Mammography Facility Inspections

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SUBJECT:	IMPLEMENTATION DATE
Mammography Facility Inspections	July 18, 2005
	COMPLETION DATE
	September 30, 2008

DATA REPORTING

PRODUCT CODES	PROGRAM ASSIGNMENT CODES	
Product Codes: 90I_ZH – screen/film mammography system 90M_UE – full-field digital mammography system Establishment Type E	85014 85014A 85014C 85014F 85S001	Routine Inspections Quality Assurance Audits Compliance (Coord./Tech. Asst.) Follow-up Inspections State Inspections

Field Reporting

A. Mammography Program Reporting and Information System (MPRIS)

Routine Inspections - Inspectors should record all data and observations during an inspection into the Field Inspection Support System (FISS) software, using the laptop computer provided by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH). They should then upload the inspection (computer data) into the MPRIS within five working days after the inspection. The inspector would usually print a report of the inspection observations from the computer and give this to the facility at the conclusion of the inspection. This report is titled "MQSA Facility Inspection Report," but may also be referred to as the "post-inspection report." The inspector should date and sign the report. In some instances, State inspectors will mail the report back to the facility, following review by his or her supervisor. Where serious violations are found (Level 1, Repeat Level 1, and/or repeat Level 2), FDA may do a follow-up inspection or send a Warning Letter to the facility. In cases where a Warning Letter is sent, a compliance inspection should be done within two to three months after the Warning Letter.

FDA field offices may keep printed copies of the post-inspection and inspection detail reports in the corresponding FDA district file for the facility. Likewise, the States may print out the inspection reports for their records. In those cases where FDA inspectors inspect non-federal facilities, the State should be copied on the inspection report and other correspondence.

B. FACTS Reporting

FDA MQSA inspectors should report all MQSA-related operations (investigations, audits of inspectors, coordination and technical assistance, training, etc.), into the Field Accomplishments and Compliance Tracking System (FACTS). FACTS data entry for inspections isn't needed, since the inspection time is transferred to FACTS from inspections uploaded into FISS by FDA inspectors.

Special Instructions Concerning Audits. MQSA auditors should audit FDA and State MQSA inspectors to ensure they are following FDA procedures and guidance for MQSA inspections. The majority of audit inspections are expected to be joint inspections during an annual inspection. Districts should refer to the MQSA Auditors Guide for more information regarding audits. **When an inspector uploads an audit inspection, it is automatically entered into FACTS as an audit so there is no need for a separate entry into FACTS for these audits. When you are an auditor on a Joint Audit inspection, your time for the audit will be transferred to FACTS as an Operation 13-Domestic Investigation with a Status Code of "Completed."**

> **Joint Audit Inspection:** An audit performed by an MQSA auditor simultaneously with an annual inspection by a State or FDA inspector.
>
> **Independent Audit**: A visit to a facility by an MQSA auditor on a date subsequent to an inspection conducted by a State or FDA inspector. Your time should transfer over to FACTS in the same manner as for a joint audit inspection.

Note: When entering investigations or other operations in FACTS for a specific mammography facility, you should enter the MQSA facility ID number in the cross reference block.

Mentored inspections: When you are the mentor on a Mentored inspection your time will be transferred to FACTS as Operation 83-Training Given by FDA with a Status Code of "Completed."

C. SPECIAL

Correspondence with Facilities – You should send copies of Warning Letters to the State, the facility's accreditation body, and Division of Compliance Management and Operations (HFC-210). You should provide copies of all correspondence of regulatory significance (e.g., minutes of meetings, follow-up letters to facility) to the appropriate state officials.

New or Uncertified Facilities – FDA field personnel and State agencies that receive information that a mammography facility is suspected of performing mammography while uncertified should send an electronic mail message to Division of Mammography Quality and Radiation Programs (DMQRP) as soon as possible (see compliance contacts in Attachment A), with a copy to the Regional Radiological Health Representative (RRHR).

Compliance Information - The Facility Noncompliance Tracking and Management System (FaNTMS), part of MPRIS, is designed to track corrective actions for inspection observations. Each district designates personnel to update FaNTMS, which would normally include FDA MQSA auditors and inspectors as well as compliance personnel. For inspections where the facility is requested to respond (see Part V, A.1.a.), FaNTMS should be updated. Districts should enter data regarding all correspondence with the facility, including Warning Letters and the receipt of facility response letters. This system should be updated no later than 15 business days after the letter is sent or received.

FaNTMS users usually include MQSA auditors and inspectors, compliance officers, and compliance technicians. Only authorized users may update FaNTMS. To get an account set up for a new user, districts should contact MPRIS Computer Support via telephone or e-mail (301-827-4330 or computersupport@cdrh.fda.gov).

D. FACILITIES

All facilities that have been entered into the MPRIS database should also appear in the FACTS Firm File, with identifying Central Files Numbers (CFNs) or Firm Establishment Identifiers (FEIs). However, FACTS users should also enter the facility's MQSA ID number into FACTS as a cross-reference.

PART I - BACKGROUND

Breast cancer is a leading cause of cancer death among women and is most treatable in the early stages. Research indicates that, with widespread use of high-quality mammography, breast cancer mortality could be significantly reduced through the identification of early cancerous lesions and early implementation of treatment. However, the quality of mammography at some facilities has been found to be inadequate, resulting in missed diagnosis of early lesions, delayed treatment, and otherwise avoidable increases in mortality. Concerns about mammography quality and breast cancer prompted the establishment of various private, State, and Federal programs for ensuring quality mammography.

Disadvantages of such programs were that they were either voluntary, such as the Mammography Accreditation Program of the American College of Radiology (ACR), or were mandatory but did not apply to all facilities in the United States, such as State programs and programs administered by the Centers for Medicare and Medicaid (CMS) (formerly Health Care Financing Administration (HCFA)). Also, most of these programs lacked important mammography quality evaluation criteria or oversight mechanisms, such as clinical image review and on-site inspections of facilities. Therefore, on a nationwide level, there were no universal mandatory standards for providing safe, accurate, and reliable mammography services.

Congress passed the Mammography Quality Standards Act (MQSA) to set uniform, national quality standards for mammography. The MQSA amended part F of Title III of the Public Health Service Act (the MQSA) (42 U.S.C. 262 et seq.) by adding new section 354 (42 U.S.C. 263b) to require certification and inspection of all mammography facilities by the Department of Health and Human Services. Under the MQSA, only certified facilities that are in compliance with uniform Federal standards for safe, high-quality mammography services may lawfully continue operation after October 1, 1994. Performing mammography after this date requires an MQSA certificate. The requirements under MQSA apply to all facilities producing, processing, or interpreting mammograms for screening or diagnostic purposes, except for facilities of the Department of Veterans Affairs.

FDA was given interim rule authority to establish regulations implementing provisions of section 354(b), (c), (d), (e), and (f) of the MQSA pertaining to certification procedures and quality standards for mammography on December 21, 1993. A more detailed legislative history and rationale for these regulations are provided in the preamble for the accreditation regulations published on December 21, 1993 (58 F.R. 67558).

MQSA Requirements

1. A National Mammography Quality Assurance Advisory Committee. Among other things, the advisory committee will advise the Secretary on the appropriate quality standards for the mammography facilities and the accreditation bodies (section 354(n) of the MQSA (42 U.S.C. 263b(n)).

2. Standards for interpreting physicians, radiologic technologists, medical physicists, and mammography facility inspectors (section 354(f), (g) of the MQSA (42 U.S.C. 263b(f), (g)).

3. Designation of boards or organizations eligible to certify the adequacy of training and experience of particular mammography personnel (section 354(f)(2) of the MQSA (42 U.S.C. 263b(f)(2)).

4. Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs (section 354(f) of the MQSA (42 U.S.C. 263b(f)).

5. Establishment of standards governing record keeping for mammograms (images and paper records), requirements concerning mammography reporting, and notification of results to patients (section 354(f)(1)(G) of the MQSA (42 U.S.C. 263b(f)(1)G)).

6. Annual physics survey, consultation, and evaluation of mammography facilities performed by a certified or State-licensed/approved medical physicist (section 354(f)(1)(E) of the MQSA (42 U.S.C. 263b(f)(1)(E)); 21 CFR 900.12(e)(9)).

7. Accreditation of mammography facilities by private, nonprofit organizations or State agencies which have met the standards established by the Secretary for accreditation bodies and has been approved by the Secretary. It also requires that, as a part of the overall accreditation process, clinical mammograms from each facility be evaluated for quality (section 354(d)(1)(A)(iv), (e)(1)(B)(i) of the MQSA (42 U.S.C. 263b(d)(1)(A)(iv), (e)(1)(B)(i)).

8. Annual inspection of mammography facilities, to be performed by Federally-certified inspectors. The MQSA also requires a Federal audit of inspections conducted by States (section 354(g)(1), (3) of the MQSA (42 U.S.C. 263b(g)(1), (3)).

After October 1, 1994, no mammography facility, whether in a hospital, doctor's office, mobile van, military base, or any other public or private enterprise may operate legally, unless the facility is:

Accredited by an approved accreditation body (currently, the American College of Radiology and the States of Arkansas, Iowa, and Texas) and

Certified by FDA or a State approved by FDA (currently the States of Illinois, Iowa, and

South Carolina).

Reauthorization

On October 9, 1998, the president signed into law the Mammography Quality Standards Reauthorization Act of 1998 (Public Law 105-248). The following is a summarized list of the major changes to MQSA from this law:

1. Changes to the requirements for retention of medical records.

2. Requiring that all women receive notification of the results of their mammogram.

3. Authorizing FDA to inspect all facilities, including facilities performing mammography without a certificate, and to inspect uncertified facilities to document illegal activity.

4. Authorizing FDA to conduct a demonstration program to inspect certain facilities less often than annually.

5. Allowing FDA to contract with local, as well as State governments, to conduct annual inspections.

6. Authorizing FDA to require facilities to notify patients when the quality of mammography presents a significant risk to individual or public health.

7. Changes to the Civil Money Penalties requirements to include failure to notify patients when required.

Final Regulations

On April 28, 1999, the current MQSA facility regulations went into effect (21 CFR Part 900). Prior to this date, facilities were covered by interim regulations that took effect on October 1, 1994 (21 CFR 900.2(t)).

Exceptions

Veterans Health Administration (VHA): Mammography facilities in the Department of Veteran Affairs are exempt from MQSA. However, VHA has established internal standards equivalent to the MQSA standards. Under an interagency agreement (IAG) with VHA, FDA conducts inspections of VHA facilities. VHA facilities are evaluated against the same requirements as FDA certified facilities. The inspections are conducted using the same procedures and software as certified facilities. FDA provides the inspection reports to the VHA who is responsible for assuring compliance of their facilities with VHA standards. Under the IAG, VHA reimburses FDA for the costs for these inspections.

Interventional Mammography: Facilities using mammography equipment exclusively for the purpose

of interventional procedures (procedures such as stereotactic breast biopsy, needle localization, fine needle aspiration, or galactography) currently are not required to be accredited or certified and should not be inspected. The exemption for equipment used exclusively for interventional procedures took effect on September 30, 1994 (21 CFR 900.2(aa)(1)).

Investigational Mammography Equipment: There is an exemption in effect for mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device exemption regulations under 21 CFR 812 (21 CFR 900.2(aa)(2)).

Fees

Once facilities are inspected, they are usually charged a fee for the inspection (section 354(r) of the MQSA (42 U.S.C. 263b(r)). Facilities that qualify as government entities (federal, state, and local) are exempt from inspection fees. Fees are usually collected for annual inspections and follow-up inspections. The total fee for an annual inspection should be based on the FDA's cost for an inspection for a facility. Since follow-up inspections do not usually cover all aspects of the facility's operation, the fee is lower than for the annual inspection. Independent audit and compliance inspections are not charged to the facility (see section A of Part III for an explanation of inspection types). For information on the current fee structure, go to http://www.fda.gov/CDRH/MAMMOGRAPHY/inspection_fees.html.

PART II - IMPLEMENTATION

A. Objective

This compliance program provides guidance for:

1. Inspections and investigations of mammography facilities under MQSA.

2. Actions that FDA may take to ensure that mammography facilities are in compliance with MQSA.

B. Program Management Instruction

1. Resource Instruction

MPRIS is a vital part of the program. It allows immediate access to and update of information on mammography facilities. All MQSA inspectors and compliance officers, who work with violative MQSA facilities, should have access to MPRIS, including exchange of information and updating capabilities. MPRIS also provides electronic mail capability for inspectors. State inspectors also have access to their State's inspections.

The FDA's RRHRs, along with the Division of Mammography Quality and Radiation Programs (DMQRP) and the Division of Human Resource Development in ORA, are responsible for training and oversight of FDA and State inspectors. These and other functions are described in Part VII A. (DMQRP responsibilities). DMQRP staff will train MQSA inspectors. Only certified MQSA inspectors can perform MQSA inspections (see section 354(g)(1)(D) of the MQSA (42 U.S.C. 263b(g)(1)(D)).

FDA districts without a certified FDA MQSA inspector should work with their RRHR to arrange for a certified inspector or MQSA auditor from the regional office or other districts to perform MQSA inspections and audit functions.

All MQSA inspectors should follow FDA inspection procedures provided by DMQRP (MQSA Inspection Procedures, version 4.52 or later). FDA inspectors should wear personnel dosimeters (radiation badges) distributed by the Field Health Physicist at WEAC if they perform inspections or accompany an inspector. State contract inspectors should wear the personnel dosimeter normally provided by the State. All FDA and State inspectors must present identification (provided only to MQSA-certified inspectors) to facility personnel prior to the start of each inspection. This identification is required by MQSA (section 354(g)(1)(B) of the MQSA (42 U.S.C. 263b(g)(1)(B)). Credentials issued to FDA investigators should not be used as a substitute.

2. Planning Instructions

Each District (or Regional Radiological Staff, where appropriate) should develop a strategy:

a. To work with the RRHR to have State Radiation Programs inspect certified facilities annually under the terms of its contract, and

b. To encourage voluntary compliance of facilities and, where necessary, send Warning Letters, conduct follow-up or compliance inspections, or recommend regulatory actions to bring violative facilities into compliance.

District Office or Regional Radiological Staff should work through the RRHR to assure that State contract inspections are done in accordance with FDA policy and contract requirements (Refer to Part II B.9. - RRHR Management Activities).

3. States as Certifiers (SAC) Program

FDA may approve States to certify mammography facilities under MQSA. Under section 354(q) of the MQSA (42 U.S.C. 263b(q)), FDA may authorize a State to carry out specific responsibilities, which include:

a. Issuing MQSA certificates to mammography facilities

b. Conducting inspections of mammography facilities

c. Sending letters and evaluating responses from mammography facilities in violation of MQSA standards and regulations

d. Taking regulatory actions under MQSA, where appropriate, against mammography facilities

This authorization does **not** allow States to carry out the following responsibilities under MQSA, which must be carried out by FDA:

e. Conducting MQSA inspection audits of State inspectors

f. Developing MQSA facility standards

States approved as a SAC State would perform most of the functions currently performed by FDA field offices for facilities in their State. An exception would be inspection audits, which would still be performed by approved FDA auditors. Also, while the Act allows the State to take regulatory action against facilities, FDA still has the authority to also take action, when necessary (section 354(q)(3)(B) of the MQSA (42 U.S.C. 263b(q)(3)(B)).

FDA final regulations for State certification became effective on May 7, 2002 (21 CFR 900.20 through 900.25). Go to http://www.fda.gov/CDRH/MAMMOGRAPHY/facilities-rev.html#1 for a current list of SAC States.

Field Office Guidance: With the exception of inspection audits and SAC oversight functions, field offices will not normally be responsible for assessing compliance of mammography facilities in SAC States. There are several exceptions. The first is where FDA and the State decide to work together to bring a facility into compliance. Another exception is that FDA certifies and inspects federal facilities in SAC States.

4. Veterans Health Administration (VHA) Inspections

Mammography facilities operated by VHA, which is part of the U.S. Department of Veterans Affairs, are exempt from the requirements of MQSA (see 354(a)(3)(A) of the MQSA (42 U.S.C. 263b(a)(3)(A)). The law does not require that these facilities be certified or inspected by FDA. However, to assure that the quality of mammography at their facilities is equivalent to certified facilities, VHA requires all their mammography facilities be accredited by the American College of Radiology and meet VHA standards that are equivalent to FDA standards.

Under an interagency agreement (IAG) with VHA, FDA inspects VHA facilities. Their facilities are evaluated against the same requirements as FDA certified facilities. FDA inspects these facilities using the same procedures and software as certified facilities. FDA provides the inspection reports to the VHA which is responsible for assuring compliance of their facilities with VHA standards. Under the IAG, VHA reimburses FDA for the costs for these inspections.

5. Inspection Demonstration Program

In May of 2002, as part of the 1998 reauthorization of MQSA, FDA began a demonstration program to inspect, less frequently, those facilities that had excellent inspection records (substantially free of inspection violations) (section 354(g)(6) of the MQSA (42 U.S.C. 263b(g)(6)). The facilities in this demonstration will skip at least one annual inspection and, depending on the results, may be inspected in the future every other year. The program consists of study and control groups of 160 facilities located in 14 States. Results of this program are expected in late 2004 and will be analyzed in 2005.

6. Inspection Follow-up and Regulatory Action

Facilities should be informed of adverse observations during the inspections in one of several ways. The most common method is for the inspector to leave a printed inspection report at the close of the inspection (some States may mail this report to the facility after State supervisory review).

FDA may use various regulatory actions against a facility that fails to comply with the standards and regulations under MQSA. These include:

a. Warning Letter – formal notification to the facility regarding serious violations that could result in regulatory action, if not corrected.

b. Additional Mammography Review (AMR) – under 21 CFR 900.12(j)(1), FDA may require additional mammography review to investigate whether violative conditions at a facility may have seriously affected the quality of mammography. Should this AMR shows that the quality of mammography represents a serious risk to human health, FDA may require patient and physician notification, as well as other regulatory actions. An AMR may consist of a review of mammograms to assess the clinical image quality of mammography at a facility. In some instances, the review could include mammography reports to assess the quality of mammographic interpretations.

c. Directed Plan of Correction – a specific set of requirements imposed to assure that the facility performs mammography in compliance with MQSA and allows monitoring of the facility's continued compliance (section 354(h)(1)(A) of the MQSA (42 U.S.C. 263b(h)(1)(A)).

d. Civil Money Penalties – fines imposed for violations of MQSA (section 354(h)(3) of the MQSA (42 U.S.C. 263b(h)(3)).

e. Patient and Physician Notification (wording in MQSA is "Patient Information") – FDA required notification for patients and physicians when the mammography at the facility has been found to be a serious risk to human

health (section 354(h)(2) of the MQSA (42 U.S.C. 263b(h)(2)).

f. Suspension or revocation (of the facility's MQSA certificate) – action taken to stop a facility from performing mammography in violation of MQSA (section 354(i) of the MQSA (42 U.S.C. 263b(i)).

g. Action under 21 CFR 900.13(a) (certificate determined to be no longer in effect) – if a facility's accreditation has been revoked by its accreditation body, FDA may determine that its certificate is no longer in effect. This action is equivalent to suspension of the facility's certificate prior to a hearing. A facility whose certificate is no longer in effect must stop performing mammography.

h. Injunction - court order which stops a facility from performing mammography where continued operation may represent a serious risk to human health or when a facility continues to perform mammography without a certificate (section 354(j) of the MQSA (42 U.S.C. 263b(j)).

7. Scheduling Inspections

In most cases, a facility gets its 6 month provisional certificate and then goes on to get its full 3 year certificate. This facility should be inspected within 10-14 months of its initial provisional certification date and then every 10-14 months from its most recent inspection. However, there are exceptions to this general policy that can be found under section 2.1.2 Routine Annual Facility Inspections - When should a facility be inspected? in the MQSA inspection procedures.

8. Inspection Priorities

a. **Highest Priority**

1) Immediate inspections to investigate allegations of serious risk to human health, performing mammography without a certificate, continuing serious violations, or fraud

2) Follow-up inspections for facilities with a history of serious violations (facility failed to respond or provided inadequate response after violative inspection, facilities under Directed Plans of Correction, facilities considered for regulatory actions with no recent inspection)

3) Compliance inspections (inspections to follow up on a Warning Letter)

b. **Moderate Priority** - Inspections under moderate priority should be scheduled ahead of facilities with lesser problems, but still within 10 to 14 months after the previous inspection. The scheduling of these inspections should also take into

account the location of the facility, as well as travel costs, availability of personnel, and other constraints.

1) Inspections of facilities with a history of violations not serious enough for highest priority (example: Level 1 and/or repeat Level 2 observations, but response to last annual inspection was adequate)

2) Inspections of facilities with violations under State regulations that parallel MQSA requirements, but not serious enough for highest priority

3) Facilities that have complaints against them concerning quality standards (including complaints from accreditation bodies), but not serious enough for highest priority

4) Facilities that have "reinstated for accreditation" and have never been inspected (section 2.1.2 Routine Annual Facility Inspections - When should a facility be inspected? in the MQSA inspection procedures for more information about when to inspect reinstated facilities)

Note: Reinstatement for accreditation is a process that allows facilities that are no longer accredited and certified to apply for accreditation to have the certificate reinstated. This facility may then be considered a new facility and eligible for a provisional certificate. Reinstatement applies to any facility that:

1. **let its certificate expire**
2. **withdrew its accreditation**
3. **was denied accreditation or reaccreditation**
4. **had its accreditation suspended or revoked**
5. **had its certificate suspended**

In situations 3-5 above, the facility must have corrected its problems to the satisfaction of the accreditation body before being reinstated (see 21 CFR 900.11(c)(1)(iii)). After receiving the provisional certificate, the facility may resume performing mammography while completing the requirements for certification (21 CFR 900.11(c)(3)).

c. **Normal Priority –** see section 7 of this Part for further information on scheduling these inspections.

d. **Low Priority** - new provisionally certified facilities (inspection of these facilities should be delayed, if possible, until 10-14 months after their initial provisional certification date. The only time a new provisionally certified facility should be high priority is when serious MQSA violations and/or mammography quality problems are suspected).

9. RRHR Management Activities

The RRHR should coordinate and supervise agency contracts with States performing MQSA inspections, including the following:

a. Work with contract States to have each facility within the State inspected following the guidance under sections 7 and 8 of this Part and to expedite submission of the inspection results for those facilities to the MPRIS to ensure timely follow-up action by FDA.

b. Monitor annual inspection audits of State and FDA personnel by qualified MQSA auditors to ensure that proper procedures and techniques are used during inspections.

c. Administer tests and practical examinations to inspectors who are training for MQSA inspector certification.

d. Monitor State and FDA inspection workload and manpower resources and give periodic assessments to DMQRP/CDRH.

e. Coordinate and supervise MQSA inspection contracts with States.

f. Coordinate with States for the performance of special inspections (e.g., follow-up inspections, special assignment inspections).

g. Authorize a State to inspect a facility without prior notification.

h. Authorize a State to release information regarding an MQSA facility inspection (unless information is required to be released under State law).

RRHRs should be copied on all correspondence with State programs, including State inspectors, as well as all facility correspondence.

PART III - INSPECTIONS

A. Facility Inspections

Note: Only FDA and State inspectors who have been certified by FDA may perform MQSA inspections (including follow-up inspections) (see Section 354(g)(1)(D) of the MQSA (42 U.S.C. 263b(g)(1)(D)).

A facility inspection may consist of equipment testing (x-ray equipment and film processors), a review of quality assurance and quality control records, medical physicist reports, medical audit and outcomes analysis records, personnel records, and medical records. Both test data and inspection observations should be included in each inspection report. Unlike most FDA inspections, the facility should generally be given at least five days notice before the start of the inspection. This notification enables the facility to reschedule patients (see Attachment M for a sample confirmation note).

Note: A Notice of Inspection (form FDA 482) is not required for an MQSA inspection.

Under some circumstances, where the continued performance of mammography may threaten the public health (mammographic quality is seriously substandard) or where fraud may be suspected (for example, where there is concern that quality control records had been falsified), districts may decide to conduct an unannounced inspection. In the event that districts decide to conduct an unannounced inspection, the inspector should place a memorandum in the facility's establishment file with the reasons why he or she conducted an unannounced inspection. States must get clearance from the RRHR prior to conducting unannounced MQSA inspections (States may conduct unannounced State inspections without FDA authorization when operating under State law).

FDA MQSA inspectors should inspect all federal facilities, including military. This would include federal facilities in SAC States and military facilities in United States territories and foreign countries.

The following are the inspection types that can be selected in the FISS software used for inspections:

Annual Inspection: The most common type of inspection, which is done 10-14 months after the previous inspection. Inspection fee applies (go to http://www.fda.gov/CDRH/MAMMOGRAPHY/inspection_fees.html for inspection fee information).

Follow-Up Inspection: An inspection conducted to verify corrective action identified from a facility response or to document ongoing violations prior to taking regulatory action or sending a Warning Letter. Follow-up inspections usually are limited to areas

found noncompliant during the previous inspection. Inspection fee applies (go to http://www.fda.gov/CDRH/MAMMOGRAPHY/inspection_fees.html for inspection fee information).

Compliance Inspection: An inspection conducted as a follow up to a Warning Letter to determine if violations continue. No inspection fee.

Headquarters-Initiated Inspection: Any inspection requested by CDRH or initiated by a district to investigate complaints about a facility. No inspection fee.

Joint Audit Inspection: An audit performed by an MQSA auditor simultaneously with an annual inspection by a State or FDA inspector. Since this is an annual inspection, it has an inspection fee (see section C of this Part for more information about audits).

Independent Audit: A visit to a facility by an MQSA auditor on a date subsequent to an inspection conducted by a State or FDA inspector (see section C of this Part for more information about audits). No inspection fee.

Guidelines for facility inspections:

1. Inspectors should follow the MQSA inspection procedures (Reference A.5. in Part VI).

2. Districts and contract States should select facilities for inspection based on priority (see Inspection Scheduling and Priority in Part II, B.7. and B.8.).

3. Inspectors should contact the facility by telephone at least five days before the inspection and follow up with a fax notice (the laptop computer may be used for this purpose). If the facility does not have a fax system, then the inspector should mail a notice to the facility. The facility person contacted by phone and notified by fax or letter should be a person in authority and not a clerical employee. Examples of contact individuals would be the chief technologist, lead or other interpreting physician, and quality control technologist. Inspectors should also explain that personnel critical to mammography quality assurance should be notified regarding the time and date of the inspection and be available during the inspection.

Note: On occasion, when FDA, the State, or an accreditation body is informed of possible serious violations or a risk to health at a facility inspected less than 10 months previously, FDA may need to inspect as soon as possible. For these inspections, the inspector should select an inspection type of "Headquarters Initiated" at download. This inspection type should also be used for other special inspections that aren't annual, follow-up, or independent audits. Inspections uploaded with this inspection type wouldn't normally be billed for an inspection fee.

4. At the facility, the inspector should:

   a. Wear a personnel radiation dosimeter (thermoluminescent detector (TLD) or film badge) provided either by FDA or the appropriate State Agency when performing the x-ray system testing.

   b. Discuss the inspection with facility personnel about what is involved, prior to conducting any equipment testing or review of facility records, unless this was covered on the telephone prior to the inspection.

   c. During the inspection, enter inspection data into the laptop computer. The inspector should upload the data to MPRIS within five working days after the inspection.

   d. Provide the facility with the MQSA Facility Inspection Report (indicated as "post-inspection report" in the inspection software program), which contains test results and inspection observations (some States may mail this printout to the facility after State supervisory review). The inspector should discuss these observations with the most responsible person at the facility, even when the inspection report is mailed to the facility at a later time. The inspector should also record in the inspection report if the report is left at facility during the inspection or mailed, as well as the person who received or was mailed the report. If the person who was mailed the report is different from the most responsible person at the facility, the most responsible person should also be mailed a copy of the inspection report. When the report is mailed, the date it is mailed should be recorded in the inspection report. It is very important that the inspector make management at the facility aware of the inspection observations and what they need to do in response to these observations. The inspector should identify areas of noncompliance, especially any Level 1 and/or repeat observations. See the MQSA Inspection Procedures for more information on discussing inspection observations with management.

In addition to the MQSA Facility Inspection Report, the facility should receive a document entitled *Important Information about Your MQSA Inspection*, which contains guidance to the facility as to how to interpret its inspection report (see Attachment L). This identifies the different levels of inspection observations and how the facility should respond to FDA, based on the highest level of observation. A check box is present on the form for the inspector to indicate which information pertains to the facility's inspection.

e. Document any x-ray system damage (real or claimed) due to the testing of the x-ray unit or any other facility equipment on FDA form 2766, Claim for Damage to an Electronic Product (refer to Attachment D). Forward this form immediately through the RRHR to DMQRP (without delaying submission or attempting to refute the alleged damages).

Note: State contract personnel should immediately report any damage to an x-ray system to the RRHR. The RRHR should determine what follow up is required (use of FDA form 2766 is not required for State inspections). Under the Federal Tort Claims Act, FDA is not responsible for any damage to facility equipment by State contract employees.

f. **Documentation**: FDA may need documentation or other evidence for a regulatory action (Directed Plan of Correction, Civil Money Penalties, suspension or revocation, or injunction). Regarding records reviewed during the inspection, **the inspector should collect copies of records that show why he or she made a specific inspection observation. This would apply for any Level 1, 2, or repeat Level 3 observation.** Copies of records should also be collected when numerous problems with records may result in a Warning Letter being sent, although no Level 1 observations are present. If in doubt, the inspector should collect copies of records.

Note: Since FDA jurisdiction depends upon a facility performing mammography when the violations occurred, the inspector should copy records showing that mammography was being performed at the time of the violations. Since the facility can be charged with violating MQSA for each mammogram done while failing to comply, you should document as many mammograms as possible that are associated with specific violations. If it is not possible to document every mammogram, the inspector should record the number of mammograms performed during the time period when the facility was in violation of MQSA regulations. FDA inspectors should also prepare an affidavit tying all records copied to the

violations observed and the mammograms done when the violations took place.

Examples of records that could be collected during an inspection include:

1) medical physicist reports,

2) mammography reports or patient letters (patient names and identification must be purged for State inspections; for FDA inspections, names and identification should be purged unless records were copied to support regulatory action),

3) records concerning personnel qualifications, and

4) quality control records for film processing, phantom images, and other tests.

When films such as phantom images, STEP, and FOG tests are produced as part of the equipment testing, these films should remain with the office that conducted the inspection (either the contract State, the FDA district, or FDA regional office), unless specifically requested by the FDA district (or regional office, where appropriate) or DMQRP to be transferred to another location. The inspector should identify records collected with:

1) name and facility ID number of the facility,

2) date of the inspection, and

3) name or initials of the inspector.

The inspector should forward to the appropriate district or regional office copies of records collected during State inspections for Level 1, 2, or repeat Level 3 observations (see Attachment E). The State should retain films produced during inspections that show minor or no observations. For Level 1 phantom image failures, States may need to send phantom films to the MQSA auditor to confirm the Level 1 score.

Note: No documentation of interstate commerce is necessary for MQSA inspections.

g. **Patient Records:** Inspectors may need to collect copies of records, such as mammography reports, mammography logbooks, or letters to patients about mammography results. FDA MQSA inspectors will most likely collect these records when visiting facilities as part of investigations or follow-up

inspections, though records may be copied during routine inspections to document medical record violations under 21 CFR 900.12(c).

In general, whenever an inspector needs to copy a record containing patient names or other identifying information, he or she also needs to protect patient confidentiality. All inspectors bear a legal and ethical responsibility to prevent unauthorized disclosure of this information. However, FDA also should have accurate documentation of serious violations under MQSA. FDA may need patient names to establish that a violation has occurred, to follow up specific complaints, or to prove that a copy of a record made during an inspection or investigation is a true copy of the original record. The inspector should not purge the copy made during the inspection, if this copy is going to be used as evidence for a potential compliance case **(this only applies to FDA inspectors, since FDA contracts with States prohibit State inspectors from making copies without removing patient names or other identifying information**). As with any confidential FDA document, the inspector should not disclose these records outside of the FDA or State. The inspector should only share unpurged records containing patient identifiers with other agency or State employees on a "need to know" basis, in accordance with 21 CFR Parts 20 and 21. In addition, FDA advises that if copies of these records are required for use by authorized personnel, inspectors and/or compliance officers should purge additional copies of all patient identifiers whenever there is no need for that particular information to be shared. Patient identifiers would include names, hospital identification numbers, social security numbers, or any other name or code related to a specific patient.

h. **Written Inspection Reports**: For inspections or follow-up inspections that reveal serious violations that may result in regulatory action, FDA inspectors should prepare, in addition to the MQSA Inspection computer data that is uploaded to MPRIS, a complete Establishment Inspection Report (see Investigations Operations Manual (IOM), Section 593).

i. **Inspection refusal:** In the event that a facility refuses to allow an inspection, the district should contact the Division of Compliance Management and Operations (HFC-210) about getting an inspection warrant (see Regulatory Procedures Manual, Chapter 6). When State inspectors are refused, the inspector or their State supervisor should contact the RRHR.

B. Compliance Follow-Up for Inspections

The District Office (or Regional Radiological staff, where appropriate) should:

1. Thoroughly review compliance activity for any facility where regulatory action is being considered. The district's review should include the evaluation of all of the following factors:

    a) Inspection data from MPRIS and copies of facility records

    b) Responses to Warning Letters and copies of any other correspondence with the facility

    c) The results of an Additional Mammography Review (AMR) for a facility (see 21 CFR 900.12(j)(1))

    d) State actions against the facility, under State laws and regulations

    e) Equipment maintenance schedules and service records

    f) Medical physicist reports

    g) Written consumer (patient) complaints, employee complaints, or medical physicist complaints

    h) Written comments or concerns from the inspector

2. Ensure that whenever corrective actions are evaluated, the FaNTMS database is updated to reflect the compliance status of a facility.

3. Monitor inspection results, responses to inspection observations (especially those contained in Warning or Directed Plan of Correction Letters), follow-up inspection data, and identify facilities for possible regulatory follow up.

4. Prepare and send Warning Letters and perform any follow up associated with the letters.

C. Inspection Quality Assurance Audits

1. FDA Auditors should audit all FDA and State MQSA inspectors to ensure they are following FDA procedures and guidance for MQSA inspections. The MQSA Auditor's Guide provides information on how to conduct audits.

2. Each inspector should be audited at least once for each fiscal year. Field Management Directive No. 76 provides general guidance on the MQSA audit program. In addition, the MQSA Auditor's Guide, dated January 1998, contains procedures and policies pertaining to implementation of the audit program. An audit may be either:

   Joint Audit Inspection: An audit performed by an MQSA auditor simultaneously with an annual inspection by a State or FDA inspector.

   Independent Audit: A visit to a facility by an MQSA auditor on a date subsequent to an inspection conducted by a State or FDA inspector.

Note: The majority of audit inspections are expected to be joint inspections during an annual inspection. Districts consult with the RRHR and follow the MQSA Auditor's Guide before performing an independent audit.

D. Follow-Up and Compliance Inspections

Note: FDA MQSA inspectors should do all follow-up and compliance inspections.

Facilities will be asked to respond to Level 1 and repeat Level 2 inspection observations within 15 working days after the inspection and Level 2 and repeat Level 3 inspection observations within 30 working days. Inspectors have been instructed to explain to facility management how to respond to the inspection observations and will provide them with a revised version of the *Important Information about Your MQSA Inspection* document (see Attachment L). If the facility management fails to respond or the response is inadequate to Level 1 or repeat Level 2 observations, you should send a Warning Letter to the most responsible individual at the location and also a copy to the most responsible individual, if off site. Typically, this Warning Letter is preceded by a follow-up inspection. A compliance inspection should be performed two to three months following the Warning Letter to ensure that the violations have been corrected. If this inspection shows continuing violations, you should consider regulatory action, such as a Directed Plan of Correction or Civil Money Penalties. These steps are outlined on the flowchart in Attachment H.

When using the guidance in the paragraph above, there are several things the district should consider:

1. If facility management fails to respond within 15 (or 30) working days, there may be a reasonable explanation why they haven't responded, such as miscommunication within the facility. Before sending a Warning Letter for Level 1 or repeat Level 2 observations, the district should contact them (may be verbal or written) and ask that they respond in writing or come in for a face-to-face meeting. If this fails to resolve the violations, the district should proceed with the follow-up inspection or Warning Letter.

2. If the facility has a violative history, facility management may find it difficult to provide convincing evidence that problems are permanently corrected. If the facility's response contains promises of corrections similar to previous inspections, the district should consider it inadequate and schedule a follow-up inspection for Level 1 or repeat Level 2 observations.

3. If FDA previously sent the facility a Warning Letter for an MQSA inspection, it probably falls under item two above. If a follow-up inspection shows continuing violations, the district should consider regulatory action instead of another Warning Letter.

4. For certain types of facility problems, such as Level 1 observations for phantom image testing by the inspector or Level 1 interpreting physician qualifications, we may require the facility to undergo Additional Mammography Review (AMR) under 21 CFR 900.12(j)(1). Since the AMR shouldn't be delayed, we may notify the facility about the AMR prior to a follow-up inspection. The Director of the Division of Mammography Quality and Radiation Programs (DMQRP) would usually send an untitled letter to the facility requiring AMR. DMQRP will work closely with the district when requesting AMR and will copy it when results are provided by the accreditation body or other review entity. If the AMR shows that the quality of mammography may represent a serious risk to human health, we can require the facility to notify patients and physicians under 21 CFR 900.12(j)(2). More information about AMR can be found in section A.3. in Part V.

Follow-up and compliance inspections should take priority over routine, annual inspections. A fee is usually charged for all follow-up inspections, but no fee should be charged for compliance inspections which should occur two to three months after the Warning Letter was sent.

In violative cases, districts need to obtain adequate documentation of the violations. This means that for violative follow-up inspections, the inspector should prepare a complete narrative report for the inspection (see Investigations Operations Manual (IOM), Section 593), in addition to any information or data recorded in the MPRIS inspection software.

E. Uncertified Facilities

1. Background

FDA may learn that a facility may be performing mammography without a certificate from several sources. A State radiation control program, an accreditation body, consumers, and current or former employees may report the facility.

A facility that can be shown to be performing mammography without a certificate may be a candidate for regulatory action. However, in most cases, FDA would handle these violations like most Level 1 observations. Examples of facilities performing mammography without a certificate could include:

a. new mammography facilities that fail to apply to an accreditation body (this application is required prior to provisional certification)

b. facilities that continue to perform mammography after being notified that their certificate has expired, been suspended, been revoked, or no longer is in effect

Facilities can be assessed civil money penalties or enjoined from operating if they perform mammography without a certificate and have a violative history (see Part V for more information). **If the facility performs mammography without a certificate for 90 days or longer, FDA may require AMR.**

Since other violations and problems could support regulatory action by FDA, the district should inspect against all MQSA requirements, if possible.

2. **Facility Investigations and Inspections**

a. If the district becomes aware that a facility may be performing mammography without a certificate, it should inspect the facility as soon as possible. The district should also contact DMQRP prior to the inspection to verify certification status and to obtain any documentation it may have regarding the facility's certification history.

b. The inspector should conduct a routine MQSA inspection and also document the illegal mammography. The documentation the inspector collects to show illegal mammography should consist of copies of mammography reports (the more recent, the better). Mammography reports are documents that contain the physician's interpretation of the mammogram and should include the date of the mammogram, the date of the interpretation, the facility name, the patient's name or some identification, physician's name, and a written interpretation. For records with patient names or identification, all personnel involved with MQSA should exercise caution to ensure confidentiality and privacy when handling these documents and information (see section A.4.g of this Part for information on the handling of patient records).

c. If the mammography reports do not contain sufficient information to document that the facility was performing mammography without a certificate, inspectors may need to copy mammography film labels. Mammography films have either a paper label attached or a label imprinted into the film with light. Either of the labels should copy easily on a conventional photocopier. The labels should contain the patient's name, the facility's name, and the date of the mammogram.

If the label cannot be photocopied, the inspector may need to photograph the label (on the facility's viewbox if the label was imprinted into the film). However, unless the mammogram has information that can be correlated with the date that the exam was performed, inspectors should not copy information from the films.

d. Inspectors may find that patient logs or schedules are good sources of information about patients who had mammograms. However, inspectors should make sure that patients listed for mammography on logs or schedules actually had mammograms at the facility. Patients on these documents may have been scheduled, but may not have had the scheduled mammogram. Inspectors may find that the logs or schedules provide indications of volume, but should not be used as a substitute for copies of mammography reports.

NOTE: Inspectors should always attempt to get a commitment from the uncertified facility to voluntarily stop performing mammography on the day of the inspection. If the facility is not willing to voluntarily stop performing mammography, FDA may need to enjoin the facility from performing mammography without a certificate. In the interim, the State should be contacted. It may have independent authority to stop the facility from performing mammography and FDA may decide to coordinate action with the State against the facility.

F. Possible Criminal Activity at a Facility

If the district suspects that a facility may have falsified records, has submitted false information to the district, or may have engaged in other possible criminal activity, it should contact the appropriate Office of Criminal Investigations (OCI) field office. The district should coordinate any district follow-up at the facility with this OCI office. **However, the district should not delay inspections or investigation of serious problems regarding the quality of mammography (that is, where a possible serious risk to human health may exist) for the purposes of documenting criminal activity, since FDA may need to require AMR at the facility.**

G. Mammography Equipment Problems (Non-MQSA)

If the district suspects that a problem with mammography x-ray unit, film processor, film, cassettes, image processing computers, or other equipment is related to the manufacturer or assembler of the equipment, it should notify the Diagnostic X-Ray Devices Branch, OCER, CDRH (HFZ-240) and the RRHR. Please refer to CP 7386.003 for guidance regarding x-ray equipment problems.

PART IV - ANALYTICAL

No laboratory testing will be done under this program.

PART V – REGULATORY / ADMINISTRATIVE STRATEGY

A. Regulatory Philosophy and Strategy

1. Inspection Observations

There are three levels of observations, from Level 1, which is the most severe, to Level 3 (see Attachment E). The type of follow-up should depend on the level of the noncompliance. The post inspection printout, called the "MQSA Facility Inspection Report" should identify all of the inspection observations.

a. Levels of Inspection Observations

Highest Level of Observation	Action by Facility
Level 1 – repeat observation	Response from facility within 15 working days
Level 1	Response from facility within 15 working days
Level 2 – repeat observation	Response from facility within 15 working days
Level 2	Response from facility within 30 working days
Level 3 – repeat observation	Response from facility within 30 working days
Level 3	Follow up during next annual inspection

b. Repeat Inspection Observations

The following list identifies characteristics pertaining to repeat inspection observations:

1. Uncorrected from previous inspection or has recurred

2. Generates the same standard statement from the inspection software as for the previous inspection

3. Can be for a different individual in a facility within the same professional category (physician, technologist, or physicist), a different x-ray system, or a different film processor

4. Response from the facility should include how it intends to correct all repeat observations, regardless of level

c. Facility Responses

Facilities should send all responses to inspection observations to the district office (or Regional Radiological Staff, where appropriate). It does not matter whether the inspection was conducted by a State or an FDA MQSA inspector. Facilities should be directed, however, to send a copy of letters they send FDA to the State. FDA recommends that contract States be consulted on the adequacy of facility responses, since State inspectors usually conduct MQSA inspections and have useful information about the facility and the inspection. In addition, the district should copy the State program for all letters sent to facilities, as well as minutes of meetings with facilities. Attachment F contains guidance on reviewing responses.

Before reviewing a facility response, the district should read Attachment F for guidance. If a facility doesn't respond to Level 1 or repeat Level 2 inspection observations when requested or doesn't respond adequately, the district should consider a follow-up inspection or Warning Letter. The district should review section D under Part III before scheduling the follow-up inspection or sending a Warning Letter.

DMQRP has provided access to all district and regional offices to the FaNTMS, a part of MPRIS. FaNTMS contains information on facility inspection data, results, and compliance information. The district should update FaNTMS when the response to the letter has been evaluated. A letter should be sent to the facility when the responses are found to be adequate (see Attachment J) and no follow-up inspection or further action is indicated.

2. Warning Letters

Facilities will be asked to respond to Level 1 and repeat Level 2 inspection observations within 15 working days after the inspection and Level 2 and repeat Level 3 inspection observations within 30 working days. Inspectors have been instructed to explain to facility management how to respond to the inspection observations and will provide them with a revised version of the *Important Information about Your MQSA Inspection* document (see Attachment L). If the facility adequately responds to inspection observations, the District should send a close-out letter to the facility. If the facility fails to respond within the appropriate time frame or the response is inadequate, the District should communicate with the facility to remind it of its obligations and encourage an adequate response to the observations within a reasonable timeframe.

If, after communicating with the District, a facility, with Level 1 or repeat Level 2 inspection observations, still fails to respond, or its response is inadequate, the district should send a Warning Letter. If the District finds that the facility's proposed corrections appear adequate, but based on the facility's past history and capabilities require further verification, the district should conduct a follow-up (fee based) inspection (rather than a Warning Letter). If similar violations are again found during the follow-up (fee based) inspection, the District should send a Warning Letter.

> Note: Districts retain direct reference authority to send Warning Letters for Level 1 and/or Repeat Level 2 observations. When sending Warning Letters, Districts must follow their standard procedures, including the need for OCC clearance. CDRH concurrence is required for Warning Letters where the most significant observation is either Level 2 or Repeat Level 3.

If, after communicating with the District, a facility with Level 2 or repeat Level 3 inspection observations still fails to respond, or its response is inadequate, the District should conduct a follow-up inspection. If similar violations are again identified during the follow-up (fee based) inspection, the District should send a Warning Letter.

In all cases Warning Letters should be sent to the most responsible individuals, not necessarily the contact people at the locations. The district should copy all contract states for all Warning Letters sent to facilities located in their states and to the facility's accreditation body (for a list of the current accreditation bodies, go to http://www.fda.gov/CDRH/MAMMOGRAPHY/accreditation.html), in addition to the normal distribution.

3. Additional Mammography Review (AMR)

If the district suspects that the mammography quality at a facility has been compromised and may present a serious risk to human health, it should recommend that the facility undergo AMR. Under an AMR, the facility must provide clinical images and other relevant information (which may include mammography reports), for review by the facility's accreditation body or by an interpreting physician not associated with the facility (21 CFR 900.12(j)(1)). The AMR review will help FDA determine whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

FDA has written guidance defining situations where AMR may be needed, as well as procedures to follow for AMR. FDA may request AMR even if it does not have evidence of violations for a Warning Letter. Several complaints from other facilities about mammographic quality would be an example of this type of situation.

a. Information the district should include with an AMR recommendation

Submit the following documents (by e-mail or fax; if you submit films, use overnight carrier) to the Division of Mammography Quality and Radiation Programs (DMQRP):

1. Recommendation memorandum summarizing facts
2. Establishment Inspection Report (EIR), if one is written
3. Documentation, copies of correspondence, exhibits, and other materials

Note: Level 1 observations (either the phantom image test or the qualifications of the interpreting physician), by themselves, may warrant an AMR recommendation. For most inspections, you may only have a State inspection. If FDA did not conduct the inspection and you don't need a follow-up inspection to further document facility problems, just submit the memorandum. In this case, you can reference the Facility ID and the date of the uploaded inspection in the memorandum.

b. Checklist for inspection documentation:

1. Level 1 phantom image scores from inspection confirmed through a second review by the MQSA auditor or an FDA MQSA inspector (or by the State, if the State has a thorough phantom image quality assurance (QA) program in place)
2. Inspector has re-scored the facility's QC phantom images and recorded any failed scores in inspection record (including dates of failed facility images to help determine AMR time frame)
3. Medical physicist survey phantom image scores recorded by inspector
4. Time frame for interpreting physician's reading and interpretation of mammograms documented by inspector
5. Actual qualifications of interpreting physician documented (or facility could not document physician's qualification)

Note: The district should not consider recommending an AMR for a lack of qualifications for an interpreting physician unless it has made reasonable attempts to assure that the physician truly lacks these qualifications. In many cases, documentation may have been missing at the time of the inspection and missing documents may have caused the inspector to cite the facility. At a later date, the facility submitted the documents that indicated that the physician was qualified at the time of the inspection. When the inspection observation is a documentation issue, the district should not consider recommending an AMR for the facility.

c. AMRs and regulatory actions

When districts find violations significant enough to consider regulatory action, it should also consider recommending AMR. The recommendation for AMR may be included in the recommendation for regulatory action, rather than as a separate memorandum.

d. How AMR recommendations are approved

DMQRP approves all requests for AMRs, regardless of the type of problem(s) that resulted in the recommendation to request an AMR from the facility. DMQRP must also approve the plan for the AMR, including the selection of the reviewing interpreting physician(s) (if not selected by the accreditation body) and the number and timeframe of the exams reviewed. DMQRP will use the results of the AMR to determine whether to require Patient and Physician Notification by the facility. DMQRP will update the district of the status of AMRs.

4. Regulatory Actions under MQSA

a. General sanctions information

Note: Whenever the district finds serious conditions at a facility where the reliability, clarity, and accuracy of interpretation of mammograms may be suspect, it should consider AMR for the facility, in addition to considering a regulatory action. It should not delay an AMR while considering regulatory action.

Generally, the district should have at least repeat Level 1, Level 1, and/or repeat Level 2 observations from the most recent inspection and have prior notice before considering regulatory action for a facility (usually a Warning Letter; see Chapter 10 of the Regulatory Procedures Manual for other examples of prior notice). Before considering regulatory action, the district should usually have done a follow-up or compliance inspection to document current problems. While a single inspection may indicate the need for some type of regulatory action, it would be a rare situation.

Factors to consider prior to recommendations for regulatory action

1. **Prior Notice**: FDA may take regulatory action without prior notice if the situation presents a danger to health or constitutes intentional, gross, or flagrant violations. When the district finds the above conditions, it should contact DMQRP and the RRHR to discuss options for regulatory action.

2. **Corrections and History:** The district should also consider the facility's commitment to correct the problems, including corrections made during the inspection, and the inspection history of the facility. The district should review all relevant information and evidence, including any information and recommendations from the inspector.

3. **Follow-Up and Compliance Inspections:** The district should consider a follow-up or compliance inspection by an FDA MQSA inspector before recommending regulatory action. In most cases, you should conduct an inspection to show that violations continue and to gather sufficient documentation.

There are a variety of sanctions or regulatory actions that FDA may impose under MQSA, including Directed Plan of Correction (DPC), Patient and Physician Notification (PPN), Civil Money Penalties (CMP), and suspension or revocation of a facility certificate. FDA may also seek injunctions against facilities in federal district court. Of these actions, the DPC, PPN, and suspension can be implemented fairly quickly.

b. Directed Plan of Correction (DPC)

Under section 354(h)(1)(A) of the MQSA (42 U.S.C. 263b(h)(1)(A)), FDA may impose "Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner." FDA is not limited to the problems or types of violations the DPC can address, nor is FDA restricted by MQSA for what a DPC may require of a facility. FDA, therefore, has options we can require of the facility to correct problems.

The district may decide that the DPC works best for many situations, since it can prevent continued use of specific personnel, procedures, or equipment, without FDA suspending their certificate. FDA may limit the DPC to address a particular problem at a facility. An effective DPC would require a facility to immediately address significant observations and allow FDA to monitor corrections under the plan.

The following are examples of conditions or requirements the district may include in a DPC:

1. The facility would cease using a mammographic x-ray system with poor performance until the system repairs showed acceptable improvement in image quality.

2. The facility would have a qualified medical physicist evaluate specific problems with a follow-up report to FDA.

3. The facility could not use unqualified interpreting physicians to read and interpret mammograms or radiologic technologists to perform mammograms. FDA can maintain this prohibition until the personnel meet the MQSA requirements (21 CFR 900.12).

4. The facility would have to undergo AMR.

If FDA requires a facility to discontinue use of specific equipment or personnel as part of a DPC, the facility need not stop performing mammography. A facility may have only one x-ray system or employ one interpreting physician, but the facility may bring in a mobile unit or temporary personnel. In this manner, they can continue to operate until they correct problems.

FDA should require monitoring of the facility under DPC. The district will be responsible for monitoring compliance with the DPC. Monitoring under a DPC could include, but is not limited to, the following:

1. Submission of copies of records to the district office, such as quality control (QC) charts, on a regular schedule to demonstrate appropriate record keeping.

2. A survey by a qualified medical physicist, regardless of whether the facility is due for its annual survey.

3. Follow-up inspections by FDA or the State.

4. A site visit to the facility by the accreditation body.

c. Payment for the Cost of On-Site Monitoring

Under section 354(h)(1)(B) of the MQSA (42 U.S.C. 263b(h)(1)(B)), FDA may require the facility to pay for on-site monitoring of the facility.

Monitoring could include routine inspections by FDA or State MQSA inspectors to monitor continued compliance by the facility. FDA would choose an inspection frequency based on how often we may need to check on facility compliance. FDA could adjust the frequency of the inspections, based on the results of previous inspections.

d. Patient and Physician Notification (PPN)

FDA has authority to require PPN when the quality of mammography at a facility represents a significant risk to individual or public health. This authority can be found under 21 CFR 900.12(j)(2) and 354(h)(2) of the MQSA (42 U.S.C. 263b(h)(2)) (wording in the Act is “Patient Information”).

FDA would usually consider PPN after finding serious problems with mammographic quality at a facility through an AMR. The notification to the patients and/or their referring physicians may be that the quality of the mammograms was inadequate, the interpretation of the mammogram by the interpreting physician was inadequate, or both.

e. Civil Money Penalties (CMP)

A CMP is a fine levied against the facility and/or individuals by the FDA for violations of MQSA after FDA has given the facility an opportunity for an administrative hearing. The most likely situations where FDA might want to assess CMP would be where violations were serious, but were not continuing. As an example, we may find that a facility is performing mammography without a certificate, but agrees to stop when discovered. We may decide to assess CMP in this situation.

A facility may be subject to CMP up to $10,000 for failure to obtain a certificate (section 354(h)(3)(A) of the MQSA (42 U.S.C. 263b(h)(3)(A)) and up to $10,000 for failure to notify a patient of risk (section 354(h)(3)(C) of the MQSA (42 U.S.C. 263b(h)(3)(C)). Other violations may also be subject to CMP (354(h)(3)(B), (D) of the MQSA (42 U.S.C. 263b(h)(3)(B), (D)).

Before assessing a CMP, FDA would notify the facility by letter of our intent to assess a penalty and provide instructions for requesting a hearing. FDA has specific regulations for CMP hearing procedures at 21 CFR Part 17.

f. Suspension

Suspension of the facility's certificate prevents them from performing mammography (section 354(i) of the MQSA (42 U.S.C. 263b(i)). For this reason, FDA normally would not consider this sanction, unless one or more of the following conditions are present:

1. Lesser sanctions, such as a DPC, have failed to bring the facility into compliance.

2. The facility has refused to permit inspection.

3. The conditions at the facility represent a serious risk to human health.

4. Violations at the facility were intentional.

FDA has two different ways in which suspension could occur:

1. FDA would notify the facility by letter that we intend to suspend the facility's certificate and that they may request a hearing. Only after the facility waives their right to a hearing, or after a hearing, would we suspend the certificate.

2. FDA would notify the facility by letter that we have suspended their certificate and that they may request a hearing. Either conditions 3 or 4 above would be required to suspend a certificate prior to a hearing. We would normally hold a hearing to allow the facility to contest the suspension or present their views on whether we should lift the suspension.

i. FDA may employ one or more of the following factors in deciding whether to suspend a facility's certificate prior to holding a hearing:

1. Failure to comply with the required standards presents a serious risk to human health.

2. The refusal to permit inspection makes immediate suspension necessary.

3. There is reason to believe that the violative acts were intentional or otherwise rise to a level that presents a threat to public health.

In the event that the facility requests a hearing, FDA will use the process outlined in 21 CFR Part 16.

g. Revocation

Revocation of a certificate is an action taken by the FDA that prohibits a facility from operating, with the expectation that it will not be operating in the future. We may seek to revoke a facility's certificate for the same violations mentioned under suspension of a certificate. Unlike suspension, if we revoke a facility's certificate, the owner or operator of the facility may not operate that facility or any other facility for two years after the date of revocation (section 354(i)(3) of the MQSA (42 U.S.C. 263b(i)(3)). We intend suspension to be a temporary action to encourage a facility to comply with the quality standards. We would generally revoke a certificate of a facility that cannot or will not comply with the regulations. We may seek revocation when a facility continues to operate after suspension of its certificate. In some circumstances, we may suspend a certificate without a prior hearing, but revocation actions always require an opportunity for a hearing. We would use the same process under 21 CFR Part 16 for hearings that are employed for suspension.

h. Injunction

An injunction under MQSA is a court order prohibiting a facility from continuing any activity related to the provision of mammography that would constitute a serious risk to human health or to stop a facility from performing mammography without a certificate (section 354(j) of the MQSA (42 U.S.C. 263b(j)). Violation of the order can result in criminal contempt sanctions. FDA would normally use this mechanism when other FDA actions, including other sanctions, have failed to bring a facility into compliance or to stop a facility from performing mammography without a certificate. Under certain circumstances, where continued operation of a facility constitutes a serious hazard to the public health, we may choose this as a course of action.

5. Violations under State Law for Mammography Facilities

Many States have mammography facility requirements that overlap with MQSA requirements. In some cases, the State may have different or more stringent requirements than FDA. States may also decide to take regulatory action against a facility for violations that would normally not result in similar action by FDA.

For these reasons, States should copy FDA on letters they send to facilities pertaining to mammography requirements or violations. Under State contracts, the State must report to the RRHR or other designated field contact any adverse action taken against a facility under State authority within ten working days of the event in instances where a significant violation has occurred that would result in FDA taking action under MQSA.

B. Case Guidance

1. General Information

Preliminary contacts with DMQRP: When the district finds that specific facility problems may be serious enough for regulatory action, it should send an e-mail to DMQRP prior to submission of a recommendation package. This e-mail should include:

a. A summary of the facts relating to the facility's violative operation, including information obtained from inspections and investigations.

b. A brief history of the facility's prior violations, if present, and whether prior notice was given and when.

c. A description of why this would be a candidate for regulatory action, versus trying to get the facility to voluntarily comply.

After the e-mail is sent, the district may want a conference call with DMQRP and other headquarters units to discuss the merits of the case.

Recommendation package: After consultation with DMQRP, the district may submit a recommendation to DMQRP. The district should include the following with the recommendation memorandum:

a. Establishment Inspection Reports and reports for any investigations.

b. Exhibits and documentation (affidavits, photographs, copies of facility records).

c. Copies of correspondence, including Warning Letters.

d. Draft documents for approval (see specific documents mentioned below pertaining to specific actions).

The district should submit all recommendations for regulatory action to DMQRP. For any documents or records that are in electronic format, please submit these documents by electronic mail or on disc. You do not have to submit copies of inspection reports from the inspections uploaded into MPRIS, unless the inspection could not be uploaded and only a paper report is available.

2. Directed Plan of Correction (DPC)

Draft documents to submit: DPC letter

Approval official: Director, Division of Mammography Quality and Radiation Programs, OCER, CDRH

FDA headquarters units involved in the review process: DMQRP (review of DPC letter by Office of the Chief Counsel (OCC))

Appeal process for facility: 21 CFR 10.75 – Request for appeal to the Director of the Office of Communication, Education, and Radiation Programs, CDRH

3. Civil Money Penalties (CMP)

Draft documents to submit: Draft Notice of Opportunity of Hearing (for CDRH Director's signature) and draft complaint (for OCC attorney's signature) (see 21 CFR 17.5)

Approval official: Director, CDRH

FDA headquarters units involved in the review process: CDRH, ORA/OE/DCMO, OCC

Appeal process for facility: 21 CFR 17 – Hearing before FDA administrative law judge

4. Suspension and/or Revocation

Draft documents to submit: Draft Notice of Intent to Suspend (or Revoke) or Notice of Suspension letter (for Office of Communication, Education, and Radiation Programs Director's signature)

Approval official: Director, Office of Communication, Education, and Radiation Programs, CDRH

FDA headquarters units involved in the review process: CDRH, OCC

Appeal process for facility: 21 CFR 16 – Regulatory hearing before FDA-appointed presiding officer

5. Injunction

Draft documents to submit: see Chapter 6 of the Regulatory Procedures Manual

Approval official: United States District Judge

FDA headquarters units involved in the review process: CDRH, OCC

Appeal process for facility: Hearing before the United States District Judge signing the order

PART VI - References, Attachments and Program Contacts

A. REFERENCES

1. United States Code, Title 42, *Mammography Quality Standards Act of 1992* (Public Law 102-539)

2. United States Code, Title 42, *Mammography Quality Standards Reauthorization Act*, (Public Law 105-248)

3. Code of Federal Regulations, Title 21, Part 900

4. Federal Register, Final Quality Standards for Mammography (62 F.R. 55852, Oct. 28, 1997)

5. MQSA Inspection Procedures (version 4.52 or later)

6. *Compliance Guidance - The Mammography Quality Standards Act Final Regulations* Documents. These can found at http://www.fda.gov/cdrh/mammography/index.html. New documents pertaining to MQSA are posted on this site in draft and final. Once issued in final, they are eventually incorporated into the **Policy Guidance Help System**, which can be found at http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM

7. Investigations Operations Manual, FDA

8. Regulatory Procedures Manual, FDA

9. Federal Register, Interim Quality Standards for Mammography (58 F.R. 67558, Dec. 21, 1993)

10. United States Code, Title 21, Federal Food, Drug, and Cosmetic Act, As Amended

11. Compliance Program 7382.003, Field Compliance Testing of Diagnostic (Medical) X-ray Equipment

12. MQSA Auditor's Guide (http://www.fda.gov/ora/inspect_ref/igs/mqsa.html)

B. ATTACHMENTS

List of CDRH personnel to contact on inspection and compliance procedures, case management, inspection audits, and workplans

A. List of CDRH personnel to contact on inspection computer support and testing equipment

B. List of MQSA Auditors

C. Form FDA 2766 Claim for Damage to an Electronic Product

D. Observation Statements for MQSA Inspections

E. Guidance for Evaluating a Facility Response

F. Guidance for an Additional Mammography Review (AMR)

G. Flowchart - Follow-Up for MQSA Inspections

H. Warning Letter for inspections with Level 1 and or repeat Level 2 inspection observations

I. Adequate Response Letter to Facility

J. Example of MQSA Facility Inspection Report

K. Important Information about Your MQSA Inspection (given to facility at the close of the inspection)

L. Sample MQSA Inspection Confirmation (5 days prior to inspection)

C. PROGRAM CONTACTS

1. CDRH Contact - Questions concerning this compliance program should be directed to Michael P. Divine, Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs, OCER (HFZ-240) (301) 594-3763. Secondary contact may be made with the individuals listed on Attachments A through C.

2. ORA Contact - The ORA Headquarters contact for this compliance program and state contract issues is Stephen G. Toigo, Division of Federal-State Relations ORO (HFC-152), (301) 443-3360.

PART VII - CENTER RESPONSIBILITIES

A. CDRH/OCER/DMQRP:

1. Provide calibrated test equipment for use by all FDA and State inspectors (calibration of x-ray monitors by the Radiation Metrology Branch, DECS/OST/CDRH (HFZ-143)).

2. Review regulatory action recommendations and provide assistance and guidance in the preparation of compliance cases, including the Directed Plan of Correction. For Civil Money Penalties, suspension, revocation, and injunctions under MQSA, DMQRP and the CDRH Office of Compliance will work closely together regarding these actions.

3. Maintain/develop computer software for direct access to MPRIS by inspectors, auditors, and RRHR's.

4. Monitor and evaluate inspector performance through FDA audits and inspection data analysis.

5. Recommend specific sites for special inspections when requested.

6. Develop and revise facility inspection procedures.

7. Provide training courses for MQSA inspectors and administer MQSA inspector certification and quality assurance programs.

8. Develop regulatory guidance for inspectors and FDA field offices.

B. Program Review - On a routine basis, but not less often than annually, this program will be reviewed. This review will be the results of this program and any needed improvements to increase program effectiveness. Program changes and recommendations should be submitted to the Chief, Inspection and Compliance Branch, DMQRP (HFZ-240) for consideration.

Attachment A

FDA/CDRH/OCER/DMQRP Personnel to Contact Inspection Procedures and Use of Instrumentation

1.	Walid G. Mourad	301-594-3778 (Information Management Branch, DMQRP)
2.	Charles R. Gunzburg	301-594-3587 (Inspection and Compliance Branch, DMQRP)
3.	Michael P. Divine	301-594-3763 (Inspection and Compliance Branch, DMQRP)

Inspection Field Workplan

	Ellyce F. Ratskoff	301-827-2980 (Inspection and Compliance Branch, DMQRP)

FDA/CDRH Personnel to Contact for Facility Compliance Issues and Case Management

1.	Michael P. Divine	301-594-3763 (Inspection and Compliance Branch, DMQRP)
2.	Sharon M. Davis	301-827-8772 (Inspection and Compliance Branch, DMQRP)
3.	Ellyce Ratskoff	301-827-2980 (Inspection and Compliance Branch, DMQRP)
4.	Charles R. Gunzburg	301-594-3587 (Inspection and Compliance Branch, DMQRP)
5.	Nancy Wynne	301-594-3534 (Inspection and Compliance Branch, DMQRP)

Attachment B

Contact Information - Inspection Computer Support and Testing Equipment

Computer, Printer, Inspection Upload/Download, or E-mail Issues	Contact MPRIS Computer Support via telephone or e-mail (301-827-4330 or computersupport@cdrh.fda.gov).
MDH Test Equipment Issues ONLY (Issued by the MQSA Program)	Contact Jannita Ridgell via phone or email (301-443-2536 ext 151 or jzr@cdrh.fda.gov).
MQSA Issued Inspection Equipment Questions (e.g., film requests; sensitometer or densitometer problems; non-MDH calibration questions; phantom problems; need for other equipment, including magnifying glass, ruler, aluminum filters, timers, fog folders)	Contact Stephanie Belella via phone or email (301-827-3997 or 301-594-3332 or swb@cdrh.fda.gov).

DO NOT return instruments to headquarters for calibration or repairs until calling the appropriate individual and thus obtaining instructions for return.

Attachment C

MQSA Auditors and RRHRs

The following list includes Regional Radiological Health Representatives (RRHRs) who are responsible for oversight of State MQSA contracts and auditors who are qualified to conduct quality assurance audits of MQSA inspectors. RRHR responsibilities are outlined in section B.9. of Part II. For more information on MQSA audits, consult the MQSA Auditors Guide.

Central Region

Rachel T. Evans	RRHR
Rachel T. Evans	Chicago District
R. Terry Bolen	Cincinnati District
Dennis E. Swartz	Detroit District
Thomas W. Garvin	Minneapolis District
Robert E. Davis	Philadelphia District

Northeast Region

Ronald Bernacki	RRHR
Michael J. Leal	New England District
James R. Wormuth	New York District

Pacific Region

Vacant	RRHR
Beverly A. Thomas	Los Angeles District

Southeast Region

Tom Trout	RRHR
Janeth Caycedo	Florida District
Karen R. Smallwood	New Orleans District
Jorge E. Martinez	San Juan District

Southwest Region

all Southwest Region auditors are assigned to the regional office, though some are physically located in a district office

Scotty Hargrave	RRHR
Robert G. Antonsen	Denver District
Reggie D. Cope	Kansas City District
John D. Mays	Southwest Regional Office
Deborah M. McGee	Southwest Regional Office

Attachment D

Form FD-2766 Claim for Damage to an Electronic Product

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	CLAIM FOR DAMAGE TO AN ELECTRONIC PRODUCT *(See instructions on Reverse)*

I COMPLETED BY CLAIMANT

NAME AND MAILING ADDRESS (include Zip Code)

I hereby request $ _____ for damage to my _____, make _____,

Model No. _____, Serial No. _____, which was damaged during Food and

Drug Administration testing on _____, 19 _____.

SIGNATURE	DATE

II COMPLETED BY FOOD AND DRUG INSPECTOR

I affirm that the _____ listed above, with a (repair/replacement) value of $_____,

was (damaged/damaged beyond repair) in my presence during an official test under the provisions of Public Law 90-602.

PRINTED NAME, ORGANIZATION, AND ADDRESS	SIGNATURE
	DATE

III COMPLETED BY IMMEDIATE SUPERVISOR, EMPLOYEE, OR REPRESENTATIVE

I affirm that the above employee or representative was on official government business when this claim for damage arose

PRINTED NAME AND	SIGNATURE	DATE

IV COMPLETED BY OFFICE OF COMPLIANCE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

COMMON ACCOUNTING NUMBER	CDRH CLAIM

COMMENTS

FORM FD 2766 (1/93)

Attachment E

Observation Statements for MQSA Inspections

Mammography Program Reporting and Information System (MPRIS)
Field Inspection Sub-System (FISS)

The following list of observations (i.e., violations of MQSA) is generated during mammography facility inspections by the FISS inspection software. The inspector prints a report (called the MQSA Facility Inspection Report) from his or her laptop computer. He or she gives the facility the report at the close of the inspection (some States mail this report to the facility at a later date). This report contains one or more of the statements below.

You should consult Part V, under section A.1.a, for guidance on the appropriate follow up, if any, to different levels of inspection observations. You should contact personnel in CDRH, listed in Attachment A, if you have any questions regarding a specific inspection and the observations involved.

With certain exceptions, you will find the requirements that relate to these observations in 21 CFR 900.12 (see CFR references in brackets "[]"). Where certain requirements are found elsewhere in 21 CFR, we have indicated the source of the requirement. Where we have used braces "{}", this indicates that the FISS software will insert information specific to a given facility, such as the name of a person at the facility, a room number, or a location ("site") where interpreting physicians read the mammograms.

Inspection Demonstration Program – as explain in Part II, B.5., FDA began a demonstration program to inspect some facilities frequently. These facilities in this demonstration will skip at least one annual inspection. Since the inspection of these facilities will cover two years of facility records, rather than one, some the inspection report statements below will slightly different wording. These inspections can be identified by having the inspection type of Biennial Inspection in the inspection detail report.

Level 1 Observation

(**Facility requested to respond within 15 working days**)

Accreditation – 21 CFR 900.4(a), (b), & (c)(4)

The x-ray system for unit {unit number}, room {room name or number} has been used clinically for at least a year and is not accredited.

Certification – 21 CFR 900.11(a)

The facility was performing mammography without a valid certificate.

Personnel - 21 CFR 900.12(a)

Failed to produce documents verifying that the interpreting physician met the initial requirement of being currently licensed to practice medicine in a State: {name of physician} [§900.12(a)(1)(i)(A)].

Failed to produce documents verifying that the interpreting physician met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 3 months of initial training in the interpretation of mammograms: {name of physician} [§900.12(a)(1)(i)(B)(1) and (2)].

> **Note:** physicians may be cited for failure to have certification or 2 months of training, which was a requirement under §900.12(a)(1)(ii)(A) and (B) of the regulations in effect prior to April 28, 1999.

Failed to produce documents verifying that the radiologic technologist met the initial requirement of being currently licensed in a State or certified by an FDA-approved body: {name of technologist} [§900.12(a)(2)(i)(A) and (B)].

Failed to produce documents verifying that the medical physicist met the initial requirement of being currently licensed or approved by a State, or certified by an FDA-approved body to perform physics surveys: {name of physicist} [§900.12(a)(3)(i)(A)].

Failed to produce documents verifying that the medical physicist met the initial requirement of having a masters degree or higher in a physical science with at least 20 semester hours of physics: {name of physicist} [§900.12(a)(3)(i)(B)].

Failed to produce documents verifying that the medical physicist met the initial requirement of being currently licensed or approved by a State, or certified by an FDA-approved body to perform physics surveys: {name of physicist} [§900.12(a)(3)(ii)(A)].

Failed to produce documents verifying that the medical physicist met the requirement of having a bachelor's degree or higher in a physical science prior to April 28, 1999: {name of physicist} [§900.12(a)(3)(ii)(B)(1)].

Equipment - 21 CFR 900.12(b)

The x-ray system for unit {unit number}, room {room name or number} is not specifically designed for mammography [§900.12(b)(2)].

Medical Records and Mammography Reports - 21 CFR 900.12(c)

The system to communicate results is not adequate for {name of site} because:

- there is no system in place to provide timely medical reports [§900.12(c)(2)(i) and (3)(i)].
- there is no system in place to provide timely lay summaries [§900.12(c)(2)].
- there is no system in place to communicate serious or highly suggestive cases as soon as possible [§900.12(c)(3)(ii)].

Quality Assurance—Equipment - 21 CFR 900.12(e)

Processor QC records were missing {number of days} consecutive days for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

> **Note:** If the number of consecutive days missing is five or greater, this is a Level 1 observation.

Processor QC records were missing {number of days} out of {number of days} days of operation in month {name of month}. Processor QC records missing {percentage}%, for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

> **Note:** If percentage is equal to or greater than 30 for the worst month, this is a Level 1 observation.

The processing speed (using the S.T.E.P. procedure) is less than 65 for standard processing: processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

The processing speed (using the S.T.E.P. procedure) is less than 85 for extended processing: processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

Mammograms were processed in processor {name of processor}, room {room name or number} at site {name of site}, when it was out of limits on {number of days} days [§900.12(e)(1)(i), (ii), and/or (iii)].

> **Note:** If the number of days out of limits is five or greater, this is a Level 1 observation.

Phantom QC records were missing for {number of weeks} weeks for unit {unit number}, room {room name or number} [§900.12(e)(2)].

> **Note:** If the number of weeks missing is four or greater out of 12, this is a Level 1 observation.

The phantom image score (using an FDA- approved mammography phantom) is less than 3 fibers for unit {unit number}, room {room name or number} [§900.12(e)(2)(iii)].

The phantom image score (using an FDA- approved mammography phantom) is less than 2 masses for unit {unit number}, room {room name or number} [§900.12(e)(2)(iii)].

The phantom image score (using an FDA-approved mammography phantom) is less than 2 speck groups for unit {unit number}, room {room name or number} [§900.12(e)(2)(iii)].

The average glandular dose (using an FDA-approved mammography phantom) is 350 mrad or greater (film-screen systems) for unit {unit number}, room {room name or number} [§900.12(e)(5)(vi)].

Physicist survey for x-ray unit {unit number}, room {room name or number} was not conducted in over two years [§900.12(e)(9)(i)].

Level 2 Observation

(**Facility requested to respond within 30 working days; if repeat, 15 days**)

Accreditation – 21 CFR 900.4(a), (b), & (c)(4)

The x-ray system for unit {unit number}, room {room name or number} is not accredited.

> **Note:** if the x-ray unit has been used for less than one year and is not accredited, this is a Level 2 observation.

Personnel - 21 CFR 900.12(a)

Failed to produce documents verifying that the interpreting physician met the initial requirement of having 60 hours of medical education in mammography: {name of physician} [§900.12(a)(1)(i)(C)].

> **Note:** physicians may be cited for failure to have 40 CME credit hours of initial training in mammography, which was a requirement under §900.12(a)(1)(ii)(C) of the regulations in effect prior to April 28, 1999.

Failed to produce documents verifying that the interpreting physician met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months: {name of physician} [§900.12(a)(1)(i)(D)].

Failed to produce documents verifying that the interpreting physician met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months: {name of physician} [§900.12(a)(1)(ii)(A)].

Failed to produce documents verifying that the interpreting physician met the continuing education requirement of having taught or completed at least 15 category 1 continuing education units in mammography in 36 months: {name of physician} [§900.12(a)(1)(ii)(B)].

Failed to produce documents verifying that the interpreting physician met the requirement of having 8 hours of training in the new mammographic modality: {name of physician} [§900.12(a)(1)(ii)(C)].

Failed to produce documents verifying that the radiologic technologist met the initial requirement of having 40 contact hours training specific to mammography: {name of technologist} [§900.12(a)(2)(ii)].

> **Note:** technologists may be cited for failure to have specific mammography training, which was a requirement under §900.12(a)(2)(iii)(A) of the regulations in effect prior to April 28, 1999.

Failed to produce documents verifying that the radiologic technologist met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months: {name of technologist} [§900.12(a)(2)(iii)(A)].

Failed to produce documents verifying that the radiologic technologist met the requirement of having 8 hours of training in each mammographic modality: {name of technologist} [§900.12(a)(2)(iii)(E)].

Failed to produce documents verifying that the radiologic technologist met the continuing experience requirement of having performed 200 mammography examinations in 24 months: {name of technologist} [§900.12(a)(2)(iv)(A)].

> **Note:** radiologic technologists will not be evaluated for this until 4/28/2001, when 24 months have passed since this requirement took effect.

Failed to produce documents verifying that the medical physicist met the initial requirement of having 20 contact hours of documented specialized training in conducting surveys of mammography facilities: {name of physicist} [§900.12(a)(3)(i)(B)(2)].

Failed to produce documents verifying that the medical physicist met the initial requirement of having the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units: {name of physicist} [§900.12(a)(3)(i)(B)(3)].

Failed to produce documents verifying that the medical physicist met the alternative initial requirement of having, prior to April 28, 1999 and after fulfilling the degree requirement, 40 contact hours of documented specialized training in conducting surveys of mammography facilities: {name of physicist} [§900.12(a)(3)(ii)(B)(2)].

Failed to produce documents verifying that the medical physicist met the alternative initial requirement of having, prior to April 28, 1999, and after fulfilling the degree requirement, the experience of

conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units: {name of physicist} [§900.12(a)(3)(ii)(B)(3)].

Failed to produce documents verifying that the medical physicist met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months: {name of physicist} [§900.12(a)(3)(iii)(A)].

Failed to produce documents verifying that the medical physicist met the continuing experience requirement of having surveyed at least 2 mammography facilities and a total of at least 6 mammography units in 24 months: {name of physicist} [§900.12(a)(3)(iii)(B)].

> **Note:** medical physicists will not be evaluated for this until 4/28/2001, when 24 months have passed since this requirement took effect.

Failed to produce documents verifying that the medical physicist met the requirement of having 8 hours of training in surveying units of the new mammographic modality: {name of physicist} [§900.12(a)(3)(iii)(C)].

Equipment - 21 CFR 900.12(b)

The x-ray system for unit {unit number}, room {room name or number} does not include the following:

- Image receptors for 2 sizes [§900.12(b)(4)(i)].
- Moving grids for 2 sizes [§900.12(b)(4)(ii)].
- Post-exposure display in AEC mode (for focal spot) [§900.12(b)(7)(iii)].
- Post-exposure display in AEC mode (for target material) [§900.12(b)(7)(iii)].
- Compression paddles for 2 sizes [§900.12(b)(8)(ii)(A)].

Medical Records and Mammography Reports - 21 CFR 900.12(c)

{any number up to 10} of {5 or 10} random reports reviewed did not have identification of a qualified interpreting physician for site {name of site} [§900.12(c)(1)(iii)].

> **Note:** Any number from one to the maximum reviewed without an identification of a qualified interpreting physician is a Level 2 observation.

{any number up to 10} of {5 or 10} random reports reviewed did not contain an assessment category for site {name of site} [§900.12(c)(1)(iv)].

> **Note:** Any number from one to the maximum reviewed without an assessment category is a Level 2 observation.

Quality Assurance—Equipment - 21 CFR 900.12(e)

Processor QC records were missing {number of days} consecutive days for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

> **Note:** If the number of consecutive days missing is two, three, or four, this is a Level 2 observation.

Processor QC records were missing {number of days} out of {number of days} days of operation in month {name of month}. Processor QC records missing {percentage}%, for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

> **Note:** If percentage is less than 30, but greater than or equal to 10 for the worst month, this is a Level 2 observation.

The processing speed (using the S.T.E.P. procedure) is greater than or equal to 65, but less than 80 standard processing: processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

The processing speed (using the S.T.E.P. procedure) is greater than or equal to 85, but less than 100 for extended processing: processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1)].

Mammograms were processed in processor {name of processor}, room {room name or number} at site {name of site}, when it was out of limits on {number of days} days [§900.12(e)(1)(i), (ii), and/or (iii)].

> **Note:** If the number of days out of limits is two, three, or four, this is a Level 2 observation.

Corrective actions for processor QC failures were not documented at least once for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(8)(ii) with reference to §900.12(e)(1)(i), (ii), and/or (iii)].

Phantom QC records were missing for {number of weeks} weeks for unit {unit number}, room {room name or number} [§900.12(e)(2)].

> **Note:** If the number of weeks missing is two or three out of 12, this is a Level 2 observation.

The phantom QC is not adequate for unit {unit number}, room {room name or number} because:

- The image was not taken at clinical setting [§900.12(e)(2)(i)].

- The background density was < 1.20 [§900.12(e)(2)(i)].

Corrective action for a failing image score (before further exams) was not documented for unit {unit number}, room {room name or number} [§900.12(e)(8)(ii) with reference to §900.12(e)(2)(iii)].

The measured fog density is equal to {darkroom fog density} for darkroom {room name or number} at site {name of site} [§900.12(e)(4)(i)].

> **Note:** If the darkroom fog density is equal to or greater than 0.10, this is a Level 2 observation.

The medical physicist's survey for x-ray unit {unit number}, room {room name or number} is incomplete because the following tests were not done:

- No AEC performance capability [§900.12(e)(5)(i)]

  - Test not done for 2, 4, and 6 cm phantom thicknesses at typical kVp(s) [§900.12(e)(5)(i)(A)]
  - Numerical results were not given [§900.12(e)(9)(ii)]

- No focal spot size/resolution measurement [§900.12(e)(5)(iii)]

  - Test not done for all clinically used focal spots [§900.12(e)(5)(iii)].
  - Numerical results were not given [§900.12(e)(9)(ii)].

- No AEC performance – Reproducibility [§900.12(e)(5)(v)]

  - Numerical results were not given [§900.12(e)(9)(ii)].

- Average glandular dose [§900.12(e)(5)(vi)]

    - Exp. & HVL measurements at same clinical kVp [§900.12(e)(5)(vi)].
    - Did not use an FDA-approved phantom (or equivalent) dose [§900.12(e)(5)(vi)].
    - Numerical results were not given [§900.12(e)(9)(ii)]

- No artifact evaluation [§900.12(e)(5)(ix)].

- No phantom image [§900.12(e)(9)(i) with reference to §900.12(e)(2)]

    - Test not done at the kVp normally used clinically [§900.12(e)(9)(i) with reference to §900.12(e)(2)(i)].
    - Did not use an FDA-approved phantom (or equivalent) [§900.12(e)(9)(i) with reference to §900.12(e)(2)].
    - Less than 3 object scores were given [§900.12(e)(9)(i) with reference to §900.12(e)(2)(iii)].

- No QC test - new modalities [§900.12(e)(9)(i) with reference to § 900.12(e)(6)].

Manufacturer recommended QC procedures were not followed for digital unit {unit number}, room {room name or number} [§900.12(e)(6)].

Monitor QC was not done per manufacturer's recommendation for digital unit {unit number}, room {room name or number} [§900.12(e)(6)].

Manufacturer recommended procedures for laser film or other display method were not used for digital unit {unit number}, room {room name or number} [§900.12(e)(6)].

Performance verification test was not conducted after each move for mobile unit {unit number}, room {room name or number} [§900.12(e)(7)].

Physicist survey report for x-ray unit {unit number} in room {room name or number} was not conducted within 14 months [§900.12(e)(9)(i)].

The time period between the previous and current surveys for x-ray unit {unit number} exceeds 14 months [§900.12(e)(9)(i)].

The person who conducted or supervised the survey for x-ray unit {unit number}, room {room name or number} is not identified in the report [§900.12(e)(9)(v)].

The mammography equipment evaluation (by a medical physicist) for unit {unit number}, room {room name or number} or related processor was not done [§900.12(e)(10)].

There is no written procedure for infection control at site {name of site} [§900.12(e)(13)].

Quality Assurance-Mammography Medical Outcomes Audit – 21 CFR 900.12(f)

There were no examples of nor attempts to get biopsy results for site {name of site} [§900.12(f)(1)].

Not all positive mammograms were entered in the tracking system for site {name of site} [§900.12(f)(1)].

There was no designated reviewing interpreting physician for site {name of site} [§900.12(f)(3)].

Medical audit and outcome analysis was not done for the facility as a whole at site {name of site} [§900.12(f)(1)]

Medical audit and outcome analysis was not done separately for each individual at site {name of site} [§900.12(f)(2)]

Medical audit and outcome analysis was not performed annually at site {name of site} [§900.12(f)(2)]

Consumer Complaint Mechanism – 21 CFR 900.12(h)

There is no written procedure for handling consumer complaints at site {name of site} [§900.12(h)(3)].

Level 3 Observation

(**No response requested. Will be checked at next inspection; except for repeat Level 3 – response within 30 working days)**

Display of Certificate - 42 USC 263b(b)(1)(A)(iii) – this is a statutory requirement. There is no specific regulation for the display of the certificate.

The MQSA certificate was not displayed.

Personnel - 21 CFR 900.12(a)

The required personnel qualification documents were unavailable during the inspection [§900.12(a)(4)].

Quality Assurance -- General - 21 CFR 900.12(d)

The QA program is inadequate. For {name of site} the missing or incomplete item(s) are listed below:

- Personnel responsibilities [§900.12(d)(2)].
- QC test procedures [§900.12(d)(2)].
- Current technique tables/charts [§900.12(d)(2)].

Quality Assurance—Equipment - 21 CFR 900.12(e)

The fixer retention QC is not adequate for {name of processor}, room {room name or number} at site {name of site}. The missing or incomplete item(s) are listed below:

- The fixer retention QC records were not done at the required frequency [§900.12(e)(3)(i)].
- Corrective action was not documented at least once [§900.12(e)(8)(ii) with reference to §900.12(e)(3)(i)].

The repeat analysis QC is not adequate for site {name of site} because:

- QC was not done at the required frequency [§900.12(e)(3)(ii)].
- There was no evaluation done when the number of repeats/rejects exceeded 2% (either plus or minus) [§900.12(e)(3)(ii)].
- Corrective action within 30 days was not documented [§900.12(e)(8)(ii) with reference to §900.12(e)(3)(ii)].

The measured fog density is equal to {darkroom fog density} for darkroom {room name or number} at site {name of site} [§900.12(e)(4)(i)].

Note: If the darkroom fog density is 0.07, 0.08, or 0.09, this is a Level 3 observation.

The darkroom fog QC is not adequate for darkroom {room name or number} at site {name of site} because:

- The QC records were not done at the required frequency [§900.12(e)(4)(i)].
- The background density was < 1.20 [§900.12(e)(4)(i)].
- Corrective action (before using the failed darkroom for further exams) was not documented at least once [§900.12(e)(8)(ii) with reference to §900.12(e)(4)(i)].

The screen-film contact QC is not adequate for site {name of site} because:

- QC was not done at the required frequency [§900.12(e)(4)(ii)].
- Not all mammography cassettes in use were tested [§900.12(e)(4)(ii)].
- The 40-mesh copper test tool was not used [§900.12(e)(4)(ii)].
- Corrective action (before using the failed cassette(s) for further exams) was not documented at least once [§900.12(e)(8)(ii) with reference to §900.12(e)(4)(ii)].

Compression device QC is not adequate for unit {unit number}, room {room name or number} because:

- QC was not done at the required frequency [§900.12(e)(4)(iii)].
- Corrective action (before further exams) was not documented at least once [§900.12(e)(8)(ii) with reference to §900.12(e)(4)(iii)].

The half value layer (HVL) of the x-ray beam (in units of mm Al) is less than {value based on selected kVp value divided by 100} for unit {unit number}, room {room name or number} [§900.12(e)(5)(iv)].

The coefficient of variation (COV) for exposure reproducibility is greater than 0.05 for unit {unit number}, room {room name or number} [§900.12(e)(5)(v)].

The x-ray field does not extend to the edge of the image receptor on the chest wall side for unit {unit number}, room {room name or number} [§900.12(e)(5)(vii)(A)].

The chest wall side of the x-ray field extends beyond the chest wall edge of the image receptor by more than 2% of the SID for unit {unit number}, room {room name or number} [§900.12(e)(5)(vii)(A)].

The {right/left/nipple} side of the x-ray field extends beyond the {right/left/nipple} edge of the image receptor by more than 2% of the SID for unit {unit number}, room {room name or number} [§900.12(e)(5)(vii)(A)].

The chest wall edge of the compression paddle is visible on the test image for unit {unit number}, room {room name or number} [§900.12(e)(5)(vii)(C)].

The chest wall edge of the compression paddle extends beyond the chest wall edge of the image receptor by more than 1% of SID for unit {unit number}, room {room name or number} [§900.12(e)(5)(vii)(C)].

The medical physicist's survey for x-ray unit {unit number}, room {room name or number} is incomplete because the following tests were not done (§900.12(e)(9)):

- No kVp accuracy [§900.12(e)(5)(ii)(A)]

- Test not done at all clinically important kVp's [§900.12(e)(5)(ii)(A)].
- Numerical results were not given [§900.12(e)(9)(ii)].

- No kVp Reproducibility [§900.12(e)(5)(ii)(B)]

- Test were not done at the kVp normally used clinically [§900.12(e)(5)(ii)(B)].
- Numerical results were not given [§900.12(e)(9)(ii)].

- No beam quality (HVL) measurement [§900.12(e)(5)(iv)]

- Test not done at the kVp normally used clinically [§900.12(e)(5)(iv)].
- Numerical results were not given [§900.12(e)(9)(ii)].

- No collimation [§900.12(e)(5)(vii)]

- No x-ray field - image receptor alignment [§900.12(e)(5)(vii)(A)].
- No x-ray field - light field alignment [§900.12(e)(5)(vii)(B)].
- No compression device edge alignment [§900.12(e)(5)(vii)(C)].

- No uniformity of screen speed [§900.12(e)(5)(viii)]

- Numerical results were not given [§900.12(e)(9)(ii)].

- No radiation output [§900.12(e)(5)(x)].

- No decompression [§900.12(e)(5)(xi)].

- No evaluation of the Technologist's QC tests [§900.12(e)(9)(ii)]

- No processor QC [§900.12(e)(9)(ii) with reference to §900.12(e)(1)].
- No phantom images [§900.12(e)(9)(ii) with reference to §900.12(e)(2)].
- No analysis of fixer retention [§900.12(e)(9)(ii) with reference to §900.12(e)(3)(i)].
- No repeat analysis [§900.12(e)(9)(ii) with reference to §900.12(e)(3)(ii)].
- No darkroom fog [§900.12(e)(9)(ii) with reference to §900.12(e)(4)(i)].
- No screen-film contact [§900.12(e)(9)(ii) with reference to §900.12(e)(4)(ii)].
- No compression [§900.12(e)(9)(ii) with reference to §900.12(e)(4)(iii)].

- No pass/fail list [§900.12(e)(9)(iii)].

- No recommendations for failed items were given [§900.12(e)(9)(iii)].

Corrective action was not taken when called for in the medical physicist's survey report for unit {unit number}, room {room name or number} [§900.12(e)(8)(ii)].

Attachment F

GUIDANCE FOR EVALUATING A FACILITY RESPONSE

Facility Responses and Follow-Up Inspections

You will find additional guidance on facility responses is provided in section A. 1. c. of Part V. Since the adequacy of the facility response may trigger a Warning Letter or follow-up inspection, you should also review section A. 2. in Part V on Warning Letters and section B. in Part III on compliance and follow-up inspections.

Evaluating a Facility Response

You will find that most facilities will respond to the inspections observations and provide adequate information. In those cases where information is missing, a phone call or follow-up letter may resolve the situation.

A facility response should include all of the following items:

1. How the facility has corrected or plans to correct the problems observed

2. The date(s) corrections will take place, if the facility hasn't corrected all of the problems when it responds

3. How the facility will prevent recurrence of the problems

4. For problems involving equipment, equipment test results, including equipment settings and technique factors, raw test data, and calculated final results

5. If the observations relate to quality control or other records, sample records showing compliant recordkeeping (patient names or identification should be omitted from any copies of records submitted)

6. For personnel qualifications, one of the following:

    a. documentation that the personnel meet the requirements,

b. an indication that the personnel are no longer providing mammography services at the facility (services would be defined as interpreting physicians reading and interpreting mammograms, radiologic technologists performing mammography, or medical physicists conducting medical physicist surveys)

c. an indication that personnel have been placed under the direct supervision of a qualified physician, technologist, or physicist, as appropriate.

7. For Level 1 observations for a mammography x-ray unit, it needs to be brought into compliance before it can be used for mammograms. For a film processor, it must be brought into compliance before mammograms are processed. For Level 2 observations under 21 CFR 900.12(b), the facility does not have to stop using the equipment immediately, but needs to correct the problem in a timely manner. "In a timely manner" might mean within 30 days, but longer if parts must be ordered or a new x-ray unit or processor must be installed. For Level 2 observations under 21 CFR 900.12(e), consult §900.12(e)(8)(ii) for additional information on when the facility must take corrective action.

   NOTE: If the x-ray system noncompliance is a manufacturer or assembly problem, refer to CP 7382.003.

Facility Responses from Facilities with Violative Histories

If the facility has a violative history, facility management may find it difficult to provide convincing evidence that problems are permanently corrected. If the facility's response contains promises of corrections similar to previous inspections, you should consider it inadequate and schedule a follow-up inspection before sending a Warning Letter.

Inspection Observations Disputed by Facility

If a facility disputes inspection observations and believes that the inspection report is incorrect, the district should work with the inspector to resolve the dispute. If the inspector works with the State, the district should consult with the RRHR. For guidance on disputed observations, go the Policy Guidance Help System at http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM (check under Inspection/Report/Inspection Findings Disputed by Facilities).

Assistance with Facility Responses

If the district would like assistance when evaluating facility responses, it should refer to Attachment A for contacts.

Attachment G

Guidance for Additional Mammography Review (AMR)

FDA may require AMR to see if the mammography quality at a facility may present a "serious risk to human health" (21 CFR 900.12(j)) The term "mammography quality" encompasses all aspects of quality related to the production and interpretation of a mammogram. This may include aspects of the clinical image quality as well as other issues related to quality. Examples of reasons to require an AMR are:

1. **Inspection observations**

   A. Level 1 phantom image failure

   B. Interpreting physician
      1. Medical license: never licensed to practice medicine in a State
      2. Does not have board certification or the required initial mammography training (2 or 3 months)

      Note: For guidance on items A and B above, go to the Policy Guidance Help System at http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM**.**

   C. A combination of inspection observations, which results in a reasonable probability that mammography quality has been seriously compromised and may represent a serious risk to human health.

2. **Other**

   A. A combination of observations from various sources (inspections, complaints, interpreting physicians, etc.) which results in a reasonable probability that mammography quality has been seriously compromised and may represent a serious risk to human health.

   B. Investigations of allegations or complaints that indicate a reasonable probability exists that mammography quality has been seriously compromised and may represent a serious risk to human health. Under this category, FDA can require AMR without documented violations of MQSA.

   C. Uncertified facility

   If a facility had performed mammography without a certificate for at least 90 days, FDA may require AMR.

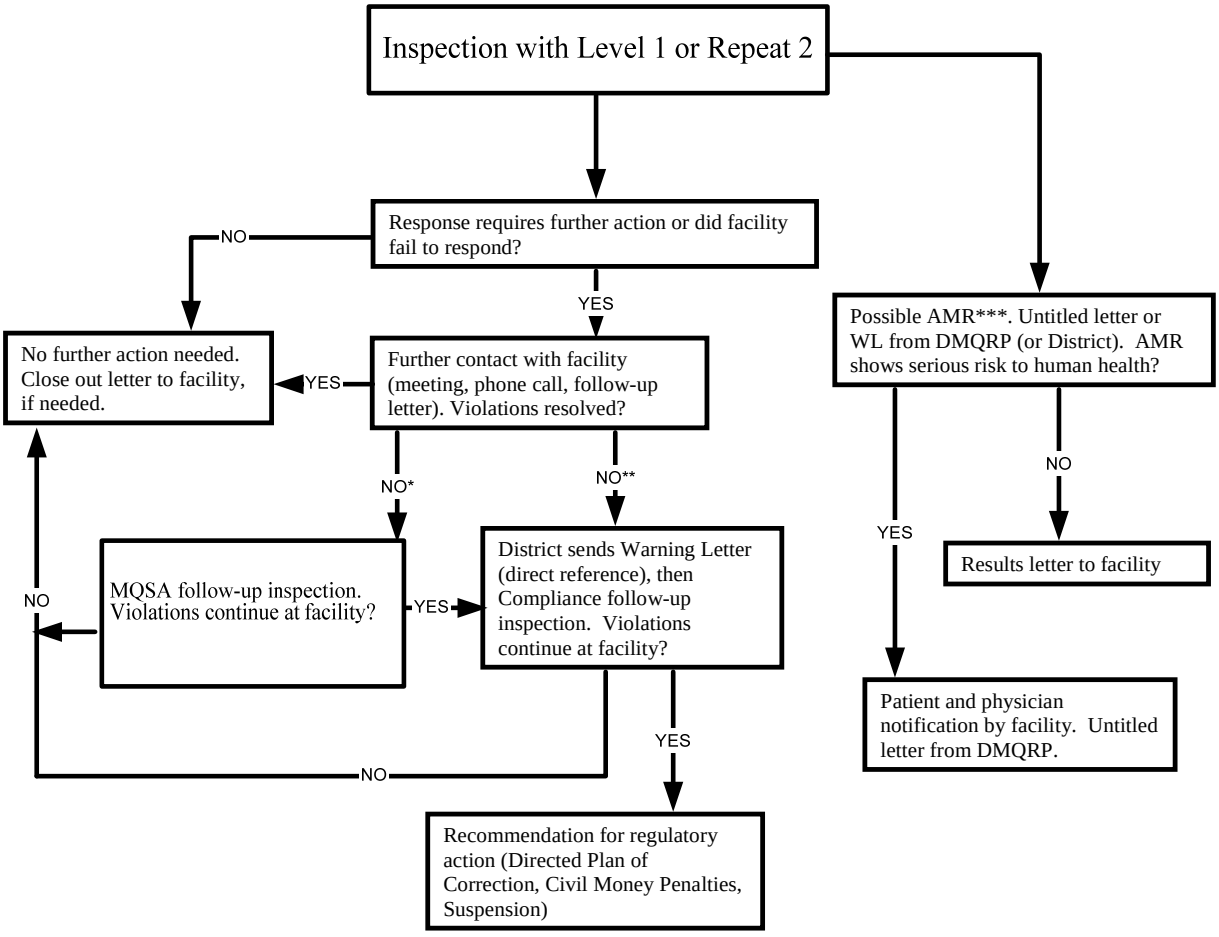
   D. Clinical image review by an accreditation body

If an accreditation body, during a review of mammograms for accreditation, reaccreditation, or for any other reason, finds that the quality of mammography may represent a serious risk to human health, this body should notify FDA within two working days. Based on this information, FDA may require AMR.

Note: An AMR may be performed regardless of whether a regulatory action will or will not be taken by the agency.

Attachment H

Follow-Up for MQSA Inspections



*Facility response to Level 1 or repeat Level 2 inspection observation appears adequate but requires further verification or facility fails to respond, or response is inadequate to Level 2 or repeat Level 3 inspection observation

** Facility fails to respond, or response is inadequate to Level 1 or repeat Level 2 inspection observation

***FDA requires Additional Mammography Review (AMR) for Level 1 phantom image score (during an inspection) or interpreting physicians. FDA may also require AMR for extensive violations.

Attachment I

(MQSA Inspection Violations Letter)

WARNING LETTER

{Date}

Certified Mail {or Overnight Mail}
Return Receipt Requested

Re: MQSA Inspection ID # _____
FEI# _____ {optional}

Name of responsible individual
Name of facility
Address

Dear _____:

On _____, a representative of the State/Commonwealth of _____, acting on behalf of the Food and Drug Administration (FDA) {or, if the inspection is conducted by FDA, replace with "a representative of the Food and Drug Administration (FDA)"} inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code (USC)**,** your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed a violation(s) of the MQSA at your facility. This violation was {These violations were} noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector {left with {Name of Person} at your facility at the close of the inspection {on date (if different from inspection date) or mailed to your facility on {Date}}. The violation(s) is/are again identified below.

> **{List here 1) repeat Level 1 observations; 2) Level 1 observations; 3) repeat Level 2 observations; 4) Level 2 observations; and 5) other less serious violations you believe should be noted. Each violation should include the parallel statement from the MQSA Facility Inspection Report and a specific citation to the appropriate part of 21 CFR Part 900}**

Example: **Level 1:** Processor Quality Control records were missing for [number of days] consecutive days from {start date for missing days} to {end date for missing days} for {name of} processor, room {name or number}, at {name of site}. [See 21 CFR 900.12(e)(1)].

Example: **Level 1:** The system to communicate results is not adequate for {name of site} because there is no system in place to communicate cases that are "suspicious" or "highly suggestive of malignancy" to the relevant health care provider(s) as soon as possible [see 21 CFR 900.12(c)(3)(ii))]

Example: **Level 2:** Failed to produce documents verifying that the interpreting physician met the continuing education requirement of having taught or completed at least 15 category 1 continuing education units in mammography in 36 months: {name of physician} [see 21 CFR 900.12(a)(1)(ii)(B)].

Example: **Level 2:** The x-ray system for unit {**unit number**}, room {**room name or number**} does not include different sized compression paddles that match the size of all full-field image receptors provided for the system. [see 21 CFR 900.12(b)(8)(ii)(A)].

{Insert one of the following two paragraphs, as appropriate:} You have failed to respond to the MQSA Facility Inspection Report as requested in the document "Important Information about your MQSA Inspection" and failed to respond to additional communication attempts by our office on {Dates}. **OR** On **{date}** we received your response to the MQSA Facility Inspection Report. Your response was inadequate in that **{insert explanation, at least in general terms, of why response is considered inadequate}.** Subsequent communication with our office on {Dates} failed to resolve the violation(s).

{Insert highlighted section if a follow-up inspection was performed:} On _____, a representative of the Food and Drug Administration (FDA) performed an MQSA follow-up inspection of your facility. This MQSA follow-up inspection revealed that your facility failed to correct the violation(s) identified below.

{List here 1) repeat Level 1 observations; 2) Level 1 observations; 3) repeat Level 2 observations; 4) Level 2 observations; and 5) other less serious violations you believe should be noted. Each violation should include the parallel statement from the MQSA Facility Inspection Report and a specific citation to the appropriate part of 21 CFR Part 900}

Example: **Level 1:** Processor Quality Control records were missing for [number of days] consecutive days from {start date for missing days} to {end date for missing days} for {name of} processor, room {name or number}, at {name of site}. [See 21 CFR 900.12(e)(1)].

Example: **Level 1:** The system to communicate results is not adequate for {name of site} because there is no system in place to communicate cases that are "suspicious" or "highly suggestive of malignancy" to the relevant health care provider(s) as soon as possible [see 21 CFR 900.12(c)(3)(ii))]

Example: **Level 2:** Failed to produce documents verifying that the interpreting physician met the continuing education requirement of having taught or completed at least 15 category 1 continuing education units in mammography in 36 months: {name of physician} [see 21 CFR 900.12(a)(1)(ii)(B)].

Because the continued failure to resolve this (these) violation(s) may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- requiring your facility to notify patients who received mammograms at your facility, and their referring physicians, of the deficiencies, the potential harm resulting from such deficiencies, appropriate remedial measures, and other relevant information **{only include this item if the violation(s) listed in the letter satisfy the standard in the statute (42 USC 263b(h)(2)) – namely the "quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f) as to present a significant risk to individual or human health"}**
- seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility **{only include this item if the violation(s) listed in the letter satisfy the requirement of the statute (42 USC 263b(j)) – namely, that continued failure to correct it "would constitute a serious risk to human health" or if the facility is performing mammography without a certificate}**

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. {**this item should only be included if one of the observations listed above is equipment failure**} equipment settings (including technique factors), raw test data, and calculated final results;

4. {**this item should only be included if one of the observations listed above relate to Quality Control or other record problems**} sample records that demonstrate proper record keeping procedures; {**add the following note if the observations relates to patient records**: **Note: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies of records you submit**}

Please submit your response to this letter to:

{insert name, address, phone number, and fax number here}

Please send a copy of your response to:

State of _____ {radiation control office}
{street address}
{city, state, zip code}

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection(s) of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact {name} at {phone number}.

Sincerely yours,

District Director

cc:
State of _____ {radiation control office}
{street address}
{city, state, zip code}

If facility is ACR accredited:

Priscilla F. Butler, M.S., FAAPM
Director, Breast Imaging Accreditation Programs,
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

If the facility is accredited by the State of Arkansas:

Jonathon Bibb
Radioactive Materials & Mammography Section
Div. of Radiation Control & Emergency Mgmt.
Arkansas Department of Health
4815 W. Markham, Slot 30
Little Rock, Arkansas 72205-3867

If the facility is accredited by the State of Texas:

Kaye J. Goss-Terry, RT(R)(M)
Mammography Certification and
Accreditation Program Manager
Texas Department of Health
Bureau of Radiation Control
1100 West 49th Street
Austin, Texas 78756-3189

bcc:
HFA-224
HFC-130
HFC-210
HFC-230
HFI-35 (redacted copy for public display)
HFR - (Regional Director)
HFR - (District Director)
HFR - (District Compliance Branch)

Revised – 7/31/2003

Attachment J

(**Adequate Response Letter to Facility**)

[Date]

Name of responsible individual
Name of facility
Address

Section 1.02 Re: MQSA Inspection ID # _____

Dear (Addressee) :

Your facility was inspected on insert date of inspection here by a representative [{from the State of state name and name of state radiation control program under contract to the Food and Drug Administration} or {of the Food and Drug Administration}]. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Section 900.12.

On insert date of facility response here , you responded by letter to the noncompliances found during the inspection [{for situations where letters are sent} as referenced in the Warning Letter dated date of letter]. Based on your response, your facility has now met the annual MQSA inspection requirement. The corrective action you have implemented will be evaluated during your next inspection.

Sincerely yours,

[name and title of district official]
____ District Office

cc:
State of _____ [radiation control office]
[street address]
[city, state, zip code]

bcc:
HFA-224
(district office)

Attachment K

Sample Inspection Report

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MQSA Facility Inspection Report
Inspection ID: 1234560009
FEI: 1000514118
Inspection Date: 12/19/2002
Print Date: 12/19/2002 18:08

Facility:
Rockville Radiology, P.C.
5588 Western Hills Road
Suite A
Rockville, NY 13088

Facility Accreditation Contact:
Martin J. Chuzzlewit, M.D.
Phone: (315) 555-2829

Facility Inspection Contact:
Belinda Cratchit, R.T.
Mammo Co-ordinator
Phone: (315) 555-2000

Compliance Contact:
Martin J. Chuzzlewit, M.D.
Director, Radiology Services
Phone: (315) 555-2000

Lead Interpreting Physician: MARTIN CHUZZLEWIT

[Equipment Test Results]

Unit number:	2
Room name or number:	Mammography Room
X-Ray unit still in use?	Yes
Manufacturer - model:	Acme Medical Systems Inc. - MARK V
Medical physicist's survey date:	06/29/2002
Image receptor type:	Film Screen

X-Ray Tests:

Calculated dose (phantom)	= 172
Reproducibility coefficient of variation (3 cassettes)	= 0.026
Beam quality: HVL (@ 25 kVp)	= 0.353

Phantom Image 1

Number of fibers	= 4
Number of speck groups	= 3.5
Number of masses	= 4

[Processor STEP Test]

Processor number: 0000000001 Processing Speed = 99 (Normal)

Manufacturer: Acme Site: Rockville Radiology, P.C.
Model: 2500 Room: Dark Room

POST INSPECTION REPORT

[Darkroom Fog Test]

Room: Dark Room Fog OD = 0
Site: Rockville Radiology, P.C.

[List of Observations]

Noncompliance Level: 1

Mammograms were processed in processor 0000000001, Acme, 2500, room Dark Room at site Rockville Radiology, P.C., when it was out of limits on at least 5 days

Noncompliance Level: 2

Corrective actions for processor QC failures were not documented at least once for processor 0000000001, Acme, 2500, room Dark Room at site Rockville Radiology, P.C.

The time period between the previous and current surveys for x-ray unit 2, Acme Medical Systems Inc., Mark V exceeds 14 months

Noncompliance Level: 3

The repeat analysis QC is not adequate for site Rockville Radiology, P.C. because:

- There was no evaluation done when the change in the number of repeats/rejects exceeded 2 (either plus or minus)

[Inspector Remarks]

3.9.1 Processor Performance QC

Mammograms were processed on May 11-12 and 15-17 when out of limits without corrective action.

3.9.4 Repeat Analysis QC

The analysis done on 4/5/2002 had 7% repeats while the 7/10/2002 analysis had 12% repeats. No documented evaluation was done to determine cause or any evidence of corrective action.

POST INSPECTION REPORT

Inspection conducted by: SETH PECKSNIFF (I1001)

Name of state or district office: New York

Address:

Telephone: (315) 555-7649

Signature of inspector: _____

If your facility is certified by FDA and you have any comments regarding the conduct of this inspection or the findings, you may contact FDA's facility Hotline at 1-800-838-7715. If your facility was issued an MQSA certificate by a State government agency, and not the FDA, please contact that State agency directly at the telephone number listed on your State MQSA certificate.

Facilities wishing to obtain additional information about the MQSA program in general may check the FDA Website at: www.fda.gov/cdrh/mammography.

Facilities wishing to obtain additional information about MQSA regulations and guidance may check the Policy Guidance Help System on the FDA Website at: www.fda.gov/cdrh/mammography/robohelp/finalregs.htm.

Attachment L

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 is to 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 repeat Level 1, Level 1, or repeat Level 2 as the most serious adverse observation:***

If the Report noted at least one repeat Level 1, Level 1, or repeat Level 2 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 $991 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 2 or repeat Level 3 adverse observation as the most serious 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 $991 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 adverse observation as the most serious 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 no adverse observations were identified:***

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/cdrh/mammography/index.html. 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.

Revised – 9/29/2003

Attachment M

MQSA
Inspection Confirmation

This notice confirms our telephone conversation of _____ 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: Fax:

_____

The MQSA inspection will cover the following areas:

- Equipment performance (including image quality and dose)
- 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

Average on-site inspection time: approximately six hours.

Testing for each mammography x-ray unit, darkroom and film processor combination: approximately one hour

The remainder of the inspector's time will be spent reviewing facility records. We recommend that you schedule a block of time for the testing of each x-ray unit and film processor combination to help minimize any inconvenience to patient care from the inspection process. For the remainder of the inspection time, staff may conduct their usual duties but should be available to the inspector during the records review portion, should he or she have questions or need assistance.