MQSA Inspection Procedures

Version 7.0

Revision 06/2015

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MQSA INSPECTION PROCEDURES

1. INTRODUCTION

This document describes the Food and Drug Administration's (FDA) facility inspection procedures under the 1992 Mammography Quality Standards Act (MQSA) final regulations. FDA published the final regulations (21 CFR 900) on October 28, 1997, with an effective date of April 28, 1999, for most requirements. Congress re-authorized the MQSA as the Mammography Quality Standards Reauthorization Act (MQSRA) in1998 and 2004. One important change in MQSRA of 1998 is clarification of the authority to inspect uncertified facilities, which is reflected in this document. Certified MQSA inspectors are to use these procedures with the MQSA inspection software Version 7.00, and laptop computer to conduct MQSA inspections.

For questions about these procedures, contact the MQSA Hotline at 1-800-838-7715. You can also fax your question(s) to 1-410-290-6351 or email FDA at MQSAhotline@hcmsllc.com (see APPENDIX 4). Also, inspectors who are on-site at a mammography facility, and in need of immediate inspection assistance, should contact the MQSA Hotline directly at the number provided above. The Hotline operator will try to immediately locate someone within DMQS to answer your call. By following this process, you can avoid excessive delays in receiving an answer to your inspection questions.

For questions regarding the inspection software, downloading and/or submitting inspections, or problems with your FDA MQSA laptop computer, contact MPRIS Computer Support via telephone at 301-796-6633 or e-mail at CDRHMQRP@CDRH.FDA.GOV. Please contact Computer Support for computer and software specific issues only. Contact the MQSA Hotline for all other MQSA matters including policy guidance, inspection procedures, and facility certification questions. .

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1.1. MQSA Training

Training and certification of MQSA inspectors is conducted by the Food and Drug Administration (FDA) Division of Mammography Quality Standards (DMQS) and the FDA regional and district offices. The national MQSA inspector certification program trains FDA and State inspectors in: basic radiation physics; the MQSA final regulations and related policies; and the MQSA inspection procedures. Training may also be provided at the FDA regional or district levels, and through electronic media.

FDA will work with each state to train a sufficient number of State inspectors such that each state can conduct the number of MQSA inspections that were agreed to in the MQSA contract between the FDA and the State.

The national MQSA inspector certification program has been approved by ASRT for 15.0 ASRT CEU Credits for MQSA Course II and 35.5 ASRT CEU Credits for MQSA Course III (No ASRT CEU Credits are awarded for MQSA Course I). Funding for other CEU training opportunities is available through the MQSA state contracts. An MQSA inspector must be certified for at least 24 months before they can receive CEU funding. CEUs earned using MQSA funding must be directly relatable to mammography and the MQSA inspection program. The training must be approved by the FDA in advance of travel to, and attendance at, a CEU course

To nominate an inspector to MQSA training, or to find out more information about the national MQSA certification course, or to discuss continuing education credits please contact your local FDA Regional Radiological Health Representative (RRHR).

1.2. FDA Issued Laptops

FDA issues a laptop to each certified MQSA inspector in a MQSA contract state, with the exception of inspectors who are identified as the back-up inspector in a given state, or states that choose to provide state owned laptops to their MQSA inspectors. FDA laptops are provided to state personnel through the MQSA contracts for the purposes of conducting MQSA inspections. FDA issued laptops remain the property of the FDA and are subject to the FDA rules and policies on IT security and inspector conduct. .

WARNING: Loading any software onto an FDA issued laptop is strictly prohibited.

A certified MQSA inspector who is identified by their state as a back-up inspector will be expected

to share an FDA issued laptop with one of the other inspectors in their state, or the back-up inspector may use a state issued laptop for the MQSA inspections. FDA will work with the State to make FISS access available via that state owned laptop. Contact MPRIS Computer Support via telephone at 301-796-6633 or e-mail to CDRHMQRP@CDRH.FDA.GOV to make arrangements to have FISS inspection software installed on a state issued laptop. In your e-mail or voice message please provide the name and contact number for state IT staff that will assist MPRIS Computer Support with the software installation.

NOTE 1: Inspectors in States-As-Certifiers programs should check with their state program managers regarding laptop issuance.

Note 2: MQSA inspectors who are FDA employees will use their ORA issued laptops to conduct MQSA inspections. The FISS inspection software must be installed on the ORA laptops before MQSA inspections can be down loaded. Please contact MPRIS Computer Support for FISS software installation.

1.2.1. Laptop Failure During an Inspection

If the computer fails during an inspection, inspectors should record the data for the inspection on a paper copy of the inspection record using the FISS 7.00 Facility Inspection Worksheet to answer all inspection questions and to document inspection findings. Once the inspector has access to a properly functioning laptop, the inspector can then enter the inspection data into FISS. Inspectors should print and mail the post-inspection report to the facility once a working laptop becomes available, or the inspector has access to the internet. To the extent possible, at the conclusion of the inspection, the inspectors should communicate to the facility any problems that were identified during the inspection. Inspectors should obtain a working computer to enter and upload the inspection data as soon as possible but no later than five working days following the inspection date. Inspectors should contact MPRIS Computer Support via telephone (301-796-6633) or e-mail to CDRHMQRP@CDRH.FDA.GOV for any problems with a laptop used to perform MQSA inspections. Conducting the inspection using a printed copy of the Facility Inspection Worksheet is preferable to canceling the inspection and having to return to the facility at a later date.

1.2.2. Preventing Theft of Laptops

Theft of portable items is on the increase all over the country, including cellular telephones and laptop computers. Often the machines are stripped and the parts are sold at local computer flea markets. The following are a few steps you can take to prevent your inspection equipment from being stolen.

- Always have your inspection equipment and FDA ID with you. Do not leave anything out in the open where it can be seen.
- Take your inspection equipment home with you. If that is not an option, lock it up someplace where you are the only person with the key.

- If you have to leave the equipment in your car, leave it in the trunk.
- Be aware of your surroundings. Are there a lot of people wandering the halls of your building? If so, lock the inspection equipment up. Are you in an open office where everyone passing through can see your equipment? If so, lock it up.
- When conducting an inspection, don't leave your equipment in a place where it can be accessed by the general public

If your laptop is stolen:

- Check if someone else may have borrowed it. Check the perimeter of the building, cabinets, etc.
- Send an e-mail to everyone in the building asking if they saw anyone hanging around or have seen the laptop. Maybe the person feels guilty about taking the laptop. Include the following escape clause in your message:

  "If the laptop is returned in the next 24 hours, no questions will be asked."
- File a police report after the laptop has been missing for 24 hours. The police will ask for the serial numbers of the laptop. It's important that you write your serial numbers down and keep them someplace separate from your laptop.
- Send a copy of the police report to:
  Division of Mammography Quality Standards (DMQS)
  Food and Drug Administration (FDA)
  10903 New Hampshire Avenue, WO66 - Rm. 4525
  Silver Spring, MD 20993-0002
  C/O Computer Support

  or fax the report to: (301) 847-8502, attention; Computer Support.

Occasionally you have to send your laptop in because it is malfunctioning. FDA cannot always send back your original laptop. Therefore, check the laptop when you receive it and verify that the serial numbers have not changed. Print the instructions provided above, and file them with your laptop serial numbers for easy reference. If you have any questions, please contact the MQSA Hotline.

1.2.3 Internet Access from the Laptop

MPRISweb and FISSweb are password protected, secure FDA websites that are accessible to all authorized users from any computer with a connection to the Internet. Section 4 of the MPRIS Rules of Behavior (found under the "User Account" menu of MPRISweb) explains in detail the rules for the use of FDA-furnished MQSA inspector laptops. These rules prohibit configuring your MQSA-furnished laptop with any additional and/or personal software for use in connecting to the internet, and state that the use of the laptop is restricted to official FDA business only. State inspector access to the Internet from FDA-provided laptops is currently available, but its use is limited to the download and submission of inspections, and access to authorized web sites, such as MPRISweb. Your laptop contains all guidance issues and inspection policies regarding MQSA.

1.3 Noting Change within a Facility

During the course of scheduling and/or performing an inspection, you may become aware of a change within a facility (i.e., name, address, ownership, or no longer providing mammography services). Inspectors should direct facility staff to notify their Accreditation Body (AB) of this change. The AB is responsible for maintaining complete and accurate information for each facility they accredit, and for electronically transferring any change(s) to FDA or the Certifying State for its use in issuing certificates and performing inspections. Inspectors should record any changed information in the Remarks Tab under the Facility Information subsection of the Facility Section of FISS (click on Address Changes button). Please include an explanation of the reason for the facility information change.

2. GENERAL INSPECTION GUIDANCE

This section provides guidance to inspectors on scheduling inspections, preparing for inspections, handling unusual situations, using the "Remarks" sections, facility grouping, and how to conduct the exit interview with the facility personnel.

2.1 Advance Notice for Inspections

FDA requires that inspectors give each facility an advance notice - at least five working days prior to the inspection. If you contact the facility by telephone, explain that you are calling to schedule the next annual MQSA inspection. Work with the facility personnel to schedule a mutually acceptable date for the inspection. Request that personnel, who are assigned to or who are familiar with the facility's mammography quality assurance program, be available during the inspection. Confirm your telephone call in writing via an Inspection Confirmation Notice (Appendix 1).

If requested, give the facility an estimate of the time it takes to complete the inspection based on your experience and past performance. You may request some information in advance, such as the facility's Employer Identification Number (EIN) or a copy of the most recent medical physicist survey report. You may also remind a facility about updating the continuing experience and continuing education records of their mammography professionals prior to the inspection.

You should fax the Inspection Confirmation Notice to the facility. Retain a copy of your fax until after you have arrived at the facility in case the facility questions the adequacy of your advance notice. If the facility does not have access to a fax machine, you should mail or e-mail it to the facility inspection contact. Also, provide a telephone number for the facility to contact you regarding any questions or concerns they might have about the inspection or the proposed date and time. For guidance regarding when to schedule routine annual facility

inspections, which type of certified facilities you should inspect first in your State, and equipment testing issues, see further details below.

2.1.1 Inspection Elements Common to Multiple Facilities

This reminder concerns the entry of information into the laptop prior to an inspection. There may be situations when you will perform inspections of facilities with different Facility ID numbers that share some common elements that you must inspect. For example, the same group of interpreting physicians may interpret mammograms at multiple facilities; and/or, the same medical physicist may perform the annual survey at multiple facilities or evaluate a piece of equipment that is shared by multiple facilities.

In these cases, for convenience to both you and the facility, enter the data into the laptop at your office prior to the actual inspection at the facility. It is important to remember that during the inspection you will still have to confirm the information you entered prior to the inspection, paying particular attention to time-sensitive items such as currency of licenses/certificates, continuing experience, continuing medical education credits, and date of current survey. Whenever possible, pre-entering such common elements into the laptop could help shorten the on-site inspection time.

NOTE: FISS requires that you enter an inspection date, under the Inspection Information subsection before you can access the other inspection questions. FISS will not accept future dates in the Date field under the Inspection Information subsection. Any information entered into FISS in advance of the on-site inspection will require the inspector edit the inspection date in FISS once you begin the on-site inspection. The official date of inspection in FISS should reflect the date of the on-site inspection, not the date of any review of records in advance of the inspection. In those rare cases where the on-site inspection takes more than one day, a printable remark should be entered under the Facility Information subsection that states the inclusive dates for the inspection.

2.1.2 Routine Annual Facility Inspections - When should a facility be inspected?

In most cases, a facility is granted a provisional MQSA certificate, after submitting a completed application for accreditation to an FDA approved accreditation body. The provisional MQSA certificate is valid for up to six months. The provisional MQSA certificate allows the facility to legally begin imaging patients and performing mammography so that the facility can acquire the clinical images needed to complete the accreditation process. If the facility completes the entire accreditation process, then the facility will receive a 3 year MQSA certificate. Newly certified MQSA facilities should be initially inspected within 10-14 months of the provisional certification date, and thereafter every 10-14 months from its most recent inspection.

For a facility that has undergone provisional reinstatement or has lost its certification for given 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 become fully accredited, and is granted a provisional reinstatement within one month following the expiration date of its 6-month 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 local FDA RRHR to discuss the scheduling of the inspection or the MQSA Hotline, at 1-800-838-7715 or MQSAhotline@hcmsllc.com, when the local RRHR is unavailable.
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 local FDA RRHR to discuss the scheduling of the inspection or the MQSA Hotline when the local RRHR is unavailable.
3. A provisionally certified facility voluntarily returns its certificate because it stops performing 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 local FDA RRHR to discuss the scheduling of the inspection or the MQSA Hotline when the local RRHR is unavailable.
4. A fully certified facility voluntarily returns its certificate because it stops performing 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 local FDA RRHR to discuss the scheduling of the inspection or the MQSA Hotline when the local RRHR is unavailable.

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. Any facility that ceases performing mammography and continues to maintain an active FDA certificate 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. All certified MQSA facilities undergo an annual medical physicist evaluation and submit to an annual inspection.

2.1.3 Equipment Testing During an MQSA Inspection

Before you test facility equipment during an MQSA inspection, make sure that the equipment is currently being used for mammography. If a facility has several x-ray systems and/or processors or laser printers, make sure you confirm with facility personnel that all systems you plan to test are currently being used for mammography and are covered under current FDA

localization, biopsy, stereotactic, or investigational units). Do not test equipment that is out of regulations (x-ray systems routinely used for mammography, not units used exclusively for service or awaiting final clearance to be used (final clearance means all assembly and testing has been completed). Before you review facility equipment records, ensure that the facility used the equipment for mammography at some point since the last inspection.

2.2 Getting Started

Upon arriving at a facility, introduce yourself and present your inspector identification card to the facility contact person. To accommodate the facility's schedule, discuss the inspection agenda and be flexible as to which part of the inspection to cover first. Advise facility personnel that you will review your inspection observations with them prior to your departure and a written report will be mailed to them after the electronic inspection record is processed. For more information, see Section 2.2.1 below.

2.2.1 Identification Cards

FDA requires that MQSA inspectors present his/her MQSA Inspector Identification Card to facility personnel at the beginning of an inspection. FDA issues this card to each inspector after he/she has completed all of the training required to conduct MQSA inspections, including the performance of at least 2 mentored inspections after passing Course III. Presenting identification at the beginning of an inspection is a mandatory requirement under MQSA Section 354(g)(l)(B), which states:

"The Secretary, or State agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected."

Upon arriving at a facility to conduct an inspection, you must present your MQSA Identification Card to the most responsible official involved with mammography. Should that person be unavailable at the time of the inspection, present your Identification Card to the most responsible person available at the facility.

If your card is lost or damaged, contact the MQSA Hotline at: 1-800-838-7715.

2.3 What to Do in Unusual Situations

Occasionally, you may encounter unusual conditions when you arrive at a facility. The following guidance should help you deal with such circumstances.

2.3.1 Operating without a Valid Certificate

1. First determine if the facility has a current certificate. If you wait until a few days before the inspection (no sooner than 7 days is recommended) to move a facility from your "Facilities with Available Inspections" list to your "Working Inspections" list, the facility certification information received from FISSweb is most likely current. If, for whatever reason, you find otherwise when you arrive at the facility, you can either recheck its certification status if you

have internet access at the facility, or call the Hotline at 1-800-838-7715 first, and tell the operator that you are conducting an inspection and you need to speak with DMQS staff to verify the certification status of a facility. If facility personnel indicate that they do not have a valid certificate, you should check (and document) the mammography patient logs to determine whether or not the facility is or has been performing mammography without a MQSA certificate and, if so, for how long. Determine if there are extenuating circumstances for not having a current certificate (e.g., the facility has recently submitted an application for accreditation or re-accreditation to their accreditation body* (AB); there has been no response from the AB; there has been a recent change in the facility's name, etc.).

* Currently, the FDA recognizes the following entities as accreditation bodies: The American College of Radiology (ACR), and the States of Arkansas (AR), Iowa (IA), and Texas (TX).

2. If you verify that the facility has been operating with an expired certificate (see Sec. 2.3.1 for details) or without a valid certificate, inform facility personnel that such performance is unlawful under MQSA (except for extenuating circumstances), immediately call the Hotline at 800-838-7715 to report the operation of a non-certified mammography facility, then proceed with your inspection. The FDA will review facility records and determine its current certification status and advise you on any additional information you may need to gather. At a minimum you should determine how long the facility operated without an MQSA certificate and the total number of mammography patients imaged during the period of non-certified operation. You should also inform the appropriate FDA MQSA Auditor or Regional Radiological Health Representative following completion of the Inspection. Instruct facility personnel to immediately contact their AB and update their status.

   For additional details regarding facilities that have changed Ownership status and related FDA Enforcement Actions, facilities that Moved or Ceased Operations, and Inspection decisions regarding those that Closed or are in the process of closing, see Sections 2.3.2.1 to 2.3.2.7).

2.3.2 Conducting Mammography with an Unaccredited Machine

There are three cases where the units in use at the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without documentation showing extenuating circumstances); 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days)*; or 3) the unit is an investigational unit installed and used under an Investigational Device Exemption (IDE) as described in the FDA's Safe Medical Devices Act of 1990. The requirements for accreditation of these units depend on the rules of the facility's accreditation body**.

***Note:** Under examples 1) and 2) above, the unit is required to have passed a mammography equipment evaluation (MEE). The MQSA inspector should test each unit regardless of its accreditation or ownership status.

****Note:** Some States may have more stringent rules and may require the facility to contact them as soon as possible and follow their guidelines prior to using any such units on patients.

Request and review the documentation covering these circumstances of the unit during the MQSA

inspection. Also, send an e-mail to MQSAhotline@hcmsllc.com about such loaner and demonstration units and inform the facility that the FDA will notify the AB that the facility is using an unaccredited unit.

FDA requires that new** units be accredited by the facility's AB and the unit must have passed a Mammography Equipment Evaluation (MEE) conducted by a medical physicist prior to being used to image patients. The facility must immediately contact its AB and follow the AB's guidelines for newly installed units, prior to using any such units on patients.

** In this context, the word "New" means that the unit is newly acquired by the facility, e.g., either new (never been used anywhere), or had been previously used elsewhere but is new to this facility.

MQSA's final regulations (900.2(aa)(2)) currently exempt investigational units installed and used under an Investigational Device Exemption (IDE). A n IDE is issued by FDA to the manufacturer. Facilities using such units should have approval letters, investigational device labels, or other documentation indicating FDA's conditional approval of their use. Also, facilities must not use such units to perform non-interventional mammographic images. As a general rule, all units used on patients, whether accredited or not, must be inspected, except for units that are exempt from MQSA's final regulations.

2.3.3 Expired Certificates Found During Inspections

When the inspector finds a facility performing mammography and is in possession of only an expired certificate

Step 1: The inspector should determine whether the expired certificate on display is the only certificate that the facility has, keeping in mind that the facility may have forgotten to replace the expired certificate with the current certificate when they received it in the mail. The new certificate may be located in the facility's administration department or in the office of the department director. Ask the mammography staff to contact all other departments that could have received the certificate in the mail.

Step 2: If facility personnel indicate that they have only the expired certificate, the inspector should confirm that they are/have been performing mammography and get as much information about what is going on with the facility as possible (e.g., has the facility submitted an application/reapplication to their accreditation body recently, have they received a response yet, has there been a change in the name of their facility recently, how many mammography patients have been imaged since the expiration of the certificate, etc.?).

The inspector should tell facility personnel that taking mammograms when their certification is expired is unlawful.

Step 3: The inspector should call the MQSA Hotline at 800-838-7715 while at the facility. The inspector should tell the hotline operator that they need assistance from DMQS staff because they are inspecting a facility with an expired MQSA certificate. The FDA will review the records regarding the certification status of this facility. Based on the information revealed during this review, FDA will advise the inspector regarding any

additional instructions for conducting the inspection.

Step 4: The inspector should take possession of their expired certificate.

Step 5: As of October 1998, the MQSA was amended to allow FDA to inspect mammography facilities, regardless of whether they are certified at the time of the inspection or not. Therefore, you should proceed with your inspection and document the total number of mammograms performed at the facility after the certificate expired, as well as any other problems that are identified during the inspection.

Note: Inspectors in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.

2.3.4 Facilities with Operational Status Changes (i.e. Facilities that Change Ownership, Facilities that Change their Facility Name, Facility Moves, Facilities that Cease Mammography but Remain Open, or Facilities that Close)

2.3.4.1 Facility Changing Ownership – New Owner Responsibility

Under MQSA, an owner/operator of a mammography facility is always responsible for the activities of that facility. If inspection observations for problems found during an MQSA inspection continue under the new management, these observations must be addressed by the new management, regardless of who owned the facility when the MQSA inspection was conducted. The fact that a change in ownership occurs does not relieve the current owner of his/her responsibilities under MQSA. Therefore, if the observations have not been addressed by the previous facility management, then the new management must address the issue(s). Facility personnel must take whatever corrective action is needed to bring the facility up to the standards required by MQSA and to assure that the problems will not continue.

2.3.4.2 Facility Changing Name but Keeping the Same Ownership, Personnel, and Equipment

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

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

2.3.4.3 FDA Enforcement Actions Following a Change in Ownership in a Facility that has Significant Violations

Agency decisions concerning enforcement actions against facilities that have changed ownership must be evaluated on a case-by-case basis. The issuance of Warning Letters, initiation of sanctions under MQSA, or other actions will depend on a variety of factors, including, but not limited to, the prior compliance profile of the facility.

If the violations occurred only under the direction of previous owners, then initiation of enforcement actions against a facility under the new management may not be appropriate. Issues such as contractual agreements surrounding the change in ownership and information about whether a "real" change in ownership has occurred (for example, a change in corporate holding name but same principals involved) may have to be evaluated and are beyond the scope of this policy.

2.3.4.4 Facilities that Move

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

FDA-issued MQSA certificates are issued with the facility name only. There is no need to issue replacement certificates for address changes. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding replacement of MQSA certificates.

2.3.4.5 Facilities that Cease Mammography Operations but Remain Open for Other Medical Services / Facilities that Permanently Close

When an inspector becomes aware that a facility has plans to cease performing mammography (i.e. a decisions to close just the mammography department at a medical facility, or a decision to permanently close an entire medical facility that holds a MQSA certificate), the inspector should share the information below with the facility management to assist them in meeting all MQSA requirements and medical records retention obligations.

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. If the facility intends to remain open but will cease performing mammography (i.e. the mammography department is closing), the facility may choose to keep the patients' mammograms and medical records rather than transferring the mammograms to

another facility (unless the patient requests such a transfer). In this case the facility should identify a contact person who will be responsible for processing requests for prior mammograms when they are received.

However, if the medical facility is going out of business and permanently closing, the facility must notify each patient to make arrangements for the transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less than 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. The facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine if their requirements are more stringent.

If medical records cannot be transferred under option 3, medical facilities must make arrangements for the long term storage of 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.

Due to the fact that some facilities have not followed the above recommendations, FDA receives inquiries at the MQSA Hotline from patients who cannot gain access to their prior mammograms records because their former mammography facility has closed and the patient was not informed of the facility closure or the record storage location and process. 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:

Division of Mammography Quality and Radiation Programs (DMQS)
Food and Drug Administration (FDA)
10903 New Hampshire Avenue, WO66 – Room 4621
Silver Spring, MD 20993-0002

Attention: Closed Facility Notification of Records Retention.

Facilities certified by States (currently Iowa, Illinois, South Carolina, and Texas) may send the above information to their respective State Certifying Agency :

Iowa:
Bureau of Radiological Health, Iowa Department of Public Health
Lucas State Office Bldg., 5th Floor
321 East 12th Street
Des Moines, IA 50319. Or call 515-281-3478

Illinois:
Illinois Emergency Management Agency, Division of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704. Or call 217-785-9923

South Carolina:
South Carolina Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull St.
Columbia, SC 29201. Or call 803-545-4435

Texas
Texas Department of State Health Services
Mammography Certification Program
1100 West 49th Street
Austin, Texas 78756
512-834-6688, Extension 2245

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

2.3.4.6 Inspection of Certified Facilities Currently Not Performing Mammography

A certified mammography facility that is no longer performing mammography at the time that the facility is contacted by the inspector to schedule the annual MQSA inspection should be inspected, or the facility should immediately contact their accreditation body to voluntarily withdraw their mammography unit from accreditation, which will trigger a change in the status of the MQSA certificate from "Certified" to "Not Certified". It is not acceptable for a facility to maintain a valid MQSA certificate and refuse to submit to annual inspection because the facility is no longer performing mammography. In keeping with the intent of the regulations, once a facility is certified, that facility must maintain its certified status by:

(1) Having an annual physics survey performed (and mammography equipment evaluations, when applicable),
(2) Undergoing periodic audits and reviews by their accreditation body,
(3) Submitting to an annual MQSA inspection,
(4) Paying an inspection fee, and
(5) Correcting any deficiencies found during inspections.

Should a certified facility choose not to meet these requirements, it must relinquish its certified status by withdrawing its MQSA certificate and its accreditation. The facility must notify its accreditation body and the FDA (MQSA Hotline Number: 800-838-7715, MQSAhotline@hcmsllc.com, Address: Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045) or the Certifying State as soon as possible. Once the facility's certified status has been relinquished, it can no longer display the MQSA certificate and cannot lawfully perform mammography.

Should the facility decide to perform mammography services in the future, it must proceed with the accreditation reinstatement process to become accredited and to receive a new MQSA certificate.

2.3.4.7 When to Inspect a Closing/Closed Facility

Facility Certification Status

Occasionally, inspectors, State programs, and FDA field offices inform DMQS about facilities that are listed as certified but that are no longer performing mammography. As you know, a facility's accreditation remains valid until it expires. Thus, the American College of Radiology (ACR) and the State Certifying Agencies require any facility that is in the process of closing its mammography operations to notify the accreditation body to voluntarily withdraw the facility's accreditation. In situations where such a facility does not contact its accreditation body about its change in operational status, the facility will continue to be listed as accredited and certified, and as such is subject to annual inspection under the MQSA.

As an example, when the closure of a mammography facility is brought to the attention of the ACR, the accreditation body will try to verify, via a letter or telephone call, the operational status of the facility. Upon validating the closure of the facility, the ACR updates its records to indicate the voluntary withdrawal of the facility's accreditation. The ACR notifies the FDA of the change to the facility's operational status. Once notified, the FDA withdraws the certification of the facility. The State Accreditation Bodies have similar procedures for verifying the operational status of a facility.

If you learn that a facility is closing or has closed, please contact the MQSA Hotline at 800-838-7715 or MQSAhotline@hcmsllc.com**.** If you have any letters or other documents confirming the closure, please fax them to us. Upon receiving this information, DMQS will work with the ACR or the State Accreditation Body to verify that the facility is no longer performing mammography. DMQS will then remove the facility's certification once the accreditation body has withdrawn the facility's accreditation. State Certifying Agencies have similar procedures for updating their certification databases.

2.4 Facility Inspections

The Mammography Quality Standards Act (MQSA) authorizes FDA, or State or local agency acting on behalf of the FDA, to conduct inspections of mammography facilities (certified or uncertified).

All certified mammography facilities are required to undergo an annual inspection to determine compliance with the certification requirements and the established quality standards of the MQSA. In order to provide inspectors with some flexibility in scheduling the annual inspections, the FDA has set an annual inspection timeframe of 10 – 14 months from the anniversary date of the previous inspection (or from the date of the facility's provisional certification for the initial inspection), within which the annual inspection must be scheduled. The focus of the discussion below is on how inspectors should schedule annual inspections of facilities that are temporarily or permanently closed or in the process

of closing within this window.

When to Conduct an Annual MQSA Inspection

If on the day that an inspector contacts a facility to schedule the annual inspection [for a date no less than 10 months after the previous inspection and no more than 14 months after the previous inspections],

1. the facility has a valid certificate, and
2. the facility appears on FDA's certified facility list, and
3. the facility is providing mammography services (until a specified closing date which is more than 10 months from its previous inspection), then the inspection should be scheduled and conducted as usual and prior to the facility's anticipated date of closure. If the inspector is unable to schedule the inspection before the facility's anticipated date of closure, the inspector should contact the FDA District Office and DMQS so that a priority FDA inspection can be scheduled before the facility's anticipated closure date. If the facility has not notified its AB or the FDA of its plans to close or cease performing mammography**,** the facility should be instructed to do so and to copy the inspector on that correspondence. If the facility has notified its AB or FDA of its plans to close or cease performing mammography**,** the inspector should request a copy of the correspondence that was submitted to the AB or the FDA.

If on the day that an inspector contacts a facility to schedule the Annual Inspection [for a date no less than 10 months after the previous inspection and no more than 14 months after the previous inspections],

1 the facility has a valid certificate, and

2 the facility appears on FDA's certified facility list, and

3 the facility is *temporarily* not performing mammography services, then the inspection should be scheduled. However, the inspector can exercise discretion to delay the date of inspection to a point **no later than** the 14-month anniversary of the previous inspection, if the facility is likely to resume performing mammography in the near future. Otherwise, the inspection (which will consist of a "records review" if the x-ray unit is not being used at the time of the inspection) should be scheduled and conducted as planned.

If on the day that an inspector contacts a facility to schedule the annual inspection [for a date no less than 10 months after the previous inspection and no more than 14 months after the previous inspection and],

1. the facility has a valid certificate, and
2. the facility appears on the FDA's certified facility list, **but**
3. the facility has *permanently* ceased performing mammography services, then the inspection should **not** be scheduled **unless** a compelling public health reason can be demonstrated to the FDA. If the facility has failed to notify its AB or the FDA of its closure plans**,** the facility should be instructed to do so, and to copy the inspector on that correspondence. If the facility has notified the AB or the FDA of its plans to close, or cease performing mammography**,** the inspector should request a copy of the

closure correspondence that was submitted to the FDA or the AB.

If, outside of the scheduling process described above, an inspector becomes aware of a facility that does not have a valid certificate or does not appear on the FDA's certified facility list, but is performing mammography (or has performed mammography in the past while uncertified), the inspector should immediately contact the appropriate FDA District Office and DMQS. The FDA will coordinate the investigation and inspection of the uncertified facility (see FDA Compliance Program Guidance Manual, Compliance Program: 7385.014 - Mammography Facility Inspections).

If you have questions, please contact the MQSA Hotline by e-mail at MQSAhotline@hcmsllc.com or by telephone at 800-838-7715, or fax at 410-290-6351.

2.5 When Certain Documents are Claimed but Unavailable for Review

When a facility is unable to furnish some of the required records at the time of the inspection, you should inquire as to why the documents are missing. Some documents can be obtained by the facility, and then faxed or e-mailed to the inspector after the on-site inspection is completed, to avoid or remove a citation from the MQSA inspection report, prior to the submission of the report to FDA (examples include: personnel records for training completed in advance of the inspection; a current medical license or a board certificate that was issued prior to the inspection date, the medical physicist survey report when the survey tests were performed prior to the inspection date, QC records for monitors or laser printers that are located off-site when the QC tests were performed prior to the inspection date).

Whenever possible, work with facility staff. Request that they send you the missing documents as soon as possible, but before you submit the inspection results (within 5 business days in most cases) to the FDA.

There are other situations in which inspectors should never eliminate an inspection citation because there is no way for the facility to resolve a noncompliance for missing documentation, (examples include: missing records for quality control tests that were not performed; missing records for personnel training that was not completed prior to the inspection; Standard Operating Procedures that did not exist prior to the inspection date). In these situations the facility can promise to make future corrections, to change their procedures, to complete training at a future time, however the facility cannot eliminate, or erase, a failure to perform QC tests in the past, a failure to create procedures, or a failure to complete required training. These are circumstances in which a MQSA citation is warranted. The facility can submit their plan of corrective action in a written response to the FDA or State Certifying Agency.

When missing documentation or a failure to perform QC tests becomes an inspection issue, inspectors should answer the appropriate FISS inspection questions as if the required records were not available, and the QC tests were not performed. This will generate a citation that will appear on the Inspection Debrief Report. The inspector should explain to the facility management if the MQSA citation, issued due to the missing records, can be eliminated from the final Post Inspection Report inspection, if the facility provides the missing records to the inspector within 5 days of the date of the on-site inspection.

Once the facility submits the documents to the inspector, and the inspector has evaluated the documents,

the inspector can edit the answers to the corresponding FISS inspection questions based on the inspector's review of the documents provided by the facility. Once all documents have been reviewed and the inspection questions have been finalized, submit the MQSA inspection to the FDA. If the requested documentation is not provided by the facility within 5 business day, the inspection citations will stand as noted during the inspection close-out discussion, and the inspection report is finalized. Print the Post Inspection Report and mail (fax or e-mail) the report along with the appropriate "Important Information about Your MQSA Inspection" document (see Appendix 1) to the facility.

For personnel documents, the MQSA requires that the facility provide you with all personnel documents at the time of the inspection. If the facility is unable to provide all personnel records at the time of the inspection, inspectors should answer the question in the Personnel Summary Subsection, under the Personnel Section of FISS, with a "No". This generates a Level 3 citation for not having all personnel records on hand during the inspection. This citation is independent of the individual qualification requirement questions in FISS, and should be cited whenever all required personnel records are not made available to the inspector while the inspector is on-site for the inspection. This Level 3 citation is a reminder to the facility that they should gather all required personnel documentation prior to the start of the inspection. It should not be removed if the facility provides the inspector with missing personnel records within 5 business days of the on-site inspection. We will discuss this issue further in Section 3.4.10. PERSONNEL.

2.5.1 Claimed Items during the Inspection

In the case where a facility is unable to supply proper documentation for personnel requirements or the medical physicist survey report at the time of the inspection, but claims that such documentation exists, inspectors should:

1. Answer the related FISS inspection questions as if the records did not exist. The resulting citations will appear on the **Inspection Debrief Report**. Discuss these citations with facility management and explain which citations can be eliminated from the final inspection report (Post Inspection Report) if the missing documentation is provided within the required timeframe
2. Delay submitting the inspection for up to 5 business days. If the facility supplies the proper documentation, inspectors should revise the appropriate FISS inspection questions, submit the inspection to the FDA as usual, and provide the facility with a copy of the Post Inspection Report that reflects the revised citations. If on the other hand, the facility does not supply the proper documentation within 5 business days, inspectors should submit the inspection report to FDA, and provide the facility with the Post Inspection Report that lists the citations that were discussed with the facility via the **Inspection Debrief Report**
3. With regard to personnel documents, inspectors should answer the "Summary" question in the Personnel Summary subsection with a "NO." Inspectors should not change this answer even if the facility provided the missing documents before uploading the inspection.

Note: In those cases where the facility's inability to provide the necessary documentation within the 5 business day period is beyond the facility's control, inspectors should contact the hotline (1-800-838-7715 or MQSA hotline@hcmsllc.com) for further instructions.

2.6 Using the "Remarks" Tab

While the inspection software has been designed to capture a significant amount of information concerning facility operations there are limitations to the software. There may be times when the details of the facility's compliance status cannot be captured by using the answer options provided in FISS. To address this situation, inspectors can make use of the remarks tabs on any FISS screen to provide additional information.

2.6.1 Remarks Tab - What to Include

Examples of the types of information that may be recorded in a remark include, but are not limited to:

- **Clarifications and detailed information beyond a "Yes" or "No" answers** - Yes/No answers in FISS do not always tell a complete story regarding the inspection. In many cases, important details about facility conditions will be missed, unless the inspector uses the remarks to record this useful information.
- **All failures to meet QC testing requirements, including those QC tests that do not have a matching FISS inspection question. Include dates and date ranges for missing QC tests or unresolved corrective actions** –A facility may fail to perform a QC test at the required testing frequency, or may miss days or weeks of QC testing. Additionally, QC performed by the facility may fail to meet the required QC performance criteria and the facility fails to take the corrective action for a failed QC test. In each of these cases you should use remarks to note the weeks or days of QC test failures, or time period between the first QC test failure and the date that the facility took corrective action. In some cases where no corrective action has been taken, you should note your inspection date as the end date of the problematic time period, and explain to the facility that there is a problem that warrants corrective action.
- **QC questions not covered by specific FISS inspection question** – The FISS inspection questions do not cover all QC tests required of the facility by the American College of Radiology's QC program for mammography, or the FFDM manufacturer's QC program for mammography. When an inspector notices a problem with QC tests for which a matching FISS question does not exist, the inspector should use remarks to document any concerns (i.e. missing QC tests, QC tests not performed at the required frequency or not performed per the ACR or FFDM Manufacturer's QC procedures)
- **Details regarding all failures to meet personnel requirements** - For example, if an interpreting physician or radiologic technologist failed to meet a specific initial training requirement, the amount of training they actually obtained may be important when the facility responds to the observation. If an interpreting physician had one month of training in mammography and another had no training in mammography, the amount of training that is needed for these physicians to qualify is different.
- **Equipment models that are not listed in FISS**. While FDA tries to keep the manufacturer and model tables in the inspection software up to date, inspectors may find new or previously unknown models of equipment in use at facilities. When you find a mammography unit in use at a facility, but not listed in the inspection software, record the manufacturer name and model number in the printable remarks. Also contact MQSA Hotline to confirm that FDA has approved the mammography unit for

marketing in the United States.

In FISS there are remarks tabs accessible from any data-entry screen. You may access the remarks screen by clicking on the remarks tab located at the top of all the data entry screens. The remarks screen has two separate fields:

1) Printable remarks, which will appear on the Inspection Debrief Report to assist you with the exit interview at the conclusion of the inspection, and Post-Inspection Report that the facility will receive by mail; and

2) Non-printable remarks, which become a part of the permanent inspection record, but can only be viewed via the Inspection Detail Report in MPRISweb. You may copy or cut-and-paste information from one field into the other. Each field has a limit of approximately 3000 characters for data entry.

While FDA encourages inspectors to use the remarks tab throughout the inspection screens, be aware that DMQS staff and FDA field office personnel do not routinely access and review these sections. There are too many inspections and too many remarks sections in each inspection for FDA to scan all inspections looking for messages to FDA. Therefore, when an inspector uses the remarks tabs to capture important messages or serious inspection findings, the inspector should also send an e-mail message to their MQSA auditor or the local Regional Radiological Health Representative to alert FDA to image quality concerns, or other serious issues regarding a particular facility. Inspectors can all call the MQSA Hotline if they cannot reach their local FDA field personnel.

2.6.2 Additional Information for Level 1 and Level 2 Noncompliances

During an inspection, when serious noncompliances are found, it is important to record any information relating to these noncompliances in the remarks tabs in the inspection software. When testing data leads to Level 1 or Level 2 noncompliances provide supporting information that explains the conditions of the facility that may have contributed to the Level 1 or Level 2 situation. Or explain the details of the Level 1 or Level 2 situation when the FIIS inspection questions do not capture the details.

In the event that this additional information cannot be accommodated in the remarks sections, send an e-mail message to the MQSA Auditor or local Regional Radiological Health Representative. You should include the inspection ID number, the facility name, and a complete description of the issues in this e-mail message. In the Facility Information Subsection of the inspection include the following non-printable remark; “ADDITIONAL INFO SENT BY E-MAIL to FDA."

2.7 Facility Grouping for Inspection Fee Consolidation

Some facilities, primarily mobile, may have several certificates (with the different ID numbers corresponding to different units). These facilities may be eligible for inspection fee consolidation. Sections 2.7.1 to 2.7.3 below contain additional information regarding inspection fees, the type of facility that is exempt from paying them, e.g., a Government Entity facility, criteria for facility grouping for inspection fee consolidation, conditions that mobile mammography facilities must meet for fee reduction, who should group eligible facilities for Inspection Fee Consolidation, and Billing Changes.

2.7.1 Inspection Fees

Clicking on the link below, will take you to the web page in the Policy Guidance Help System (PGHS) where there is information on the inspection fees:

http://www.fda.gov/radiation-emittingproducts/mammographyqualitystandardsactandprogram/guidance/policyguidancehelpsystem/ucm051022.htm

2.7.2 Inspection Fee Consolidation

FDA has instituted an inspection fee consolidation policy (inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them). While this was originally designed for mobile facilities, it also applies to some stationary facilities. This policy will affect only a small percentage of mammographic facilities. It is important to remember that for MQSA purposes, a mammographic facility is defined by its MQSA certificate: one certificate equals one facility. When you walk into a radiology department, you may intuitively think of it as an independent mammographic facility; however, it may actually be a small portion of a much larger operation with several mammographic machines at separated locations.

Group billing for MQSA inspections will be performed by DMQS staff. Inspectors should contact the MQSA Hotline at 1-800-838-7715 to request that inspections be grouped for billing. The hotline operators will forward the requests to the DMQS Program Management Branch's Accreditation and Certification Team, which will act upon those requests within 48 business hours and make the final group billing determination.

See Inspection Fee Consolidation in the PGHS:
http://www.fda.gov/radiation-emittingproducts/mammographyqualitystandardsactandprogram/guidance/policyguidancehelpsystem/ucm049853.htm

See Mobile Mammography Inspection Fee Reduction in the PGHS:

http://www.fda.gov/radiation-emittingproducts/mammographyqualitystandardsactandprogram/guidance/policyguidancehelpsystem/ucm051028.htm

2.7.3 Billing Changes

For changes in billing, please verify, and if necessary edit, the facility billing address and/or contact person in the Contacts Subsection of FISS at the time of the inspection. This step ensures that the inspection invoice is mailed to the proper contact, which may not be located at the facility. Please refer facility requests for other address changes to the accreditation body.

If you need technical support with modifying the facility billing information on your laptop,

please contact the Inspector Computer Support at 301-796-6633.

2.8 Repeat Observations

The inspection software will identify and list repeat observations at all three observation levels. An observation in the current inspection is termed a repeat observation and denoted (REPEAT) if the facility was cited for the same observation during the previous inspection. Furthermore, FDA considers the observation a repeat observation if it is of the same type of violation, whether or not it is part of the same entity (e.g., x-ray unit, laser printer, interpreting physician, technologist, or physicist). For example, assume that x-ray unit #1 failed the Compression Force test QC records review during the previous inspection (Level 3 observation). If either unit # 1 or unit # 2 fails the Compression Force test QC records review during the current inspection, inspectors would identify the new observation as a Repeat Level 3 observation. Likewise, if Technologist A did not meet the continuing education requirements of 15 CEU during the previous inspection (Level 2 observation) and if this requirement is not met during the current inspection by any technologist at the facility, inspectors would identify the new observation as a "Repeat Level 2 observation."

Note: Some observations can be cited at one of two different levels (depending on the seriousness). Hence, if an inspector cited such an observation at a given level (e.g., Level 2) during the previous inspection, and if he/she cited the same observation type (as defined above) during the current inspection at a higher level (e.g., Level 1), the post inspection report will automatically identify it as a repeat violation at the higher level (e.g., Repeat Level 1).

2.9 Discussion of Inspection Observations with Facility Personnel (Close-out Discussion)

At the conclusion of the inspection, you should go over your findings with the appropriate facility personnel using the Inspection Debrief Report and the Important Inspection Close-out Discussion Information document**.** From the Reports Table in FISS you can open the Inspection Debrief Report and review any noncompliances that were generated based on your answers to the FISS inspection questions. You can also review the printable remarks that you entered into the inspection report. The Inspection Debrief Report should be used during the inspection close-out to discuss the inspection findings in detail with the facility personnel. Keep in mind that the Inspection Debrief Report is available to you at all times throughout the inspection process if you need to review noncompliance citations or printable remarks during the inspection process.

During the close-out discussion you should cover the following items with the facility personnel:

- Inspection observations and their levels. Provide a copy of the Important Inspection Close-out Discussion Information document to the facility during discussion.
- Timeframes for providing you with any pending documentation (i.e. personnel records, survey report data, or revised operating procedures)
- Timeframes for you to provide the facility with the final report, and the timeframes for submission of the facility's written response if required.
- Differences between State and MQSA requirements (reporting time frames and reporting responsibilities).
- Any inspection questions or concerns facility personnel may have.

Whenever Level 1, Level 2, and/or repeat observations are present, inspectors should discuss the observations with the most responsible individual at the facility. This person is the one who has the responsibility and authority to make major decisions regarding corrective actions and general mammography operations at the facility. If this individual is not available, inspectors should discuss these observations with the highest official available. In the end, inspectors should record the name of this individual and all who participated in the close our discussion in the printable remarks.

Inspectors should explain the difference between the levels of observations and the appropriate time frame for responses at each level. In particular, inspectors should ensure that the facility understands its responsibility to provide any pending documents within the agreed upon time frame. For items that the facility has corrected during the course of the inspection, record this information in the appropriate printable remarks section. However, inspectors should not consider these items as "Corrected Before Inspection". The inspector should cite the facility for these items

When the inspection is ready for submission to FDA, the inspector or the state program manager will document the inspection delivery method, the date of delivery, and the name of the facility contact to whom the report will be mailed in the Submit Inspection Screen. After the inspection has been submitted, the Post Inspection Report (PIR) will be generated as a pdf file. The PIR and Inspection Detail Reports will also be available via MPRISweb. A printed copy of the report along with the Important Information about Your MQSA Inspection document should be mailed, faxed or e-mailed to the facility contact.

Inspectors who are also conducting their State inspections, or who discover State violations during the MQSA inspections, should identify these observations as such. They should explain the difference between State and MQSA violations to facility personnel, and make sure that the facility personnel understand the State violations are separate and should not be confused with the MQSA inspection findings.

Inspectors who cannot answer a specific facility question during the inspection, may call their local FDA MQSA contact or the MQSA Hotline at 800-838-7715. For questions that do not require an immediate answer, e-mail your local MQSA Auditor or the Regional Radiological Health Representative for assistance.

If facility personnel want to provide feedback to the FDA regarding the inspection process, inspectors should direct the facility personnel to contact the MQSA Hotline at the above number or fax their comments to the MQSA Hotline at 1-410-290-6351. Facilities may also refer to FDA's web site:
(http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm)
where we have several guidance documents, including the *"Policy Guidance Help System,"* "*Preparing for MQSA Inspections*" and, "*Mammography Facility Survey, Equipment Evaluation, and Medical Physicist Qualification Requirements Under MQSA."*

2.9.1 Inspection Citation Levels

When FDA designed the MQSA inspection program, it realized that some inspection observations 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.

There are three possible levels of observations 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 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 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 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, the inspection report will note "All Items in Compliance."

If any observations have not been corrected, or have recurred since a facility's last MQSA inspection, inspectors should identify that observation as "Repeat" observations during the exit interview.

2.9.2 Inspector Actions after Completing the Inspection

Inspectors should mail the Post Inspection Report to the facility, unless you have internet connectivity at the facility during the inspection and can submit and then print the Post Inspection Report prior to leaving the facility. When you mail, or hand, the Post Inspection Report to the facility you should include the current version of the Important Information about Your MQSA Inspection document which you can find in the MQSA Documents folder on your laptop. If you don't find this version there, try connecting again to MPRIS or contact the MQSA Hotline. We have combined all previous versions into a single document. We based the previous seven versions on the highest level of inspection observation (Repeat Level 1, Level 1, Repeat Level 2, Level 2, Repeat Level 3, Level 3, and no adverse observations). With this new combined version, there is a check box at the beginning of four different sections that relates to the highest level of inspection observation. We have combined the observations as follows:

1. Repeat Level 1, Level 1, Repeat Level 2 – response within 15 working days
2. Level 2, Repeat Level 3 – response within 30 working days
3. Level 3 – no response needed, corrections checked during next inspection
4. No observations - no response needed.

Please check the appropriate box on the document before mailing the "Important Information" document to the facility with the inspection report.

Recording the Name of the Person Receiving Report and the Date of Delivery
We have added the name and title of the facility person given or mailed (faxed or emailed) the inspection report, as well as the delivery method, and the date it was given or mailed. The FISS inspection software captures this information and prints it on the Post Inspection Report on the page with the inspector's signature block.

2.9.3 Facility Personnel Responsibility Regarding Follow-Up to Inspection Observations

The most responsible individual to address facility violations is the person at the facility who has the duty and authority 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 require, as well as ensure, the implementation of significant quality assurance changes at the facility.

As an example, the chairman of a radiology department at a facility may report to a medical director or an administrator. However, if the chairman of the department has the authority to make the types of decisions mentioned above, FDA considers the chairman to be the most responsible individual connected with the violation. In this particular example, if an inspector found serious noncompliances (listed in Attachment D of Compliance Program 7382.014, Mammography Facility Inspections, under Level 1), FDA would address a Warning Letter to the chairman of the department. FDA would also send copies of the Warning Letter 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 Contacts subsection for "most responsible individual" would be the individual who has the responsibility and authority to make major decisions, 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 tab of the Contacts subsection screen.

Highest Official for a Facility – 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, inspectors should indicate the name, title, and mailing address of this individual(s) in the remarks tab of the Contacts subsection in the inspection software.

2.9.4 Documentation and other Issues Related to Inspection Observations

Whenever Level 1 observations are found during an inspection, inspectors should collect supporting documentation (copies of facility documents) and forward it to FDA or the Certifying State, when applicable. There are exceptions. Copying of documents would not normally be required when findings are generated from equipment testing during the inspection. Also, when an observation due to the failure by the facility to maintain certain records is found, there would probably be no records to copy. When no medical physicist survey has been conducted, there should be nothing to collect. However, in other areas, such as the quality control records or the personnel records, the noncompliance found may show up while inspecting these records. In these cases, the copies of these records should be collected as evidence to support the observation.

To identify the copies, mark them with the facility name, the date of the inspection, the inspection ID number, and inspector's name or initials.

2.9.5 Inspection Findings Disputed by Facilities

In some cases, the facility may disagree with the inspector's observations. 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, Level 2 or Level 3 observation, the facility has the right to disagree with inspection observations.

Level 1 and Level 2 Observations

For Level 1 and Level 2 observations, the facility is requested to submit a written response to the observation(s). If the facility disputes an inspection observation(s), please follow these steps.

1. When a facility notifies the FDA district office in writing of a disagreement with the observations from an inspection, the FDA District/Regional MQSA compliance contact should obtain any needed additional information from the facility about the disagreement and then contact the State and/or inspector to discuss the inspection observations. After reviewing all the information, the FDA District/Regional MQSA compliance contact will determine whether the inspection observation was justified.
2. If it is determined that the inspection observation was not justified:
   a) The inspector should download the inspection record, correct the inspection data; upload the corrected inspection record within 10 days after being informed of the need for correction; print a new MQSA Facility Inspection Report; and submit it by FAX or mail to the FDA District/Regional compliance contact.
   b) The FDA district office should respond to the facility by letter (a phone call is optional) with regard to the disputed observation(s), indicating that FDA agrees with the facility, and that the inspection data has been modified to reflect the correction(s). The revised MQSA Facility Inspection Report should be included with the letter to the facility.

   Note: The facility should not be informed of any changes before the revised inspection data has been submitted to MPRIS.
3. If the inspection observation was justified:
   a) If the matter pertains to a disagreement regarding policy, the FDA District/Regional MQSA compliance contact should contact DMQS, via e-mail, regarding the dispute. Facts concerning the disputed observations should be included with this e-mail.

   b) If the matter pertains to a disagreement regarding facts or data for the inspection, the local FDA MQSA compliance contact should resolve the disagreement by contacting the facility and the State. The FDA District/Regional MQSA compliance contact may contact DMQS for additional guidance, when needed.
   c) If the inspection observation is correct, the FDA District/Regional MQSA compliance

contact should send a letter to the facility indicating that FDA supports the observations of the inspection and that the facility has a responsibility to correct the problems found. In those cases where contact has been made with DMQS 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 Observations

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

2.9.6 Inspection Errors Discovered by FDA or the State

FDA understands that it is both more efficient for inspectors and less disruptive for facilities when the State and MQSA inspections are performed back-to-back. However, it is important that inspectors take special care in communicating with facility personnel regarding which observations 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.

Additionally, State noncompliances should not be listed on the MQSA Post Inspection Report (including the printed remarks sections), in the inspection cover letters, or any other documents created for the MQSA inspection program. Inspectors should record all State noncompliances on the appropriate State forms, documents, or letters to the facility.

2.9.7 Recording State vs. MQSA Requirements

FDA understands that it is both more efficient for inspectors and less disruptive for facilities when the State and MQSA inspections are performed back-to-back. However, it is important that inspectors are deliberate and effective in communicating to facility personnel the distinction between observations related to State requirements versus MQSA requirements. Thus, inspectors should clearly identify for facilities observations that are State noncompliances and observations that are MQSA noncompliances.

Additionally, inspectors should **only** list MQSA observations on the MQSA Post Inspection Report and not State-related observations (including the printed remarks sections), in the inspection cover letters, or any other documents created for the MQSA inspection program. Rather, inspectors should keep the two categories of observations separate by recording all State noncompliances on the appropriate State forms, documents, or letters to the facility.

2.9.8 Advice to a Facility Following a Serious Citation

When a serious problem (such as a Level 1 observation) is identified at a facility, inspectors should tell facility personnel that, in the interest of public health, he/she recommends they discontinue using the equipment, personnel, or practice that resulted in this serious noncompliant observation. Inspectors should also mention that there are sanctions which the

facility could be subject to should the noncompliant observation continue.

Examples of sanctions include the imposition of a Directed Plan of Correction (specific orders by FDA identifying how a facility must correct their noncompliant observation(s)), civil money penalties (up to $11,000 per day per noncompliance), suspension or revocation of their MQSA facility certificate, or an injunction. Inspectors may also indicate that continuing to use or to perform the cited item while the violative condition exists adds to the violations already found and that it would be in the best interest of the facility to correct the problems immediately.

Background:

DMQS has received numerous questions from inspectors regarding what statements should be made to a facility with serious MQSA violations. Is it appropriate for the inspector to tell the facility to stop using certain equipment, or that certain personnel should cease performing mammography examinations or interpreting mammograms when Level 1 violations are found during the inspection? Under the MQSA, inspectors cannot order a facility to stop any practice that is or appears to be in violation of MQSA. Examples of these practices include (but are not limited to) using the services of unqualified personnel, using equipment which produces sub-standard phantom images, or using film processors which are out-of-limits.

FDA does not delegate to MQSA inspectors the authority to make specific directives, such as closing a facility down when serious noncompliance are encountered. While some inspectors believe they have the responsibility to make sure that a facility has stopped a practice that is in violation of MQSA, it is in fact, the facility's responsibility to comply with MQSA and it is the inspector's responsibility to document these noncompliant items during the inspection process.

Supplemental Information Regarding State Authority:

Some States have authorized their inspectors to order a facility to stop a violative practice or to cease the performance of mammography. The guidance described above section is not designed to limit a State from exercising its authority when a facility is found to be in violation of state law or to prohibit state inspectors from exercising any authority delegated to them by state laws, regulations, or policies. However, when a state inspector takes such action at a mammography facility during an MQSA inspection, the inspector must make it clear to the facility personnel that he/she is acting under and enforcing State laws and not shutting the facility down under the MQSA.

2.9.9 Advice to Facilities Regarding Corrective Actions

While many inspectors have backgrounds in radiologic technology, equipment service and/or quality control, an inspector should not tell a facility what he or she believes is the source of the noncompliance or try to help the facility diagnose their problems. It is one thing to point out obvious light leaks in a darkroom that has a fog problem or stained or dirty view boxes. However, it is entirely different to suggest to a facility that it replace a motor in their processor, a filter in their mammography system, or to alter their clinical technique factors. Inspectors should be very careful not to give facilities suggestions or advice that could lead to costly repairs which may not fix the problem or which might, in fact, compromise image quality. Please leave it up to facility managers, service engineers, and/or the medical physicist to evaluate how to correct technical problems of this nature.

2.9.10 Responding to FDA after the Inspection (Letters with Inspection Report and Facility Comments)

Facilities need to understand how to respond if they have received an adverse observation(s) during their inspection. Facilities need to respond in writing to any inspections with higher than a Level 3 observation. For repeated Level 1, Level 1, and repeated Level 2 observations, the facility should respond within 15 days after they receive their inspection results. For Level 2 and repeated Level 3 observations, the facility should respond within 30 days after they receive their inspection results. Non- repeated Level 3 observations do not need to be addressed in writing. However, these observations 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 mail or give to appropriate facility personnel two separate documents:

1. A cover letter entitled "Important Information about Your MQSA Inspection"
2. The post-inspection report (MQSA Facility Inspection Report).

Inspectors are strongly encouraged to attempt to discuss the observations with the most responsible individual (official) available at the time of the inspection via the Inspection Debrief Report. The inspector should also explain how to submit the facility 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 should not be sent to the MQSA Hotline of the Division of Mammography Quality Standards (DMQS) address in Silver Spring, Maryland. Inspectors and facilities in Certifying States should contact their State Certifying Agency to determine the policies that apply to them.

Facility Comments/Questions:

Facilities should be instructed only to use the MQSA Hotline number (1-800-838-7715) for general comments about the inspection process and general MQSA questions, not to ask questions about a specific inspection. If personnel at a facility have questions 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 cannot answer the questions, the FDA Auditor, Regional Radiological Health Representative, DMQS or State Certifying Agency should be contacted.

2.9.11 Copying Records during Inspections and Using Remarks

FDA's field offices have asked us to remind our inspectors to routinely copy facility records relating to inspection observations and explain their observations in the appropriate "Remarks" tab of the inspection software. By providing this information, FDA can compare facilities'

responses to specific inspection observations and records you have provided.

For any inspection where a facility must provide a written response (i.e., highest observation is Level 1 or 2, as well as repeated Level 3), follow the guidance provided below:

Personnel Records – Personnel observations are very common. Often, facilities do not have the required documentation (for example, continuing medical education). If no records are available, obviously there is nothing to copy. However, for those inspections where inspectors detect problems with a facility's records, inspectors should copy them and send them to the FDA Auditor after completion of the inspection. In the "Remarks" tab, inspectors should record all relevant information regarding the inspection observations. For example, an inspector may need to record the total number of hours or credits someone earns when they started working at the facility, or list staff members who have not completed new modality training when a new modality is installed at the facility, and still in other situations you may want to comment or capture any corrective actions taken by the facility since the last inspection.

Quality Control (QC) Records – As with personnel records, inspectors may find that a facility has not performed one or more QC tests when required. In this case, there may be nothing to copy. However, if the QC records are only partially completed, inspectors should evaluate records and document the problems by copy these records. For laser printer, film processor and phantom QC, make sure to copy all charts with missing or noncompliant data since the last inspection. Also, in situations where the software does not capture information you feel is important, inspectors should use the "Remarks" tab to document their observations (for example, problems with a facility's equipment, or procedures).

Note: Missing QC data should be tied to clinical images. For example, if the phantom image QC test was not performed in a given week, and during that week the facility did not image any patients, then the missing phantom QC test has no relevance, because no clinical images were acquired during that week.

Medical Physicist Survey Report – Ordinarily, inspectors only need to make copies of specific pages with questionable test results. For survey reports with numerous problems, however, an inspector may need to copy the entire report. The inspector should highlight on the copy of the survey report any sections of the report that is of concern. For general questions in the software, such as "Action taken (if called for in Report)?" inspectors should record in the "Remarks" tab an explanation of how the facility failed to meet the regulations.

Medical Records – Inspectors should copy mammography reports or letters that indicate problems. However, inspectors should **ensure that they have removed patient-specific information (patient names, addresses, and telephone numbers) from the copies before removing the copies from the facility or sending them to the FDA field office.** Additionally, there may be situations where an inspector needs to copy a facility's procedure for issuing reports and letters. Again, in the "Remarks" tab, inspectors should explain the problems observed with a facility's procedures, reports, or letters. Inspectors have the authority to inspect and copy patient records for MQSA purposes under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regulations. You can view the privacy rules in HIPAA at: http://www.hhs.gov/ocr.

Quality Assurance Procedures – When inspectors encounter problems with the medical audit, infection control, and consumer complaint procedures, they should copy the records showing the problems. In the "Remarks" tab, inspectors should explain why they cited the facility for these problems with their procedures.

There may be other situations where copying records or providing additional information in the "Remarks" tab would be important. In these instances and whenever an inspector has doubts, he/she should copy the records or record the information in the "Remarks" tab.

The following table, which FDA sent to all inspectors as part of a memo dated 8/29/03, gives examples of documents to copy in support of a particular observation:

Inspection Observation	**Examples of Records Supporting the Violation to Copy**
Level 1 Observations	
X-ray system not accredited for over one year	Mammography film labels (mammographic image identification labels on the film. These should copy on the copier)*
	Copy of FDA form 2579 (Report of Assembly)
Uncertified facility	Mammography reports or Mammography film labels (mammographic image identification labels on the film. These should copy on the copier)*
	Mammography log book pages showing mammograms and dates*
Interpreting physician medical license	License, letter, or pocket card
Interpreting physician board certification or 2/3 months training	Attestations, letters, training certificates, transcripts, continuing medical education documents, or board certificates
Radiologic technologist State license or certification	State licenses, attestations, letters, training certificates, or board certificates
Medical physicist license or approval by a State or certification	State licenses, attestations, letters, training certificates, or board certificates
Medical physicist degree - master's degree or higher (bachelor's degree or higher prior to 4/28/99)	Attestations, letters, training certificates, transcripts, or diplomas
Medical physicist - 10/20 hours in physics	Attestations, letters, training certificates, transcripts, or diplomas
No system to provide timely mammography reports	Mammography reporting procedures, log books*, or mammography reports*
No system to provide lay summaries	Patient letters, facility procedures, or log books*
No system to communicate serious or highly suggestive cases as soon as possible	Mammography reports, facility procedures, or log books*
Laser Printer or Film Processor QC records missing	All laser printer or film processor QC charts for that printer/processor since last inspection and demonstrating with missing days when clinical images were printed or processed
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was performed on missing QC dates)

Mammograms printed or processed when laser printer/film processor was out of limits	All laser printer or film processor QC charts for that printer/processor since last inspection when printer/processor was out of limits with no corrective action
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Phantom QC records missing	All phantom QC charts for that x-ray system since last inspection with missing weeks
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Physicist survey for x-ray system overdue for two years	Most recent survey report (or coversheet with date) for system
Level 2 Observations	
X-ray system not accredited	Mammography film labels (mammographic image identification labels on the film. These should copy on the copier)* (showing mammography unit identification)
Interpreting physician mammography education (40/60 hours)	Attestations, letters, training or continuing medical education certificates, or transcripts
Interpreting physician initial experience (240 mammograms in 6 months)	Attestations, letters, or facility tables of mammograms read
Interpreting physician continuing experience (960 mammograms in 24 months)	Letters, facility tables, or facility logs of mammograms read
Interpreting physician continuing medical education (15 Category I credits in 36 months)	Letters, training certificates, continuing medical education certificates, or attestations
Interpreting physician new modality training	Letters, attestations, training certificates, or continuing medical education certificates
Radiologic technologist mammography training	Attestations, letters, training certificates, continuing medical education certificates, or transcripts
Radiologic technologist continuing medical education (15 CEU's in 36 months)	Letters, training certificates, continuing medical education certificates, or attestations
Radiologic technologist continuing experience (200 mammograms in 24 months)	Letters, facility tables, or facility logs of mammograms performed
Radiologic technologist new modality training	Letters, attestations, training certificates, continuing medical education certificates
Medical physicist 20/40 hours survey training	Attestations, letters, training certificates, continuing medical education certificates, or transcripts
Medical physicist initial experience (1 facility and 10/20 units)	Attestations, copy or coversheet of survey, letter from facility, or listing from company providing the physics survey services
Medical physicist continuing medical education (15 credits in 36 months)	Letters, training certificates, continuing medical education certificates, or attestations

Medical physicist continuing experience (2 facilities and 6 units in 24 months)	Survey report or coversheet of survey, letter from facility, or listing from company providing the physics survey services
Medical physicist new modality training	Letters, attestations, training certificates, continuing medical education certificates
Mammography reports unsigned by interpreting physician	Mammography reports*
Mammography reports without assessment category	Mammography reports*
Laser Printer or Film Processor QC records missing	All laser printer or film processor QC charts for that printer/processor since last inspection with missing days
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on the missing QC dates)
Mammograms processed when laser printer or film processor was out of limits	All laser printer/film processor QC charts for that printer/processor since last inspection when printer/processor was out of limits with no corrective action
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Phantom QC records missing	All phantom QC charts for that x-ray system since last inspection with missing weeks.
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Phantom QC testing not at clinical or manufacturer (FFDM units) setting	Phantom QC chart, phantom QC procedure, or mammography film label (if settings on label) and a copy of the technique chart for the unit
No corrective action for failed QC phantom	All phantom QC charts for that x-ray system since last inspection with phantom failures with no corrective action documented
	Copies of mammography reports, film labels with dates, or patient logs* (to show that mammography was done on missing days)
Medical physicist survey with missing tests, missing data, incorrect settings, or failure to take correct action	Survey report or specific pages from report showing problems or test failures
Full-Field Digital Mammography (FFDM) – Failure to follow manufacturer's QC procedures for x-ray unit, monitor, laser printer, and/or other display device	Forms/charts from FFDM manufacturer's QC manual and a copy of the manufacturer's user specifications specific to the QC procedure not being followed
Performance verification test after each mobile unit move	Route schedule and patient log that shows location of unit on date in question; Phantom QC chart or other record to record phantom scores or mass readouts
Overdue medical physicist survey (14 months)	Most recent or two most survey report(s) (or coversheet(s) with date) for system

Medical physicist not identified in survey report	Survey report or coversheet
Infection Control procedure	Written procedure, forms, logs or charts and a copy of the unit manufacturer's recommendations
Medical Outcomes Audit – no examples/ attempts to get biopsy results	Printouts, forms, logs, charts, or contact records
Medical Outcomes Audit – positives not entered	Positive mammography reports, printouts, forms, logs, or charts
Medical Outcomes Audit – no review interpreting physician	Procedure, printouts, forms, logs, or charts
Consumer complaint procedure	Written procedure, forms, logs, charts, or copies of patient complaints
Repeat Level 3 Observations	
QA program is missing personnel responsibilities, QC test procedures	List of personnel responsibilities, facility procedures for QC, technique tables/charts
, repeat analysis QC, compression device QC	QC charts or records since last inspection showing frequency of tests and problems with tests
Medical physicist survey with missing tests, missing data, incorrect settings, or failure to take correct action	Survey report or specific pages from report showing problems or test failures
No corrective action for survey test failures	Survey report or specific pages from report showing both test data, final calculated results, and failure indication/statement by medical physicist

*** Patient names and identifying information MUST be removed from all copies. Leave the medical records numbers intact.**

Whenever inspectors have questions, they may contact the MQSA Hotline. As a reminder, they may also access MQSA Policy Guidance Help System on the FDA website at: http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm

2.9.12 Veteran Health Administration (VHA) Inspections

For FDA MQSA inspectors conducting VHA Inspections, please review the Inspection Debrief Report with the VHA facility representative at the end of the inspection and mail a copy of the post inspection report to the VHA facility representative after the inspection has been submitted to FDA. Once the inspection is submitted to MPRIS, FDA will send the full inspection report to the VHA's FDA Liaison. The VHA will then follow up with the facility to resolve and pending compliance issues and develop corrective action plans that will address the inspection observation(s) noted in the VHA facility's MQSA inspection report.

If FDA MQSA inspectors have questions regarding VHA inspection, please contact the local RRHR or the MQSA Hotline for additional guidance.

2.9.13 Corrected Before Inspection (CBI) Policy

When an inspector comes across a situation in which a facility has identified a quality control or personnel problem, and the facility has documented the corrective action they have taken to address the problem, and the corrective action appears to have resolved the problem based on the inspectors review of QC documentation or personnel records completed by the facility after the corrective action was implemented, then the inspector has the option of considering the situation "Corrected Before Inspection".

These corrected problems could be in any part of the inspection, but do not apply to any situation that would have a significant impact on clinical image quality, medical diagnosis, treatment. The most likely areas where this policy could be applied would be for quality control testing or personnel qualifications. Consideration needs to be given to those facilities that discover and correct their problem(s) before the problem(s) gets worse; however CBI should never be applied to situations involving Level 1 noncompliances.

Inspectors should use the Printable Remarks tab to document the problem that occurred, and to describe the documentation provide by the facility as proof of corrective action. The inspection should also state that the inspector was able to verify in some why that corrective action was effective; i.e. no additional missing QC tests after the facility took the corrective action, or all personnel currently meet the MQSA personnel requirements and are being tracked or monitored on an ongoing basis.

During the exit interview at the end of the inspection, the inspector should remind the facility personnel that the noncompliance identified as CBI should not be allowed to recur. The historical record entered into the Remarks tab and the discussion during the exit interview is important should the facility have serious problems in the future and FDA considers action against the facility at that time.

Since inspector observations and judgment are crucial in making a determination as to whether
a facility has permanently corrected a problem, the following examples are provided as some guidance to help the inspector in making this determination.

When a noncompliance is found to have previously occurred, but is no longer present at the time of the inspection, the facility should be able to provide an explanation of what actions
were taken to correct the problem. If facility personnel do not know why/how the problem was resolved, or do not know the problem existed, an inspector may assume that the noncompliance was not corrected by actions of the facility personnel. Furthermore, non-compliant item(s) that are corrected during the inspection ("on-the-spot" corrections) are not to be treated as though they were "corrected before inspection." So in both of the above scenarios the facility should be cited (i.e., the non-compliant item not having been identified as a problem by facility
personnel with actions taken to permanently correct it, and/or the correction of a non-compliant observation at the time of an inspection).

There is another example when inspectors should cite a facility. This is when there was a non- compliant observation cited during the prior year's inspection, the facility corrected the problem after that inspection, and the same noncompliance occurred again after the initial corrective action, and was again corrected by the facility. While this facility has corrected the problem(s), its corrective actions did not result in a permanent fix, and as such, the noncompliance is likely to occur again. In this type of situation, the facility should be cited.

Note: the above policy does not apply to Level 1 observations. Level 1 observations, even if corrected before the inspection, should still be cited.

2.9.14 Facilities Comments Concerning Their Inspections

The Division of Mammography Quality Standards (DMQS) is very interested in, and continually looking for comments from facilities regarding their inspection and/or inspector (both good and "not-so-good"). We use such information to assess MQSA's progress and to learn which areas in our program require adjustments and improvements.

Since MQSA inspectors are in direct contact with facilities, we ask inspectors to be aware of our need for facilities' comments and we ask that you encourage each of your inspected facilities to contact us. Facilities may contact us through the MQSA Hotline by telephone at 1-
800-838-7715, fax at 1-410-290-6351,or email FDA at MQSAhotline@hcmsllc.com.

We also encourage you to share with us any written comments that you receive. If facilities provide comments included in the facility response letters to inspection findings or send your office a separate letter, we would like you to share these comments with us.

If you have written comments from facilities that you would be willing to share with us, please fax them to 301-847-8502 or mail them to us at:

Division of Mammography Quality Standards
(DMQS) Food and Drug Administration (FDA)
10903 New Hampshire Avenue, WO66 – Room 4621
Silver Spring, MD 20993-0002

3. FISS INSPECTION SOFTWARE AND DATA RECORDING

3.1 General

Caution: Inspectors should request assistance from facility personnel for film-processing, phantom exposure, retrieval of medical records, and other areas. Inspectors should never access the facility's computers or operate the facilities equipment. Taking these precautions will protect the inspector from any allegations that the inspector damaged imaging equipment or computers, or placed viruses on facility computer systems.

Verify that the facility is following the mammography unit manufacturer's QC manual for all Full Field Digital (FFDM), Digital Breast Tomosynthesis (DBT) and Computed Radiography (CR) mammography units. The inspection phantom image should be taken following the Phantom Image QC test procedure defined in the manufacturer's QC manual for the mammography unit.

For facilities using screen-film (S-F) mammography units the facilities should follow the 1999 ACR Mammography Quality Control Manual or a substantially equivalent QC program. The inspection phantom images and the facility's weekly phantom image must be taken at the clinical technique used by the facility for a craniocaudal (CC) examination of the Standard Breast, which is defined in the Glossary.

If a facility is using more than one mammography unit, test each unit and review the appropriate QA/QC records for each. If a facility has more than one site under the same certificate (e.g., mobile facility), review the records and conduct a phantom image QC test for each unit at all sites.

Whenever you review records that contain patient names, you must protect patient privacy. If it becomes necessary to photocopy records, conceal patient names on the photocopies, to ensure confidentiality.

3.2 Data Recording

Record all data in the appropriate screens in FISSweb or FISSclient on your laptop computer as described below. You can access a hardcopy of the FISS inspection questions by going to you "MQSA DOCMENTS" folder on your laptop and locating the "FACILITY INSPECTION WORKSHEET" file. By printing at least one copy of this file, and carrying

it with you to your inspections, you will be prepared to continue with your inspection if your computer suffers a catastrophic failure during the inspection.

3.3 Inspection Assignments

For State inspectors, your supervisor or program manager can assign inspections to you using FISSweb. FDA inspectors can assign inspections to themselves per local workplanning policies. The inspections that are assigned to you will appear in the Facilities with Available Inspections section of the FISSweb main page when you log into FISSweb. Inspections can be assigned to you
all at once, or on a periodic basis (weekly, monthly, quarterly. etc.) depending on your managers preferences for issuing assignments.

When an inspection is in the Facilities with Available Inspections table of the FISSweb main page the inspection is not "locked". The most current changes in the facility's contact information, number and type of mammography units or the accreditation and certification status of the facility can be linked to the inspection via data transmission from the facility's accreditation body to the FDA (State Certifying Agency) as long as the inspection remains in the Facilities with Available Inspections table.

Once the inspection is moved to the Working Inspection list the inspection is no longer available for assignment to, or downloading by, another inspector. The inspection becomes "locked" (i.e. no longer available for updating from the main FDA database) once it is downloaded to FISSclient or the inspection date field is populated.

You should move the inspection to the Working Inspections table of the FISSweb main page, no earlier than one week prior to the scheduled inspection date. That will allow the inspection to remains connected to the FDA database for any updates that may become available prior to you inspection date. Once you moved an assigned inspection to the Working Inspections Table you can begin working on an inspection either in FISSweb or FISSclient. Keep in mind that all inspections begin and end in FISSweb, because an internet connection is needed to perform the administrative tasks of assigning and submitting inspections.

3.4 Inspection Process and FISS Inspection Questions

The main focus of this section is to familiarize you with the layout of the FISS inspection questions. When opening the inspection software, either via FISSweb or FISS client, the inspection questions will be divided into one of three sections on the FISS Inspection Status Screen; Facility, Units, and Personnel. These three categories correspond to the quality areas covered under the MQSA. Each of the three quality sections is subdivided in to subsections that contain the inspection questions as listed Exhibit 1below.

For the purpose of this document the inspection process is described in the order that the subsections appear on the FISS Inspection Status Screen, however, inspectors do not have to follow this order when conducting an inspection. Inspectors must populate the "Inspection Date" field

under the Inspection Information Subsection to access all of the inspection questions. Once the "Inspection Date" field is populated, inspectors are encouraged to cover the FISS inspection questions in whatever order is most convenient to the inspector and the facility, facilitates efficient use of the facility's and the inspector's time, and results in the least amount of disruption to patient care at the facility.

When you open the individual subsections in FISS you will find either a table of links for a specific site, piece of equipment, or personnel member, or you will find a FISS inspection questions for that quality topic. When a quality topic applies to more than one site, piece of equipment, or personnel member, clicking on the link will allow you to access the inspection questions for that specific site, equipment, or individual.

Each screen of inspection question has three tabs at the top of the screen, an Information Tab, a Remarks Tab and a Previous Inspection Tab. The Information Tab is where you capture your answer to the inspections questions. As discussed earlier the Remarks Tab is where you capture details, comments or concerns in a printable or non-printable remark format and the Previous Inspection Tab allows you to review and reference the data from the previous MQSA inspection for that quality topic. When you open a subsection or a link the Information Tab is always open. You can access the Remarks or Previous Inspection Tabs by clicking on the tab.

Any information such as the facility name, address, phone, fax numbers, facility type, name(s) of facility contacts, unit type, unit manufacturer, unit model, and any other accreditation information transmitted to the FDA (or State Certifying Agency) by the accreditation body will be pre-populated into the inspection, as well as the personnel data for any mammography personnel whose credentials were reviewed during the previous MQSA inspection. For newly certified facilities a very limited amount of accreditation information will be prepopulated into the inspection report.

Note that throughout the FISS software, if a data entry field is white, inspectors can update it. If the field is grayed out the data cannot be entered, or the data cannot be edited. You can tract your progress through the inspection and determine which questions have not been answered by noting the "Complete" and "Incomplete" indicators provided for each subsection on the FISS Inspection States Screen.

Exhibit 1: Version 7.00 Inspection Questions

Facility Section

Inspection Information

- Inspector
- Date
- Inspection Type
  - Basic
  - Joint Audit
  - Mentored
- Accompanying

Inspector Inspection
Time
On-site Other
Total
Travel Time

Facility Information

Facility ID
Name
FEI
EIN
Facility Type
Facility
Category
Continuously operating with a valid
Certificate? Displayed?
Expiration Date

Contacts

Facility Accreditation
Contact Facility
Inspection Contact Most
Responsible
Billing Contact
Inspection Report Contact

Image Output QC

Processor Performance QC
Done on all days films processed
C/A (before further exams) documented
Laser Printer QC
Done at least weekly when hardcopy printed
C/A (before further images) documented
RWS Monitor QC
Done at frequency specified by monitor manufacturer when clinical images are interpreted
C/A (before further images) documented

Additional Sites

Medical Records

Site Name
Evaluate
Evaluation

System (to communicate results) adequate:
System to provide medical reports within 30 days? System to provide lay summaries within 30 days? System to communicate serious cases ASAP

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

Medical Audit and Outcome Analysis

Site Name
Evaluate

Evaluation
All positive mammograms entered in system:
Biopsy results present (or attempt to get):
An audit (reviewing) interpreting physician is designated:
Analysis done annually:
Done separately for each individual:
Done for the facility as a whole:

Quality Assurance

Sites Name
Evaluate

Evaluation
The QA records include the following
QA Personnel assigned
Written S.O.P.'s for QC tests:
S.O.P. for infection control:
S.O.P. for consumer complaints:

Repeat Analysis QC

Site Name
Evaluate

Evaluation
Repeat analysis QC is adequate:
Done at least quarterly
Evaluation done
C/A documented

Units

Unit Evaluation

Unit Information

*Unit Number**:**
Room Name or Number: Serial Number:
X-ray Unit still in Use:
Removed from Service Date:
*Unit Type:
*Manufacturer:
*Model: AB Model: Manufacture
Date:

Evaluation

The x-ray system includes the following: Appropriately sized compression paddle(s) Post-exp. display in AEC mode for focal spot
Post-exp. display in AEC mode for target material

This unit is accredited
This unit is new
Mammo equip. evaluation (by medical physicist) done

Phantom Image Quality Evaluation

Units

Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model:

Phantom Image Quality Evaluation
Phantom image display method (inspector)
Phantom image display method (facility)
Phantom used

	Image #1	Image #2
# of fibers		
# of fiber artifacts		
# of speck groups		
# of specks in last group		
# of speck artifacts		
# of masses		
# of mass artifacts		

Quality Control (Digital)

Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model:
Phantom Image QC
Number of operating weeks missing in which test not done at least once:
Image taken at clinical (+/- 1 kVp) or manufacturer recommended setting:
C/A (before further exams) documented:
For mobile units (van, truck, ...)
Performance verification after each move:
Compression Force QC
Compression QC adequate:
Done at least semiannually
C/A (before further exams) documented
CNR QC
Done at frequency specified by unit manufacturer:
C/A (before further exams) documented:
SNR QC
Done at frequency specified by unit manufacturer:
C/A (before further exams) documented:

Quality Control (Screen-film)

Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model:
Phantom Image QC
Number of operating weeks missing in which test not done at least once:
Image taken at clinical (+/- 1 kVp) or manufacturer recommended setting:
C/A (before further exams) documented:
For mobile units (van, truck, ...)
Performance verification after each move:
Compression Force QC
Compression QC adequate:
Done at least semiannually
C/A (before further exams) documented

Survey Report

- Unit Information
- Unit Number:
- Unit Type:
- Room Name or Number:
- Manufacturer/Model:
- Survey Report Information
  - Survey Report available?
  - Date of previous survey
  - Date of current survey
  - Dose value measured by the medical physicist
    - Dose value (mGy) reported
    - Corrective Action (C/A) taken?
  - Survey conducted or supervised by
    - Action taken ?

- Survey Report Part 1
  - Resolution measurement
  - AEC performance – reproducibility (mAs)
  - AEC performance capability
  - Phantom image
  - CNR
  - SNR
  - Artifact evaluation

- Survey Report Part 2
  - Pass/fail list
  - Recommendations for failed items
  - Physicist's evaluation of technologist's QC tests:
    - Processor QC
    - Laser printer QC
    - RWS QC
    - Phantom image
    - CNR
    - SNR
    - Repeat analysis
    - Analysis of fixer retention
    - Screen-film contact
    - Compression
  - Collimation:
    - X-ray field – light field
    - X-ray field – image receptor alignment
    - Compression device edge alignment
  - kVp accuracy

kVp reproducibility
Beam quality (HVL) measurement
Uniformity of screen speed
Radiation output
Decompression

Personnel

Interpreting Physicians

Interpreting Physicians – List
Basic Information
Status
Name
Lead interpreting physician?
Evaluation
Rules qualifying under
If you selected the interim rules:
Initial qualifications under interim rules met?
Licensed?
Certified or 2 months training?
40 CME hours
Initial experience adequate?
If you selected the final rules:
Initial qualifications met?
Licensed ?
Certified or 3 months training?
60 category 1 CME hours?
Initial experience adequate?
Date completed initial requirements
Currently licensed?
Trained in all applicable mammographic modalities?
Trained mammographic modalities (check all that apply): S/F, FFDM, DBT
Continuing experience
Continuing experience adequate?
Number of exams in 24 months
Continuing education
CME credits adequate?
Number of CME's in 36 months

Technologists

Technologists - List
Basic Information
Status
Name
Evaluation
Rules qualifying under:

If you selected the interim rules:

Initial qualification under interim rules met?
Licensed or certified?
Training specific to mammography?

If you selected the final rules:

Initial qualifications met?
Licensed or certified?
40 supervised hours of training adequate

Date completed initial requirements
Currently licensed or certified?
Trained in all applicable mammographic modalities?
Trained mammographic modalities (check all that apply): S/F, FFDM. DBT
Continuing experience

Continuing experience adequate?
Number of exams in 24 months

Continuing education

CEU credits adequate?
Number of CEU's in 36 months

Medical Physicist

Medical Physicist - List

Basic Information

Status
Name

Evaluation

Degree qualifying under

If you selected "Masters (or higher)":

Initial qualification met?
Certified or state licensed/approved?
Masters (or higher) degree in a physical science?
20 contact hours of training in surveys?
Experience in conducting surveys?

If you selected "Bachelors":

Alternative initial qualifications met before 04/28/99?
Certified or state licensed/approved?
Bachelor's degree in a physical science?
40 contact hours training in surveys?
Experience in conducting surveys?

Date completed initial requirements
Currently licensed or certified?
Trained in all applicable mammographic modalities?

Trained mammographic modalities (check all that apply): S/F, FFDM, DBT

Continuing experience adequate?

Continuing Education
CME credits/year adequate?

Number of CME's in 36 months

Summary

Required personnel documents available?

Reports

Inspection Debrief
Remarks
Missing Data

Inspection Submission Screen

Inspection Information
Facility ID
Facility Name
Facility Address
Inspection ID
Inspection Date
Inspection
Type Inspector
Annual Inspection Type
Accompanying Inspector

Report Delivery Delivery Method
Date Delivered/Sent

Notes

I. FACILITY SECTION

3.4.1 Facility and Inspection Information

When you open FISSWeb the program displays the FISSweb home page. At the top of this screen you will see the Inspector Dashboard where you will find a few performance statistics such as the number of inspections you have completed during the current contract period, how many inspections you are working on, average number of days from inspection to upload. Also displayed on the home page is the Facilities with Available Inspections Table, where you can search for any inspection within your territory, and the Working Inspections Table, where your assigned inspections are located. The Facilities with Available for Inspection and Working Inspections Tables provide the following information for each facility:

- Facility ID
- Last Inspection Date
- Last Inspected By
- Locked By
- Facility Name

To start a facility inspection, you must first move the inspection from the Facilities with Available Inspections Table into your Working Inspections Table. In the data fields of the Facilities with Available Inspections section of the screen type in a facility identifier (name, facility ID#, etc.) in the appropriate text box to filter through to the inspection you are looking for. Once the facility comes up, check the radial button on the left hand side of the data line and click "Assign" at the bottom of the Facilities with Available Inspections Table. The inspection should move down to the Working Inspections Table. Multiple inspections can be assigned at one time. You can then click on the inspection ID link to open the inspection.

The inspection opens at the Inspection Status Screen. At the top of the page is the pre populated information about the facility that was transmitted to FDA by the accreditation body. If any of this information is incorrect inform the facility that they must contact their accreditation body to correct the information.

Every inspection begins by clicking on the Inspection Information Subsection and entering an inspection date. You must populate the date field in order to open all of the other data fields in the inspection. In this subsection you will enter your name, the date of the inspection, and the inspection type. You will also capture your inspection and travel time on the Inspection Information screen.

- ***Inspection Information***
  Inspector
  Date
  Inspection Type
    Basic
    Joint Audit
    Mentored
  Accompanying Inspector
  Inspection Time
    On-site
    Other
    Total

Please note the following:

- The date is the date of the on-site inspection. In those very rare situations where an inspection occurs over multiple days a remark listing the inclusive dates of the inspection should be made in this subsection.
- Most inspection will be a Basic annual inspection. In this case the word "Basic" means routine; it does not imply that anything less than a complete MQSA inspection should be performed.
- If you check "Joint Audit"* or "Mentored,"** you also must add the name and ID number of the Accompanying Inspector as well as the office or agency that they represent.
- If a certified inspector is accompanied by an individual who is not a certified MQSA inspector (a state or federal employee who is observing a MQSA inspection, or a supervisor

or MQSA program manager), the inspector must enter the name and title of the individual and the reason for their participation in the MQSA inspection in a remark. On-site inspection time is the time spent conducting the inspection at the facility.

- Time spent issuing preparing the Inspection Confirmation Notice or Reviewing documentation, printing and mailing the Post Inspection Report, or communicating with the facility after the on-site inspection is completed is "Other" time.
- Travel time is the time required to travel from the office or lodging location to the facility and on to you next location or back to the office or lodging location.

* Joint Audit inspections: When a MQSA auditor goes on an inspection with a State or FDA inspector for the purpose of performing an inspector audit as required under the MQSA regulations. The inspector must identify the in the Accompanying Inspector data field.

** Mentored Inspections: When a newly trained graduate of the MQSA Inspector Training Program, or a re-qualifying MQSA inspector who has been away from the program for so time, performs MQSA inspections under the direct supervision of an active certified MQSA inspector. The supervising inspector will download the MQSA inspection and will be the inspector of record, while the mentee will be identified as the accompanying inspector. Text must be entered in the printable remark that explains that the mentee (Name and Identification Number) has conducted the inspection under the direct supervision of the active certified MQSA inspector mentor. Both the active certified MQSA inspector mentor and the mentee must sign the Post Inspection Report.

The only exception to this rule is when a State mentee is supervised by an active certified FDA inspector. In this case the State mentee will be listed as the Inspector and the supervising FDA inspector will be listed as the accompanying inspector. This will allow the State to voucher for the inspection against the MQSA contract.

The inspection questions under the Facility Information Subsection include some pre-populated information as well as a couple of editable inspection questions.

- **Facility Information**

Facility ID
Name
FEI
EIN
Facility Type*
Facility Category
Continuously operating with a valid Certificate:
Displayed?
Expiration

A facility can legally perform mammography if the facility is certified. There are situations in which the mammography facility has a lapse, or break in their MQSA certification and the facility continues

to image patients, or a facility may operate prior to the effective date of their MQSA certificate. It is important during the inspection to determine if the facility was, "Continuously operating with a valid Certificate". Let's look at a couple of examples:

1. A mammography facility is notified by FDA that their MQSA certificate in no longer in effect and the facility must cease performing mammography because the facility failed an Additional Mammography Review performed by the American College of Radiology (ACR), at a level that posed a serious risk to human health. FDA requires the facility to notify patients and their referring healthcare providers of the clinical image quality problems at the facility. The facility successful completes the FDA required patient notifications and ACR approves the facilities corrective action plan and re-instates the facility's accreditation. FDA issues the facility a new MQS certificate.

   Six months later the facility receives their annual MQSA inspection and the inspector notes in the patient logs that there were mammography exams scheduled for the time period when the facility was not certified. Upon further investigation the inspector learns that the facility continued to provide mammography services to twenty patients after FDA told the facility that their certification was no longer in effect.

   The facility in example #1was not continuously certified while they provided mammography services. The answer to, "Continuously operating with a valid certificate:" would be "No". The inspector should include printable remarks that detail the dates that the exams were performed and how many patients were imaged during this period of uncertified operation. The inspector should also collect copies of the patient log sheets, and discuss these findings with the local MQSA auditor or the Regional Radiological Health Representative.

2. An individual purchases a medical clinic; building, equipment, records and all. He sees a MQSA certificate from the former operator on the wall in the building. He notices that there are six months left on the MQSA certificate before it expires. He figures he can save a few bucks on the accreditation and hires technologists and physicians to operate the new mammography program. He instructs his staff to perform mammography under the prior owners MQSA certificate. A month before the expiration date of the MQSA certificate the owner contacts the ACR and applies for new facility status. He tells the ACR that he has been performing mammography at that location for five months under the prior owner's MQSA certificate. ACR tells the owner to cease performing mammography because he does not have a valid MQSA certificate. Facility accreditation and MQSA certification do not automatically transfer from one owner to the next during the sale of a business. ACR informs FDA that the facility has operated uncertified. FDA conducts a 'For Cause" inspection at the facility. The inspection reveals 371 patients received mammograms at the facility during the period of uncertified operation.

   The facility in example #2 provided mammography services prior to receiving a MQSA certificate. The facility was not continuously operating with a valid certificate because they did not have a valid MQSA certificate when they began operating. The answer to the FISS inspection question "Continuously operating with a valid certificate:" is "No".

*You can refer to the Glossary of terms for clarification of the various types of mammography facilities. Also please remember that federal facilities (Army, Navy, Air Force, Federal Agencies, VHA, Federal Prisons, Indian Health Service, etc.) can only be inspected by certified MQSA inspectors employed by the FDA. State agencies working under contract for the FDA cannot perform these inspections. Occasionally a facility is miss-classified during the accreditation process. If you are assigned a facility for inspection and have reason to believe that the facility may be a federal facility, please contact the MQSA Hotline, and request FDA verify the facility's category type prior to traveling to facility for an MQSA inspection.

3.4.2 Contacts

The next FISS subsection is Contacts. In this section the inspector will capture the names and contact information for the persons with responsibility for the operations of the mammography facility. Some of these individuals may or may not be involved in the daily operations of the mammography program, but it is important to document who has authority and power to affect change in the facility's operations, who had contact with the MQSA inspector, and who may have had knowledge of prior noncompliances or participated in the inspection activities.

FISS has a nice "Copy" feature that allows you to copy the corresponding contact information from the previous inspection into the editable portion of Contact screen, if that information is still correct. Likewise, each of the contact fields includes a "Copy Facility Accreditation Contact" button which allows you to copy that information into the editable portion of each contact field, if the accreditation contact fills multiple roles at the facility.

- Contacts
  - Facility Accreditation Contact*
  - Facility Inspection Contact*
  - Most Responsible*
  - Billing Contact
  - Inspection Report Contact

- The accreditation contact is the individual identified by the facility in their accreditation application as the individual who will oversee the mammography program. The accreditation contact is usually a medical doctor, and the accreditation contacts information is normally prepopulated with information that FDA received from the accreditations body.
- The inspection contact is usually the individual that the facility wants you to contact to schedule inspections or to call if you have questions about the facility's operations.
- The most responsible individual is the person with the authority to make major changes in the facility's operation if needed. This includes having the authority to hire and/or fire technologists, interpreting physicians, and medical physicists. This individual should also have the authority purchase equipment that may need to be replaced including the mammography unit. The most responsible individual is usually someone outside of the mammography department, such as a Chief Executive Officer or president who may be

located at an off-site location.

- The billing contact is the person who should receive the bill for the MQSA inspection. It is important that the correct address be provided for this individual because that is where the MQSA inspection bill will be sent.
- The inspection report contact is the individual who will receive/received the MQSA inspection report.

*Please note that the information regarding the first three contact persons listed above will automatically be displayed on the first page of the Post Inspection Report. The name of the Inspection Report Contact and the manner in which the report was (or will be) made available to the facility are listed at the end of this report.

3.4.3 Image Output QC

Image output devices are the components that are used to view mammography images. This includes the Review Workstations (RWS) monitors used by the interpreting physicians, the laser printers used to print interpretation quality hardcopy clinical images, and the film processors used process screen-film images.

Within the Image Output QC subsection there are specific inspection questions for each of the output devices.

Image Output Devices

Processor Performance QC

Done on all days films processed

C/A (before further exams) documented

Laser Printer QC

Done at least weekly when hardcopy printed

C/A (before further images) documented

RWS Monitor QC

Done at frequency specified by monitor manufacturer when clinical images are interpreted

C/A (before further images) documented

Inspectors should review the QC records for the specific image output device and determine if the required QC tests were performed at the frequency noted above. Which QC tests must be performed will depend on the output device being evaluated. The MQSA regulations state that for imaging modalities other than screen-film, the manufacturer of the mammography unit defines the QC testing procedures for the laser printer and the RWS monitors. Some mammography unit manufacturers choose to defer to the manufacturers of the laser printers and RWS monitors for a QC testing procedures.

Because teleradiology is becoming very popular, inspectors must be diligent in asking facilities if their radiologists interpret mammograms on monitors located off-site. Examples of off-site locations included but are not limited to: sister sites within the same corporate network, a hospital, the office of a radiology practice, or even the interpreting physician's residence. Regardless of where the off-site monitors are located, they are part of the imaging chain of the facility, and as such are subject to inspection. The certified facility must provide the inspector with the QC data, and the MEE or annual survey report, for all monitors used by personnel to interpret mammograms. Inspector must review the QC records for all off-site monitors and printers, but it usually is not necessary for the inspector to visit the off-site location.

A printable remark should be used to document and dates of missing QC or any failures to follow the appropriate QC procedure for all laser printers or monitors.

3.4.4 Additional Sites

If the facility has more than one site operating under the same certificate (such as a mobile facility), select the Additional Sites Subsection and record the appropriate information in the corresponding screen. If the facility contracts with other facilities or individuals to provide mammography services (i.e. laser printers for printing hardcopy images, or monitors where softcopy images are interpreted) at a location other than the address of the certified facility being inspected, inspectors should enter those additional facilities or locations as additional sites for the facility being inspected, and record the appropriate information in the Additional Sites Subsection for each additional locations. A printable remark should be provided to identify which pieces of equipment are located at each location.

3.4.5 Medical Records

The Medical Records Subsection inspectors should document there review of the facilities system for communicating results to patients and their healthcare providers. This includes evaluating the written procedures or demonstrated process for compliance with the MQSA timeframes for communicating results. Also the inspector should randomly review a selection of mammography reports for MQSA required content and assessment categories.

Inspectors should copy mammography reports or letters that indicate problems. However, inspectors should ensure that they have removed patient-specific information (patient names, addresses, and telephone numbers) from the copies before removing the copies from the facility or sending them to the FDA field office. Additionally, there may be situations where an inspector needs to copy a facility's procedure for issuing reports and letters. Again, in the "Remarks" tab, inspectors should explain the problems observed with a facility's procedures, reports, or letters. Inspectors have the authority to inspect and copy patient records for MQSA purposes under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regulations. You can view the privacy rules in HIPAA at: http://www.hhs.gov/ocr.

Site Name
Evaluate
Evaluation
System (to communicate results) adequate:
System to provide medical reports within 30 days?
System to provide lay summaries within 30 days?
System to communicate serious cases ASAP
Random written reports
Number of random written reports reviewed
Number with assessment categories
Number with qualified interpreting physician identification

3.4.6 Medical Audit and Outcome Analysis

The facility should have a system or a procedure for reviewing and tracking outcomes of positive mammograms and correlating them with biopsy results. The facility must use this system annually both individually for each interpreting physician and for the facility as a whole.

The purpose of reviewing these records is to assure that clinical outcomes are followed-up. Inspectors should determine if the facility has a medical audit system, i.e., if it tracks or attempts to track results of positive mammograms. This can be accomplished by asking the facility to explain how they track positive mammograms, obtain biopsy results, and what if any procedures or documentation are in place for accomplishing these tasks. Ask to see a sample of a biopsy result reports from a positive mammogram performed at the facility.

Medical Audit and Outcome Analysis
Site Name
Evaluate
Evaluation
All positive mammograms entered in system:
Biopsy results present (or attempt to get):
An audit (reviewing) interpreting physician is designated:
Analysis done annually:
Done separately for each individual:
Done for the facility as a whole:

Once the inspector determines that the facility is tracking the outcomes for positive mammograms, the inspector should review the most recent report for analyzing the outcomes. The outcome analysis report should be performed annually and done separately for each facility as a whole and for each interpreting physician that reads mammograms at the facility.

FDA policy is to give each facility a year to perform mammography, plus six months track down and up follow-up on positive outcomes, plus an additional six months to analyze the outcomes data and generate a report. This means the facility will have up to two years from the initial start of their mammography operations to generate their first medical outcomes report, and then annually after that. Due to the use of electronic data management systems, many facilities can generate a medical outcomes report at any time, but the purpose of the MQSA requirement is not to generate a report for the MQSA inspector, but to add value to the practice of mammography by having the audit reviewing physician discuss medical outcomes and reading rates with the interpreting physicians in mammography practice. Thus the medical outcomes report reviewed by the inspector should not be

generated on the day of the inspection, but should represent an annual review and evaluation performed by the audit reviewing physician, and shared with the interpreting physicians.

3.4.7 Quality Assurance

In the **"Quality Assurance"** Subsection under the Facility Section of the Inspection Status Screen record answers for the following questions for the facility (and if applicable, for each additional site under the facility's certificate.

The MQSA regulations require each facility to designate a "lead interpreting physician" who is responsible for overall quality assurance and compliance with the quality standards at the facility. The QA program includes the following elements:

Quality Assurance
Sites Name
Evaluate
Evaluation
The QA records include the following
QA Personnel assigned
Written S.O.P.'s for QC tests:
S.O.P. for infection control:
S.O.P. for consumer complaints:

For a facility with one or more additional sites under the same or a different certificate(s) (e.g., mobile facilities), evaluate each site that keeps QA records.

Record in the printable remarks any deficiencies or specific problems that led you to answer "No" to any of these questions. Collect a copy of the facility's Standard Operating Procedure (S.O.P) for the inspection records if problems are noted. The collected copy of the S.O.P can be compared to any revised S.O.P procedures submitted by the facility in response to the inspection findings.

3.4.7.1 Quality Assurance Personnel Assignment:

QA personnel assignment means: 1) the identification of the lead interpreting physician, the QC technologist, the medical physicist, and the audit interpreting physician, and 2) if other individuals are assigned to perform all or part of the functions of the above personnel, the responsibilities of the new individual(s) within the QA program in general, and the QC tests in particular, must be defined.

You should look for the following documentation to determine that facilities meet the MQSA requirements for assigning responsibilities to quality assurance personnel:

- The names of personnel with QC responsibilities should be clearly identified. You should look for the names of the lead- interpreting physician, medical physicist(s), quality control technologist(s), audit (reviewing) interpreting physician(s) and any other facility personnel

with delegated quality assurance responsibilities.

- A statement of their respective responsibilities for each person with QC responsibilities. Because the regulations already specify the responsibilities of the lead-interpreting physician, medical physicist(s), quality control technologist(s), and audit interpreting physician(s), the facility does not have to restate the responsibilities of these individuals. However, if the facility delegates quality assurance responsibilities to someone other than the lead-interpreting physician, medical physicist(s), quality control technologist(s), or audit interpreting physician(s), a statement of responsibilities for that individual(s) has to be provided.

3.4.7.2 Written S.O.P.'s for Quality Control Tests

Quality Control testing procedures; 1) verify that all equipment functions in accordance with the quality standards set in the regulations, 2) monitor critical test parameters and/or conditions, and 3) describe corrective actions that must be taken within the time frames set in the regulations, including tests following such actions. Examples of such procedures are given in the quality control manuals provided to the facility by the manufacturer of the mammography unit for digital unit types, the manufacturer of the monitor, the manufacturer of the laser printer, or the 1999 ACR Mammography Quality Control Manual for screen-film unit types.

If the facility has a QC manual the answer to "Written S.O.P.'s for QC tests:" is "Yes". If the inspector knows that the facility is not using the most recent version of the QC manual for digital mammography unit types, the inspection question "Written S.O.P.'s for QC tests:" should be answered "Yes", with a printable remark that the facility should contact their service representative to determine if the newest version of the manufacturer's QC manual is applicable to the facility's unit, for the first encounter of a facility operating without the latest version of the QC manual. If in subsequent inspections the facility continues to operate without the most current version of the manufacturer's QC manual applicable to their mammography unit, the inspection questions "Written S.O.P.'s for QC tests:" should be answered "No", and the software will generate the appropriate citation.

3.4.7.3 S.O.P. for infection control

The facility must have a procedure specific to cleaning the mammography equipment and not an overarching facility procedure for general disinfection. It must address the procedures for cleaning contaminated mammography equipment to prevent the transmission of blood borne pathogens and infectious diseases, which is a more rigorous or longer cleaning procedure than simply cleaning or wiping down a mammography unit in between each patient.

To meet the MQSA requirements for infection control, the facility must:

- Provide written documentation that describes the infection control procedures used by the facility. If reference material is cited in the facility's description of its procedures, the facility must have a copy of the referenced material. The procedures used by the facility must comply

with applicable federal, state and local regulations as well as manufacturer's recommendations.

- Have documentation (e.g., Logs or charts) indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials. In those cases where there has not been an episode of contamination since the last inspection, the facility should make that clear to the inspector.

3.4.7.4 S.O.P. for consumer complaints

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

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

3.4.8 Repeat Analysis QC

Facilities are required to track and analyze the reasons for, and causes of, repeated mammograms for the purposes of improving image quality and reducing patient exposure from repeated mammograms which may not have been necessary if better techniques had been employed to acquire the original images.

Repeat Analysis QC
Site Name
Evaluate
Evaluation
Repeat analysis QC is adequate:
Done at least quarterly*
Evaluation done
C/A documented

How the repeat images are tracked varies depending on the unit type and installed software. For digital unit types the repeat images may be captured using software on the mammography unit and then exported to a computer for printing. For screen-film units repeat images may be tracked manually, with the noting the reason for a repeated image on a tally sheet. Regardless of the tracking method used, the facility must count a patient volume of at least 250 patients in its repeat analysis. This means the facility starts collecting the all rejected mammography images at the beginning of the quarterly evaluation period, and continues to collect rejected images until the total number of patients imaged during that quarter has reached 250 patients or the end of the quarterly evaluation period is reached. The facility can track repeated mammograms beyond 250 patients if they choose to so long as analysis of the repeated images is performed on a quarterly basis.

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 they 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).

* Note: 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).

Under 1995 Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requirements, the repeat analysis (in a JCAHO hospital or facility) was to be performed on the basis of each individual technologist, rather than being based on the entire facility as is the MQSA standard. JCAHO has since modified its standards to allow the analysis to be performed on a facility basis. Whether the analysis is performed after the facility or the individual technologist has examined 250 mammogram patients is 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.

II. UNITS SECTION

3.4.9 UNITS

Under the Units Section you will find the FISS inspection questions for the mammography unit

information, the phantom image quality evaluation, quality control, and the medical physicist survey. Each of these topics describes, or involves an evaluation of, the mammography unit.

3.4.9.1 Unit Evaluation

The unit evaluation questions are unique to the unit type. When you click on the link for the specific unit you want to evaluate the questions for that unit-type will appear. Prepopulated information received from the accreditation body or carried forward from the prior MQSA inspection will appear under the Unit Evaluation Subsection.

When an inspector encounters a new mammography unit at the facility, one that is not listed in the table of units on the Unit Evaluation Screen, the inspector will have to add that unit to the inspection report by clicking on the "Add Unit" link located just above the table of units on the Unit Evaluation Screen.

Unit Evaluation

Unit Information

Unit Number:*,***
Room Name or Number:
Serial Number:
X-ray Unit still in Use: **
Removed from Service Date:
Unit Type:***
Manufacturer:*
Model:* AB
Model:
Manufacture Date:

Evaluation

The x-ray system includes the following:
Appropriately sized compression paddle(s)
Post-exp. display in AEC mode for focal spot
Post-exp. display in AEC mode for target material
This unit is accredited
This unit is new
Mammo equip. evaluation (by medical physicist) done

Any time mammography equipment (units, laser printers, monitors, processors) undergoes a major repair or new mammography equipment is installed, a Mammography Equipment Evaluation (MEE) must be performed by the medical physicist. Inspectors should review the MEE report in addition to the annual survey report and note any problems with the MEE in a printable remark under the Subsection for that specific piece of equipment.

* **Note:** Unit Number, Manufacturer and Model Number are prepopulated with information

from the accreditation body.

** **Note:** The question, "X-ray unit still in use:", has 4 possible answers: "Yes" (Y), "No" (N), "Evaluate Records Only" (R) and, "Temporarily out of Service" (T). "Yes" (evaluate all) means the unit is functional on the day of the on-site inspection and should be evaluated for the phantom image test, the applicable QC records, the physics survey, and if applicable, the Mammography Equipment Evaluation (MEE). "No" means that the unit should not be evaluated for anything. It applies to a unit that is not currently in use, has had no activity whatsoever since the previous inspection, and the facility has withdrawn the accreditations for the unit. Such units will be deleted from the records for the next inspection. "Evaluate Records Only" means the unit should be evaluated only for the applicable QC records and the survey
report and/or MEE. It applies to a unit that was in service for a period of time after the previous inspection, but has since been permanently removed from service, or a unit that the facility may not be using, but is still accredited and thus could be used by the facility at any time. "Temporarily out of Service" means the unit is being repaired or otherwise unavailable at inspection time. The applicable QC records and the survey report/MEE should be reviewed for a unit that is "Temporarily Out of Service", however the unit may be unable to produce a phantom image due to it being out of service. If possible the inspector should return to the facility and perform a phantom image test after the unit is repaired and returned to service (see examples below).

***Note:** Some mammography units may operate in more than one imaging modality. In those cases, the unit may appear as two units in the table of units on the Unit Evaluation Screen, but the unit is represented by a single physical unit. Each imaging modality will have a unique unit number. In those situations where the unit operates in an imaging modality that is approved for clinical use through the FDA's certificate extension process, the unit will have two unit numbers; one provided by the accreditation body through the routine accreditation process, and one unit number in the 90's (i.e. Unit 90, Unit 91, Unit 92, etc.) provided by the FDA through the certificate extension process. For inspection purposes, treat these units as two separate units and proceed with the inspection as if the unit was physically two different mammography units.

For example, an inspector sees a single mammography unit in the exam room. The mammography unit may contain technology that allows it to produce images in the standard 2D imaging format and in the DBT imaging format. In FISS that single physical unit will be represented by two unit numbers; the 2D imaging modality will receive a unit number from the facility's accreditation body, the DBT imaging modality will receive a unit number in the 90's from the FDA through the certificate extension process.

The certificate extension process is unit based, not facility based. Inspectors should verify that the facility has an FDA certificate extension letter for each unit that FDA has approved for use by the facility. The unit will be identified by unit number and serial number in the FDA certificate extension letter.

All X-ray units that are used to image patients, except for investigational or research units and units

that are currently excluded from the regulations, such as those used only for stereotactic procedures, must be evaluated regardless of their accreditation status. Furthermore, all units at the facility that are used to image patients (with the exception of demo units, loaners, those on a trial basis, & investigational units, for which the accreditation status should be "NA") must be accredited by an AB or have an FDA certificate extension letter.

If the facility has filed an application for accreditation with an AB, the answer to the "This unit is accredited:" should be "Y" (for Yes) or "P" (for pending) depending on the current status of the accreditation application for that unit. The facility will have a certificate, letter, or unit sticker stating the unit was approved by the accreditation body, or documentation from the accreditation body stating the accreditation application was received and is under review.

If, on the other hand, the inspector answers the question "This unit is accredited:" with "No" (N), the FISS program will cite a Level 1 (L1) or Level 2 (L2) non-compliance, depending on whether the unit has been in clinical use for at least one year (L1) or less than a year (L2). The table below outlines the unit accreditation citations.

CITATION LEVELS FOR UNACCREDITED UNITS

Is the unit accredited?	Is this a new unit?	Resulting Noncompliance
Yes	Yes	No Citation
	No	
	NA	
Pending	Yes	No Citation
	No	
	NA	
No	Yes	Level 2 Citation
	No	Level 1 Citation
	NA	No Citation

FDA considers software upgrades to be "major repairs," requiring an onsite visit by the medical physicist (unless specifically exempted by an Approved Alternative Standard). Review the facility's service reports to identify modifications to the unit's software. Software upgrades may also be imbedded within a hardware change (e.g. updated software may be contained on a type of programmable chip located on one of the unit's printed circuit boards). The latter scenario may be difficult to identify, but potentially could be noted on service reports or manufacturer's instruction sheets covering system enhancements. Inspectors can contact the MQSA Hotline if they need assistance identifying software upgrades that require an MEE performed by a medical physicist.

"X-ray unit Still in Use:" Example

In general, to unit information that is incorrect, send an e-mail message to the MQSA Hotline with the correct information. Subsequently, FDA will work with the AB to correct the MPRISweb data. Meanwhile, there are some basic steps to take during the inspection to minimize any uncertainty regarding unit information, particularly for facilities with multiple units, each of which has a different accreditation and use status.

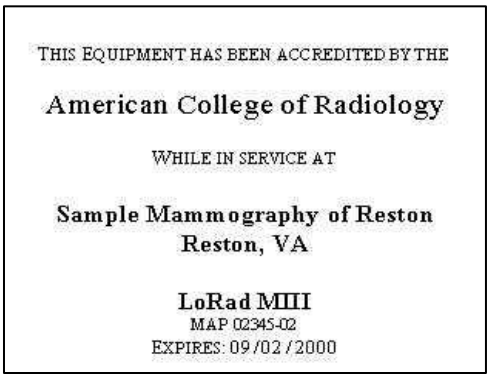
For example, a facility had two GE units (unit #1 in Room #1 and unit #2 in Room #2) that were used

from early 2000 to April 2012 and then removed from service. The facility replaced the GE units with two Siemens units (unit #3 replacing unit #1 in Room #1; and unit # 4 replacing unit #2 in Room #2) and subsequently started using the replacement units on patients.

If you inspected this facility in July 2012, you would probably have four machines listed in the Units Table on the Unit Evaluation Screen in FISS, with the inspection information as follows: the two GE units designated as accredited (if their accreditation had not yet expired) and the two Siemens units, each showing an accreditation status of Yes or Pending. For this example we will assume that a medical physicist conducted an MEE on each of the Siemens units before the facility started using them on patients. The inspector should proceed as follows:

1. Answer the question "X-ray unit still in use:" as "Evaluate Records Only" for each of the GE units and as "Yes" for each of the Siemens units"
2. Assign Room # 1 to Siemens unit #3 and Room #2 to Siemens unit #4. Verify the serial numbers of the units in each room.
3. Look for ACR accreditation stickers* on each of the Siemens units. If the AB accredited the new units (accreditation status is "y") the facility should have such a sticker attached to each unit. The last two digits in the MAP number (located in the lower part the sticker) refer to the unit number assigned by the AB.

   * Not all AB's issue stickers with accredited units, others such as TX issue state certificates instead.



Sample AB Accreditation Sticker

4. If the facility received only a preliminary approval to use the units on patients while their application for accreditation is being reviewed, the accreditation status for the new units will most likely be downloaded as "Pending."
5. If there are errors in other pre-filled information for the Siemens units (such as unit manufacturer and model), document the corrections in the printable Remarks section and send an e-mail to the MQSA Hotline referencing the facility name and inspection ID number.
6. A final note regarding unit numbers. AB's assign unit numbers. The ACR, for instance, does not (normally) re-use the unit numbers. Hence, if a facility is replacing units 1 and 2, the new ones

will be numbered 3 and 4. Both FDA and ACR use this practice to keep track of the units. Therefore, regardless of what the facilities may call the units themselves, the only thing that matters for the inspection is what numbers the AB has given them. If the facility shows what it terms units 1 and 2, and your software shows units 3 and 4, keep in mind that the latter two numbers are not "bad data" from the AB, but rather exactly how the system works. In essence, go with FISS data. It will be correct most of the time.

3.4.9.2 Phantom Image Quality Evaluation

The MQSA program uses the Phantom Image Quality Evaluation as a means of determining if the contrast, optical density, and clinical image quality are maintained at optimal levels. This is an evaluation of the entire imaging chain, from the acquisition of the image at the unit, to the viewing of the image either in softcopy format at the review workstation, or hard copy format at the laser printer, or on film developed through a film processer for screen-film images.

There are many new models of digital mammography units being sold in the United States. These digital mammography units can take clinical images in different imaging and operational modes. There is 2D imaging, 3D imaging, synthesized 2D images that are created from 3D images. This has led to a number of questions from inspectors about which imaging mode should be used during the MQSA inspection to obtain the inspection phantom image.

For digital mammography units, the inspector should follow the phantom image QC test procedure as defined in the manufacturer's QC manual for the mammography unit, regardless of how that facility uses the unit to image their clinical patients.

Phantom Image Quality Evaluation

Units

Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model:

Phantom Image Quality Evaluation
Phantom image display method (inspector)
Phantom image display method (facility)
Phantom used

	Image #1	Image #2
# of fibers		

# of fiber artifacts
# of speck groups
# of specks in last group
# of speck artifacts
# of masses
# of mass artifacts

Image 1 Calculations	Image 2 Calculations
Fibers score	Fibers score
Fibers pass/fail	Fibers pass/fail
Specks score	Specks score
Specks pass/fail	Specks pass/fail
Masses score	Masses score
Masses pass/fail	Masses pass/fail

Compliance can be demonstrated by having the inspector ask the radiologic technologist to acquire a phantom image using the facility's mammography phantom, for each mammography unit in use at the facility. For digital mammography technology, the procedures and techniques for acquiring the phantom image can be found in the QC manual of the mammography unit manufacturer. For screen-film mammography the Phantom Image QC test procedure in in 1999 ACR Mammography Quality Control manual should be followed. For screen-film technology the facility must set the kVp for the phantom image test to a value that is within ±1 kVp of the clinically used kVp for patients with a standard breast.

Inspectors should be present in the mammography room when the phantom image is taken. The inspector should verify with the technologist that this is the same test procedure she follows for the weekly phantom image QC test, and that the procedure agrees with the test procedure found in the appropriate FFDM manufacture's QC manual or the ACR manual.

For digital mammography the phantom image should be scored on one of the display methods recommended by the FFDM unit manufacturer for the weekly phantom test (this could be the acquisition work station (AWS) or the review work station (RWS), depending on the FFDM unit), with the viewing conditions the facility uses to review and score its phantom images. If the phantom image is scored using softcopy, the inspector should ask the facility to print a hardcopy of the inspection phantom image. If the printer is located off-site, the inspector should ask the facility to have a hardcopy of the inspection phantom image printed and mailed to the inspector's office.*

For screen-film mammography the phantom image should be scored at the viewboxes used by the radiologist whenever possible, with the proper masking used to eliminate any extraneous light and low level room lighting. The inspector should retain the inspection phantom image film.*

> ***Note:** The inspection phantom images should be retained by FDA and State MQSA inspectors, and stored with the inspection reports. These phantom images should be provided to the MQSA Auditor, if requested, during the inspector audit process.

Inspectors should be considerate and conscientious when requesting access to the reading rooms of

the radiologist. The MQSA inspection should be as minimal of disturbance to the radiologist as possible. Informing the technologist that the inspector would like to view the inspection phantom in the location where the radiologist reads clinical images at the beginning of the inspection can facilitate access to the reading room at the time that is most convenient for the radiologist. If access to the reading room is not possible, the inspector may score the phantom image at the Acquisition Workstation (AWS) or viewbox that the technologist uses for her quality control tests.

Inspectors will record their phantom image score as Phantom Image #1 for each unit under the Phantom QC Evaluation Subsection of the Units Section. For digital mammography the inspector must note the display method (e.g., softcopy or hardcopy) that is used to score the inspection phantom image as well as the display method that the facility uses to score their weekly phantom image bay answering the FISS questions; "Phantom image display method (inspector)" and "Phantom image display method (facility)".

The inspector should record the number of objects and artifacts in each of the three object types as stated below. Additional guidance regarding phantom image scoring can be found below in Section 3.4.9.2.A or in the 2000 FDA Phantom Image Scoring video available from DMQS.

- *Fibers (0 to 6 in integers or halves, e.g., 0, 0.5, 1, 1.5, …5, 5.5, 6)*
- *Fiber artifacts (0,0.5, or 1)*
- *Speck groups (whole and partial) that you can see (an integer from 0 to 5)*
- *Specks in the last scored group (an integer from 2 to 6)*
- *Speck artifacts (any integer from 0 to 6)*
- *Masses (0 to 5 in integers or halves, e.g., 0, 0.5, 1, 1.5, …4, 4.5, 5*
- *Mass artifacts (0, 0.5, or 1)*

If the net number of objects visualized in all categories in the inspection phantom image is equal to or above the minimum phantom image score of 4 Fibers, 3 Speck Groups, and 3 Masses required by the MQSA regulations, then the phantom image evaluation is complete.

When the phantom image taken by the inspector fails to meet the minimum phantom image score for any object group, the inspector will score the last weekly QC phantom image taken by the facility. The inspector will record the phantom score that the inspector obtains from scoring the facility's most recent weekly QC phantom image as Phantom Image #2 in FISS under the Phantom QC Evaluation Subsection of the Units Section. The inspector should request a hardcopy of all phantom images whose scores are documented in the FISS inspection record.

By scoring the facility's most recent weekly phantom image you may be able to determine if the problem that was detected in your inspection phantom image was present when the facility last performed the phantom image QC during their routine weekly QC testing. If the problem that is causing the phantom image score to fail was present when the facility performed their weekly QC, corrective action should have been taken by the facility, or at least be in-process depending on the timing of your inspection and the facility's last phantom image QC test.

If Phantom Image #2 passes, the phantom image quality evaluation is complete. No citation will be issued by the FISS software; however the inspector should include a printable remark in the inspection report which states the phantom image taken on the day of the inspection failed. The facility should be directed to follow the corrective action recommendations listed in the mammography unit manufacturer's QC manual for a failing phantom image. The inspector should also note any promises of correction made by the facility in the printable remarks.

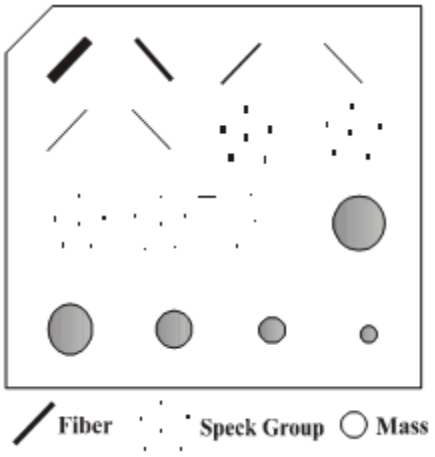
If Phantom Image #2 fails the phantom image quality evaluation, the FISS software will cite the facility at a Level 1 or Level 2 noncompliance depending on the phantom image net score. The

inspector should note in a printable remark any actions taken by the facility to attempt to correct or address the failure of the facility's weekly phantom image. The inspector should also note any promises of correction made by the facility in the printable remarks.

> **Note:** For the Hologic Selenia units, the phantom test passing score as defined by the manufacturer is 5 Fibers, 4 Speck Groups, 4 Masses or 4.5 Fibers, 4 Speck Groups, 3.5 Masses under certain conditions. Also, for the Siemens Mammomat NovationDR, the phantom test passing score as defined by the manufacturer is also 5 Fibers, 4 Speck Groups, 4 Masses or 4 Fibers, 3 Speck Groups, 3 Masses under certain conditions. While these phantom image scores are required by the manufacturers of these unit, and must be met by the facility in their QC program; for regulatory action, FDA uses the passing phantom image score established by the FDA-approved accreditation bodies and referenced in the MQSA regulations, which is 4 Fibers, 3 Speck Groups, 3Masses, for all mammography units and imaging modalities.

If the phantom image fails at a Level 1noncompliance, consult APPENDIX 3, "MQSA Guide for Additional Mammography Review (AMR)," for further action.

3.4.9.2A Phantom Image Scoring - General Procedure



An illustration of the shape and location of each of the test objects in the FDA-approved mammography phantom.

Always count the number of visible objects from the largest object of a given type (fiber, speck group, or mass) downward, until a score of 0.0 or 0.5 is reached, then stop counting for that object type.

Fibers – Count each fiber as one point if the full length of the fiber (or a one mm less) is visible and the location and orientation of the fiber are correct. Count a fiber as 0.5 point if more than half, but not all the fiber is visible, and its location and orientation are correct. If a fiber-like artifact appears anywhere in the insert area of the image, but is not in an appropriate location or orientation, subtract the "artifactual" fiber only from the last "real" fiber scored if the artifactual fiber is equally or more apparent. Note that the highest value that you can subtract for artifacts is the score of the last real fiber.

Speck groups – For digital images, displayed as softcopy images on a monitor, you may view the speck groups through the magnifier feature of the monitor software. For screen-film images use the large field of view 2.5X magnifying glass provided to assist in the visualization of specks. Count each speck group as one point. A full speck group is counted as one if four or more specks are visible in the group in the proper locations. The speck group is counted as 0.5 (half a speck group) if two or three specks in the group are visible. If noise or speck-like artifacts are visible in the wrong locations in the phantom insert but are as apparent as the real specks being counted, deduct them one for one from the individual specks you counted. Subtract artifactual specks only from "real" specks in the last group counted. Note that the highest value that you can subtract for artifacts is the score of the last real speck group.

Masses – Count each mass as one point if a density difference is visible in the correct location and the mass appears to be generally circular against the background. Count each mass as 0.5 point if a density difference is visible in the correct location, but the mass does not have a generally circular appearance (less than 0.75 of the circumference is visible). If there is a mass-like artifact appearing in the wrong location anywhere in the phantom insert, subtract the "artifactual" mass only from the last "real" mass scored if the artifactual mass is equally or more apparent. Note that the highest value you can subtract for artifacts is the score of the last real mass.

Note: Inspectors should enter scores for the artifactual fibers, specks, and masses described above in the computer program directly as an artifact count, which will be subtracted by the computer from the "raw" count of objects in each category. Note in particular, the way the computer counts specks (real or artifactual): 1 speck within a group of specks is counted as 0.0 or no speck groups, 2-3 specks within a group of specks is counted as 0.5 or half a speck group, and 4 or more specks within a group of specks is counted as 1.0 or a whole speck group.

> **Note:** There are a total of 16 imaging objects (6 fibers, 5 speck groups and 5 masses) in the phantom. For the purposes of this test, the minimum number and type of objects that must be visible in order to get a passing score are: the 4 largest fibers, the 3 largest masses, and the 3 largest speck groups.

3.4.9.3 Quality Control

The purpose of reviewing Quality Control (QC) records is to assure that the technologist's QC tests are routinely done at the frequencies required, that records of these tests are in order, and corrective actions are taken when test results exceed action limits.

Review all of the QC records for the past 12 months or since the last inspection*, whichever is longer. For a new facility review the records back to the date of the provisional certification. Under the Quality Control Subsection the inspector will see the Quality Control tests that are applicable to the unit-type that you are inspecting.

- For digital units types review the facility's QC documentation for the following QC tests:.

Quality Control (Digital)
Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model:

Phantom Image QC
Number of operating weeks missing in which test not done at least once:**
Image taken at clinical (+/- 1 kVp) or manufacturer recommended setting:
C/A (before further exams) documented:
For mobile units (van, truck, ...)
Performance verification after each move:
Compression Force QC
Compression QC adequate:
Done at least semiannually **
C/A (before further exams) documented
CNR QC
Done at frequency specified by unit manufacturer:
C/A (before further exams) documented:
SNR QC
Done at frequency specified by unit manufacturer:
C/A (before further exams) documented:

- For screen- film unit types review the QC record for the Phantom Image and the Compression Force QC tests

Quality Control (Screen-film)

Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model:
Phantom Image QC
Number of operating weeks missing in which test not done at least once: **
Image taken at clinical (+/- 1 kVp) or manufacturer recommended setting:
C/A (before further exams) documented:
For mobile units (van, truck, ...)
Performance verification after each move:
Compression Force QC
Compression QC adequate:
Done at least semiannually**
C/A (before further exams) documented

The inspector should determine; if the QC tests were performed at the required frequencies when patients were imaged using the mammography unit; was corrective action taken for any failing QC tests within the appropriate timeframe defined by the unit manufacturer or the ACR.

When QC problems are noted the inspector should provide printable remarks that document; what problem occurred; how long was the problem allowed to continue before corrective action was taken; and how many patients were imaged during the time period when the quality control tests were not performed.

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, FDA believes that charting/graphing of 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.

FDA has made the decision to document these specific QC tests with an inspection questions in FISS.

There are additional QC tests that the facility must perform to meet the QC requirements of the manufacturer of the digital mammography unit and/or the ACR accreditation requirements. Inspectors should review the QC documentation for any additional QC tests that the facility must perform and note any failed QC tests or any failure to meet QC requirements in a printable remark. Please explain which QC test is the source of the noncompliance and what problem was noted, and any other remarks that would explain the condition of the facility and the situation might have impacted the clinical image quality at the facility.

> ***Note:** This requirement is for equipment currently in use. The QC 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. However, for mammography units, laser printers, film processors, and/or monitors that are no longer used clinically at the facility, the records need only be kept for that equipment until the next annual inspection, unless the State has more stringent requirements.
>
> ****Note:** The Weekly Phantom Image Test must be performed each week. However, the test need not be performed on the same day each week. (For facilities that operate intermittently, see the alternative standard at the end of the Phantom Image QC section).
>
> The Quarterly Tests must be performed 4 times a year. The 4 months that are chosen must be spaced 3 months apart (such as February, May, August, and November). However, for any of the 4 selected months, each test may be performed on any day (not necessarily the same day) in the month.
>
> The Semi-annual Tests must be performed 2 times a year. The 2 months that are chosen must be spaced 6 months apart (such as January and July). However, for any of the 2 selected months, each test may be performed on any day (not necessarily the same day) in the month.

3.4.9.4 Survey Report

The purpose of reviewing the annual physics survey report is to assure that all the physicist's QC tests and other tasks required in the annual survey were done properly and the report contains a summary of test results and recommendations for corrective action(s) where needed.

Inspectors should review the most recent medical physicist's survey report (unless reviewed in the previous inspection) and record all survey-related entries in the Survey Report Subsection. For each section of the report, record the specific information requested. Record in the "Remarks" section any other observations.

The date of the previous survey should be pre-populated for any previously inspected mammography units. For new mammography units, inspectors can place the date of the current survey report in the "Date of previous survey" data fields and the "Date of current survey" data fields.

If the mammography unit underwent a major repair at any time since the last inspection, or since beginning operations for a new facility, the inspector should also determine if a Mammography Equipment Evaluation (MEE) was performed by the medical physicist, and review the MEE report in

addition to the annual survey report.

Survey Report

Unit Information
Unit Number:
Unit Type:
Room Name or Number:
Manufacturer/Model: Survey
Report Information
Survey Report available? Date
of current survey
Survey conducted or supervised by
Action taken?
Date of previous survey
Dose value measured by the medical physicist
Dose value (mGy) reported
C/A taken before resuming clinical use?
Survey Report Part 1
Resolution measurement
AEC performance – reproducibility (mAs) AEC
performance capability
Phantom image
CNR SNR
Artifact evaluation

Survey Report Part 2
Pass/fail list
Recommendations for failed items
Physicist's evaluation of technologist's QC tests:
Laser printer QC -
RWS QC Phantom
image CNR
SNR
Repeat analysis
Analysis of fixer retention
Screen-film contact
Compression
Collimation:
X-ray field – light field
X-ray field – image receptor alignment
Compression device edge alignment kVp
accuracy
kVp reproducibility
Beam quality (HVL) measurement
Uniformity of screen speed Radiation
output

Decompression

For digital mammography medical physicists must follow the QC procedures assigned to the medical physicist in the mammography unit manufacturer's QC manual. These tests will vary a little from manufacturer to manufacture, thus it is important that the inspector review the QC manual to guide them through the review of the survey report.

For screen-film mammography FDA expects most medical physicists to follow the 1999 ACR Mammography QC Manual. The regulations specify test criteria, action limits, and outcome results for the majority of the tests but only specify minimum requirements for others.

In addition to these tests, the annual survey report must contain:

- An evaluation of the technologist's QC tests for the period between the previous survey and the one referenced in the report. The one exception to this rule is a newly installed unit.

When a new unit is first installed, there is no technologist QC for the medical physicist to evaluate for the new unit. The medical physicist will give the facility a few months to operate the new unit before he/she evaluates the technologist's QC. Depending on the scheduling of the MQSA inspection and the timing of the Mammography Equipment Evaluation for the newly installed unit, the survey report may, or may not, contain an evaluation of the technologist's QC. Inspectors should answer the Physicist Evaluation of Technologist's QC questions found under the Physicist Survey Report Part 2 section with a "N/A" for new installations that are inspected prior to the medical physicist's review of the technologist's QC.

- Test conditions, technique factors, measured or calculated results and a pass/fail indication for each of the physicist's tests

- Documentation of any failed tests and/or problems identified along with recommendations for corrective actions for each.

The report must be dated and signed by the medical physicist who performed the survey or supervised the performance of the survey. If another person conducted all or part of the survey under the direct supervision of the medical physicist, that person and the part of the survey he/she conducted must also be identified in the report.

When reviewing the survey report, confirm that the physicist recognized when data or analysis showed that the equipment was not properly performing, and subsequently recommended appropriate corrective action(s). Regardless of who corrected the problems, the facility should have a written note or report indicating what was done. The facility should have retest data or documentation showing the dates of corrective actions and that any such action taken was successful.

If the physicist recommended taking actions regarding items that did not fail one or more of the required tests, and if the facility chose not to follow them, the facility must at least document that it evaluated the recommendation. In this case, you should answer the question "Action Taken" above with "NA" (Not Applicable) and enter any additional comments in the remarks tab.

Inspectors should give the facility a little time (a few days) before they answer the question "Survey report available" with a "No" answer and submit the inspection to FDA, if the survey was recently completed (less than 30 days before the inspection) but the report is not yet available. If this is the case, and if the facility sends you the report shortly after you complete the on-site inspection, you may then review the report, answer the appropriate survey report questions in FISS, and submit the inspection. As a reminder, the regulations require the physicist to send the report to the facility in 30 days. Therefore, you should be thoughtful in answering this question.

For a unit with a status designation of "Evaluate Records Only," or "Temporarily out of service," if the survey was due before the unit was removed from service but the report was not available, answer the "Survey report available" question with a "No". If the survey report was due after the unit was removed from service answer the "Survey report available" question with "N/A" because survey report is not required at this time and the unit has been removed from service. If the survey report was available but had been evaluated before, and it was 14-months or less since the survey was performed then answer the "Survey report available" question with "NA." If it was available but has never been evaluated, answer the "Survey report available" question with "Yes" and continue to evaluate the report.

If parts of the survey report were conducted on different dates, the survey date will be the date of the most recent item completed.

Note: It is assumed that the person who conducted or directly supervised the performance of the survey is the person whose name (or signature) is identified on the report. If that name appears on the facility personnel list from the previous inspection, it will be pre-populated into the screen. Otherwise, the inspector should record the name of the medical physicist, add it to the personnel list, evaluate his/her qualifications, and record your observations in the Survey Report Subsection. If no name or signature is identified in the report, select "unsigned." If you left it blank, it will be included in the missing data report.

There are many scenarios regarding the appropriate answers (for an annual inspection) in the survey report for new units, units that have been in clinical use for at least a year, units that have been removed from service, and units that are temporarily out of service. Those scenarios are summarized below:

Survey Report Availability Scenarios – Data entry options for Survey Subsection

Survey Report Status	Unit Status	Scenario	FISS Citation
No Survey Report	Old Unit*	"Previous Survey Date" Blank	Level 1 – Over 2 years without a survey
No Survey Report	Old Unit*	"Previous Survey Date" < 14 Months from the Current MQSA Inspection Date	No citation

No Survey Report	Old Unit*	"Previous Survey Date" > 14 Months from the Current MQSA Inspection Date	L2 – Survey not conducted within 14 months
No Survey Report	New Unit**		L2- No MEE prior to use
Report Available	New Unit*	" Current Survey Date" <14 Months from Current MQSA Inspection Date	No Citation
Report Available	Old Unit*	"Previous Survey Date" - Blank	Treated as missing data not required for upload
Report Available	Old Unit*	"Previous Survey Date" < 14 Months from Current Inspection Date	No Citation
Report Available	Old Unit*	"Previous Survey Date" > 14 Months from Current Inspection Date	L2- the time between the previous and current survey is over 14 months
Report Available	New Unit*	"Previous Survey Date" - Blank	No citation
Report Available	Temporarily Out of Service	" Previous Survey Date" < 14 Months from the Current Inspection Date	No Citation
Report Available	Temporarily Out of Service	" Previous Survey Date" > 14 Months from the Current Inspection Date	Level 2 – More than 14 months between current and Previous survey
Report Available	Temporarily Out of Service	" Previous Survey Date" - Blank	No Citation – Missing data Report
Report Available	Evaluate Record Only	" Previous Survey Date" < 14 Months from the Current Inspection Date	No Citation
Report Available	Evaluate Record Only	" Previous Survey Date" - Blank	No Citation – Missing Data Report

*"Old" Unit- a mammography unit that has been in clinical use for at least a year
** "New" Unit – a mammography unit that has been in service for less than a year

III. PERSONNEL

3.4.10 Personnel

The purpose of reviewing personnel qualification records is to assure that all health professionals associated with mammography at the facility meet the minimum initial qualifications (licensing, certification, initial specific training and experience, etc.), the new mammography modality training (if applicable), and continuing experience and education requirements set by the regulations.

The regulations require facilities to maintain records that document the qualifications of all the mammography professionals (interpreting physicians, radiologic technologists, and medical physicists) who worked or are currently working at the facility.* Facilities must make these records available for MQSA inspectors to review and must not discard documentation of the person's qualifications until the person has permanently left the facility, the next annual inspection has been completed, and FDA has determined that the facility is in compliance with the MQSA personnel requirements. Acceptable documentation for all personnel requirements is summarized in separate tables at the end of each personnel section.

* MQSA regulations require that all personnel providing mammography services meet the quality standards related to their profession, even if they provide only temporary service.

Inspectors should review personnel records for all interpreting physicians, radiologic technologists, and medical physicists involved in mammography activities at the facility and verify compliance with the regulations. Advise the facility in advance by way of the inspection notification letter that they should make all the necessary personnel documents available during the inspection.

For inspection purposes, employees who were hired by the facility since the previous inspection (or all employees in the case of a new facility that has not yet had its first annual inspection) and are no longer at the facility at the time of the inspection, will have their qualifications verified only for the beginning date* of their employment by the facility. Records of past employees that were evaluated during the previous inspection but had left the facility since that date will not be routinely evaluated.

> ***Note:** For employees who left the facility and were rehired more than once since the previous inspection (or since the start of certification for new facilities), records of qualifications will be verified for each of the starting dates within the period described above or until a non-compliance with that qualification is discovered. Also, if a locum tenens individual works sporadically throughout the year, it may be necessary to verify his or her compliance regarding continuing experience and continuing education up to four times (once per quarter, if they worked in all four quarters).

Record all the required data in this section in the Personnel Section of FISS. A Subsection containing the personnel specific inspection questions for each of the three primary personnel positions can be found on the Inspection Status Screen. Under each subsection inspectors will find a list of personnel for each personnel category. Click on the individual's names to access the FISS personnel questions.

3.4.10.1 Interpreting Physicians

Interpreting Physicians – List
- Basic Information
  - Name
  - Lead interpreting physician?
- Status
  - Evaluate
  - On Hold

Rules qualifying under
If you selected the interim rules:
- Initial qualifications under interim rules met?
  - Licensed?
  - Certified or 2 months training?
  - 40 CME hours
  - Initial experience adequate?

If you selected the final rules:
- Initial qualifications under final rules met?
  - Licensed ?
  - Certified or 3 months training?
  - 60 category 1 CME hours?
  - Initial experience adequate?

Date completed initial requirements
- Trained in all applicable mammographic modalities?
- Trained mammographic modalities (check all that apply): S/F, FFDM, DBT*

Continuing experience
- Continuing experience adequate?
- Number of exams in 24 months

Continuing education
- CME credits adequate?
- Number of CME's in 36 months

Each physician responsible for interpreting mammograms at the facility must meet the following specific requirements in the final regulations [CFR 900.12(a)(1)] unless exempt because they previously qualified under the interim regulations prior to April 28, 1999:

1. State License – The facility's records must contain a license to practice medicine in a State for each interpreting physician. For documentation, FDA accepts any of the following; copy of the license, a pocket card, or a letter from the licensing board (bearing the board's letterhead) stating that the physician is licensed.

2. Certification OR Training.

a. Certification. The facility's records must contain, for each interpreting physician, a certificate from an FDA-approved body (see note below). FDA also accepts a copy of the certificate, or a letter from the approved body (bearing the body's letterhead), or a letter from the ACR if the physician is certified by the ABR or the AOBR specifically stating that the physician is certified, or a listing of the physician in the directory of the American Board of Medical Specialties (ABMS).

Beginning with the medical residency graduating classes of 2014, The ABR changed their examination requirements to a two part exam. The Core Exam is taken after 36 months of residency and the Certifying Exam is taken 18 months after the resident has graduated from residency. This change means inspectors must rely on the residency letters for medical residents who graduate in the year 2014 or later. These individuals will not receive their ABR certification until at least 18 months after their graduation from medical residency.

Note: The FDA-approved bodies are: the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), and the Royal College of Physicians & Surgeons of Canada (RCPSC). For all three, the certificate must be in radiology or diagnostic radiology.

OR

b. Three Months (420 hours) of Full-Time Training. For each interpreting physician, the facility's records must contain written documentation showing at least three months of full-time training in mammography. The documentation must indicate that the interpreting physician received training in mammographic interpretation, and in radiation physics, effects, and protection. It must also indicate the name of the institution or educational organization, the dates of training, the name of the course or training program, and the hours and/or credits received for the course or training.

3. 60 hours of Medical Education in Mammography – For each interpreting physician, the facility's records must contain written documentation showing at least 60 hours of category I medical education in mammography. At least 15 of these credits must have been acquired within the three years immediately prior to the date when the individual met the initial qualifications. The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training. FDA accepts residency time specifically devoted to mammography, if documented in writing by an appropriate official of the training program.

Note: For interpreting physicians who use the three-month full-time training as an alternate to certification, the necessary 60 hours could be part of that training. If documentation is not available, proper attestation will be acceptable for CME's earned prior to October 1, 1994, unless those CME's were earned as part of the three months full-time training, in which case attestation is not acceptable for training received at any date.

4. Initial Experience – Each interpreting physician must have read and interpreted, under the direct supervision of an interpreting physician, mammograms from the examinations of at least 240 patients in the six-month period prior to the date the individual met the initial qualifications,

or in any six-month period during the last two years of a residency in diagnostic radiology, for those who became board-certified at the first allowable time as defined by the appropriate certifying board.

FDA considers interpreting physicians who met the initial qualification requirements under the interim regulations (prior to April 28, 1999) as having met this requirement.

For each interpreting physician who meets this requirement directly, the facility must have on file a signed statement or other documentation stating that this requirement has been met in the specified six months. The documentation should indicate the name of the facility and the date range in which this requirement was met. It should be signed by the residency program director or by the physician providing the direct supervision. Also, attestation will be acceptable for initial experience gained prior to October 1, 1994.

5. New Mammographic Modality Training – The interpreting physician must have at least 8 hours training in each new mammographic modality before using that mammographic modality.

After April 28, 1999, before an interpreting physician may begin independently using a new mammographic modality for radiography of the breast, he or she must obtain 8 hours of training in that new mammographic modality. If the interpreting physician started using this mammographic modality before April 28, 1999, he/she is considered to have met the 8-hour training requirement. The interpreting physician can obtain the required training from many sources, including, but not limited to, residency training, special training courses, continuing education, and training provided by the manufacturer. 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. Also, the new modality training for interpreting physicians is not required to meet the Category I continuing medical education requirement, however if the interpreting physician wants to count the new modality training towards his/her continuing education requirements, then in those situations the new modality training must be identified by the training provider as meeting Category I training requirements.

*** Note:** As of April 2015, three DBT systems have been approved for marketing in the United States: Hologic Selenia Dimensions, GE SenoClaire, and Siemens Mammomat Inspiration. Due to the technological differences between these DBT systems, and differences in their FDA-approved Indications for Use (IFU), each manufacturer's DBT system is currently treated as a separate mammographic modality under the MQSA definition. Facilities that perform mammography using any of these DBT modalities are subject to MQSA requirements.

Under MQSA, personnel need to receive 8 hours of initial training prior to independently using any new mammographic modality, defined as a modality in which the person has not previously been trained. However, the FDA's DMQS recognizes that there are many features which are common to different DBT systems, while some features are unique to each specific system. Therefore, training must include both the common features of DBT and the unique features of the particular DBT system, but these two aspects of the training may be obtained either in a single training program or in separate settings. Once personnel have received training in the common features of DBT, they do not need to repeat this portion of the training when receiving training in

the unique features of a particular system. When training is provided in the unique features of a particular DBT system the training certificate should state that the training covered the unique features of the DBT unit of manufacturer "X" (where "X" is the name of the DBT manufacturer). For further details and sample training scenarios, please see the link below.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm447869.htm

Once an interpreting physician has completed all of the initial training and experience requirements, the MQSA requires personnel to maintain at least a minimum level of continuing education and continuing experience.

6. Continuing Experience – The interpreting physician must continue to read and interpret mammograms from the examination of at least 960 patients over the 24-month period:

- preceding the inspection date, or
- from the end of the calendar quarter preceding the inspection date, or
- from any date in between the two.

Note: In both 4 and 6, interpreting physicians may meet film reading requirements by combining readings from multiple facilities or by double or multi- reading films.

7. Continuing Education (15 CME Credits/36 months) – The interpreting physician must continue to participate in continuing medical education programs, either by teaching or completing a total of at least 15 continuing medical education (CME) credits in mammography over the 36-month period:

- preceding the inspection date, or
- from the end of the calendar quarter preceding the inspection date, or
- from any date in between the two.

The facility's records must contain, for each interpreting physician, written documentation showing that the individual has taught or completed at least 15 category I CME units in mammography. At least 6 of these must be in each mammographic modality used by the interpreting physician (Note: Inspectors will defer citing facilities for the mammography modalityspecific continuing education requirement indefinitely). The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training. The CME's must be related to the diagnosis or treatment of breast disease.

3.4.10.2 Technologists

Technologists

Technologists - List
Basic Information
Status

Name
Evaluation
Rules qualifying under:
If you selected the interim rules:
Initial qualification under interim rules met?
Licensed or certified?
Training specific to mammography?
If you selected the final rules:
Initial qualifications met?
Licensed or certified?
40 supervised hours of training adequate
Date completed initial requirements
Currently licensed or certified?
Trained in all applicable mammographic modalities?
Trained mammographic modalities (check all that apply): S/F, FFDM. DBT*
Continuing experience
Continuing experience adequate?
Number of exams in 24 months
Continuing education
CEU credits adequate?
Number of CEU's in 36 months

Each technologist independently performing mammograms must meet the following specific requirements [see final regulations, October 28, 1997, §900.12(a)(2)] unless exempt because they previously qualified under the interim regulations prior to April 28, 1999:

1. License OR General Certificate – For each technologist, the facility's records must contain a license from a State or a general certificate from an FDA-approved body (see note below)*. A copy of the license or certificate, a pocket card, or a letter from the licensing board or certifying organization (bearing the board's or organization's letterhead) stating that the technologist is licensed or certified, is acceptable.

*** Note:** Currently, the only FDA-approved body is the American Registry of Radiologic Technologists (ARRT). Radiologic Technologists, who were originally certified by the American Registry of Clinical Radiologic Technologists (ARCRT) and were later registered by the ARRT, when the ARCRT ceased to exist, also meet FDA certification requirements.

2. Training – Have qualified as a radiologic technologist prior to April 28, 1999,
OR
Have 40 contact hours of documented supervised training specific to mammography, including:
- breast anatomy & physiology, positioning & compression, quality assurance/quality control techniques, imaging of patients with breast implants
- the performance of 25 supervised exams.

For each technologist, the facility's records must contain written documentation from a medical or other institution showing the amount of training received. The documentation must indicate that

credits were received for courses in mammography, including the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours or credits for the course or training.

3. New Modality Training - 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, the technologist shall have at least 8 hours of continuing education units in the new modality.

*** Note:** As of April 2015, three DBT systems have been approved for marketing in the United States: Hologic Selenia Dimensions, GE SenoClaire, and Siemens Mammomat Inspiration. Due to the technological differences between these DBT systems, and differences in their FDA-approved Indications for Use (IFU), each manufacturer's DBT system is currently treated as a separate mammographic modality under the MQSA definition. Facilities that perform mammography using any of these DBT modalities are subject to MQSA requirements.

Under MQSA, personnel need to receive 8 hours of initial training prior to independently using any new mammographic modality, defined as a modality in which the person has not previously been trained. However, the FDA's DMQS recognizes that there are many features which are common to different DBT systems, while some features are unique to each specific system. Therefore, training must include both the common features of DBT and the unique features of the particular DBT system, but these two aspects of the training may be obtained either in a single training program or in separate settings. Once personnel have received training in the common features of DBT, they do not need to repeat this portion of the training when receiving training in the unique features of a particular system. When training is provided in the unique features of a particular DBT system the training certificate should state that the training covered the unique features of the DBT unit/technology of manufacturer "X" (where "X" is the name of the DBT manufacturer). For further details and sample training scenarios, please see the link below.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm447869.htm

Once a radiologic technologist has completed all of the initial training and experience requirements, the MQSA requires personnel to maintain at least a minimum level of continuing education and continuing experience.

4. Continuing Education – Each radiologic technologist must obtain at least 15 continuing education units in mammography during the 36 months immediately:

- preceding the inspection date, or
- from the end of the calendar quarter preceding the inspection date, or
- from any date in between the two

5. Continuing Experience – Each radiologic technologist must perform at least 200 mammograms in the 24 months immediately:

- preceding the inspection date, or
- from the end of the calendar quarter preceding the inspection date, or
- from any date in between the two.

3.4.10.3 Medical Physicist

Medical Physicist
Medical Physicist - List
Basic Information
Status
Name
Evaluation
Degree qualifying under
If you selected "Masters (or higher)":
Initial qualification met?
Certified or state licensed/approved?
Masters (or higher) degree in a physical science?
20 contact hours of training in surveys?
Experience in conducting surveys?
If you selected "Bachelors":
Alternative initial qualifications met before 04/28/99?
Certified or state licensed/approved?
Bachelor's degree in a physical science?
40 contact hours training in surveys?
Experience in conducting surveys?
Date completed initial requirements
Currently licensed or certified?
Trained in all applicable mammographic modalities?*
Trained mammographic modalities (check all that apply): S/F, FFDM, DBT* Continuing experience adequate?
Continuing Education
CME credits/year adequate?
Number of CME's in 36 months
Summary
Required personnel documents available?

Each medical physicist providing services to a mammography facility must meet the following specific requirements [see final regulations, October 28, 1997, §900.12(a)(3)]:

Initial Qualifications

1. State License, State Approval, or Board Certification.

The facility's records must contain, for each medical physicist, documentation indicating approval or licensing by a State or certification from an FDA-approved body.*

FDA accepts a copy of the approval, license or certificate, a pocket card, or a letter from the state or
FDA- approved body (bearing the body's letterhead) stating that the physicist is licensed or certified.

***Note:** the FDA-approved bodies are the American Board of Radiology (either in diagnostic radiological physics or radiological physics) or the American Board of Medical Physics (in diagnostic imaging physics).

2. Qualifying Degree – A Masters or higher degree in a physical science, with a minimum of 20 semester hours (30 quarter hours) in physics.

All qualifying degrees must be from the physical sciences. In this context, physical science degree means a degree in one of the specialties or sub-specialties of physics, chemistry, radiation science (including medical physics and health physics), or engineering.

Acceptable documentation for this requirement must indicate that the physicist has the appropriate degree, including the name of the institution or educational organization, the date of degree, and the subject area in which the degree was awarded. FDA accepts a copy of the degree or a letter from the institution that awarded the degree.

3. Specialized Training – Have 20 contact hours of documented specialized training in conducting surveys

Physicists may use various types of training to meet the requirement for specialized training in conducting surveys, including continuing medical education units (CME), formal academic training, or other types of training programs. To satisfy the specialized survey training requirements, CME's must be specifically related to technical or QA topics pertinent to mammography facility surveys. Therefore, not all CME's that are acceptable as continuing education units will satisfy the requirement for specialized training. Additionally, physicists who qualified before April 28, 1999, and obtained their survey training prior to this date may count the survey training for both CME's and the "specialized training in conducting surveys" requirement. However, physicists who qualify after April 28, 1999, may only use the survey training to meet their initial requirements and not as CME's. Physicists originally qualified prior to October 27, 1997, under the education, training, and experience route in the interim regulations, would meet the final regulations if they conducted at least one facility survey and a total of 10 units.

4. Initial Experience – Have the experience in conducting surveys of at least one mammography facility and a total of at least 10 mammography units.

Note: Surveys conducted after April 28, 1999, to meet this requirement must be conducted under direct supervision of a fully qualified medical physicist who meets the initial requirements listed in 1–4, as well as the continuing requirements.

FDA recognizes that some physicists may be unable to visit multiple facilities to meet the experience requirements. FDA, therefore, allows the survey of the same facility and the same

mammography units to count towards the total requirements for initial, continuing, and re-qualification training and experience. However, there are restrictions on the frequency under which we will allow such re-surveying. For the unit survey requirements in each of these categories, physicists can count no more than one survey of any single unit in any 60-day period towards the total. For both the continuing experience and re-qualification requirements, the physicist can count no more than one survey of a specific facility in any ten-month period.

Acceptable documentation to establish experience may be a written statement by the company that provides medical survey services, the physicist's supervisor, or the management of the facility surveyed, indicating where and when the physicist performed the required number of surveys, or an official listing from a company that provides medical physicist survey services.

Alternative Initial Qualifications

1. Have qualified as a medical physicist and maintained active status under the interim regulations
(Certified, State licensed or State approved);

AND prior to April 28, 1999, have:

2. Qualifying Degree – A bachelor's degree or higher in a physical science (with 10 semester hours or equivalent in physics). AND

3. Specialized Training – Have 40 contact hours of documented specialized training in conducting surveys. AND

4. Initial Experience – Have the experience in conducting surveys of at least one mammography facility and a total of at least 20 mammography units.

Note: If documentation is not available for requirements 3 or 4 above (under initial or alternative initial requirements), proper attestation will be acceptable only for training or experience gained prior to October 1, 1994.

Note: Persons meeting the initial qualifications through the alternative requirements cannot supervise others in conducting mammography surveys for the purpose of meeting the initial or continuing experience requirements.

5. New Mammographic Modality Training* – The medical physicist must have at least 8 hours training in each new mammographic modality before conducting surveys on that mammographic modality.

After April 28, 1999, before a medical physicist may begin independently surveying a new mammographic modality for radiography of the breast, he or she must obtain 8 hours of training in that new mammographic modality. Medical physicists who started conducting surveys on this mammographic modality before April 28, 1999, are considered to have met the 8-hour training requirement. The medical physicist can obtain the required training from many sources, including, but not limited to, special training courses, continuing education, and training provided by the manufacturer.

* Note: As of April 2015, three DBT systems have been approved for marketing in the United States: Hologic Selenia Dimensions, GE SenoClaire, and Siemens Mammomat Inspiration. Due to the technological differences between these DBT systems, and differences in their FDA-approved Indications for Use (IFU), each manufacturer's DBT system is currently treated as a separate mammographic modality under the MQSA definition. Facilities that perform mammography using any of these DBT modalities are subject to MQSA requirements.
Under MQSA, personnel need to receive 8 hours of initial training prior to independently using any new mammographic modality, defined as a modality in which the person has not previously been trained. However, the FDA's DMQS recognizes that there are many features which are common to different DBT systems, while some features are unique to each specific system. Therefore, training must include both the common features of DBT and the unique features of the particular DBT system, but these two aspects of the training may be obtained either in a single training program or in separate settings. Once personnel have received training in the common features of DBT, they do not need to repeat this portion of the training when receiving training in the unique features of a particular system. When training is provided in the unique features of a particular DBT system the training certificate should state that the training covered the unique features of the DBT unit of manufacturer "X" (where "X" is the name of the DBT manufacturer) For further details and sample training scenarios, please see the link below.

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm447869.htm

Once a medical physicist has completed all of the initial training and experience requirements, the MQSA requires that personnel to maintain at least a minimum level of continuing education and continuing experience.

6. Continuing Experience – Effective the later of July 1, 2001, or two years after meeting the initial qualifications, the medical physicist must have surveyed 2 facilities and 6 units over the 24- month period:

- preceding the inspection date, or
- from the end of the calendar quarter preceding the inspection date, or
- from any date in between the two.

Guidance regarding how to meet this requirement is similar to that given above for the initial experience.

7. Continuing Education (15 CME Credits/36 months) – The medical physicist must participate in continuing medical education programs, either by teaching or completing a total of at least 15 continuing medical education (CME) credits in mammography over the 36-month period:

- preceding the inspection date, or
- from the end of the calendar quarter preceding the inspection date, or
- from any date in between the two.

For meeting the continuing education requirement for physicists, FDA accepts CEU credits or units either related to the diagnosis and/or treatment of breast disease or to areas that will aid medical physicists in improving the quality of the survey. At least 1 of these credits must be in each mammographic modality used by the medical physicist (Note: Inspectors will defer citing facilities for the mammography modality specific continuing education requirement indefinitely). The documentation must indicate the name of the institution or educational organization, the dates of training, the name of the course or training, and the hours and/or credits for the course or training.

GLOSSARY

Accreditation Body (AB). An entity that has been approved by FDA under Sec. 900.3(d) to accredit mammography facilities. As of 9/1/08, the FDA-approved AB's are: The American College of Radiology (ACR), the State of Arkansas (SAR), the State of IA (SIA), and the State of Texas (STX). State accreditation bodies may only accredit mammography facilities within their state.

Air kerma. The amount of kerma (see separate definition) in a given mass of air. It is measured in units of Gray (Gy). For x-rays with energies below 300 keV, 1Gy =100 rad and is equivalent to 114 Roentgens (R) of exposure.

American Board of Radiology (ABR). The American Board of Radiology is a not-for profit organization, that is an independent national board, and a member of the American Board of Medical Specialties. The ABR certifies physicians and physicists who practice in the disciplines of diagnostic radiation, radiation oncology, and medical physics. Physicians and physicist become board certified by the ABR after having demonstrated knowledge, skill, and understanding of their discipline to the ABR. The ABR is a body recognized by FDA to certify radiologists and medical physicists.

American Society of Radiologic Technologists (ASRT). The ASRT tracks continuing education credits for radiologic technologists who are members of ASRT. This organization also transfers CE information to ARRT on behalf of ASRT members. provides its members with publications that can be reviewed for continuing education credits.

Artifact. Any unwanted or complicating structure visible in the image, or any aspect of an image not part of the object being imaged.

Automatic exposure control (AEC) systems. Automatic exposure control systems, often referred to as phototimers, are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the x-ray intensity after passage through the patient and image receptor.

Average glandular dose. Calculated from values of entrance exposure in air, the x-ray beam quality (half-value layer), kVp, and compressed breast thickness, average glandular dose is the energy deposited per unit mass of glandular tissue (by far the most radiosensitive tissue in the breast) averaged over all the glandular tissue in the breast. See also: dose. The average, or mean, glandular dose is the value, which can be used to estimate the risk associated with an x-ray exposure.

Base density. The optical density due to the supporting base of the film alone. The base

density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

Base-plus-fog-density. The optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base-plus-flog-density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

Cassette. A light-tight case, usually made of thin, low x-ray absorption plastic, for holding x-ray film. One or two intensifying screens for the conversion of x-rays to visible light photons are mounted inside the cassette so that they are in intimate contact with the film.

Compression device. A plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film, and to help separate structures within the breast. Ideally, the compression device is made of rigid, thin plastic and has a flat bottom surface that is parallel to the plane of the image receptor and a chest wall edge that is perpendicular to the plane of the image receptor to assist in moving breast tissue away from the chest wall and into the field of view.

Computed Radiography (CR). A radiographic technology whereby, x-rays expose a photostimulable phosphor plate, which captures the latent radiographic image. The phosphor plate is subsequently placed into a device that generates a digital image. When this (CR) plate is used in the bucky of a screen-film cassette in a mammography unit, a full field digital mammogram is obtained. An x-ray unit equipped with a CR plate approved for mammography is considered a full field digital mammography (FFDM) unit.

Control chart. A graphical means of displaying data in which the variable of interest is plotted on the vertical axis as a function of time (date) on the horizontal axis. The control chart also allows for easy and rapid review of the data to determine whether the process is "in control."

Control limit. The upper and lower control limits are those values which when exceeded indicate that the process is "out of control" and requires that some action be taken immediately. It is prudent to immediately repeat the measurement to verify that the system is "out of control" before taking corrective action. If the repeated measurement is "out of control," then corrective action is required immediately.

Corrective action plan (CAP). A set of procedures designed to correct deficiencies observed.

Craniocaudal (CC) view. One of the two routine views for mammography. The image receptor is placed caudal to (below) the breast and the vertical x-ray beam is directed from cranial to caudal (downward) through the breast.

Dedicated mammography equipment. X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and that can consistently produce mammographic images of optimum quality.

Densitometer. An instrument which measures the degree of blackening or optical density of film.

Detents. Mechanical settings that limit or prevent the movement or rotation of an X-ray tube, cassette assembly, or image receptor system or allow exposure for specified tube orientation.

Developer. A chemical solution that changes the film latent image to a visible image composed of black metallic silver.

Developer replenishment. The process whereby fresh developer replenisher is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper chemical activity and level of solution in the developer tank.

Direct supervision. Means that:
1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records, or
2) During the performance of the physics survey and/or mammography equipment evaluation, direct supervision means that the supervising medical physicist must have qualified under the Master's or higher pathway, and be present to observe and correct, as needed, the performance of the supervisee. This requires that the supervising medical physicist 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 supervising medical physicist must observe and correct, as needed, the performance of the individual being supervised, and review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

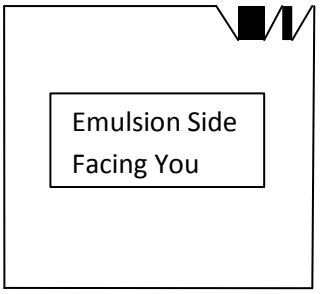
The supervising medical physicist and supervisee must also jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC records; however, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued.
3) During the performance of a mammography examination, direct supervision means that

the supervising radiologic technologist must be a qualified as a mammography technologist under the MQSA, and be present to observe and correct, as needed, the performance of the trainee. This requires that the supervising radiologic technologist be in the examination room itself at the time the examination is being conducted to provide reasonable assurance that any mistakes made by the trainee are corrected before the patient is irradiated or harm is done to the patient.

Dose. The amount of energy deposited in tissue per unit mass due to X-ray exposure. The S.I. unit of absorbed dose is the Gray (Gy). One Gray equals 100 rads; 1 milliGray (mGy) equals 0.1 rad (1 mrad).

Emulsion side identification. In single-sided mammography films, the emulsion is coated on one side of the base only. To identify the emulsion side, note that when looking at the film in the portrait orientation (the long dimension is vertical), the film notches are in the upper right hand corner (along the shorter dimension) when the emulsion side is facing the observer.

Identifying the Emulsion Side of Mammography Film



Exposure. The amount of x-irradiation, quantified by measuring the amount of ionization in air caused by the radiation.

Facility ID. The 6-digit FDA number displayed on the front of the certificate, just below the accreditation body name and above the certificate expiration date. This is not to be confused with Certificate Number, which is also displayed on the front of the certificate in the extreme lower right corner.

Fixer. A chemical solution which removes the undeveloped silver halide crystals from film. The fixer also helps film drying by hardening the gelatin containing the black metallic silver.

Fixer retention. The incomplete removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph (often within a year).

Focal spot size. The focal spot is the area of the target or anode that is bombarded by electrons from the cathode of the x-ray tube to produce x-rays. The smaller the focal spot, the better the limiting spatial resolution of the x-ray system, especially in magnification mammography.

Fog. The unwanted density added to a radiograph due to action of the developer on the unexposed silver halide crystals or by light, radiation, or heat exposure during storage, handling, and processing.

Full Field Digital Mammography (FFDM). Technology for radiographic imaging of the breast using a digital image receptor and, therefore, is a mammographic modality. The FFDM image receptor is large enough to image the average size breast in a single exposure.

Grids. A set of thin, closely spaced lead strips, inter-spaced by fiber or aluminum for mammographic applications. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor. Scattered radiation reduces image contrast in mammography and limits the detection of low-contrast structures such as fibers and masses.

Half-value layer (HVL). The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the exposure rate by one-half. HVL is a measure of beam quality and is usually specified in millimeters of aluminum for diagnostic units. The higher the HVL, the more penetrating the x-ray beam.

Image contrast. The optical density difference between adjacent areas of a radiograph resulting from a difference in the x-ray attenuation.

Image quality. The overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, image contrast and noise are common measures of image quality.

Inspection Report types. Several types of inspection reports are defined below.

Inspection Debrief Report – Refers to an electronic report available in FISS that includes the inspection citations and all of the printable remarks. The Inspection Debrief Report is used during the inspection close –out discussion to display the preliminary inspection findings to the inspector. The inspector should review the Inspection Debrief report to determine if their prior answers to the FISS inspection questions are correctly reflected in the appropriate inspection citations. Printable remarks should also be reviewed for details, content, and appropriateness.

Inspection Detail Report – A MQSA inspection report generated to document every

FISS inspection question and the inspector's answer, as well as the printable and non-printable remarks made by the inspector. This report is typically for internal use only and should not be given to the facility.

Post Inspection Report (PIR). The MQSA inspection report generated in FISS and provided to the facility to document the inspection findings. The PIR is the official inspection report of the MQSA program.

Image sharpness. The overall impression or perception of detail and clarity in a radiographic image.

Inspection types. Several types of inspections are defined below. Inspections may fall under one or more of the following types:

Basic inspection - Refers to the routine but mandatory facility inspection conducted by a federally certified MQSA inspector. This includes the "Basic" or routine inspection (done in the overwhelming majority of cases), the "Joint Audit" inspection, and the "Mentored" inspection, both of which are defined below.

Follow-up (Fee-Based) inspection - Usually conducted by FDA MQSA inspectors to assess corrective actions the facility has taken since the previous annual inspection. It incurs a fee. State inspectors should not conduct these inspections unless requested to do so by the FDA District Office or FDA's Regional Radiological Health Representative (RRHR).

Compliance (Non Fee-Based) inspection - Usually conducted by FDA MQSA inspectors to assess corrective actions the facility has taken after being sent a Warning Letter (which may be the case if the results of a follow-up inspection were unsatisfactory). It does not incur a fee. State inspectors should not conduct these inspections unless requested to do so by the FDA District Office or FDA's Regional Radiological Health Representative (RRHR).

Joint Audit inspection – This inspection is conducted together by a certified MQSA inspector and an FDA MQSA auditor to assess the performance of the certified inspector during a routine annual inspection. When this type of inspection is used, ID numbers for the inspector and the auditor are recorded.

Mentored 'M' inspection – This inspection is conducted together by an MQSA inspector in training or re-qualification (either a new graduate, one that had been through an audit and judged to require mentoring, or a re-qualifying inspector) who is being mentored and a certified inspector acting as the mentor. When this type of annual inspection is used, ID numbers for the mentor and the one being mentored should be recorded.

Kerma. The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

Kilovoltage, peak (kVp). The maximum potential difference setting between the anode

and the cathode in an x-ray tube. This setting is also the maximum energy of x-rays emitted by the x-ray tube in kilo-electron volts (keV).

Mammogram. A radiographic image of the breast (an image produced through mammography).

Mammographic modality. A technology for radiography of the breast, such as screen-film, full field digital mammography (FFDM), and Xeromammography.

Mammography Equipment Evaluation (MEE). An onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in Sec. 900.12(b) and (e).

Mean glandular dose. See average glandular dose.

Milliampere (mA) setting. The electron current passing from the cathode to the anode in an x-ray tube. For a fixed kVp, the tube output of x-rays per unit time from is linearly proportional to the mA setting.

Milliampere-seconds (mAs). The product of electron current (mA) and the exposure time (seconds). For a fixed kVp, the total X-ray output is linearly proportional to mAs.
Operating level. The central value about which day-to-day measurements are expected to fluctuate. An example would be the empirically determined mid-density on a sensitometric film.

Phantom (breast). A test object which simulates both the average composition of the breast, and the various structures within it. An ideal breast phantom would allow objective rather than subjective analysis and would be sensitive to small changes in mammographic image quality.
The RMI 156 phantom was adopted by the ACR Mammography Accreditation Program and has been frequently referred to as the "ACR" phantom.

Processor. An automated device that transports film at a constant speed by a system of rollers through developing, fixing, washing, and drying cycles.

Processor artifact. Any unwanted or artificial density appearing on a radiograph due to the processor.

Quality assurance (QA). A management tool that includes policies and procedures designed to optimize the performance of facility personnel and equipment.

Quality control (QC). The routine performance and interpretation of tests of equipment function and the corrective actions taken in response to detected deficiencies.

Quality control technologist. The technologist assigned the task of quality control testing and maintaining records of radiographic imaging systems.

Repeat analysis. A systemic approach to determining the causes for repeated radiographs.

Replenishment rate. The amount of chemicals added per sheet of film in order to maintain the proper chemical activity of developer and fixer solutions.

Safelight. A lighting fixture with appropriate filters that produces light which will not fog radiographic film exposed to it for a specified period of time. The filter removes most of the light to which the radiographic film is sensitive. Most safelights will fog film if the amount of light or exposure time is increased, i.e., there is no such thing as a "safe" light.

SAR. State of Arkansas

Screen (intensifying). Microscopic phosphor crystals coated on a plastic support which emit visible light when exposed to x-irradiation, thereby creating a latent image on x-ray film.

Screen-film combination. A particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

Screen-film contact. The close proximity of the intensifying screen to the emulsion of the film, essential in order to achieve a sharp image on the film.

Screen-film mammography. Mammography performed with high-detail intensifying screen(s) in intimate contact with the film.

Sensitometer. A device used to reproducibly expose film to a number of known levels of light.

Sensitometric strip. A sheet of film exposed by a sensitometer. Such strips are used to determine the range of densities, from minimum to maximum, resulting from a reproducible exposure.

Sensitometry. A quantitative measurement of the response of film to radiation (including

light) exposure and photographic processing.

SFL. State of Florida

SIA. State of Iowa

SIL. State of Illinois

Small Field Digital Mammography (SFDM). The use of a small digital image receptor (usually an add-on component to a Screen-Film (S-F) system) to produce mammographic images. Because this small receptor cannot image the entire breast in a single exposure, it cannot generally be used for screening examinations and in almost all cases is limited to only a portion of the breast for either interventional or diagnostic purposes. When used for diagnostic purposes, SFDM is considered a subpart of the FFDM modality.

SSC. State of South Carolina

STX. State of Texas

Standard Breast. A 4.2 cm* compressed breast consisting of 50% adipose and 50% glandular tissue.
* A phantom, which has the same transmission properties as this standard breast, is the RMI 156 phantom. This phantom is typically referred to as the "ACR" phantom since it is this phantom that was adopted by the ACR Mammography Accreditation Program.

The American Registry of Radiologic Technologist (ARRT). A credentialing organization that certifies technologists, and administers continuing education and ethics requirements, to ensure high quality patient care in the areas of medical imaging, interventional procedures and radiation therapy. ARRT is a body recognized by FDA to certify radiologic technologists.

Viewbox. A device providing a relatively uniform surface luminance for viewing mammographic films. Mammographic viewboxes should have a luminance level of at least 3,000 nit (candela per sq. meter).

Xeromammography (XM). The technology whereby xeroradiography principles and techniques are used for breast imaging.

Xeroradiography (XR). A technology whereby an x-ray beam is used to form an electrostatic latent image on a photoconductive surface. This latent image is then made visible by a dry processing technique.
Inspection Debrief Report

APPENDICES

Appendix 1: Inspection Confirmation Notice and Post Inspection Correspondence

1. Scheduling the MQSA Inspection

After contacting the facility by telephone and coming to a mutually agreeable inspection date with the facility, the following confirmation notice should be sent to the facility, completely filled out. The MQSA Inspection Confirmation Notice should be faxed to the facility as a first option, or mailed to the facility if the facility does not have fax capabilities. This notice should always provide a telephone number to allow the facility to contact the inspector regarding any questions the facility might have about the inspection process, or to inform the inspector of equipment or other problems that may occur at the facility in the days leading up to the inspection.

To minimize time spent at the facility during the inspections, inspectors may make arrangements with facilities to review documents submitted to the inspector's office prior to the inspection; such as personnel documentation. If this arrangement has been made, the inspector should mention this in the confirmation notice as a reminder. See next page for the MQSA Inspection Confirmation Notice.

MQSA Inspection Confirmation Notice (sample)

This notice confirms our telephone conversation of {insert date here} regarding the scheduled inspection. If you have questions, contact the inspector at the telephone number below.

Date and time of inspection:

Name and address of facility:

Facility person contacted:
Facility telephone number:

Inspector name:

Inspector office address:

Inspector telephone number:

Inspector fax: number:

The MQSA inspection will cover the following areas:

- Equipment performance (Phantom Image quality)
- Technologist and physicist quality control/quality assurance (QC/QA) tests and tasks
- Medical audit and outcome analysis records
- Medical records (mammography reports and films)
- Personnel qualification records

The average on-site inspection time is approximately six hours. Testing for each mammography x-ray unit takes approximately 20 minutes. We recommend that you schedule a block of time for the testing of each mammography unit to help minimize any inconvenience to patient care from the inspection process. The remainder of the inspector's time will be spent reviewing facility records. During the records review portion of the inspection staff may conduct their usual duties but should be available if the inspector has questions or needs assistance locating information within the records.

On the day of the inspection, please have available for review by the inspector, all QC documentation and QC manuals for any laser printers, monitors, and film processors, used to print, view and interpret, or process mammograms, taken at your facility. This includes QC records and QC manuals for equipment that is located off-site, at a location other than the address where this inspection will take place.

2. Close-Out of the MQSA Inspection

At the conclusion of the MQSA inspection the inspector will need an internet connection and access to a printer in order to provide the facility with a copy of the Post Inspection Report (PIR) while on-site at the facility. Additionally, some states require supervisory review of the PIR prior to issuance of the report to the facility. When the PIR cannot be provided to the facility at the conclusion of the inspection, the Important Inspection Close-Out Discussion Information document should be provided to the facility at the conclusion of the inspection. This document when reviewed along with the Inspection Debrief Report will provide the facility with preliminary information about the inspection findings and the instructions for submitting any pending documentation to the inspector. See next two pages for the Important Inspection Close-Out Discussion Information document.

Inspectors, who do not have the ability to issue the finalized PIR while on-site at the facility, should carry copies of this document for issuance to facilities at the conclusion of the MQSA inspection. Prior to issuing the Important Inspection Close-out Discussion Information document the appropriate boxes regarding the PIR delivery method and inspectional findings should be noted on the document.

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Mammography Quality Standards Act (MQSA)
Important Inspection Close-out Discussion Information

This document is designed to assist you in understanding the preliminary findings of your inspection. The on-site equipment evaluation and records review portion of your MQSA inspection is complete. The inspector has reviewed and discussed the preliminary inspection findings with you. If you have any pending documentation, you have five business days to submit this documentation to the inspector.

You will be provided a final MQSA Facility Inspection Report as soon as possible by the following method:

- ☐ Inspection report will be faxed to facility
- ☐ Inspection report will be mailed to facility
- ☐ Inspection report will be emailed to facility

FDA classifies each adverse inspection observation into one of three category levels based on FDA's assessment of how the observation may affect the quality of mammography. A **Level 1** observation indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography performed at the facility. A **Level 2** observation indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item. A **Level 3** observation indicates that the facility meets all major MQSA requirements with only minor problems. The category levels are also used to determine how the facility should respond to the observation(s). Identical observations found during two consecutive inspections are identified as repeats.

☐ ***Your inspection identified at least one Level 1 or repeat Level 1 as the most serious adverse observation:***

The preliminary results of this inspection identify at least one Level 1 adverse observation during your annual inspection, and **you should correct all inspection observations as soon as possible.** Along with the final inspection report, you will receive specific instructions on how to respond to the observations identified during this inspection.

☐ ***Your inspection identified at least one repeat Level 1 or repeat Level 2 as the most serious adverse observation and previous inspections have found at least one of these observations at your facility.***

The preliminary results of this inspection identify at least one repeat Level 1 or repeat Level 2 adverse observations. Because your facility has a history of repeat Level 1 or repeat Level 2 adverse observations during your annual inspection, and **you should correct all inspection observations as soon as possible.** Along with the final inspection report, you will receive specific instructions on how to respond to the observations identified during this inspection.

☐ ***Your inspection identified at least one Level 2 or repeat Level 3 as the most serious adverse***

observation:

The preliminary results of this inspection note at least one Level 2 or repeat Level 3 adverse observation as the most serious observation during your annual inspection, and **you should begin to correct all inspection observations as soon as possible.** Along with the final inspection report, you will receive specific instructions on how to respond to the observations identified during this inspection.

☐ ***Your inspection identified at least one Level 3 as the most serious adverse observation:***

The preliminary results of this inspection note at least one Level 3 adverse observation as the most serious observation during your annual inspection. This indicates that your facility meets all key MQSA requirements but fails to meet minor mammography quality item(s). You will not have to respond in writing to the FDA regarding any adverse observation, however, **you should correct each problem as soon as possible**. During your next MQSA inspection, we will check to ensure that each problem was corrected.

☐ ***Your inspection identified* no adverse observations:**

The preliminary results of this inspection identify no adverse observations at your facility. This indicates that your facility meets all key MQSA requirements.

Where to Submit Pending Documentation:

Submit your pending documentation to:

Inspector's Name
[Street Address]
[City, State, Zip Code]
Telephone;
Fax:
E-mail Address:

Additional information:

Additional information on meeting MQSA requirements may be found at FDA's mammography Internet site at http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm. Please note that there are many FDA requirements pertaining to mammography. This close-out discussion pertains only to observations related to your inspection and does not necessarily address other obligations you have under the law.

State Requirements:

The inspector may have identified observations regarding State requirements during your inspection or the State may later send a letter to your facility. Please communicate directly with the State regarding these observations.

3. Issuance of the MQSA Post Inspection Report

At the time that the finalized MQSA Post Inspection Report (PIR) is ready for issuance to the facility, the Important Information about Your Mammography Quality Standards Act (MQSA) Inspection document should be issued as a cover letter along with the Post Inspection Report (PIR). The Important Information about Your Mammography Quality Standards Act (MQSA) Inspection includes, information on the regulatory severity of the inspection findings; a discussion of additional regulatory actions that can be taken by FDA against the facility; important information regarding the timeframes for submitting written responses to FDA; the name and addresses of the person(s) to whom the facility must submit their written response.
See the following four pages for the Important Information about Your Mammography Quality Standards Act (MQSA) Inspection document.

Inspectors, who have the ability to issue the finalized PIR while on-site at the facility, should carry copies of the Important Information about Your Mammography Quality Standards Act (MQSA) Inspection document for issuance to the facilities along with the PIR at the conclusion of the MQSA inspection.

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Important Information about Your Mammography Quality Standards Act (MQSA) Inspection

The accompanying MQSA Facility Inspection Report (Report) provides the results of your MQSA inspection. This document will assist you in reviewing the Report.

FDA has classified each adverse inspection observation into one of three category levels. A **Level 1** observation indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography performed at the facility. A **Level 2** observation indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item. A **Level 3** observation indicates that the facility meets all major MQSA requirements with only minor problems. Adverse inspection observations are placed into a category level based on FDA's assessment of how the observation may affect the quality of mammography. The category level is also used to determine how the facility should respond to the observation. Identical observations found during two consecutive inspections are identified as repeats.

If your report identified at least one Level 1 or repeat Level 1 as the most serious adverse observation:

If the Report noted at least one Level 1 adverse observation during your annual inspection, **you should correct all inspection observations as soon as possible.** Because of the nature of the observation(s), FDA may issue your facility a Warning Letter, perform a Follow-up Inspection, and/or take other regulatory action to determine that each problem at your facility has been corrected.

The decision to issue a Warning Letter, perform a Follow-up Inspection and/or take other regulatory action will be based on FDA's review of:

- your inspection report
- all written correspondence we receive from your facility within 15 working days of you receiving your inspection report, indicating how each problem has been corrected
- your facility's past history of MQSA violations (if any) Please

note: A fee of $1,144 is charged for a follow-up inspection.

We suggest that any correspondence address all adverse observations listed in the accompanying MQSA Facility Inspection Report and include:

- Facility ID number (from your FDA certificate).
- Listing of corrective actions performed or proposed to correct the problem(s).
- Date that each corrective action was or will be completed.
- Copies of service records and/or other supporting documents showing any corrective action already completed.
- For equipment test items, copies of raw test data and calculated final results.

- For quality control and medical records, copies of records that show that the records are in compliance (delete patient names and other patient identifiers).
- For personnel qualification issues, documentation showing that the person(s) actually met the requirement(s) or what steps the facility has or will take to address the problem.
- The steps taken to prevent the reoccurrence of the problem(s).

If your report identified at least one repeat Level 1 or repeat Level 2 as the most serious adverse observation and previous inspections have found at least one of these observations at your facility.

If your facility has a history of repeat Level 1 or repeat Level 2 adverse observations during your annual inspection, you should correct all inspection observations as soon as possible and consider comprehensive changes to your quality assurance program (please review 21 CFR 900.12(d) of the MQSA quality standards for more information on the requirements for your quality assurance program). Because of the nature of the observation(s), FDA may issue your facility a Warning Letter, perform a Follow-up Inspection, and/or take other regulatory action to determine that each problem at your facility has been corrected.

The decision to issue a Warning Letter, perform a Follow-up Inspection and/or take other regulatory action will be based on FDA's review of:

- your inspection report
- all written correspondence we receive from your facility within 15 working days of you receiving your inspection report, indicating how each problem has been corrected
- your facility's past history of MQSA violations

Please note: A fee of $1,144 is charged for a follow-up inspection.

We suggest that any correspondence address all adverse observations listed in the accompanying MQSA Facility Inspection Report and include:

- Facility ID number (from your FDA certificate).
- Listing of corrective actions performed or proposed to correct the problem(s).
- Date that each corrective action was or will be completed.
- Copies of service records and/or other supporting documents showing any corrective action already completed.
- For equipment test items, copies of raw test data and calculated final results.
- For quality control and medical records, copies of records that show that the records are in compliance (delete patient names and other patient identifiers).
- For personnel qualification issues, documentation showing that the person(s) actually met the requirement(s) or what steps the facility has or will take to address the problem.
- The steps taken to prevent the reoccurrence of the problem(s). This should include having the facility's most responsible individual discuss these problems with the lead interpreting physician and other staff about these problems. **You should consider changes to your standard operating procedures, management practices, oversight for the quality assurance program, and recordkeeping to assure that future inspections are free from adverse observations. A detailed explanation of any changes should be included in your response.**

If your report identified at least one Level 2 or repeat Level 3 as the most serious adverse observation:

If the Report noted at least one Level 2 or repeat Level 3 adverse observation as the most serious observation during your annual inspection, **you should correct all inspection observations as soon as possible.** Because of the nature of the observation(s), FDA may issue your facility a Warning Letter and/or perform a Follow-up Inspection to determine that each problem at your facility has been corrected.

The decision to issue a Warning Letter and/or perform a Follow-up Inspection will be based on FDA's review of:

- your inspection report
- all written correspondence we receive from your facility within 30 working days of you receiving your inspection report, indicating how each problem has been corrected
- your facility's past history of MQSA violations (if any)

Please note: A fee of $1,144 is charged for a follow-up inspection.

We suggest that any correspondence address all adverse observations listed in the accompanying MQSA Facility Inspection Report and include:

- Facility ID number (from your FDA certificate).
- Listing of corrective actions performed or proposed to correct the problem(s).
- Date that each corrective action was or will be completed.
- Copies of service records and/or other supporting documents showing any corrective action already completed.
- For equipment test items, copies of raw test data and calculated final results.
- For quality control and medical records, copies of records that show that the records are in compliance (delete patient names and other patient identifiers).
- For personnel qualification issues, documentation showing that the person(s) actually met the requirement(s) or what steps the facility has or will take to address the problem.
- The steps taken to prevent the reoccurrence of the problem(s).

If your report identified at least one Level 3 as the most serious adverse observation:

If the Report noted at least one Level 3 adverse observation as the most serious observation during your annual inspection, this indicates that the facility meets all key MQSA requirements but fails to meet a minor mammography quality item. You do not have to respond in writing to the FDA regarding any adverse observation, however, **you should correct each problem as soon as possible**. During your next MQSA inspection, we will check to ensure that each problem was corrected.

***If your report identified* no adverse observations:**

If the Report identified no adverse observations at your facility, this indicates that the facility meets all key MQSA requirements and no correspondence with FDA regarding your inspection is necessary.

Where to Submit Correspondence:

Submit your written correspondence to:

Food and Drug Administration*
[Street Address]
[City, State, Zip Code]

Send a copy to:

[State radiation control office]*
[Street Address]
[City, State, Zip Code]

* For questions about addressing an adverse observation, you may contact the [name and title of FDA compliance officer, MQSA auditor, or other person] at [FDA phone number]. If you have other questions regarding your inspection, please contact [inspector name and title] at [inspector phone number].

Additional information:

Additional information on meeting MQSA requirements may be found at FDA's mammography Internet site at http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm. Please note that there are many FDA requirements pertaining to mammography. The Report you received pertains only to observations related to your inspection and does not necessarily address other obligations you have under the law.

State Requirements:

The inspector may have identified observations regarding State requirements during your inspection or the State may later send a letter to your facility. Please communicate directly with the State regarding these observations.

Appendix 2: FDA Certificate Extension Program

Certified facilities that have installed FDA-approved FFDM or DBT units for which FDA has not approved an accrediting body, may start using the mammography unit on patients only after they have been informed in writing by FDA's Division of Mammography Quality Standards (DMQS) that they have met all the necessary requirements under MQSA. In the absence of AB performance standards for such units, the MQSA requirements are evaluated through a procedure developed by DMQS, which is outlined below. Until FDA approves AB standards for these units, it will continue to use this procedure for allowing certified facilities under MQSA to use new x-ray technology on patients.

Facilities with FFDM or DBT units for which there is no FDA approved accreditation body must continue to apply to and be approved by the FDA for extension of their certificates to include the use of an FFDM or DBT unit, in order to operate those units legally. To begin this procedure, a facility must submit an application directly to DMQRP. If the application is approved, DMQRP will send a letter to the facility allowing it to use the specified FFDM unit (s) on patients. This procedure extends the facility's certification to include the specified FFDM units.

Requests for FFDM or DBT certification extension need to include all the information listed in the document **MQSA Facility Certification Extension Requirements** and should be forwarded to:

FFDM and DBT Certification Extension Program
Division of Mammography Quality Standards
FDA/CDRH/OIR
10903 New Hampshire Ave., WO66-4528
Silver Spring, MD 20993-0002
Phone: 301-796-5919
Fax: 301-847-8502

Throughout the clinical use of these units, facilities must follow all the QC procedures recommended by the FFDM unit manufacturer.

Appendix 3: Procedures for an Additional Mammography Review

1 Introduction

We are issuing this guide to assist FDA field offices and MQSA inspectors in following up on inspections or investigations where an AMR may be warranted. Under 21 C.F.R. Part 900.12(j), it states:

(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 have 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.

On February 25, 2000, we issued a document entitled Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2. On page 45 of this document, we included guidance specific to inspections where Level 1 observations were present for phantom image failure or qualifications of interpreting physicians. This document can no longer be downloaded as a separate document from the Web. All of the guidance from Document #2 is now included in a comprehensive Policy Guidance Help System. We have provided this help system to all MQSA inspectors on the laptop computers that they use for inspections. You should review the guidance on AMR from this Help System prior to implementing the procedures outlined in this inspection guide.

2 Instructions to Inspectors (During and After the Inspection)

These instructions include steps that will help ensure that FDA has been informed about the extent of the problems and the time frame(s) over which they were present. The time frame(s) is important, since we will use it to set the boundaries of the AMR. For the phantom image test, the additional follow up that you should conduct and other information you should collect during the inspection will help us determine whether an AMR will be done.

For both the phantom image test and the qualifications of the interpreting physician, FDA should verify that the inspection observations are valid before considering an AMR. The section below entitled **Additional Evaluations of Phantom Image** provides instructions on methods that you may use to verify that the inspector's Level 1 phantom image test result is valid.

If both phantom images mentioned above fail at Level 1, determine the extent of imaging problems. Evaluate the facility's weekly phantom images to see if an ongoing problem can be determined.

Evaluate the most recent 12 weekly phantom images. Facilities are only required to keep the phantom images for the last 12 weeks, but some facilities may have phantom images dating back to the last inspection. If any of these images also shows a Level 1 phantom score, continue scoring images back to the last inspection (or as far back as they kept images) until the scores no longer show a Level 1 observation. To speed up the review, only score one phantom image per month, if Level 1 observations continue to show up in these images. In addition, record the phantom image score from the most recent medical physicist survey report (if the medical physicist has recorded the numerical scores; if not, record whether he or she passed or failed the facility for the x-ray unit survey). Record the facility's phantom image scores and the medical physicist's scores in the Remarks section for Phantom Image Quality Evaluation.

Tell the facility that the scores are preliminary and that further evaluation may be required. In the event that the facility agrees with your preliminary scores, recommend the facility immediately determine the cause of the problem and correct the problem before additional mammograms are produced using the equipment that caused the failure.

You or your supervisor should contact your FDA district office (or regional office, where appropriate) about this situation as soon as possible.

3 Documenting Level 1 Findings in FISS Remarks

Depending on the scope, size, and impact on clinical image quality, of a Level 1 finding inspectors may need to document additional information under the Remarks tabs of the inspection or in an additional written document.

Phantom Failure: Document under the Quality Control Remarks tab the scores of facility QC phantom films with failing phantom scores for x-ray unit with Level 1 inspection phantom score:

Date of phantom film _____
Net Fibers Score_____
Net Speck Score_____
Net Mass Score _____

Date of phantom film _____
Net Fibers Score_____
Net Speck Score_____
Net Mass Score _____

Date of phantom film _____
Net Fibers Score_____
Net Speck Score_____
Net Mass Score _____

Repeat these as often as needed

If the phantom failure occurred during the annual survey document the score of medical physicist phantom film under the Survey Remarks tab:

Date of phantom test _____
Net Fibers Score_____
Net Speck Score_____
Net Mass Score _____
Pass/fail (no numerical score)? _____

Level 1 Interpreting Physician Matters: For Interpreting Physicians with Level 1 observations, document under the Personnel Remarks tab the dates when the interpreting physicians was reading and interpreting mammograms at facility.

IP Starting date at facility (if physician started since last inspection) _____
IP Ending date at facility (if no longer reading at facility) _____
Number (or estimate) of mammograms read by the IP in the past 24 months preceding the inspection date (from continuing experience documentation) _____
Total number of mammograms performed at the facility in the past 24 months preceding the inspection date _____

4 Additional Evaluations of Phantom Image

Every Level 1 phantom score from an inspection must be followed up with at least one additional confirmatory evaluation, as part of an established phantom-image quality assurance process. This process may consist of one of the following:

State Program Office review process: The State conducting the inspection may develop a process where a designated inspector or group of inspectors are responsible for providing confirmatory scores for the Level 1 phantom images. The important factor is that the inspector conducting the confirmatory review must have adequate training in phantom image evaluation and also routinely review and score phantom images (either through conducting MQSA inspections or through regular evaluations of inspection phantom films). The Regional Radiological Health Representative (RRHR) and/or MQSA auditor should evaluate the State's process before accepting that State's review for phantom image scoring.

MQSA auditor review process: In the event that the State prefers not to establish a process as outlined above or if the inspection is conducted by an FDA MQSA inspector, the auditor can provide confirmatory scoring for the Level 1 phantom images.

Division of Mammography Quality and Radiation Programs (DMQRP) review process: In the event that the State cannot establish a process as outlined above and there is no MQSA auditor to cover the State, the films may be shipped to DMQRP for confirmatory scoring.

In all cases where the Level 1 phantom images must be mailed to another location for scoring, use overnight shipping to expedite the scoring. Shipping costs for the films may be included for inspections under cost-reimbursement contracts, where applicable.

Appendix 4: Further Assistance

MQSA Hotline

DMQS established the MQSA Hotline to assist you in the performance of your duties as a certified MQSA inspector. The Hotline is staffed between 8:30 AM and 4:30 PM, EST, Monday through Friday.

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For assistance while performing an inspection or for other emergency situations:
Call: 800-838-7715 or Fax: 410-290-6351

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For assistance in non-emergency situations: E-mail the Hotline: MQSAhotline@hcmsllc.com.
Calling individual division staff defeats the purpose of the MQS Hotline. By using the MQSA Hotline, we will be able to respond more efficiently to your needs and to track the types of calls, thereby enabling us to make improvements in training and inspector quality assurance or performance.

Computer Support

For help with problems regarding your FDA laptop, the FISS software, or MPRISweb call MPRIS Computer Support at: 301-796-6633 or e-mail atCDRHMQRP@CDRH.FDA.GOV.

FDA Regional Radiological Health Representatives (RRHR)

To identify the local MQSA auditors for your area, or for additional guidance on inspection procedures, MQSA regulations of policies, or MQSA contract issues, inspectors and program managers can contact their local FDA (RRHR) for additional assistance.

Northeast Region (NER) - States: CT, MA, ME, NH, NY, RI, VT & FDA Districts: NYK, NEW

George T. Allen, Jr.
Phone: 508-869-6023 (x1102)
Email: george.allen@fda.hhs.gov

Central Region (CER) - States: DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV **&** FDA Districts: BLT, CIN, DET, MIN, NWJ, PHI

Jeff Sincek
Phone: 614-227-5780 (x1111)
Email: Jeffrey.sincek@fda.hhs.gov

Southeast Region (SER) - States: AL, FL, GA, LA, MS, NC, PR, SC, TN **&** FDA Districts: ATL, FLA, SJN, NOL

Karen Smallwood
Phone: 615-366-7823
Email: Karen.smallwood@fda.hhs.gov

Southwest Region (SWR) - States: AR, CO, IA, KS, MO, NE, NM, OK, TX, UT, WY **&** Districts: DEN, KAN, DAL

Scotty Hargrave
Phone: 214-253-4930
Email: Scotty.Hargrave@fda.hhs.gov

Pacific Region (PAR) - States: AK, AZ, CA, HI, ID, NV, OR, WA, MT **&** Districts: LOS, SAN, SEA

Terri Jones
Phone: 949-677-6806
Email: terri.jones@fda.hhs.gov