papers and the courses/lectures pertain to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography. FDA has no way of determining the proper amount of credit to give for any individual article/paper or course/lecture. However, an organization authorized to award credit can assess and document the appropriate amount of CME/CEU awarded. The medical physicist must get a letter or other documentation from the authorized organization stating how many CME/CEU's are awarded and the date the credit was given. FDA would then accept the amount awarded toward the continuing education requirement.

Question 1. ^+How is an individual's starting date for beginning to meet the MQSA continuing requirements determined?^- *+~~Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?*~~

+~~Yes, the~~- ^+The^- date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

For continuing experience for medical physicists and radiologic technologists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians is either October 1, 1994 or the date on which someone initially qualifies, whichever is later.

Question 2: Does the ^+starting^- date *+~~on which personnel initially qualify to work independently~~*- ever change due to personnel taking time off after they qualify or if they re-qualify when they are found to be deficient for either continuing experience or continuing education?

No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 3: Are there specific areas that are acceptable for continuing medical education *+~~and others that are not acceptable~~*-?

Except for credits in each mammographic modality used, FDA does not require specific subject areas for continuing medical education. All continuing education units related to the diagnosis or treatment of breast disease or to other areas that will aid facility personnel in improving the quality of mammography, may be acceptable toward meeting the continuing education requirement. ^+Because of the external pressures affecting mammography facilities that have caused facility closures and a decrease in the number of personnel performing mammography, topics such as medical malpractice and mammography billing and reimbursement are becoming increasingly important to the continued viability of many mammography facilities. Because of this, CME/CEU mammography training that addresses these areas may be accepted toward meeting the MQSA CME/CEU requirement. However, the number of hours devoted to these topics should not constitute a majority of the 15 hour requirement.^-

Question 5: Under the *+~~final~~*- regulations, if less than 36 months have passed since a medical physicist^+'s starting date^- *+~~initially qualified to work independently~~*-, will he/she still be evaluated for continuing education during an inspection? *+~~What about continuing medical education if less than 36 months have passed since initial qualification?*-~~

If less than 36 months have passed since the medical physicist^+'s starting date^- *+~~initially qualified~~*-, insufficient time has passed to cite the facility during an inspection for any failure of these personnel to meet the continuing education requirements. However, inspectors will try to draw the attention of facilities to situations in which it appears the medical physicist will not be likely to fulfill the continuing education requirement in a timely manner.

Question 7: If medical physicists do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including those personnel who have left the facility but returned later, to provide mammography services?

Medical physicists who have not worked in mammography for two years or more after meeting the initial requirements *+~~may*-~~ need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing medical education (CME) requirements. While under direct supervision, these personnel *+~~should~~*- ^+must^- obtain the necessary continuing experience and CME to requalify before resuming independent work in mammography. 21 C.F.R. 900.12(a)(3)(iv). A facility may be cited during an inspection if such personnel work without supervision prior to obtaining sufficient hours of CME and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriate requirements prior to letting them provide mammographic services independently. If these personnel are working independently and

do not have the required continuing experience and CME, the facility may be cited for these problems.

Question 8: Under FDA's interim regulations, when personnel were found deficient for not having at least 15 continuing medical education (CME) credits or units in the previous 36 months, they were given up to 90 days to obtain this training while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued *+~~after~~*-^+under^- FDA's final regulations *+~~take effect on April 28, 1999~~*-?

No^+.^- ~~*+, FDA does not intend to apply this policy after April 28, 1999. Also, any part of the 90-day period that might extend beyond April 28, 1999 will terminate on April 28, 1999.*-~~

Inspector Instructions: [DELETE AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Medical Physicist Continuing Experience

Citation:

900.12(a)(3)(iii)(B): Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(3)(i) and (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

Any of the following options may be used to determine if the medical physicist's continuing experience requirement has been met:

Option 1: The inspector counts back 24 months from the date of the inspection. For example, if the inspection is conducted on November 10, 2001, the relevant time period would be determined by counting back 24 months from November 10, 2001 to November 10, 1999. *+~~The facility may choose this option if the records for all interpreting physicians are updated to the inspection date.~~*-

Option 2: The inspector counts back 24 months from the end of the previous full calendar quarter immediately preceding the inspection date. For the inspection

date of November 10, 2001, the relevant time period would be determined by counting back from the end of the previous calendar quarter, i.e., September 30, 2001 *+~~for the said case~~*- to October 1, 1999.

Option 3: The inspector may also count 24 months from any date between the inspection date and the end of the previous full calendar quarter. This could be the case if the facility's records are updated to such a date, i.e., between September 30, 2001 and November 10, 2001, in the above example.
FDA recommends that the facility try to consistently use the same dating option for all personnel providing services to it. However, this is not required.

It is important for medical physicists who perform surveys at multiple facilities to update all facilities on the number of surveys performed at other sites to ensure that their recorded experience is complete and accurate.

Question 1: ^+How is an individual's starting date for beginning to meet the MQSA continuing requirements determined?^- *+~~Is the date when a medical physicist must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does he/she determine this date and why is this so important?*-~~

^+The date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys).^- *+~~Yes, the date a medical physicist must begin meeting the continuing experience and continuing education requirements is the date on which he/she completed all of the initial requirements and are allowed to practice independently at mammography facilities or conducting medical physicist surveys.~~*- This is used as the starting date for evaluating continuing experience and continuing education requirements.

For continuing experience for medical physicists and radiologic technologists, this date is April 28, 1999 (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

Question 2: Does the ^+starting^- date *+~~on which personnel initially qualify to work independently*-~~ ever change due to personnel taking time off after they qualify or if they requalify when they are found to be deficient for either continuing experience or continuing education?

No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the

requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 3: Under the *+~~final~~*- regulations, if less than 24 months have passed since a medical physicist^+'s starting date^- *+~~initially qualified to work independently~~*-, will he/she still be evaluated for continuing experience during an inspection?

If less than 24 months have passed since the medical physicist initially qualified, insufficient time has passed to cite the facility during an inspection for any failure of the physicist to meet the continuing experience requirements. However, inspectors will try to draw the attention of facilities to situations in which it appears that personnel will not be likely to fulfill continuing experience requirements in a timely manner.

Question 5: If medical physicists do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

Medical physicists who have not worked in mammography for two years or more after meeting the initial requirements *+~~may~~*- need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing medical education (CME) requirements. While under direct supervision, these personnel *+~~should*-~~ ^+must^-obtain the necessary continuing experience and CME to requalify before resuming independent work in mammography. 21 C.F.R. 900.12(a)(3)(iv).A facility may be cited during an inspection if such personnel work without supervision prior to obtaining sufficient hours of CME and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriate requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME, the facility may be cited for these problems.

~~*+Question 7: When is the earliest a facility can be cited for using a medical physicist who has failed to meet the continuing experience requirement? When does a medical physicist need to start keeping records documenting this requirement?~~

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

~~The medical physicist could begin keeping records documenting the continuing experience from June 30, 1999 or the date he or she completed the initial requirements, whichever is later. However, FDA recommends that physicists currently in the field or their facilities begin keeping these records even before June 30, 1999. This will allow time to "work the bugs" out of their recording system and/or to identify situations in~~

~~which workloads may have to be adjusted to meet the requirement before FDA begins citing facilities for failure to meet the requirement.*-~~

Question *+~~10~~*- ^+9^-: Under the interim regulations, physicians could not count interventional mammographic examinations toward the initial or continuing experience requirements. Will this same policy be extended to medical physicists under the final regulations?

Yes. Because interventional mammography is currently excluded from MQSA regulations, surveys of interventional mammographic facilities or units *+~~can not~~*-^+cannot^- count toward the initial or continuing experience requirements. 21 C.F.R. 900.2(aa)(1).

Inspector Instructions: [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Medical Physicist Degree

Citation:

900.12(a)(3)(i)(B)(1): Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g. 30 quarter hours) of college undergraduate or graduate level physics.

Discussion:

Question 3: I have a degree in a physical science obtained at a non-US institution. Is that acceptable toward meeting the requirement?

A degree from a non-US institution is acceptable if the physicist can provide information showing that his or her foreign degree is accepted by an accredited US institution, the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by one of the professional certifying bodies approved by FDA. *+~~In cases where acceptance of a foreign degree by either an accredited US institution or by one of the FDA-approved professional certifying bodies can not be provided, FDA will evaluate such degrees on a case-by-case basis.~~*-

Medical Physicist Initial Experience

Citation:

900.12(a)(3)(i)(B)(3): Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section.

Discussion:

Question 7: Under the interim regulations, physicians could not count interventional mammographic examinations toward the initial or continuing experience requirements. Will this same policy be extended to medical physicists under the final regulations?

Yes. Because interventional mammography is currently excluded from MQSA regulations, surveys of interventional mammographic facilities or units *+~~can not~~*- ^+cannot^- count toward the initial or continuing experience requirements.

Medical Physicist Initial Training

Citation:

900.12(a)(3)(i)(B)(2): Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.

Discussion:

Medical Physicist New Mammographic Modality Training

Citation:

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

Discussion:

Copies of certificates earned or other documentation from the training provider will suffice for the new mammographic modality training. ^+FDA will continue to accept a limited form of attestation for CME received after October 1, 1994, in certain cases. (see Attestation - Acceptable Uses for Personnel Requirements)^-

Question 1: What are examples of *+~~new~~*- mammographic modalities? What types of training would be acceptable as training in new mammographic modalities?

The term mammographic modality refers to a technology for radiography of the breast. 21 C.F.R. 900.2(z). Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is ^+full field^- digital mammography ^+(FFDM)^-. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in ^+FFDM^- *+~~digital mammography~~*-, if they are to begin providing services or interpretations using this ^+mammographic^- modality after April 28, 1999. However, if those personnel ^+gained their experience using investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution)^- *+~~started using this modality before April 28, 1999~~*-, they are considered to have met the 8 hour requirement.

New ^+mammographic^- modality training can be in many forms, including, but not limited to, graduate training, special training courses, continuing medical education, and training provided by the manufacturer.

Question 2: Some personnel may receive some training in full-field digital mammography as part of their initial qualifications. In addition to counting toward their initial requirements, can this training also be applied to the 8-hour *+~~new~~*- ^+mammographic^-modality training requirement?

Yes. They may use this training in digital mammography to count toward the 8-hour *+~~new~~*- ^+mammographic^- modality training.

Question 3: Some personnel may receive continuing medical education (CME) in full-field digital mammography as part of the CME requirement. Can they also use this toward meeting the initial 8-hour *+~~new~~*- ^+mammographic^-modality training requirement?

Yes. They may use this CME in full-field digital mammography to count toward the 8-hour *+~~new~~*- ^+mammographic^- modality training.

Question 4: ^+Can experience obtained using investigational Full Field Digital Mammography (FFDM) units count toward the 8 hour mammographic modality training requirement?^- *+~~Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the medical physicist began providing services for FFDM units?*-~~

Yes. Medical physicists who began testing and performance evaluations of ^+investigational^-FFDM units ^+(units that were used for research purposes before being approved by FDA for commercial distribution)^- *+~~before April 28, 1999, the effective date of the final regulations~~*-, are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these medical physicists must either attest to or document that they were providing such services. Attestation should be done using an FDA attestation form (or equivalent) indicating where and when the FFDM testing and performance evaluations were performed. An example of acceptable documentation would be a letter from an appropriate official at the facility where the work was done. For more information, see acceptable documents for medical physicists in the PGHS.

Medical physicists who begin working with ^+non-investigational^- FFDM ^+units^- after April 28, 1999 must document that they had 8 hours of training in that mammographic modality before independently surveying FFDM units. Medical physicists must document this training using the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information, see acceptable documents for medical physicists in the PGHS.

Question 8: I'm a medical physicist and received training in digital image receptors used for stereotactic biopsy. Can that training count toward the 8 hours of training specific to FFDM?

+~~No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM.~~ ^+Training received in digital image receptors used for stereotactic biopsy can count toward the 8 hours of training specific to FFDM if the training is essentially the same as that being given for FFDM. For example, if the medical physicist received training in the performance of a QC test for stereotactic digital image receptors, and the FFDM QC test is essentially the same as the stereotactic QC test, that training could count toward the 8 hours of training specific to FFDM.^-

Medical Physicist State License/Approval or Certification

Citation:

900.12(a)(3)(i)(A): Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics surveys.

Discussion:

The FDA recognizes medical physicists certified with specialties in diagnostic radiological physics, radiological physics, or diagnostic imaging physics by the following organizations:

American Board of Radiology (ABR)

American Board of Medical Physics (ABMP).

A medical physicist who is state licensed or state approved in one state is qualified to conduct surveys in any other state under MQSA. However, MQSA permits states to have more stringent requirements than the MQSA standards. If the second state has regulations, policies, guidelines, or some other means based on regulatory authority that allows it to regulate medical physicists, then, under state law, the medical physicist must meet *+~~their~~*- ^+its^-requirements in order to practice. It can require the physicist to have its approval to practice within its borders in addition to meeting one of the options under MQSA. The physicist would still be qualified under MQSA, but physicists lacking such approval *+~~would~~*- ^+could^-be cited under the state regulations.

Attestation is not acceptable for ^+State^- licenses^+, State approvals,^- or ^+board^-certification.

^+Question 2: FDA-approved medical physicist certification boards have started issuing certificates that have an expiration date. If a medical physicist allows his board certification to expire, must he or she obtain recertification to continue providing services to mammography facilities?

No. With respect to the requirement in 21 CFR 900.12(a)(3)(i)(A), FDA has always considered board certification to be an initial requirement that does not expire. FDA will accept an expired certificate as meeting this requirement.^-

Reestablishing the Medical Physicist Continuing Education Requirement

Citation:

900.12(a)(3)(iv)(A): Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows: (A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

Discussion:

Question 1: Under FDA's interim regulations, when personnel were found deficient for not having at least 15 continuing medical education (CME) credits or units in the previous 36 months, they were given up to 90 days to obtain this training while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued *+~~after~~*-^+under^- FDA's final regulations *+~~take effect on April 28, 1999~~*-?

No^+.^- ~~*+, FDA does not intend to apply this policy after April 28, 1999. Also, any part of a 90-day extension period that might have extended beyond April 28, 1999 will terminate on April 28, 1999.*-~~

Inspector Instructions: [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Reestablishing the Medical Physicist Continuing Experience Requirement

Citation:

900.12(a)(3)(iv)(B): Medical physicists who fail to meet the continuing experience requirement of paragraph (a)(3)(iii)(B) of this section shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section to bring their total surveys up to the required two facilities and six units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

Inspector Instructions: [DELETE AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Radiologic Technologist Overview

Discussion:

Under 21 C.F.R. 900.12(a)(2):

In order to independently perform mammographic examinations, one must qualify as a radiologic technologist. To do this, one must document all of the following requirements:

1. Be State licensed to perform general radiographic procedures, or have a general Certification from an FDA-approved body to perform radiologic examinations.

2. Have prior to April 28, 1999, qualified as a radiologic technologist under the interim regulations; OR completed 40 contact hours of specific training in mammography in the topics specified in the regulations, including performance of a minimum of 25 examinations under direct supervision.

3. Maintain continuing education (15 CEU's/36 months).

4. Maintain continuing experience (200 examinations/24 months).

5. Requalification: Radiologic technologists failing to maintain the continuing requirements must requalify prior to independently performing mammographic examinations.

(a) Continuing Education: Must bring total up to 15 CEU's/36 months**.**

(b) Continuing Experience: Perform a minimum of 25 mammography examinations under direct supervision.

6. Maintain a valid State license or general certification.

^+

Radiologic Technologist Qualification Worksheet	
This worksheet may be used by facilities to help ensure that their personnel meet all applicable requirements prior to providing mammography services.	
Initial Qualifications Met Before 4/28/99 (INTERIM)	Initial Qualifications Met After 4/28/99 (FINAL)
Need one of the following: ___ General radiography license (any State) ___ General certification (ARRT or ARCRT)	Need one of the following: ___ General radiography license (any State) ___ General certification (ARRT)
Need one of the following: ___ 40 hours of mammography training ___ ARRT (M) ___ CA Mammography Certification ___ AZ Mammography Certification ___ NV Mammography Certification ___ Completion of prior FDA accepted course or training (attestation allowed if training completed prior to 10/1/94)	Need all of the following: ___ 40 hours of mammography training Including the following subjects: ___ Breast Anatomy ___ Physiology ___ Positioning/Compression ___ QA/QC ___ Breast Implants ___ 25 supervised patient exams (generally up to 12.5 hours can be counted toward the 40 hours, but must be documented)
START DATE _____ (The later of 10/1/94 or date the last initial qualification was completed)	
___ 8 hours initial training in additional mammographic modality used (if applicable) DATE COMPLETED_____	
Continuing Qualifications	
All of the following: ___ 200 patient exams in the 24 months prior to the current date (applicable 24 months after start date) ___ 15 CMEs in the 36 months prior to the current date (applicable 36 months after start date)	

^-

Acceptable Documents for Radiologic Technologists

Discussion:

The table below summarizes the types of documentation that radiologic technologists may use to document their initial qualifications, as well as their continuing requirements and requalification requirements, prior to MQSA and under the interim and final regulations.

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained after 4/28/99
State Licensure	1. State license/copy with expiration date 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy with expiration date 2. Confirming letter from State licensing board 3. Pocket card/copy of license	1. State license/copy with expiration date 2. Confirming letter from State licensing board 3. Pocket card/copy of license
Board Certification (ARRT or ARCRT)	1. Original/copy of current certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate	1. Original/copy of current certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate	1. Original/copy of current certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate
Initial Training (~40 hours-interim regs) (40 hours-25 supervised exams-final regs)	1. Attestation 2. Letter or other document from training program 3. CEU certificates 4. Letter or other document confirming in-house or formal training 5. ARRT(M) Mammography certificate 6. California Mammography certificate 7. Arizona Mammography certificate 8. Nevada Mammography certificate	1. Letter or other document from training program 2. CEU certificates 3. Letter or other document confirming in-house or formal training 4. Approved RT training courses 5. ARRT(M) Mammography certificate 6. California Mammography certificate 7. Arizona Mammography certificate 8. Nevada Mammography certificate	1. Letter or other document from training program 2. CEU certificates 3. Letter or other document confirming in-house or formal training 4. ^+ARRT(M) Mammography certificate but only if issued after 1/1/01 5. Certain State issued Mammography certificate(s)-facilities need to check with their State inspectors^-
Initial Mammography Modality Specific training-8 hours-final regs	1. Attestation for training or experience with investigational units 2. Mammography Modality Specific CEU certificates 3. CEU certificates plus agenda, course outline or syllabus 4. Confirming letters from CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. Attestation for experience with investigational units 2. Mammography Modality Specific CEU certificates 3. CEU certificates plus agenda, course outline or syllabus 4. Confirming letters from CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses 6. Letter from facility where experience was obtained documenting experience in the new mammographic modality	1. ^+Attestation for experience with investigational units^- 2. Mammography Modality Specific CEU certificates 3. CEU certificates plus agenda, course outline or syllabus 4. Confirming letters from CEU granting organizations 5. Letters, certificates or other documents from manufacturers' or other formal training courses

Continuing Experience (200/24 months-final regs)	N/A	N/A	1. Letter, table, facility logs or other documentation from training program or mammography facility
Continuing Education (15 CME/36 months)	N/A	~~1.~~ *+~~CEU certificates~~ ~~2. Confirming letters from CEU granting organizations~~ ~~3. Formal training courses~~ 4. ~~Letters, certificates or other documents from manufacturers' or other formal training courses~~*-^+N/A^-	1. CEU certificates 2. Confirming letters from CEU granting organizations 3. Formal training courses 4. Letters, certificates or other documents from manufacturers' or other formal training courses
Continuing Mammographic Modality Specific Education-final regs^+(Enforcement delayed indefinitely)^-	N/A	~~1.~~ *+~~Mammography Modality Specific CEU certificates~~ ~~2. CEU certificates *+(*- plus agenda, course outline or syllabus~~ ~~3. Confirming letters from CEU granting organizations~~ 4. ~~Letters, certificates or other documents from manufacturers' or other formal training courses~~*-^+N/A^-	1. Mammography Modality Specific CEU certificates 2. CEU certificates *+(*- plus agenda, course outline or syllabus 3. Confirming letters from CEU granting organizations 4. Letters, certificates or other documents from manufacturers' or other formal training courses
Requalification-Experience–final regs–done under direct supervision	N/A	N/A	1. Letter, table, facility logs or other documentation from training program or mammography facility (done under direct supervision)
Requalification- Education	N/A	~~1.~~ *+~~CEU certificates~~ ~~2. Confirming letters from CEU granting organizations~~ ~~3. Letter or other document confirming in-house or formal training~~ 4. ~~Letters, certificates or other documents from manufacturers' or other formal training courses~~*-^+N/A^-	1. CEU certificates 2. Confirming letters from CEU granting organizations 3. Letter or other document confirming in-house or formal training 4. Letters, certificates or other documents from manufacturers' or other formal training courses

Radiologic Technologist Continuing Education

Citation:

900.12(a)(2)(iii)(A) and (C): Continuing Education Requirements:

(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter

preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

Copies of certificates earned or other documentation from the training provider will suffice for the continuing education qualification. FDA will continue to accept a limited form of attestation for CME/CEU received after October 1, 1994 in certain cases. ^+(see Attestation - Acceptable Uses for Personnel Requirements)^-

Option 1: The inspector counts back 36 months from the date of the inspection and includes all applicable continuing education credits received by each individual during that 36-month period. For example, if the inspection is conducted on November 10, 1997, the relevant continuing education credits for each person would be those earned from November 10, 1994, to November 10, 1997.

Option 2: The inspector counts back 36 months from the end of the full calendar quarter immediately preceding the inspection date and includes all applicable continuing education credits received by each individual during that 36-month period. For the inspection date of November 10, 1997, the relevant continuing education credits for each person would be those earned from October 1, 1994, through September 30, 1997.

Option 3: Additionally, if the facility so chooses, inspectors may also count back 36 months from any date between the inspection date and the end of the previous full calendar quarter, and count the applicable continuing education received by each individual during that period towards meeting the continuing education requirement.

FDA recommends that the facility try to consistently use the same option for all radiologic technologists providing services to it. However, this is not required.

Question 2: ^+How is an individual's starting date for beginning to meet the MQSA continuing requirements determined?^- *+~~Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?*~~

+~~Yes, the~~- ^+The^- date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or

conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

For continuing experience for radiologic technologists and medical physicists, this date is April 28, 1999, (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

Question 3: Does the ^+starting^- date *+~~on which personnel initially qualify to work independently~~*- ever change due to personnel taking time off after they qualify or if they re-qualify when they are found to be deficient for either continuing experience or continuing education?

No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 4: Are there specific areas that are acceptable for continuing medical education *+~~and others that are not acceptable~~*-?

Except for credits in each mammographic modality used, FDA does not require specific subject areas for continuing medical education. All continuing education units related to the diagnosis or treatment of breast disease or to other areas that will aid facility personnel in improving the quality of mammography, may be acceptable toward meeting the continuing education requirement. ^+Because of the external pressures affecting mammography facilities that have caused facility closures and a decrease in the number of personnel performing mammography, topics such as medical malpractice and mammography billing and reimbursement are becoming increasingly important to the continued viability of many mammography facilities. Because of this, CME/CEU mammography training that addresses these areas may be accepted toward meeting the MQSA CME/CEU requirement. However, the number of hours devoted to these topics should not constitute a majority of the 15 hour requirement.^-

Question 6: Under the *+~~final~~*- regulations, if less than 36 months have passed since a radiologic technologist^+'s starting date^- *+~~initially qualified to work independently~~*-, will he/she still be evaluated for continuing education during an inspection?

If less than 36 months have passed since the technologist^+'s starting date^- *+~~initially qualified~~*-, insufficient time has passed to cite the facility during an inspection for any failure of the technologist to meet the continuing education requirements. However, inspectors will try to draw the attention of facilities to situations in which it appears that

personnel will not be likely to fulfill continuing education requirements in a timely manner.

Question 8: If radiologic technologists do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

Personnel who have not worked in mammography for two years or more after meeting the initial requirements *+~~may~~*- need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing medical education (CME/CEU) requirements. While under direct supervision, these personnel *+~~should~~*- ^+must^- obtain the necessary continuing experience and CME/CEU to requalify before resuming independent work in mammography. 21 C.F.R. 900.12(a)(2)(iii)(D), (iv)(B). A facility may be cited during an inspection if such personnel work without supervision prior to obtaining sufficient hours of CME/CEU and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriated requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME/CEU, the facility may be cited for these problems.

Question 9: Under FDA's interim regulations, when personnel were found deficient for not having at least 15 continuing medical education (CME) credits or units in the previous 36 months, they were given up to 90 days to obtain this training while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued *+~~after~~*-^+under^- FDA's final regulations *+~~take effect on April 28, 1999~~*-?

No^+.^- ~~*+, FDA does not intend to apply this policy after April 28, 1999. Also, any part of the 90-day period that might extend beyond April 28, 1999, will terminate on April 28, 1999.*-~~

Inspector Instructions: [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Radiologic Technologist Continuing Experience

Citation:

900.12(a)(2)(iv)(A): Continuing experience requirements. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the

inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

Discussion:

^+The term "starting date" is used to describe the date on which an interpreting physician, radiographic technologist, or medical physicist has met all initial MQSA requirements and must begin to meet the continuing requirements for his or her specialty.^-

+~~Either~~- ^Any^- of the following options may be used to determine if the radiologic technologist's continuing experience requirement has been met:

Option 1: The inspector counts back 24 months from the date of the inspection. For example, if the inspection is conducted on November 10, 2001, the relevant time period would be determined by counting back 24 months from November 10, 2001 to November 10, 1999. *+~~The facility may choose this option if the records for all interpreting physicians are updated to the inspection date.~~*-

Option 2: The inspector counts back 24 months from the end of the previous full calendar quarter immediately preceding the inspection date. For the inspection date of November 10, 2001, the relevant time period would be determined by counting back from the end of the previous calendar quarter, i.e., September 30, 2001 *+~~for the said case~~*- to October 1, 1999.

Option 3: The inspector may also count 24 months from any date between the inspection date and the end of the previous full calendar quarter. This could be the case if the facility's records are updated to such a date, i.e., between September 30, 2001 and November 10, 2001, in the above example.
FDA recommends that the facility try to consistently use the same dating option for all radiologic technologists providing services to it. However, this is not required.

Documentation:

It will generally be sufficient if the technologist's file contains a letter, table, or printout from each facility at which he or she performs mammography examinations, signed by a responsible facility official. The document should state that the technologist has performed a given number of examinations at that facility in a given time period. It is assumed that these numbers are based upon more extensive records, such as facility logs, that can be reviewed if there are any questions. The facility logs themselves can then be used as documentation. Provision of summary letters, tables, or printouts will speed up the inspection and rarely will the more detailed records be requested.

FDA recommends that these numbers be provided and updated on at least a quarterly basis. Facilities that plan to use the date of inspection as the end of the 24 months may wish to update them more frequently, perhaps monthly, to minimize the effort needed at the last minute in preparing for an inspection.

Question 1: ^+How is an individual's starting date for beginning to meet the MQSA continuing requirements determined?^- *+~~Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?~~*-

+~~Yes, the~~- ^+The^- date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

For continuing experience for radiologic technologists and medical physicists, this date is April 28, 1999 (the effective date of the final regulations), or the date on which someone initially qualifies to work independently, whichever is later. The starting date for evaluating continuing experience for interpreting physicians is either October 1, 1994, or the date on which someone initially qualifies, whichever is later.

The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists is either October 1, 1994 or the date on which someone initially qualifies, whichever is later.

Question 2: Does the ^+starting^- date *+~~on which personnel initially qualify to work independently~~*- ever change due to personnel taking time off after they qualify or if they requalify when they are found to be deficient for either continuing experience or continuing education?

No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

Question 3: Under the *+~~final~~*- regulations, if less than 24 months have passed since a radiologic technologist^+'s starting date^- *+~~initially qualified to work independently~~*-, will he/she still be evaluated for continuing experience during an inspection?

If less than 24 months have passed since the technologist^+'s starting date^- *+~~initially qualified~~*-, insufficient time has passed to cite the facility during an inspection for any failure of this technologist to meet the continuing experience requirements. However, inspectors will try to draw the attention of facilities to situations in which it appears that personnel will not be likely to fulfill continuing experience requirements in a timely manner.

Question 4: If radiologic technologists do not start working directly in mammography after meeting the initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel,

including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

Personnel who have not worked in mammography for two years or more after meeting the initial requirements *+~~may~~*- need to work under direct supervision when they return to mammography, if they do not meet the continuing experience and continuing medical education (CME/CEU) requirements. While under direct supervision, these personnel *+~~should~~*- ^+must^- obtain the necessary continuing experience and CME to requalify before resuming independent work in mammography. 21 C.F.R. 900.12(a)(2)(iii)(D), (iv). A facility may be cited during an inspection if such personnel work without supervision prior to obtaining sufficient hours of CME/CEU and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriate requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME/CEU, the facility may be cited for these problems.

~~***+Question 6: When is the earliest a facility can be cited for using a radiologic technologist who has failed to meet the continuing experience requirement? When does a radiologic technologist need to start keeping records documenting this requirement?***~~

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

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

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Radiologic Technologist Mammography Specific Training

Citation:

900.12(a)(2)(ii)(A)(B) and (C): Mammography requirements. All mammographic examinations shall be performed by radiologic technologists who meet the following mammography requirements: Have, prior to April 28, 1999 qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

(B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and

(C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams.

Discussion:

Copies of certificates earned or other documentation from the training provider will suffice for initial mammography specific training. If documentation is not available, proper attestation will be acceptable for records dated up to October 1, 1994. FDA will continue to accept a limited form of attestation for CME/CEU received after October 1, 1994, in certain cases. ^+(see Attestation - Acceptable Uses for Personnel Requirements)^-

Since training does not expire, expired certificates can be accepted as documentation. For example, if a technologist earned the ARRT(M) in the past but allowed it to expire, it still counts as 24 hours towards meeting the initial training requirement. The technologist can not, however, allow her ARRT(R) to expire if she is using it to meet 900.12(a)(2)(i). Maintenance of either a state license or the ARRT(R) is necessary to show that general qualifications are being maintained.

+~~The term mammographic modality currently refers to a technology for radiography of the breast. Examples are screen-film mammography and xeromammography. An example of a new mammographic modality that may be available in the near future is digital mammography. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, this 8 hour training requirement would not apply. New modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer.~~-

^+The term mammographic modality refers to a technology for radiography of the breast. 21 C.F.R. 900.2(z). Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is full field digital mammography (FFDM). Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in FFDM, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel gained their experience using investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution), they are considered to have met the 8 hour requirement. New mammographic modality training can be in many forms, including, but not limited to, professional training, special training courses, continuing medical education, and training provided by the manufacturer.^-

Question 3: If a technologist earned the ARRT(M) in the past but allowed it to expire, can she still count it as 24 hours towards meeting the initial training requirement?

Yes, training does not expire so she can continue to use the expired ARRT(M) as meeting 24 hours of the initial training requirement. The technologist *+~~can not~~*- ^+cannot^-, however, allow her ARRT(R) to expire if she is using it to meet the license or certification requirement. Maintenance of either a state license or the ARRT(R) is necessary to show that general qualifications are being maintained.

Question 5: Under the interim regulations, FDA accepted certain specific State certificates in mammography as meeting the specific training in mammography requirement. For new technologists, will FDA continue to accept State certificates in mammography as adequate initial training under the final regulations?

To meet the final regulations, the requirements for the State certificate would have to involve at least 40 contact hours of instruction and include the performance of a minimum of 25 examinations under the direct supervision of a qualified radiologic technologist to completely meet the mammography training requirement under the final regulations. The technologist should check with the appropriate State agency to see what the State certificate covers. Also see Acceptable Documents for Radiologic Technologists for more detail.^-

+~~The technologist may count this certificate as meeting 24 hours of the 40 hour training requirement. Hence, each technologist qualifying after April 28, 1999, who has passed this examination, would need to get an additional 16 hours of training. The ARRT advanced certificate in mammography also did not include the performance of a minimum of 25 examinations under the direct supervision of a qualified radiologic technologist. The technologist would need to get this initial experience.-~~

*+~~Question 12: Can simulated examinations (person not irradiated) count toward the initial, or continuing, or requalification experience requirement?~~

~~No. Simulated examinations are not acceptable toward meeting the experience requirements. While simulations may be useful, the full experience benefit cannot be achieved without the ability to evaluate and learn from the films obtained during an actual examination.~~ *-

Radiologic Technologist New Mammographic Modality Training

Citation:

900.12(a)(2)(iii)(E): Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.

Discussion:

Question 1: What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities?

The term mammographic modality refers to a technology for radiography of the breast. 21 C.F.R. 900.2(z) Examples of long available mammographic modalities are screen-film mammography and xeromammography. An example of a relatively new mammographic modality is ^+full field^- digital mammography ^+(FFDM)^-. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in ^+FFDM^- *+~~digital mammography~~*-, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel ^+gained their experience using investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution)^- *+~~started using this modality before April 28, 1999~~*-, they are considered to have met the 8 hour requirement. ^+New mammographic modality training can be in many forms, including, but not limited to, professional training, special training courses, continuing medical education, and training provided by the manufacturer.^-

Question 2: Some personnel may receive some training in full-field digital mammography as part of their initial qualifications. In addition to counting toward their initial requirements, can this training also be applied to the eight hour *+~~new~~*- ^+mammographic^- modality training requirement?

Yes. They may use this training in digital mammography to count toward the eight hour *+~~new~~*- ^+mammographic^- modality training.

Question 3: Some personnel may receive continuing medical education in full-field digital mammography as part of the CME/CEU requirement. Can they also use this toward meeting the initial eight hour *+~~new~~*- ^+mammographic^- modality training requirement?

Yes. They may use this CME/CEU in full-field digital mammography to count toward the eight hour *+~~new~~*- ^+mammographic^- modality training.

Question 5: ^+Can experience obtained using investigational Full Field Digital Mammography (FFDM) units count toward the 8 hour mammographic modality training requirement?^- *+~~Is the applicability of the requirement for 8 hours of training in each mammographic modality used affected by when the radiologic technologist began performing examinations with FFDM units?~~*-

Yes. Radiologic technologists who began performing FFDM examinations ^+on investigational FFDM units (units that were used for research purposes before being approved by FDA for commercial distribution)^- *+~~before April 28, 1999, the effective date of the final regulations~~*-, are considered to have met the requirement for 8 hours of training with that mammographic modality. However, these radiologic technologists must either attest to or document that they were providing such services. Attestation should be

done using an FDA attestation form (or equivalent) indicating where and when the FFDM examinations were performed. An example of acceptable documentation would be a letter from an appropriate official at the facility where the examinations were performed. For more information, see acceptable documents for radiologic technologists in the PGHS.

Radiologic technologists who begin working with ^+non-investigational^- FFDM ^+units^- after April 28, 1999 must document that they had 8 hours of training in that mammographic modality before independently performing FFDM examinations. Radiologic technologists must document this training using the same methods as those used to document other training (certificates, letters from the training provider, etc.). For more information see, acceptable documents for radiologic technologists in the PGHS.

Reestablishing the Radiologic Technologist Continuing Education Requirement

Citation:

900.12(a)(2)(iii)(D): Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

Discussion:

Question 1: Under FDA's interim regulations, when personnel were found deficient for not having at least 15 continuing medical education (CME) credits or units in the previous 36 months, they were given up to 90 days to obtain this training while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued *+~~after~~*-^+under^- FDA's final regulations *+~~take effect on April 28, 1999~~*-?

No^+.^- ~~*+, FDA does not intend to apply this policy after April 28, 1999. Also, any part of a 90-day extension period that might have extended beyond April 28, 1999, will terminate on April 28, 1999.*-~~

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Reestablishing the Radiologic Technologist Continuing Experience Requirement

Citation:

900.12(a)(2)(iv)(B) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a minimum of 25 mammography examinations under the direct supervision of a

qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

Discussion:

~~*+Question 4: Can simulated examinations (person not irradiated) count toward the initial, or continuing, or requalification experience requirement?~~

~~Simulated examinations are not acceptable toward meeting the experience requirements. While simulations may be useful, the full experience benefit cannot be achieved without the ability to evaluate and learn from the films obtained during an actual examination.^-~~

Inspector Instructions: [DELETE FROM PGHS AND INCORPORATE INTO INSPECTION PROCEDURES DOCUMENT]

Annual Equipment Quality Control Tests

Citation:

900.12(e)(5): Annual quality control tests. Facilities with screen-+~~file~~*-^+film^- systems shall perform the following quality control tests at least annually.*

Discussion:

These tests and their regulatory requirements are summarized in the Summary Table of Annual Quality Control Tests below. The test results must fall within the listed action levels. Results outside these action levels indicate the need for corrective action within the time periods specified in the table.

Summary Table of Annual Quality Control Tests

^+

Test	***Final Regulation Citation***	***Regulatory Action Levels***	***Scope***	***Required documentation 900.12(d)***	***Timing of required corrective action****
AEC	*900.12(e)(5)(i)*	*O.D. exceeds the mean by more than ±0.15 (over 2-6 cm thickness range), or the phantom image density at center is less than 1.20*	*All x-ray units, 2-6 cm thickness range~~;~~ using appropriate kVp's~~).~~ - required in contact mode only. - Mag. Mode testing is required only for equipment evaluations*	*The two most recent survey reports.*	*Within 30 days of the date of the test.*
KVp	*900.12(e)(5)(ii)*	*Exceeds ±5% of indicated or selected kVp C.O.V. exceeds 0.02*	*All x-ray units at 3 kVp's – lowest measurable clinical , most frequently used clinically, and highest clinical obtainable*	"	"
Focal spot condition	*900.12(e)(5)(iii)*	*system resolution*	*All x-ray units, all clinically used target materials and focal spots Resolution measurement - Contact mode: At most used SID - Mag mode (if clinically used): At SID w/mag value closest to 1.5 - Must be done for all clinically used screen-film combinations*	"	"

HVL	*900.12(e)(5)(iv)*	*See table in regulations*	*All x-ray units, all clinically used target-filter combinations*	"	"
Air Kerma and AEC reproducibility	*900.12(e)(5)(v)*	*Reproducibility C.O.V. exceeds 0.05*	*All x-ray units*	"	"
Dose	*900.12(e)(5)(vi)*	*Exceeds 3.0 mGy (0.3 rad) per exposure*	*All x-ray units, all clinically used screen/film combinations, targets, and filters used for the standard breast.*	"	*Before any further examinations are performed using the x-ray unit ~~machine~~*
X-ray field / light field / compression device alignment	*900.12(e)(5)(vii)*	*Exceeds 2% SID at chest wall* *Paddle visible on image*	*All x-ray units, all combinations of collimators, image receptor sizes, targets, and focal spots clinically used for full-field imaging in the contact mode*	"	*Within 30 days of the date of the test*
Screen speed uniformity	*900.12(e)(5)(viii)*	*O.D. variation exceeds 0.30 from the maximum to the minimum*	*All cassettes – may be grouped by size and speed – limit holds within groups – groups must be identifiable to the technologist*	"	"
System artifacts	*900.12(e)(5)(ix)*	*Determined by physicist*	*All x-ray units and processors, all clinically used cassette sizes, focal spots & target-filter combinations. Also see approved alternative standard substituting "all targets and filters" for all "target-filter combinations"*	"	"
Radiation output	*900.12(e)(5)(x)*	*Less than 7.0 mGy/sec (800 mR/sec)*	*All x-ray units*	"	"
Automatic decompression control	*900.12(e)(5)(xi)*	*Failure of override or manual release*	*All x-ray units (if auto is provided)*	"	"
Any applicable annual new mammographic modality tests	*900.12(e)(6)*	*As specified by the equipment manufacturer*	*All x-ray units*	"	*Before any further examinations are performed*
Phantom Image	*900.12(e)(9) see (e)(2)*	*As specified by the facility's accreditation body*	*All x-ray units, all target-filter and screen-film combinations used clinically for the standard breast*	"	"

* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.^-

*+

~~***Test***~~	~~***Final Regulation Citation***~~	~~***Regulatory Action Levels***~~	~~***Required documentation***~~	~~***Timing of required corrective action****~~
~~*AEC*~~	~~*900.12(e)(5)(i)*~~	~~*O.D. exceeds the mean by more than ±0.30 (over 2-6 cm thickness range), or the phantom image density at center is less than 1.20*~~	~~*The two most recent survey reports.*~~	~~*Within 30 days of the date of the test.*~~
~~*KVp*~~	~~*900.12(e)(5)(ii)*~~	~~*Exceeds ±5% of indicated or selected kVp*~~ ~~*C.O.V. exceeds 0.02*~~	"	"

~~*Focal spot*~~	~~*900.12(e)(5)(iii)*~~	~~*See table in regulations*~~	~~"~~	~~"~~
~~*HVL*~~	~~*900.12(e)(5)(iv)*~~	~~*See table in regulations*~~	~~"~~	~~"~~
~~*Air Kerma and AEC reproducibility*~~	~~*900.12(e)(5)(v)*~~	~~*Reproducibility C.O.V. exceeds 0.05*~~	~~"~~	~~"~~
~~*Dose*~~	~~*900.12(e)(5)(vi)*~~	~~*Exceeds 3.0 mGy (0.3 rad) per exposure*~~	~~"~~	~~*Before any further examinations are performed using the x-ray machine*~~
~~*X-ray field / light field / compression device alignment*~~	~~*900.12(e)(5)(vii)*~~	~~*Exceeds 2% SID at chest wall*~~ ~~*Paddle visible on image*~~	~~"~~	~~*Within 30 days of the date of the test*~~
~~*Screen speed uniformity*~~	~~*900.12(e)(5)(viii)*~~	~~*O.D. variation exceeds 0.30 from the maximum to the minimum*~~	~~"~~	~~"~~
~~*System artifacts*~~	~~*900.12(e)(5)(ix)*~~	~~*Determined by physicist*~~	~~"~~	~~"~~
~~*Radiation output*~~	~~*900.12(e)(5)(x)*~~	~~*Less than 4.5 mGy/sec (513 mR/sec)*~~	~~"~~	~~"~~
~~*Automatic decompression control*~~	~~*900.12(e)(5)(xi)*~~	~~*Failure of override or manual release*~~	~~"~~	~~"~~
~~*Any applicable annual new modality tests*~~	~~*900.12(e)(6)*~~	~~*To Be Determined*~~	~~"~~	~~*Before any further examinations are performed*~~

~~* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.*~~

~~*+Question 2: Is uniformity of screen speed to be evaluated separately for each size or speed class of cassette or combined for all cassettes of all sizes and speed classes?~~

~~The intent of this regulation is to provide the technologist performing the examination reasonable assurance that there will be consistency and reproducibility between the images produced using the same type cassette. However, a facility may use cassettes specifically designed to be of different speeds to deal with various clinical problems. In addition, cassettes of different sizes, even from the same manufacturer, may yield different screen speeds due to differences in design and the use of different types of screens. In those cases where a facility has clearly and permanently identified groups of cassettes of different speeds, has established mammographic technique charts to compensate for the different speed cassettes, and has made these charts available to all their radiologic technologists, the facility can group these cassettes for purposes of the screen speed uniformity test. As long as the difference between the maximum and minimum optical density of all cassettes within a group does not exceed 0.30, the requirement has been met. For any group of cassettes used to image the standard breast, the facility must assure that the radiation dose does not exceed the requirement limit of 3.0 milligray (mGy).~~

Question 3: Does the condition of the focal spot have to be measured at all possible magnification values?

The facility is required to evaluate the focal spot condition only for the clinically used magnification factor as close to 1.5 as can be achieved with the system.

Question 4: What is meant by the term "focal spot condition" and how does it relate to "system resolution"?

"Focal spot condition" is a general term that was coined to serve as a heading for the section of the regulations that includes tests that yield information on the focal spot. One of these tests involves a measurement of focal spot dimensions, the other assesses the system resolution. The focal spot measurements provide information about focal spot sizes, whereas the system resolution test provides an evaluation of the performance of the entire system (focal spot measurement evaluates only one component of the system). Thus the system resolution is an outcome-based test and has a greater value in image quality evaluation. Therefore, FDA makes the system resolution test mandatory effective October 28, 2002.

The regulations do not prohibit the use of focal spot measurements in addition to the system resolution test. FDA believes if the system resolution test indicates a problem, focal spot measurements should be performed to determine if the focal spot is the cause of the problem. In many cases, the focal spot will not be the cause of the system resolution test failure, and other factors in the imaging chain will have to be evaluated to identify the actual problem.

Question 5: Where in the x-ray field should focal spot size be measured?

Under the final regulations, the FDA has provided flexibility to facilities to use procedures that best enable them to meet the requirements. Facilities should be aware that the focal spot size measurement can vary depending on where it is measured in the x-ray field. Therefore, facilities should follow the manufacturer's recommendation or physicist's judgment or any appropriate QC manual for the appropriate procedure to meet the focal spot tolerance limit listed in the regulation.

Question 6: Has FDA specified a standard method for placement of the high frequency end of the bar pattern when performing the system resolution test?

No. Facilities are free to determine the placement of the high frequency end of the bar pattern as long as the bars within the pattern remain oriented perpendicular or parallel to the anode-cathode axis.

Question 7: When measuring light field misalignment, must the misalignment at each edge be within 2% of the SID or is it the total misalignment (both edges) in either the length or width dimension that must be within 2% of the SID?

The total misalignment (both edges) in either the length or width dimension must be within 2% of the SID.

~~**Question 8: Radiation output must be measured "at any SID where the system is designed to operate." Does this mean that I must measure the output at all possible SID settings?**~~

~~Since the maximum SID setting represents the "worst case" scenario, radiation output needs to be measured only at the maximum SID setting.~~

~~**Question 9: My facility uses two distinct groups of small sized cassettes of different speed classes to image the** standard breast~~**. Must annual dose measurements be obtained for both groups of cassettes?**~~

~~Yes.*~~

***+~~Calibration of~~*- Air Kerma ^+Calibration^-**

Citation:

900.12(e)(12): Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of ±6 percent (95 percent confidence level) in the mammography energy range.

^+Compression Device Performance- Semiannual Quality Control Tests

Citation:

900.12(e)(4) (iii)(A)(B): Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(iii) Compression device performance.

(A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

Question 1: Several mammography units have initial compression devices that generate more than 45 pounds of pressure. Will they have to be replaced or modified?

Yes, these units will have to be replaced or modified to meet the regulations. The regulations require that effective October 28, 2002, the initial power drive compression must not exceed 45 pounds (200 newtons). The purpose of this requirement is to help prevent patient injury due to the use of excessive compression force. Units providing a maximum initial compression force of more than 45 pounds (200 newtons) are non-compliant after October 28, 2002. Compression forces greater than 45 pounds (200 newtons) are allowed in the fine adjustment mode.

Question 2: When I perform the semiannual compression QC test, our unit's initial power drive provides an initial compression force of 37 pounds. However, it cannot maintain that force. The force decreases to less than 25 pounds in approximately 1 second. How long does the initial power drive have to maintain a force of at least 25 pounds?

If the initial power drive is the sole means of providing compression for this mammographic unit, the unit must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations (see Question 4, Application of Compression), the unit must be repaired, modified or replaced.

If the unit also has fine adjustment control (required on all units as of October 28, 2002, 21 C.F.R. 900.12(b)(8)(i)(B)), the initial power drive must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to engage the fine adjustment control. The fine adjustment control must then maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations (see Question 4, Application of Compression, the unit must be repaired, modified or replaced.

^+Processor Performance -^- Daily QC Tests

Citation:

900.12(e)(1)(i),(ii),(iii): 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.

Question 1: *+~~Are facilities required to do daily QC on the back-up processor (general purpose or dedicated for mammography) as they do on their~~*- ^+Is an intermittently used processor (so called back-up processor) held to the same QC standards as the^-primary mammography processor?

~~*+No, they are not. However, back-up*-~~ ^+Yes. Intermittently used (so called back-up)^- processors used for mammography will be held to the same quality standards as the primary processor(s) used for mammography. It is the responsibility of the facility to assure that the processor is in control (monitored parameters are within the action limits) before processing any clinical images. One way to achieve this is to establish a baseline for any processor that might be used as a back-up for processing mammograms. Subsequently, on the day the back-up processor is needed, the daily processor QC tests should be performed prior to processing clinical images and if the test results fall outside the action limits, clinical images should not be processed until all problems have been fixed and the new test results show that the processor is in control.

^+Question 6: In which situations should facilities establish new processor operating levels?

The most warranted and common situations for a facility to establish new processor operating levels are when processor QC testing is initiated for a new processor or when a significant change is made in the processing system. Some significant changes that may necessitate the establishment of new operating levels include: change in film brand/type, change in chemical brand/type, change in replenishment rates, change in specific gravity automixer settings, change of sensitometer or densitometer, or a change in processing conditions (standard vs. extended). Replacement of chemistry (same brand/type) as part of routine preventative maintenance should not necessitate establishment of new operating levels.

Facilities should not use the establishment of new operating levels to correct problems in the processing system, but should troubleshoot and solve the problem with appropriate corrective action. FDA recommends that the facility consult with its medical physicist prior to establishing new operating levels.

Question 7: During the time a facility is establishing new operating levels (typically done by performing a five-day data plot average): A) does the facility continue to plot the data on the processor chart?; B) Is the facility exempt from having to stay within the old processor action limits during the five-day averaging period?

While establishing new operating levels (during which time the facility can continue to process mammograms), the facility must continue to perform the daily processor QC tests and should plot the data in the same manner it usually does. This may be done on the same graph as the previous data or on a different graph. In either event, this new data should be clearly identified as being derived during the establishment of the new operating levels, so that both the facility and the inspector are aware of the origins of this data. Because no operating level has yet been established, the facility is exempt from having to stay within any processor action limits during this five-day averaging period. FDA recommends that during the five-day averaging period, the facility daily perform and evaluate a phantom image as a means of monitoring image quality. Because phantom optical densities may also vary during this time period, the facility may limit its evaluation of the phantom image to the fiber/speck/mass scores. If the facility follows this recommendation and the scores fall below the minimum requirement, the facility

must cease performing mammography until the problem has been corrected.^- 21 C.F.R. 900.12(e)(8)(ii)(A).

Decompression ^+-^- Annual Quality Control Test

Citation:

900.12(e)(5)(xi)(A)(B)(C): 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.

Discussion:

Question 1: We have a DMR unit in which the automatic decompression override status is displayed only under certain conditions, does this still meet the requirement to be continuously displayed?

Yes. If the "certain conditions" referred to are:

1. ^+If the^-*+~~The~~*- automatic decompression override status displays only when compression is applied, or
2. If there are other messages displayed in addition to the override status, ^+so that^- the display of the override status will cycle with the other messages, thus override status will be interrupted briefly while the other messages are displayed (this feature is also characteristic of some other models of GE mammographic units).

+~~We have~~- ^+FDA ^- determined that these conditions satisfy the intent of the requirement, which is that there must be means to alert the operator to the status of the automatic decompression override so that he or she may change that status, if he or she wishes, before producing the mammographic images.

^+Mammography^- Equipment Evaluations

Citation:

900.12(e)(10): Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled 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.

Discussion:

^+According to Section 900.12(e)(10) of the regulations, mammography equipment evaluations must be conducted by a medical physicist for x-ray units and processors that are newly installed, have been disassembled and reassembled, or have undergone major repairs. Furthermore, such 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."

For an x-ray unit that is new to the facility, the word "applicable" refers to the following:

Performing all the annual tests listed in section (e)(5) [except (e)(5)(viii), which need not be included if no new cassettes are added], the "other modality" tests listed in (e)(6) (if applicable), the compression device performance test listed in (e)(4)(iii)(B), and the phantom image test listed in (e)(2); and

Verifying that the new x-ray unit meets the equipment standards listed in Sections (b)(1-10). These standards relate to the design aspects of the unit as provided by the manufacturer. Furthermore, if the new unit is a film-screen unit and is the first and/or the only one at the facility, then (b)(11), (b)(12), (b)(14), and (b)(15), which relate to the screen-film combination and the lighting and viewing conditions used at the facility, must also be verified.

Note: If new cassettes are also added, then the screen-film contact test listed in (e)(4)(ii) and the uniformity of screen speed listed in (e)(5)(viii) must be performed.

Note that an evaluation of the facility's QA program, including the QC tests and corrective actions taken by the facility, is not included in mammography equipment evaluations (as described in paragraphs 1 and 2 above). However, such an evaluation is always included in the annual survey. 21 C.F.R. 900.12(e)(9).

For a new processor, the "applicable" equipment evaluation tests are described in question 7 below.

Question 1: When are "*+~~additional~~*- mammography equipment evaluations" required and who must conduct the evaluations?

Whenever a new unit or processor is installed, or a unit or processor is reassembled, or major components are changed or repaired, an evaluation of the mammography unit or image processor is required. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks,

replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist.

The ^+mammography^- equipment evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. The ^+mammography^- equipment evaluation must be performed by a qualified medical physicist or by an individual under the direct supervision of the medical physicist. The evaluation will be used to determine whether the new or changed equipment meets the requirements of applicable standards in 900.12(b) and (e). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The facility must maintain (until the next inspection that verifies compliance) the report of the ^+mammography^- equipment evaluation and all documentation showing that all problems identified in the ^+mammography^- equipment evaluation were corrected before the equipment was used on patients. 21 C.F.R. 900.12(d)(2).The report should document the date(s) on which the mammography equipment evaluation was performed and who performed the evaluation.

Question 4: Can a medical physicist sign-off on *+~~an*-~~ ^+a mammography^- equipment evaluation done by a surrogate if the medical physicist was not present during the evaluation?

No. The qualified physicist would have to be present during the equipment evaluation and, at a minimum, provide direct supervision over his/her surrogate (supervisee). Direct supervision means that the supervisor (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. 21 C.F.R. 900.2(o)(2). This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the tests are completed.

The supervisor must be identified in the report. The qualifications of the supervising medical physicist will be checked during the inspection. The names of all those being supervised should also be identified in the report.

Question 5: What are the minimum tests and/or reviews that the medical physicist must perform for a facility survey, survey of a mammography unit, ^+mammography^- equipment evaluation of a unit or processor that has been installed or disassembled and reassembled, and an equipment evaluation of a unit or processor that has undergone a major repair?

Facility Survey (900.12(e)(9))	All tests as described in 900.12(e)(2), (e)(5), and, if applicable, (e)(6). Evaluate adequacy of the results of all tests conducted by the facility in accordance with 900.12(e)(1) through (e)(7)

Survey of a mammography unit (900.12(e)(9))	All tests as described in 900.12(e)(2), (e)(5) {except e(5)(viii)}, and if applicable (e)(6)
Equipment evaluation of a unit or processor that has been installed or disassembled and reassembled (900.12(e)(10))	All applicable tests and equipment requirements described in 900.12(b) and (e). ^+The decision as to what constitutes applicable tests and equipment requirements for the disassembled and reassembled unit should be made by the medical physicist.^-
Equipment evaluation of a unit or processor that has undergone a major repair (900.12(e)(10))	Only those tests and equipment requirements described in 900.12(b) and (e) that are applicable to the repaired component of the unit or processor. The decision as to what constitutes applicable tests and equipment requirements for the repaired component should be made by the medical physicist.

For more information, check additional guidance about the specific item being installed, reassembled or repaired.

Question 7: What constitutes *+~~an~~*- ^+a mammography^- equipment evaluation (what tests must the medical physicist perform) for a processor that has undergone major repairs or is a new processor to the facility?

At a minimum, the following tests must be done for a processor that has been replaced, undergone major repairs, or is a new processor to the facility: processor testing as described in 900.12(e)(1), phantom testing as described in 900.12(e)(2), and applicable portions of the system artifact evaluation as described in 900.12(e)(5)(ix). The medical physicist must also verify that the appropriate chemical solutions are being used, as described in 900.12(b)(13). If a change in clinical technique factors (for the standard breast) is involved ^+such that the dose could reasonably exceed 300 mrad (3.0 mGy),^- *+~~that could significantly increase patient dose,~~*- a determination of dose as described in 900.12(e)(5)(vi) must be done.

^+We recommend that the fixer retention test described in 900.12(e)(3)(i) be performed and, in those cases where the integrity of the darkroom has been compromised, that the darkroom fog test described in 900.12(e)(4)(i) also be performed.^-

^+Note also that these processor evaluations apply to all processors used clinically by the facility, even those at remote sites (if any).^-

Question 8: Must the ^+mammography^- equipment evaluation report be sent to the facility within 30 days?

The regulations do not specify when the ^+mammography^- equipment evaluation report must be sent to the facility. However, the facility cannot use the equipment until it has documentation (written preliminary or final equipment evaluation report) showing that the equipment passes all the appropriate tests.

Equipment Failing to Meet Requirement

Discussion:

Question 1: At the time of the inspection, a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service?

No. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients and the facility remains subject to *+~~possible~~*- citation ^+for having a mammographic unit that did not meet one or more of the requirements at the time of the inspection^-.

Focal Spot Condition^+/System Resolution – Annual Quality Control^- *+~~QC~~*- Test

Citation:

900.12(e)(5)(iii): Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

^+*900.12(e)(5)(iii)(A)(1)(2)(3)(4)(5): (A) System Resolution.*

(1) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(2) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(3) When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.

(4) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.

(5) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

900.12(e)(5)(iii)(B): Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions	
	Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

^-

Discussion:

Question 2: What is meant by the term "focal spot condition" and how does it relate to "system resolution"?

"Focal spot condition" is a general term that was coined to serve as a heading for the section of the regulations that includes tests that yield information on the focal spot. One of these tests involves a measurement of focal spot dimensions, the other assesses the system resolution. The focal spot measurements provide information about focal spot sizes, whereas the system resolution test provides an evaluation of the performance of the entire system (focal spot measurement evaluates only one component of the system). Thus the system resolution is an outcome-based test and has a greater value in image quality evaluation. Therefore, FDA ^+made^- *+~~makes~~*- the system resolution test mandatory effective October 28, 2002.

The regulations do not prohibit the use of focal spot measurements in addition to the system resolution test. FDA believes if the system resolution test indicates a problem, focal spot measurements should be performed to determine if the focal spot is the cause of the problem. In many cases, the focal spot will not be the cause of the system resolution test failure, and other factors in the imaging chain will have to be evaluated to identify the actual problem.

Question 3: Where in the x-ray field should focal spot size be measured?

Under the *+~~final~~*- regulations, the FDA has provided flexibility to facilities to use procedures that best enable them to meet the requirements. Facilities should be aware that the focal spot size measurement can vary depending on where it is measured in the x-ray field. Therefore, facilities should follow the manufacturer's recommendation or physicist's judgment or any appropriate QC manual for the appropriate procedure *+~~to meet the focal spot tolerance limit listed in the regulation~~*-.

^+**Question 4: A facility is using more than one type of screen-film combination. Must it perform the QC tests separately for each combination used?**

It depends. For the majority of the QC tests, the type of screen-film combination used in the test is irrelevant to the test outcome. However, for the following QC tests, the regulations spell out specific requirements:

1. System Resolution - must be measured for each screen-film combination used at the facility with its corresponding unit(s).
2. Phantom Image and Dose – each of these must be conducted for each screen-film combination clinically used for the standard breast. 21 C.F.R. 900.12(e)(2), 900.12(e)(5)(vi)

Note that the phantom image test applies to both the weekly QC and the annual test conducted by the medical physicist as part of the survey report. If only one combination is routinely used for the standard breast and the other combination is used for non-routine examinations of the standard breast, FDA recommends that the dose and phantom image QC tests also be conducted for the other combination, because the outcome of both tests is heavily influenced by the film-screen combination used.

Note that testing for the uniformity of screen speed must be conducted for all screens and cassettes respectively. 21 C.F.R. 900.12(e)(5)(viii). Hence, by default, it includes all types of screens used, but this does not preclude performing this test with only one type of film. System artifacts must be performed for each cassette size. 21 C.F.R. 900.12(e)(5)(ix).

Question 5: Has FDA specified a standard method for placement of the high frequency end of the bar pattern when performing the system resolution test?

No. Facilities are free to determine the placement of the high frequency end of the bar pattern as long as the bars within the pattern remain oriented perpendicular or parallel to the anode-cathode axis.^-

***+~~Focal Spot Dimension QC Test~~**

~~Citation:~~

~~900.12(e)(5)(iii)(B): Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.~~

~~Table 1~~

~~Focal Spot Tolerance Limit~~

~~Nominal Focal Spot Size (mm)~~	*~~Maximum Measured Dimensions~~*	*~~Width (mm)~~*
~~0.10~~	*~~0.15~~*	*~~0.15~~*
~~0.15~~	*~~0.23~~*	*~~0.23~~*
~~0.20~~	*~~0.30~~*	*~~0.30~~*
~~0.30~~	*~~0.45~~*	*~~0.65~~*
~~0.40~~	*~~0.60~~*	*~~0.85~~*

~~0.60~~ ~~0.90~~ ~~1.30~~
*-

~~*+Medical Physicist*-~~ Annual ^+Physics^- Survey

Citation:

900.12(e)(9)(i),(ii),(iii),(iv),(v): Surveys.

(i) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.

(ii) The results of all rests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

(iii) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

(iv) The survey report shall be sent to the facility within 30 days of the date of the survey.

(v) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

Discussion:

Question 5: When performing a physics survey or ^+mammography^- equipment evaluation on a unit with multiple target/filter combinations, what tests or measurements must be performed for each combination?

For a unit with multiple target/filter combinations, the following tests must be performed for each clinically used target/filter combination:

- Focal spot condition (for different target materials (tracks) only) (21 C.F.R. 900.12(e)(5)(iii)(A)(3)
- X-ray field/light field/image receptor/compression paddle alignment (for different target materials (tracks) only) (21 C.F.R. 900.12(e)(5)(vii))
- Beam quality and half-value layer (21 C.F.R. 900.12(e)(5)(iv) and (vi))
- *+~~Automatic exposure control performance~~*-
- System artifacts (21 C.F.R. 900.12(e)(5)(ix)) ^+Also see Approved Alternative Standards^-

Question 7: *+~~Under the interim regulations,~~*- ^+Does^- FDA allow*+~~ed~~*- some flexibility with respect to scheduling physics surveys*+~~. Will this continue under the final regulations~~*-?

Yes. While the medical physics survey must be performed annually, FDA realizes that surveys cannot usually be scheduled exactly on the anniversary date of the previous survey. Therefore an occasional period of up to 14 months between surveys is acceptable. Facilities may choose, however, to have the physics surveys performed at higher frequencies (shorter intervals) during any annual cycle.

~~*+Question 9: Will physics surveys performed before 4/28/99 but inspected after 4/28/99 be evaluated against the standards of the final regulations?~~

~~No. Physics surveys performed under the interim regulations (before April 28, 1999) will be evaluated against the standards of the interim regulations even if the facility is inspected after April 28, 1999.*~~

Mobile Units Equipment Quality Control

Citation:

900.12(e)(7): Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

Discussion:

Question 3: How does a facility demonstrate satisfactory performance for mobile units after they are moved to a new location?

For those facilities with mobile units, each mammography unit must be tested after moving to a new examination location and before examining any patients to verify the adequacy of the image quality produced by each unit.

As an example of an acceptable test, a phantom image can be taken in the AEC mode (or the mode used clinically) after the move but prior to patient examination. This image is then either processed and evaluated at the mobile unit site (if possible), or processed off-site and evaluated to verify performance prior to examining patients. A passing ^+object^- score for this phantom image *+~~verifies~~*- ^+will be accepted as evidence^- that the unit is performing adequately after *+~~moving~~*-^+the move^- and before patient examination.

Another example^+, for use when processing is not immediately available,^- is to (1) for a given kVp, record the mAs resulting from a phantom exposure (in the AEC mode under typical clinical conditions or the mode used clinically); (2) compare that mAs to a standard mAs value previously established as ensuring output consistency; and (3) if the two readings are within +/- 10%, proceed with clinical examinations; otherwise take

corrective actions to bring the two values within this limit before proceeding with clinical examinations. A crucial follow-up to this test by the facility is to process (using a processor in control) and score ^+the objects in^- the phantom image taken in step (1) at the earliest time available and before batch processing any of the clinical images. If this phantom ^+image score^- fails because of any processing problems, the problems should be corrected prior to processing any of the clinical images. If the phantom image ^+score^- fails due to a non-processor problem, the mobile facility should still process all the films. Each clinical exam should be evaluated individually to determine whether any of the patients have to be recalled to have their images repeated. The entire imaging chain must be checked and adjusted or repaired prior to further clinical use.

If the facility takes a phantom image as part of its post-move/pre-examination testing, it *+~~must~~*- ^+needs to^-document the ^+object score of the^- phantom image *+~~score~~*-. The facility *+~~must~~*- ^+needs to^-keep the written records of post-move/pre-examination tests for the last 12 months or since the last inspection, whichever is longer, and the phantom images for the last 30 days.

Other tests designed by qualified personnel (the medical physicist should be consulted) could be acceptable but may have to be evaluated by the inspector on a case-by-case basis.

Question 5: We use FDA's guidance for mobile facilities where we produce a phantom image after a move of the mobile unit and we monitor the mAs. We then process the phantom image later, prior to processing the mammograms. If we move the mobile unit more than once per week, do we also have to produce a weekly phantom image in addition to the phantom produced after each move?

If you use the mode of operation and/or technique factors used clinically for a standard breast for the phantom images that you produce after each move, you do not have to perform an additional weekly phantom image. ^+However, the image used for the weekly phantom test must be evaluated for all required density measurements in addition to the object scores. 21 C.F.R. 900.12(e)(2).^-

Other Modalities Quality Control Tests

Citation:

900.12(e)(6): Quality Control tests — other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

Discussion:

Question 1: What are the required quality control tests for new mammographic modalities?

Mammography systems with image receptor modalities other than screen-film must undergo periodic quality control tests following procedures that are recommended by the

manufacturer of the mammographic modality. As is the case for screen-film QC, the facility must keep records of these tests and all applicable corrective actions for the longer of: last 12 months or since the last annual inspection which verifies compliance, or until the test has been done two additional times at the required frequency. 21 C.F.R. 900.12(d)(2). Regardless of the mammographic modality, the mean glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom must not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. 21 C.F.R. 900.12(e)(5)(vi). If the test results exceed the action level, corrective action must be taken within ^+the required^- time frames *+~~as specified in Table 2 (where applicable) or as recommended by the manufacturer (for the new mammographic modality tests)~~*-. 21 C.F.R. 900.12(e)(8).

Quality Control Tests Other Than Annual

Applicable Citations:

900.12(e)(1)(i),(ii),(iii): 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.

900.12(e)(2)(i),(ii),(iii),(iv): 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 900.3(d) or 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.

900.12(e)(3)(i),(ii): Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(i) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(ii) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed

900.12(e)(4)(i),(ii),(iii)(A)(B): Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(I) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

(iii) Compression device performance.

(A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

Discussion:

^+Question 3: We perform a required quality assurance test more frequently than stated in the regulations. If the results of this test lie outside the regulatory action limits, must we take corrective actions based on this test or can we wait until the test is repeated at its regularly scheduled time?

Regardless of when it is performed, if the facility documents that the results of a required quality assurance test lie outside the regulatory action limit, the facility must take the appropriate corrective action(s) within the specified regulatory time frame.^- 21 C.F.R. 900.12(e)(8).

Question *+~~3~~*-^+4^-: Under the final regulations, must facilities chart the data for quality control tests, such as processor sensitometry or phantom image evaluation?

No. While facilities are required to keep records for the required QC tests, facilities are not required to record the data on charts or graphs. 21 C.F.R. 900.12(d)(2).However, we believe that charting/graphing of these test data provides a valuable tool for the facility to monitor trends associated with the data and to take corrective action prior to equipment performance exceeding regulatory action limits. The use of charts/graphs will also serve to expedite the inspection process *+~~resulting in significant savings in facility time and resources~~*-.

^+Repeat Analysis and Fixer Retention-^- Quarterly Equipment Quality Control Tests

Citation:

900.12(e)(3)(i),(ii): Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(i) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(ii) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

Discussion:

^+**Question 2: How long must we maintain the actual films from the repeat analysis?**

Because of the various types of films that may be included in a repeat/reject analysis and the various ways that facilities determine which films go into the analysis, the answer depends on the specifics of the situation. The following points cover the major possibilities.

1. Films that are included in the repeat/reject analysis but were considered by the interpreting physician (IP) to be necessary to interpret the study are considered part of the original mammogram and MUST be maintained for 5/10 years as required in the regulations and the law. 21 C.F.R. 900.12(c)(4)(i). For example, suppose a Rt. MLO film was sub-optimal but contained diagnostic information that was used by the IP to interpret the study. If the IP wanted that film included in the repeat/reject analysis, he or she could do so, but because this Rt. MLO was necessary for the interpretation, it would have to remain with the rest of the study and MUST be kept for 5/10 years. This would be the case even if the facility had done a second Rt. MLO.

2. If, however, the Rt. MLO was sub-optimal and was not considered to contain any additional diagnostic information over what the repeat Rt. MLO did, then the first Rt. MLO would not have to be considered necessary to interpret the study. In that case, the first Rt. MLO should be included in the repeat/reject analysis but would NOT have to be kept for 5/10 years. Once it was included in the repeat/reject analysis, the actual film could be discarded.

3. QC films that are included as part of the analysis (e.g., daily processor and weekly phantom), are still governed by applicable regulation and those films that were a necessary part of the QC test should be kept according to the guidance regarding these films (last 30 days for the daily processor QC and the last 12 weeks for the weekly phantom QC).

4. The written records of the repeat/reject analysis (not necessarily the actual films) MUST be kept as required by the regulations "until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer."^- 21 C.F.R. 900.12(d)(2).

Radiation Output ^+-^- Annual Quality Control Test

Citation:

900.12(e)(5)(x)(A)(B): Radiation output.

(A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

Discussion:

Question 2: Radiation output is to be measured over a 3 second period. Can exposures of less than 3 seconds meet the requirement as long as the total output meets the requirement?

Yes. The intent of this regulation is to ensure that all mammography units have the capability of achieving the proper film exposure level without excessively long exposure times. Units that are capable of producing at least *+~~13.5~~*- ^+21.0^- mGy air kerma (*+~~1539~~*- ^+2400^- mR) within a 3 second period or less meet the requirement. *+~~After October 28, 2002, units must be capable of producing at least 21 mGy air kerma (2400 mR) within a 3 second period or less.~~^-

^+Darkroom Fog^- Semiannual Equipment Quality Control Tests

Citation:

900.12(e)(4)(i),(ii),(iii)(A)(B): Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

~~+(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.~~*

~~(iii) Compression device performance.~~

~~(A) A compression force of at least 111 newtons (25 pounds) shall be provided.~~

*(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).**

Discussion:

Question 1: What optical density (or range) should the facility use for the screen-film contact test and what is the criteria for determining pass or fail for a cassette?

The final regulations do not specify an optical density, range, or a pass-fail criteria because there has not been a consensus of expert opinion on these. If a facility follows the same criteria as in the interim regulations, namely a range of 0.70 to 0.80 for the density and fails a cassette for any poor contact area exceeding one centimeter, it would be acceptable. However, this does not preclude the facility from using other appropriate criteria.

Question 2: I have been following the ACR manual and have used an optical density range of 0.7-0.8 when doing my screen-film contact test. The film manufacturer recommends that I use a higher optical density. What should I use under the final regulations?

The final regulations do not reference a specific manual giving facilities flexibility to use procedures that best enable them to meet the requirements. In this specific case, the facility may follow the manufacturer's recommendation, their medical physicist's recommendation, or an appropriate manual in performing the screen-film contact test or any other QC test.

Question 3: Must the screen-film contact and uniformity of screen speed tests be performed on new cassettes prior to clinical use and must the medical physicist perform the tests?

The screen-film contact and uniformity of screen speed tests must be performed on new cassettes prior to clinical use. Because the screen-film contact test is a semi-annual QC test, the QC technologist may perform this test. The uniformity of screen speed test is part of the annual physicist's survey and, in that context, must be performed by the medical physicist. However, in the context of cassettes being added during the course of the year (between annual physics surveys), the QC technologist (or someone with adequate training designated by the QC technologist) can perform this test in consultation with the medical physicist. The facility is reminded, however, that if the newly acquired cassette(s) are used to image the standard breast and are of a significantly slower speed from the existing group of cassettes, a mean glandular dose measurement must be performed for the new group of cassette(s). In such a case, the medical physicist must perform this dose measurement test before this group of cassettes is used on patients.

Question 4: What compression device performance requirements are in effect prior to October 28, 2002?

Until October 28, 2002, the only requirements regarding compression device performance are that it be provided and that it be capable of generating at least 25 pounds

of pressure. The pressure can be generated using manual or power drive or a combination of both.

Question 5: Several mammography units have initial compression devices that generate more than 45 pounds of pressure. Will they have to be replaced or modified after October 28, 2002?

Yes, these units will have to be replaced or modified to meet the regulations. The regulations require that effective October 28, 2002, the initial power drive compression must not exceed 45 pounds (200 newtons). The purpose of this requirement is to help prevent patient injury due to the inappropriate use of excessive compression force. Units providing a maximum initial compression force of more than 45 pounds (200 newtons) will be non-compliant after October 28, 2002. Compression forces greater than 45 pounds (200 newtons) are allowed in the fine adjustment mode.*-

Question *+6*-^+1^-: We are a mobile facility with a van that does not have on-board processing. We have a film-changing room on the van where we load and unload cassettes with film during the day. When the van returns to our main office, we batch process the films. Do we have to perform a semiannual test for darkroom fog in this film-changing room?

Yes. Since you use a room to load and unload cassettes with film, you must test this room for darkroom fog as well as the darkroom for your processor. Both rooms have the potential to fog films and degrade image quality.

***+Question 7: When I perform the semiannual compression QC test, our unit's initial power drive provides an initial compression force of 37 pounds, however, it cannot maintain that force. The force decreases to less than 25 pounds in approximately 1 second. How long does the initial power drive have to maintain a force of at least 25 pounds?**

If the initial power drive is the sole means of providing compression for this mammographic unit, the unit must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses compression force during clinical examinations (see Question 4, Application of Compression), the unit must be repaired, modified or replaced.

If the unit also has fine adjustment control (required on all units as of October 28, 2002), the initial power drive must maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to engage the fine adjustment control. The fine adjustment control must then maintain a compression force of at least 25 pounds for the length of time it usually takes the radiologic technologist to complete an average exposure. If, during the semiannual compression QC test, the unit cannot maintain a force of at least 25 pounds for the specified timeframe, it fails the test and must be repaired, modified or replaced. If the unit passes this test, but still loses

~~compression force during clinical examinations (see Question 4, Application of Compression), the unit must be repaired, modified or replaced.*~~

Screen Film Contact- Semiannual Quality Control Tests

Citation:

900.12(e)(4)(ii): Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(ii)Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

Question 1: What optical density (or range) should the facility use for the screen-film contact test and what is the criteria for determining pass or fail for a cassette?

The final regulations do not specify an optical density, range, or a pass-fail criteria because there has not been a consensus of expert opinion on these items. If a facility follows the same criteria as in the interim regulations, namely a range of 0.70 to 0.80 for the density and fails a cassette for any poor contact area exceeding one centimeter, it would be acceptable. However, this does not preclude the facility from using other appropriate criteria.

Question 2: I have been following the ACR manual and have used an optical density range of 0.7-0.8 when doing my screen-film contact test. The film manufacturer recommends that I use a higher optical density. What should I use under the regulations?

The regulations do not reference a specific manual thereby giving facilities flexibility to use procedures that best enable them to meet the requirements. In this specific case, the facility may follow the manufacturer's recommendation, its medical physicist's recommendation, or an appropriate manual in performing the screen-film contact test or any other QC test.

Question 3: Must the screen-film contact and uniformity of screen speed tests be performed on new cassettes prior to clinical use and must the medical physicist perform the tests?

The screen-film contact and uniformity of screen speed tests must be performed on new cassettes prior to clinical use. 21 C.F.R. 900.12(e)(10) Because the screen-film contact test is a semi-annual QC test, the QC technologist may perform this test. The uniformity of screen speed test, including the screen artifact test, is part of the annual physicist's survey and, in that context, must be performed by the medical physicist. 21 C.F.R. 900.12(e)(5)(viii), (e)(9). However, in the context of cassettes being added during the course of the year (between annual physics surveys), the QC technologist (or someone with adequate training designated by the QC technologist) can perform this test in consultation with the medical physicist. However, in all cases where the newly acquired cassette(s) are nominally of a different speed from the existing group of cassettes [e.g.,

speed class 100 (regular) for the new cassettes vs. 150 (fast) for the existing cassettes], the medical physicist should provide oversight. If these new cassettes are used to image the standard breast and require higher technique factors such that the dose could reasonably exceed 300 mrad (3.0 mGy), a mean glandular dose measurement must be performed for the new group of cassette(s). In such a case, the medical physicist must perform this dose measurement test before this group of cassettes is used on patients. 21 C.F.R. 900.12(e)(10).

***+~~System Resolution Annual Quality Control Test~~**

~~Citation:~~

~~900.12(e)(5)(iii)(A)(1)(2)(3)(4)(5): (A) System Resolution.~~

~~(1) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.~~

~~(2) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.~~

~~(3) When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.~~

~~(4) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.~~

~~(5) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.~~

~~Discussion:~~

~~Question 1: A facility is using more than one type of screen-film combination. Must it perform the QC tests separately for each combination used?~~

~~It depends. For the majority of the QC tests, the type of screen-film combination used in the test is irrelevant to the test outcome. However, for the following QC tests, the regulations spell out specific requirements:~~

~~1. System Resolution – must be measured for each screen-film combination used at the facility with its corresponding unit(s).~~

~~2. Phantom Image and Dose – each of these must be conducted for each screen-film combination clinically used for the standard breast.~~

~~Note that the phantom image test applies to both the weekly QC and the annual test conducted by the medical physicist as part of the survey report. If only one combination is routinely used for the standard breast and the other combination is used for non-routine~~

~~examinations of the standard breast, FDA recommends that the dose and phantom image QC tests also be conducted for the other combination, because the outcome of both tests is heavily influenced by the film-screen combination used.~~

~~Note that testing for the uniformity of screen speed must be conducted for all screens and cassettes respectively. Hence, by default, it includes all types of screens used, but this does not preclude performing this test with only one type of film. System artifacts must be performed for each cassette size.~~

~~Question 2: Has FDA specified a standard method for placement of the high frequency end of the bar pattern when performing the system resolution test?~~

~~No. Facilities are free to determine the placement of the high frequency end of the bar pattern as long as the bars within the pattern remain oriented perpendicular or parallel to the anode-cathode axis. *-~~

+~~Uniform~~- Screen Speed ^+Uniformity -^- Annual Quality Control Test

Citation:

900.12(e)(5)(viii): Uniformity of screen speed. Uniformity of the screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

Discussion:

Question 3: Must the screen-film contact and uniformity of screen speed tests be performed on new cassettes prior to clinical use and must the medical physicist perform the tests?

The screen-film contact and uniformity of screen speed tests must be performed on new cassettes prior to clinical use. 21 C.F.R. 900.12(e)(10). Because the screen-film contact test is a semi-annual QC test, the QC technologist may perform this test. The uniformity of screen speed test ^+, including testing for screen artifacts,^- is part of the annual physicist's survey and, in that context, must be performed by the medical physicist. 21 C.F.R. 900.12(e)(5)(viii), (e)(9). However, in the context of cassettes being added during the course of the year (between annual physics surveys), the QC technologist (or someone with adequate training designated by the QC technologist) can perform this test in consultation with the medical physicist. *+~~The facility is reminded, however, that~~*- ^+However, in all cases where^- *+~~if~~*- the newly acquired cassette(s) are ^+nominally of a different speed from the existing group of cassettes [e.g., speed class 100 (regular) for the new cassettes vs. 150 (fast) for the existing cassettes], the medical physicist should provide oversight. If these new cassettes are^- used to image the standard breast and ^+require higher technique factors such that the dose could reasonably exceed 300 mrad (3.0 mGy),^- *+~~are of a significantly slower speed from the existing group of cassettes,~~*- a mean glandular dose measurement must be performed for the new group of cassette(s). In such a case, the medical physicist must perform this dose measurement test before this group of cassettes is used on patients. 21 C.F.R. 900.12(e)(10).

Use of Test Results

Citation:

900.12(e)(8)(i),(ii)(A)(B): Use of test results.

(i) After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

(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)(ii), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;

(B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

Discussion:

^+For tests done as part the facility's quality assurance program, the following identify the time requirements for correcting the failure.

Before any further examinations are performed or any films are processed using a component of the mammography system that failed:

The processor quality control test
The phantom image quality test
The darkroom fog test
The screen-film contact test
The compression device performance test
The average glandular dose test
All "other modality" tests except those that have been allowed a 30 day correction period under an approved alternative requirement
The post-move performance test of a mobile unit

Within 30 days of the test date:

The fixer retention in film test
Repeat analysis
The automatic exposure control performance test
The kilovoltage peak accuracy and reproducibility tests
The focal spot condition test
The beam quality and half value layer test
The breast entrance air kerma and AEC reproducibility tests

The X-ray field/light field/image receptor/compression paddle alignment tests
The uniformity of screen speed test
The system artifacts test
The radiation output test
The automatic decompression capability test

The above information applies to the tests done as part the facility's quality assurance program. The situation is different if the test is done as part of an MEE. In that case 21 CFR 900.12(e)(10) requires that all problems must be corrected before the new or changed equipment is put into service for examinations or film processing. No 30 day alternative is provided for failures of any tests that are part of the MEE.^-

^+**Question 3: What is the facility required to do if a test result falls outside the limits defined in the regulations?**

The test results must fall within the listed acceptable limits in order to continue normal operations. Results outside these limits indicate the need for corrective action. This action depends on the test and does not necessarily mean that facilities have to cease examining patients. Specifically, facilities must not process mammograms when the processor parameters fall outside operating limits. Also, they must not use x-ray units when either the parameters that monitor phantom image QC or the compression force on the x-ray unit fall outside action limits. Likewise, facilities must not use a darkroom when the fog level exceeds the limit in that room, nor use cassettes that fail the screen-film contact test. In the case of darkroom fog, if the source of the fog is determined to be due to a safelight, then films can be processed with that safelight off until such time as the safelight problem has been corrected and the darkroom passes the fog test. With all other test failures, the equipment may continue to be used before corrective actions are performed but such actions must be carried out within 30 days of the test. **See #Summary Table of Quality Control Tests Other Than Annual.**

Question 4: We perform a required quality assurance test more frequently than stated in the regulations. If the results of this test lie outside the regulatory action limits, must we take corrective actions based on this test or can we wait until the test is repeated at its regularly scheduled time?

Regardless of when it is performed, if the facility documents that the results of a required quality assurance test lie outside the regulatory action limit, the facility must take the appropriate corrective action(s) within the specified regulatory time frame.

^+Phantom Image -^- Weekly Equipment Quality Control Tests

Citation:

900.12(e)(2)(i),(ii),(iii),(iv): (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 900.3(d) or 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.

Discussion:

Question 4: Under what circumstances should I establish a new baseline optical density (OD) operating level?

A new baseline OD operating level may need to be established when switching to a new type of film or if the AEC density selector settings in the mammographic unit have been re-calibrated during servicing of the unit. Before changing operating levels, check that there isn't an underlying problem that needs to be corrected. A new level may be established if the interpreting physician(s) has/have made an intentional decision to modify background optical densities of the clinical images. For example, many facilities are choosing to increase film density to take advantage of the film's increased contrast at higher ODs. ^+(See question 8)^-

Question 6: *+~~Under the interim regulations, it was required (by referencing the ACR manual) that the "added" test object used to perform the image contrast test be placed on top of the phantom. Will this continue to be a requirement under the final regulations or could the added test object be located in some other position?*-~~ ^+Under the regulations can the "added" test object used to perform the image contrast test be placed in positions other than on top of the phantom?^-

It is the intent of the regulation that the test object be placed on top of the phantom in a consistent, and if possible, permanent location in the image area. Consistency in positioning the added test object is necessary to achieve a meaningful operating level density difference between the background of the phantom and the added test object that must not vary by more than +/- 0.05 OD of the established operating level. However, the position of the test object is not specified in the *+~~final~~*- regulations. If a facility believes it beneficial to place the "added" test object in a different position (e.g., adjacent to the phantom), it will have to assure consistent positioning of the "added" test object, as well as provide the additional x-ray attenuation needed to give a background OD equal to that of the phantom.

Question 12: If the optical density (OD) for the weekly phantom test falls below 1.20 (and/or changes by more than +/- 0.20 from the established operating level), must the unit be recalibrated or can we adjust the density setting to obtain a 1.20 OD?

If the OD at the center of the phantom image falls below the required minimum of 1.20 (and/or changes by more than +/- 0.20 from the established operating level), the facility should follow pathway A, B, or C; below, based on the situation at the facility:

A. If the film is of a different type (e.g., switch from Min-R 2000 to Min-R E) from the previous week's passing test, the facility should establish new phantom QC operating levels.

B. If the film emulsion batch is unchanged from the previous week's passing test:

1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images.
2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications.
3. If the facility has been tracking mAs, check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images. If the mAs has changed by more than 15%, and the facility has been using the same kVp, the same mammography unit density setting, and the processor is operating within its action limits, then the medical physicist should be called to check the entire imaging chain, including the mammography unit. If the mAs has not changed by more than 15%, then proceed with step 4.

If the facility has not been tracking mAs, the facility should consult with its medical physicist for what to do next.

4. If no problems are found in steps 2 and 3, adjust the density control setting to obtain an optical density of at least 1.20 at the center of the phantom image (or obtain an optical density within +/- 0.20 of the established operating level).
5. Adjust the density control setting used clinically to be consistent with the changes made in step ^+4.^-

C. If the film is of the same type but of a different emulsion batch from the previous week's passing test, the facility should follow the steps as described in B 1 through 5.

If the optical density again falls below 1.20 (and/or changes by more than +/- 0.20 from the established operating level) the next time the weekly phantom test is performed, the facility should follow the appropriate pathway (based on the film emulsion used) from the following three options:

a. If film of a different type (e.g., switch from Min-R 2000 to Min-R E) is used, the facility should establish new phantom QC operating levels.

b. If film of the same emulsion batch is used (assuming the same kVp and mammography unit density settings are used, and the processor is operating within its action limits), the facility should consult with its physicist and check the entire imaging chain before performing mammograms.

c. If film of the same type (but not of the same emulsion batch) is used, the facility should repeat steps B 1 through 5.

Question 15: We use the BACE mode in our Bennett machine to image our patients with the standard breast. In this mode the unit automatically determines the exposure technique factors based on the thickness of the compressed breast. During normal clinical use, the breast compresses and the system provides accurate thickness readings and technique factors. However, when we use this mode (as required by the regulations) for the weekly phantom test, we do not compress the phantom (to avoid damaging the paddle or the phantom) leading to inaccurate thickness readings. These inaccurate thickness readings may cause the unit to select inappropriate exposure technique factors. Can we manually adjust the scale to the thickness of the standard breast before we expose the phantom using the BACE mode? Given the situation described above, is it permissible to expose the phantom using *+~~the~~*- ^+a different^- AEC ^+mode^- (see Phantom Images Exposed in Fully Automatic Mode if that is the Clinically Used Technique), rather than the BACE mode?

You are permitted to manually adjust the scale to the thickness of the standard breast before exposing the phantom using the BACE mode. Because you do not use the AEC mode to image your patients with the standard breast, you may not use *+~~the~~*- ^+a different^- AEC mode to perform the weekly phantom test.

Question 17: What is considered adequate weekly phantom QC monitoring for a facility that has multiple processors and multiple ^+x-ray^- units?

The answer depends on whether the ^+x-ray^- units and processors are used interchangeably, whether the processors are matched (established operating levels for mid density and density difference for all processors are within 0.05 optical density), and whether each processor is operating within its own pre-established action limits.

If the processors are not matched and the facility is processing clinical films from its multiple ^+x-ray^- units interchangeably through its processors, the facility must conduct the weekly phantom image test for each ^+x-ray^- unit-processor combination. In this example, if a facility has 5 ^+x-ray^- units and 2 processors, a total of 10 phantom images must be performed each week.

If the processors are matched and the facility is processing clinical films from its multiple ^+x-ray^- units interchangeably through its processors, it is acceptable to produce a weekly phantom image from all ^+x-ray^- units and process them through any processor, as long as each processor is tested with a phantom image at least once each week of use. (Note: in this scenario each processor must be operating within its own pre-established action limits). This will reduce the number of phantom images that must be performed. In this example, if a facility has 5 ^+x-ray^- units and 2 processors, a total of 5 phantom images must be performed each week. Note: At least 1 phantom image must be processed through each processor.

Interpreting Physician Responsibilities

Citation:

900.12(d)(1)(i),(ii)(A)(B): (1) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(i) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(ii) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

(A) Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

(B) Participate in the facility's medical outcomes audit program.

Discussion:

Question 1: What are the responsibilities of the lead interpreting physician?

In general, the lead interpreting physician must ensure that the quality assurance program, including personnel assignments, all equipment quality control tests, records, and corrective actions, the annual physicist's survey, and medical audit and outcomes analysis, meet the required standards. He or she must ensure that the individuals he or she has assigned to quality assurance tasks are qualified to perform these tasks and that their performance is adequate.

Regarding medical outcome audits, he or she must either review and discuss the audit results with the other interpreting physicians or assign this task to another interpreting physician (the *+~~reviewing~~*- ^+audit^- interpreting physician). For facilities with only one interpreting physician, that person will be the lead interpreting physician.

Question 2: What are some examples of corrective actions that facilities may include in the procedures to be followed by interpreting physicians when they see images of poor quality? What constitutes participation in medical audits?

Examples of corrective actions and procedures that interpreting physicians must follow regarding poor quality images would be providing feedback to technologists and physicists on image optical density and contrast, patient motion and other artifacts, compression, technique factors, and positioning. Participation in medical audits means either being designated as the *+~~reviewing~~*- ^+audit^- interpreting physician with responsibilities for analyzing and discussing medical audit outcome data with other interpreting physicians, or discussing this data with the lead or *+~~reviewing~~*- ^+audit^- interpreting physician.

Quality Assurance Program

Citation:

900.12(d): Quality Assurance — general. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

Discussion:

Question 8: Our facility has multiple mammographic units and uses several different screen-film combinations. What QC tests are we required to perform?

The required QC tests are summarized in the following table.

Table: QC Tests* Required for Facilities Using Multiple Units & Screen-Film Combinations

Test	Units Tested	S-F Combinations Tested With Each Unit
Focal Spot Condition System Resolution ~~*+OR~~ ~~b) Focal Spot Dimensions (up to 10/28/2002)*-~~	All units**	For all S-F combinations clinically used with the unit in question. (900.12(e)(5)(iii) ~~*+For b), one S-F combination or direct exposure film.*-~~
Phantom Image	All units used to image the standard*** breast	All S-F combinations clinically used for the standard breast (900.12(e)(2))
Phantom Image	All units that are used only for non-standard breasts, and/or magnification work	One S-F combination, using clinical techniques that would be used for phantom images submitted to the accreditation body
Dose	All units used to image the standard breast	All S-F combinations clinically used for the standard breast with their corresponding techniques (900.12(e)(5)(vi)
Dose	All units that are used only for non-standard breasts, and or magnification work	One S-F combination, using clinical techniques that would be used for the standard breast
Darkroom Fog	Any unit (one only)	All film types clinically used (900.12(e)(4)(i))
Uniformity of Screen Speed	Any unit (one only)	All clinically used screens (cassettes), one film type (appropriate for cassette used). Also see guidance on grouping of cassettes (Question 1 under *+~~Uniform~~*- Screen Speed ^+Uniformity^- Annual Quality Control Test) (900.12(e)(5)(viii)).
Screen-Film Contact	Any unit (one only)	All clinically used screens (cassettes), one film type (900.12(e)(4)(ii))

AEC Performance - Reproducibility	All units	One S-F combination (typically used with the unit) (900.12(e)(5)(v))
AEC Performance – kVp & Thickness Tracking	All units used clinically in the 2-6 cm thickness range	One S-F combination (typically used with the unit) (900.12(e)(5)(i))
Collimation and System Artifacts	All units	One S-F combination (typically used with the unit) (900.12(e)(5)(ix))
kVp Accuracy & Reproducibility, HVL, Decompression, and Radiation Output	All units	None

* This table does not cover other required QC tests that are independent of the x-ray unit or screen-film combination (e.g., the daily processor QC, the fixer retention, and repeat analysis), or additional tests that are required for units with multiple targets and filters.

** In this table, "All units" refers to those that are used clinically.

*** The standard breast referenced in this table is defined in the regulations as "a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue."

Quality Assurance Records

Citation:

900.12(d)(2): Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks, are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Discussion:

Question 1: What quality assurance (QA) records must be maintained ~~*+?~~ ~~Where~~*- and for how long?

The facility must maintain quality assurance (QA) records that show:

1) Personnel Responsibilities: qualified mammography personnel assigned appropriate QA tasks
2) Technique Charts/Tables: the mammography techniques and procedures used in conducting mammograms
3) Quality Control (QC) test Records: including QC test procedures, test performance and monitoring, data analysis and timely corrective actions for each.
4) Procedures for safety and protection of patients and personnel.

These records must be maintained until the next annual inspection that would verify compliance or until an individual test has been performed two additional times at the required frequency, whichever is longer. Verifying compliance implies that if QC records for a given test were found to be deficient and the facility was cited during an annual inspection, these records must be kept until the facility corrects the problem to FDA's satisfaction. This also means that records for semi-annual tests may have to be kept longer than the period between two successive annual inspections, and records for annual tests must include the most recent two.

+~~While the test result records must be maintained as described above, the actual QC test films need to be retained for only the most recent 30 days. The actual phantom images need to be retained for only the most recent 12 weeks.~~- ^+While the test result records must be maintained as described above, FDA realizes that maintaining a large number of QC test images may be overly burdensome. Therefore the QC test images need to be retained according to the following schedule.

Images produced from daily QC tests – previous 30 days
Images produced from weekly QC tests – previous 12 weeks
Images produced from monthly QC tests – until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements
Images produced from quarterly QC tests – until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements
Images produced from semi-annual QC tests – until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer ^-

Question 5: How should facilities retain QA/QC records for equipment (film processors and/or mammographic units) that were in use for a period of time between the previous MQSA inspection and the current inspection, and have since been retired from use and replaced with new equipment?

The requirement for maintenance of QA/QC records for equipment currently being used is that these records must be maintained until the next annual inspection has been completed and ^+it is^- *+~~FDA has~~*- determined that the facility is in compliance with the requirements or until the test has been performed two additional times at the required frequency, whichever is longer. However, for film processors and/or mammographic units that are no longer at the facility, the records need only be kept for that equipment until the next annual inspection has been completed and ^+it is^- *+~~FDA has~~*- determined that the facility is in compliance with the requirements.

Quality Control Technologist Responsibilities

Citation:

900.12(d)(1)(iv): (1) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

*(iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality *+~~central~~*- ^+control^- technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.*

Discussion:

Question 2: What documentation ^+must a facility have to document that personnel, other than the QC technologist, are qualified to perform QC testing^- *+~~is needed for such actions~~*-?

Acceptable documentation of appropriate training includes facility records (if done in-house), or certificates or letters from the training organization, or formal training sessions provided to such individuals, identifying the person ^+trained,^- who gave the training, subject matter ^+covered^-, date^+(s)^-, and *+~~length~~*- ^+number of hours^- of training.

Facility Survey, Equipment Evaluations, & Medical Physicist Requirements

Discussion:

The complete text of the document, "Mammography Facility Survey, Equipment Evaluations, and Medical Physicist Qualification Requirements Under MQSA," is available on the Guidance page of FDA’s Mammography Website.

You may also obtain it by fax from the CDRH Facts on Demand at 1 800 899 0381 or 301 827 0111 using a touch tone telephone. At the first voice prompt press "1" to enter the system, at second voice prompt press "1" to obtain documents, and then enter the document number, "6409." Follow the remaining voice prompts to complete your request. Longer documents may be sent after normal business hours.

^+MQSA Inspection Procedures Document

Discussion:

The complete text of the document, "MQSA Inspection Procedures Document," is available on the Guidance page of FDA’s Mammography Website.^-