

## Mammography Facility Inspections

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SUBJECT:  Mammography Facility Inspections		IMPLEMENTATION DATE
		COMPLETION DATE
<b>DATA REPORTING</b>		
<b>PRODUCT CODES</b>	<b>PROGRAM ASSIGNMENT CODES</b>	
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) or a laptop provided by ORA. They should then upload the inspection (computer data) into 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 need to keep 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, though electronic storage as outlined in the State contracts is acceptable. 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 (inspections, audits of inspectors, coordination and technical assistance, training, etc.), into the Field Accomplishments and Compliance Tracking System (FACTS). Additional FACTS data entry is needed to ensure the FACTS inspection record is closed properly.

Inspections under the MQSA program will transfer into FACTS under Operation Code 12 – Domestic Inspection, PAC 85014 for annual inspections or PAC 85014F for follow-up inspections once they are uploaded from the Facility Inspection Support System (FISS).

**Note:** If the inspection revealed any adverse observations, the inspection will not transfer into FACTS until all noncompliances are resolved in MPRIS.

The MQSA inspections will have a FACTS status code of “In Progress” and will be located in the Personal In-Box of the inspector. MQSA inspectors should open the inspection in FACTS and complete the FACTS endorsement/coversheet in accordance with the Investigations Operations Manual and/or their district’s policy. The inspector should electronically sign the FACTS coversheet, set the inspection status code to “Awaiting Endorsement” (or “Completed” depending on your FACTS account privileges), and make any necessary adjustments to the hours initially reported in FISS for the completion of the inspection. The local supervisor of the MQSA inspector should endorse the inspection in FACTS to complete the FACTS record.

If the home district of the MQSA inspector is different than the home district of the mammography facility, the procedure you should follow is different. The MQSA inspector in this case should send notification to the Investigations Branch manager in the home district of the facility, informing him or her that the MQSA inspection has been completed and the status code has been set to “Awaiting Endorsement” (or “Completed” depending on your FACTS account privileges) in FACTS. MQSA inspectors should provide the FACTS Assignment ID to the Investigations Branch manager. The Investigations Branch Manager should search the district’s Organizational In-Box using the FACTS Assignment ID provided by the inspector to find the inspection. The inspection should be endorsed by the Investigations Branch Manager and closed in FACTS. Note: The MQSA inspector should send the inspection report and any other supporting documentation to the home district of the mammography facility for file.

**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 annual inspections (the auditor

accompanying the audited inspector). Districts should refer to the MQSA Auditors Guide for more information regarding audits.

**When an MQSA inspector uploads an audit inspection to MPRIS the audit inspection data will transfer into FACTS as an Operation Code 13 – Domestic Investigations, PAC 85014A. MQSA auditors SHOULD NOT create a record in FACTS for joint audits. The FACTS record of the audit will be automatically created by the transfer of the data from MPRIS to FACTS. This FACTS record will include the on-site inspection time entered into FISS by the MQSA inspector.**

Auditors can search for the FACTS documentation for the joint audit by selecting the “Navigate” function in their FACTS In-Box and then moving through the following selections: “Investigative Operations” and then “Investigations”. In the “Investigations Search” window the auditor should enter the home district of the facility as the “Accomplishing District” (regional employees may have to select their regional code). The auditor should also enter the date of the audit as the “Start Date” and PAC Code 85014A under “PAC”. Click “ExeQry” to execute the query. The up and down arrows should be used to move through the selected records until you come to the one you are looking for. You can update the record to include additional time spent by the auditor conducting paper audit reviews or other audit activities for the audit by clicking on the “Accomplishment Hours” function to bring up the “Accomplishment Hours” screen. You must click on the “Update” button to add any additional hours to the data visible on the screen.

**Note: When entering inspections, investigations, or other operations in FACTS for a specific mammography facility, the MQSA inspector should verify the information located under the “Firms” function. This includes entering the MQSA facility ID number in the “Cross Reference” function of the screen.**

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

**Compliance, Coordination and Technical Assistance:** Inspectors and auditors should enter time spent providing technical assistance and compliance reviews under the MQSA program into FACTS under “Miscellaneous Accomplishments”, Operation Code 92- Coordination/Technical Assistance, and PAC 85014C.

**Training:** All hours spent in training activities should be reported into FACTS as Operation Code - 83 Training/Education Given or Operation Code 84 – Training Received, PAC 85014.

## 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** - MPRIS Web has a section that is designed to track corrective actions for inspection observations. Each district designates personnel to update the compliance section of MPRIS Web 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.), MPRIS Web 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. See Attachment N for more information regarding MPRIS Web.

MPRIS Web users usually include MQSA auditors and inspectors, compliance officers, and compliance technicians. Only authorized users may update MPRIS Web. To get an account set up for a new user, districts should contact MPRIS Computer Support via telephone or e-mail or [computersupport@cdrh.fda.gov](mailto: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, South Carolina, and Texas).

## Reauthorization

On October 25, 2004, the president signed into law the Mammography Quality Standards Reauthorization Act of 2004 (Public Law 108-365). The following is a summarized list of the major changes to MQSA from this law:

1. Temporary renewal certificate – these certificates allow facilities an additional 45 days to complete the accreditation process which have met the requirements for submission of materials, but the accreditation body is unable to complete the reaccreditation process before the certification expires.
2. Limited provisional certificate - these certificates allow facilities to produce mammograms for educational purposes while an onsite visit from an accreditation body is in progress. This certificate is only valid for 72 hours.
3. National Mammography Quality Assurance Advisory Committee – added that at least 2 industry representatives with expertise in mammography equipment be included on the committee and changed the frequency of meetings from biannually to annually.

## 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 inspection (FISS) 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 (see 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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm111000.htm>.

## 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 Web 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 Web, including exchange of information and updating capabilities. State inspectors also have access to their State's inspections, as well as other information, regarding facility certification status.

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 or auditor 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 (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>). FDA inspectors should wear personnel dosimeters (radiation badges) distributed by the Radiation Safety Officer ((781) 729-5700 x713) 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))). Official FDA credentials issued to 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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm049115.htm> 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 (FISS) 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. FDA shouldn't direct facility personnel to respond to FDA regarding the inspection observations nor should it evaluate responses for these observations.

#### 5. 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 advisory, regulatory, and other actions for 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 (see Attachment G). Should this AMR show 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.

**Note:** AMR isn't a regulatory action, but may be combined with other actions where serious violations have been found.

- 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))).

## 6. 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 (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>).

## 7. 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: repeat level 1, 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, <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>)

**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).

## **8. 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. The facility should generally be given at least five days notice before the start of the inspection. This notification enables the facility make adjustments to patient scheduling or communicate conflicts or concerns with the proposed inspection date (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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm111000.htm> 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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm111000.htm> 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. This inspection type should also be used for any other inspection at a facility that doesn't fall under one of the other types. 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).

Guidelines for facility inspections:

1. Inspectors should follow the MQSA inspection procedures (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>).
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 or email notice (see Attachment M). 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 FISS 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 section 2.8 of the MQSA Inspection Procedures (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>) 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.

**Note:** A new section to this document was recently added which is titled “Your report identified at least one repeat level 1, level 1, or repeat level 2 as the most serious adverse observation and previous inspections have found at least one of these observations at your facility” If a facility has past and current inspection observations of this significance, you should point out the paragraph at the end of this section that discusses the steps it needs to take to prevent the reoccurrence of the problem(s).

- 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 allegations of damage to an x-ray system or other facility equipment 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:** 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 observations. 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. FDA may need documentation or other evidence for a regulatory action (Directed Plan of Correction, Civil Money Penalties, suspension or revocation, or injunction).

**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 (see Appendix 3 of the MQSA inspection procedures; <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>).

**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 the Policy Guidance Help System, there is a section on the Health Insurance Portability and Accountability Act (HIPAA), a federal law which provides protection for patient information. Under 45 CFR 164.512(b) and (d) of the HIPAA regulations issued by the Department of Health and Human Services, facilities are allowed to release patient information to an MQSA inspector without patient authorization because MQSA inspectors are performing health oversight activities required by law.

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 MPRIS Web 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 and Mentoring

1. **Audits:** 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 (<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074895.htm>), dated January 1998, provides information on how to conduct audits. Districts should work with the RRHRs if they require assistance in meeting the auditing workplan. Each inspector should be audited at least once during each federal fiscal year. Field Management Directive No. 76 provides general guidance on the MQSA audit program. In addition, the Auditor's Guide contains procedures and policies pertaining to implementation of the audit program. An audit consists of a joint inspection performed by an MQSA auditor simultaneously with an annual inspection by a State or FDA inspector, as well as the review of uploaded inspection records.
2. **Mentoring:** mentoring is a requirement for newly-trained MQSA inspectors (those that have passed Course III training) that must be completed before they may begin conducting inspections independently. Mentoring consists of the new inspector being accompanied on an inspection by another experienced inspector. Each newly-trained inspector must be mentored during two inspections within 90 days after passing Course III training before conducting inspections independently. While most State inspectors will be mentored by another experienced State inspector, an FDA auditor or another experienced FDA inspector will usually mentor newly-trained FDA inspectors. FDA auditors or experienced FDA inspectors may also mentor State inspectors, when necessary. Mentoring is also used to re-qualify inactive Federal and State personnel. This includes personnel who retire and are hired back as contractors, or personnel who were involved in the MQSA program in the past and then reassigned to other non-MQSA duties and are now returning to the MQSA program.

## 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 repeat level 1, 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 repeat level 1, 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 repeat level 1, 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. You should always check the facility's inspection history whenever an inspection has repeat level 1, level 1, or repeat level 2 observations. The Inspection History Report in MPRIS Web is convenient for this purpose. 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 repeat level 1, 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) (see Attachment G). 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 FISS 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 and the RRHR. Please refer to CP 7386.003 for guidance regarding x-ray equipment problems.

**H. Complaints about Patient Access to Mammograms**

Occasionally, districts may receive complaints from patients, health care providers, facilities, or others that patients cannot get access to their mammograms. Under 21 CFR 900.12(c)(4)(ii), facilities must transfer original mammograms and copies of the patient's reports when requested by, or on behalf of, a patient to a medical institution, or to a physician or health care provider of the patient, or to the patient directly. If you receive complaints of this type, please contact the Inspection and Compliance Branch (see Attachment B for contact information). While facilities that are still operational, whether certified or not, may be the subject of regulatory action for failure to provide mammograms when requested, some may be closed. Even if the facility is closed, the Division of Mammography Quality and Radiation Programs tries to work with patients to locate and obtain their records

## 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 FISS 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 MPRIS Web. MPRIS Web contains information on facility inspection data, results, and compliance information. The district should update MPRIS Web 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 repeat level 1, 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 to 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 repeat level 1, 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 repeat level 1, 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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm049115.htm>), 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 (see Attachment G). 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** (see Appendix 3 of the MQSA inspection procedures; <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>):

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**

All requests for AMRs require DMQRP approval, 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 in 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. 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 Acts of 1998 and 2004*, (Public Laws 105-248 and 108-365)
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 which can be found at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114146.htm>)
6. *Compliance Guidance - The Mammography Quality Standards Act Final Regulations* Documents. These can found at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/default.htm>. 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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.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 7386.003, Field Compliance Testing of Diagnostic (Medical) X-ray Equipment (<http://www.fda.gov/downloads/ICECI/ComplianceManuals/ComplianceProgramManual/ucm125442.pdf>)

12. MQSA Auditor's Guide  
(<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074895.htm>)

## B. ATTACHMENTS

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

- A. List of CDRH personnel (inspection, compliance, audits, and workplans)
- B. List of CDRH personnel to contact on inspection computer support and testing equipment
- C. List of MQSA Auditors
- D. Form FDA 2766 Claim for Damage to an Electronic Product
- E. Observation Statements for MQSA Inspections
- F. Guidance for Evaluating a Facility Response
- G. Guidance for an Additional Mammography Review (AMR)
- H. Flowchart - Follow-Up for MQSA Inspections
- I. Warning Letter for inspections with repeat level 1, level 1 and or repeat level 2 inspection observations
- J. Adequate Response Letter to Facility
- K. Example of MQSA Facility Inspection Report
- L. Important Information about Your MQSA Inspection (given to facility at the close of the inspection)
- M. 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, [michael.divine@fda.hhs.gov](mailto:michael.divine@fda.hhs.gov). 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 Preetham Sudhaker, Division of Federal-State Relations ORO (HFC-152), [preetham.sudhaker@fda.hhs.gov](mailto:preetham.sudhaker@fda.hhs.gov).

## 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, DIAM/OSEL/CDRH) (Note: the MQSA inspection procedures no longer include routine radiation measurements. Radiation measurements, such as exposure measurements for dose, beam quality, and reproducibility, would only be done as needed to investigate possible problems.
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 Web by inspectors, auditors, and RRHR's.
4. Recommend specific sites for special inspections when requested.
5. Develop and revise facility inspection procedures.
6. Provide training courses for MQSA inspectors and administer MQSA inspector certification and quality assurance programs.
7. 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, Diagnostic Devices Branch, DMQRP for consideration.

Attachment A

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

1. Normica Facey [normica.facey@fda.hhs.gov](mailto:normica.facey@fda.hhs.gov) (Diagnostic Devices Branch, DMQRP)
2. Michael P. Divine [michael.divine@fda.hhs.gov](mailto:michael.divine@fda.hhs.gov) (Diagnostic Devices Branch, DMQRP)

**Inspection Field Workplan**

3. Ellyce F. Ratskoff [ellyce.ratskoff@fda.hhs.gov](mailto:ellyce.ratskoff@fda.hhs.gov) (Inspection and Branch, DMQRP)

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

1. Michael P. Divine [michael.divine@fda.hhs.gov](mailto:michael.divine@fda.hhs.gov) (Diagnostic Devices Branch, DMQRP)
2. Normica Facey [normica.facey@fda.hhs.gov](mailto:normica.facey@fda.hhs.gov) (Diagnostic Devices Branch, DMQRP)
3. Sean Boyd [sean.boyd@fda.hhs.gov](mailto:sean.boyd@fda.hhs.gov) (Diagnostic Devices 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 <a href="mailto:computersupport@fda.hhs.gov">computersupport@fda.hhs.gov</a> ).
MQSA Issued Inspection Equipment Questions (e.g., film requests; sensitometer or densitometer problems; phantom problems; need for other equipment, including magnifying glass, ruler, aluminum filters, timers, fog folders)	Contact Pete Shandruk <a href="mailto:petro.shandruk@fda.hhs.gov">petro.shandruk@fda.hhs.gov</a> ).

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

## 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
Jeff Sincek	Regional Radiological Health Staff
Vacant	Baltimore District
Rachel T. Evans	Chicago District
R. Terry Bolen	Cincinnati District
Charles Spyr	Detroit District
Vacant	Minneapolis District
Vacant	New Jersey District
Robert E. Davis	Philadelphia District

### Northeast Region

Michael J. Leal	RRHR
George Allen, Jr.	New England District
James R. Wormuth	New York District

### Pacific Region

Terri Jones	RRHR
Beverly A. Thomas	San Francisco
Beverly A. Thomas	Los Angeles District

### Southeast Region

Karen R. Smallwood	RRHR
Abraham Maekele	Atlanta District
Janneth Caycedo	Florida District
Karen R. Smallwood	New Orleans District
Janneth Caycedo	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)	
<b>I COMPLETED BY CLAIMANT</b>		
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	
<b>II COMPLETED BY FOOD AND DRUG INSPECTOR</b>		
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	
<b>III COMPLETED BY IMMEDIATE SUPERVISOR, EMPLOYEE, OR REPRESENTATIVE</b>		
I affirm that the above employee or representative was on official government business when this claim for damage arose		
PRINTED NAME AND	SIGNATURE	DATE
<b>IV COMPLETED BY OFFICE OF COMPLIANCE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH</b>		
COMMON ACCOUNTING NUMBER	CDRH CLAIM	
COMMENTS		

FORM FD 2766 (1/93)

## 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. We have also included in brackets the Noncompliance Code in MPRIS for the inspection observation. This will assist you with database searches for inspections with these specific observations using the Noncompliance Inspection Report in MPRIS Web (Example: [§900.12(c)(1)(iv); Some reps w/o res - 2]).

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.

### **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 [Unit not accredited - 1].

**Certification – 21 CFR 900.11(a)**

The facility was performing mammography without a valid certificate [No valid cert. - 1].

**Personnel - 21 CFR 900.12(a)**

Failed to produce documents verifying that the interpreting physician {name of physician} met the initial requirement of holding a valid state license to practice medicine [§900.12(a)(1)(i)(A) & (a)(4); No license/IP - 1].

Failed to produce documents verifying that the interpreting physician {name of 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 [§900.12(a)(1)(i)(B)(1) and (2) & (a)(4); No cert/3mo.tr/IP - 1].

**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 (see also §900.12(a)(1)(iii)(A)) [No cert/2mo.tr/IP - 1].

Failed to produce documents verifying that the radiologic technologist {name of technologist} met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body [§900.12(a)(2)(i)(A) and (B) & (a)(4); No lic/cert/tech - 1].

Failed to produce documents verifying that the medical physicist {name of physicist} met the initial requirement of holding a valid state license or approval letter, or being certified by an FDA-approved body to perform physics surveys [§900.12(a)(3)(i)(A) & (a)(4); No lic/cert/MP - 1].

Failed to produce documents verifying that the medical physicist {name of physicist} met the initial requirement of having a masters degree or higher in a physical science with at least 20 semester hours of physics [§900.12(a)(3)(i)(B) & (a)(4); MS not in Phys.sci/MP - 1].

Failed to produce documents verifying that the medical physicist {name of physicist} met the alternative initial requirement of having, prior to April 28, 1999, a bachelors degree or higher in a physical science with at least 10 semester hours of physics [§900.12(a)(3)(ii)(B)(1) & (a)(4); BS not in Phys.sci/MP - 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); Sys not for mammo - 1].

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

The system to communicate results is not adequate for {name of site} because [Comm.sys not adequate - 1]:

- 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 at least 5 consecutive days for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1) & (d)(2); Proc. QC consec d - 1].

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

Processor QC records in the month of {name of month} were missing for at least 30% of operating days, for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1) & (d)(2); Proc. QC Miss.% - 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); Underprocessing/s - 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); Underprocessing/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 at least 5 days [§900.12(e)(1)(i), (ii), and/or (iii), (e)(8)(ii), & (d)(2); Proc. out of limits - 1].

**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 at least 4 weeks for unit {unit number}, room {room name or number} [§900.12(e)(2) & (d)(2)]; Ph. QC missing - 1].

**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); Low ph. score/f - 1].

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); Low ph. score/m - 1].

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); Low ph. score/sp - 1].

**Note:** The phantom image score noncompliance codes for full-field digital mammography units will have “d” (example: “Low ph. score/m(d) – 1”)

A medical physicist survey for x-ray unit {unit number}, {unit manufacturer}, {unit model}, room {room name or number} was not conducted in over two years 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) & (d)(2); No phys. survey - 1].

## 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 [Unit not accredited - 1].

**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 {name of physician} met the initial requirement of having 60 hours of category I medical education in mammography [§900.12(a)(1)(i)(C) & (a)(4); No 60 CME/IP - 2].

**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 [No 40 CME/IP - 2].

Failed to produce documents verifying that the interpreting physician {name of physician} met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months [§900.12(a)(1)(i)(D) & (a)(4); No init.exp./IP - 2].

Failed to produce documents verifying that the interpreting physician {name of physician} met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [§900.12(a)(1)(ii)(A) & (a)(4); No cont.exp./IP - 2].

Failed to produce documents verifying that the interpreting physician {name of physician} met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months [§900.12(a)(1)(ii)(B) & (a)(4); No cont.ed/IP - 2].

Failed to produce documents verifying that the interpreting physician {name of physician} met the requirement of having 8 hours of training in the new mammographic modality [§900.12(a)(1)(ii)(C) & (a)(4); No new.mod.trng/IP - 2].

Failed to produce documents verifying that the radiologic technologist {name of technologist} met the requirement of having 8 hours of training in each mammographic modality [§900.12(a)(2)(ii) & (a)(4); No 40 mamm.tr./tech - 2].

**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 [No mamm.tr./tech - 2].

Failed to produce documents verifying that the radiologic technologist {name of technologist} met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months [§900.12(a)(2)(iii)(A) & (a)(4); No cont.ed/tech - 2].

Failed to produce documents verifying that the radiologic technologist {name of technologist} met the requirement of having 8 hours of training in each mammographic modality [§900.12(a)(2)(iii)(E) & (a)(4); No new.mod.trng/tech - 2].

Failed to produce documents verifying that the radiologic technologist {name of technologist} met the continuing experience requirement of having performed 200 mammography examinations in 24 months [§900.12(a)(2)(iv)(A) & (a)(4); No cont.exp/tech - 2].

Failed to produce documents verifying that the medical physicist {name of physicist} met the initial requirement of having 20 contact hours of documented specialized training in conducting surveys of mammography facilities [§900.12(a)(3)(i)(B)(2) & (a)(4); Cont. train < 20/MP - 2].

Failed to produce documents verifying that the medical physicist {name of 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 [§900.12(a)(3)(i)(B)(3) & (a)(4); Surv. exp.<1fac.10units/MP - 2].

Failed to produce documents verifying that the medical physicist {name of 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 [§900.12(a)(3)(ii)(B)(2) & (a)(4); Cont. train < 40/MP - 2].

Failed to produce documents verifying that the medical physicist {name of 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 [§900.12(a)(3)(ii)(B)(3) & (a)(4); Surv. exp.<1fac.20units/MP - 2].

Failed to produce documents verifying that the medical physicist {name of physicist} met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months [§900.12(a)(3)(iii)(A) & (a)(4); No cont.ed/MP - 2].

Failed to produce documents verifying that the medical physicist {name of 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 [§900.12(a)(3)(iii)(B) & (a)(4); No cont.exp/MP - 2].

Failed to produce documents verifying that the medical physicist {name of physicist} met the requirement of having 8 hours of training in surveying units of the new mammographic modality [§900.12(a)(3)(iii)(C) & (a)(4); No new.mod.trng/MP - 2].

### **Equipment - 21 CFR 900.12(b)**

The x-ray system for unit {unit number}, room {room name or number} does not include the following [Unit missing features - 2]:

- 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); >= 1 rep.w/oID - 2].

**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 acceptable assessment category for site {name of site} [§900.12(c)(1)(iv); Some reps w/o res - 2].

**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 at least 2 but less than 5 consecutive days for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1) & (d)(2); Proc. QC consec d - 2].

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

Processor QC records in the month of {name of month} were missing for at least 10% but less than 30% of operating days, for processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1) & (d)(2); Proc. QC Miss.% - 2].

**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 at least 65, but less than 80 for standard processing: processor {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1); Underprocessing/s - 2].

The processing speed (using the S.T.E.P. procedure) is at least 85, but less than 100 for extended processing: {name of processor}, room {room name or number} at site {name of site} [§900.12(e)(1); Underprocessing/e - 2].

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 at least 2 but less than 5 days [§900.12(e)(1)(i), (ii), and/or (iii), (e)(8)(ii), & (d)(2); Proc. out of limits - 2].

**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)(1)(i), (ii), and/or (iii), (e)(8)(ii), & (d)(2); No c/a proc QC - 2].

Phantom QC records were missing for at least two weeks but less than four weeks for unit {unit number}, room {room name or number} [§900.12(e)(2) & (d)(2); Ph. QC missing - 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 [Oth ph QC inadeq - 2]:

- The image was not taken at clinical setting [§900.12(e)(2)(i) & (d)(2)].
- The background density was  $< 1.20$  [§900.12(e)(2)(i) & (d)(2)].

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit {unit number}, room {room name or number} [§900.12(e)(2)(iii), (e)(8)(ii), & (d)(2); no c/a-phantom QC - 2].

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); Low ph. score/f - 2].

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); Low ph. score/m - 2].

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); Low ph. score/sp - 2].

**Note:** The phantom image score noncompliance codes for full-field digital mammography units will have “d” (example: “Low ph. score/m(d) – 2”)

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); High fog density - 2].

**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 inadequate or not done [§900.12(e)(9) & (d)(2); Incomplete survey - 2]:

- 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)].

The FFDM manufacturer QC (excluding monitor & printer QC) procedures for digital unit {unit number}, {unit manufacturer}, {unit model}, room {room name or number} were not followed [§900.12(e)(6) & (d)(2); no mfr-recom.qc/dm - 2].

The manufacturer recommended Printer QC procedures for digital unit {unit number}, {unit manufacturer}, {unit model}, room {room name or number} were not followed [§900.12(e)(6) & (d)(2); no mfr-recom.proc/dm - 2].

The manufacturer recommended QC procedures for the monitor for digital unit {unit number}, {unit manufacturer}, {unit model}, room {room name or number} were not followed [§900.12(e)(6) & (d)(2); no monitor QC/dm - 2].

A performance verification test was not conducted after each move for mobile unit {unit number}, room {room name or number} [§900.12(e)(7) & (d)(2); No ver. move-ph.qc - 2].

A medical physicist's survey has not been conducted for x-ray unit {unit number} in room {room name or number} within the last 14 months [§900.12(e)(9)(i) & (d)(2); Last survey >14 mo].

The time period between the previous and current surveys for x-ray unit {unit number} exceeds 14 months [§900.12(e)(9)(i) & (d)(2); >14 mo bet. surveys].

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) & (d)(2); Surv.rep.unsigned].

The mammography equipment evaluation (by a medical physicist) for unit {unit number}, room {room name or number} was not done [§900.12(e)(10) & (d)(2); Eval.(by MP) not done].

The mammography equipment evaluation (by a medical physicist) for processor/laser printer {processor/laser printer manufacturer}, {processor/laser printer model}, room {room name or number} was not done [§900.12(e)(10) & (d)(2); Proc.Eval(by MP) not done].

The facility has not specified adequate procedures to be followed for infection control or did not follow them when required at site {name of site} [§900.12(e)(13) & (d)(2); No SOP/infect.ctrl.].

### **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) & (d)(2); No biopsy results].

Not all positive mammograms were entered in the tracking system for site {name of site} [§900.12(f)(1) & (d)(2); Not all pos.entered].

There is no designated audit (reviewing) interpreting physician for site {name of site} [§900.12(f)(3) & (d)(2); No desg.reviewing IP].

Medical audit and outcome analysis was not done for the facility as a whole at site {name of site} [§900.12(f)(1) & (d)(2); No analysis whole fac.]

Medical audit and outcome analysis was not done separately for each individual at site {name of site} [§900.12(f)(2) & (d)(2); No individ. analyses]

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

### **Consumer Complaint Mechanism – 21 CFR 900.12(h)**

The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required at site {name of site} [§900.12(h)(3); No SOP/complaint].

## **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. [Cert. not displd]

**Personnel - 21 CFR 900.12(a)**

The required personnel qualification documents were unavailable during the inspection [§900.12(a)(4); No req. pers. docs].

**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 [QA program inadeq]:

- 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} because [F.r. QC inadeq]:

- The fixer retention QC records were not done at the required frequency [§900.12(d)(2) & (e)(3)(i)].
- Corrective action was not documented at least once [§900.12(d)(2), (e)(3)(i), & (e)(8)(ii) ].

The repeat analysis QC is not adequate for site {name of site} because [R.a. QC inadeq]:

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

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); High fog density].

**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 [DR fog QC inadeq]:

- The QC records were not done at the required frequency [§900.12(e)(4)(i) & (d)(2)].
- The background density was < 1.20 [§900.12(e)(4)(i) & (d)(2)].
- Corrective action (before using the failed darkroom for further exams) was not documented at least once [§900.12(e)(4)(i), (e)(8)(ii) & (d)(2)].

The screen-film contact QC is not adequate for site {name of site} because [Sf con. QC inadeq]:

- QC was not done at the required frequency [§900.12(e)(4)(ii) & (d)(2)].
- Not all mammography cassettes in use were tested [§900.12(e)(4)(ii) & (d)(2)].
- The 40-mesh copper test tool was not used [§900.12(e)(4)(ii) & (d)(2)].
- Corrective action (before using the failed cassette(s) for further exams) was not documented at least once [§900.12(e)(4)(ii), (e)(8)(ii), & (d)(2)].

Compression device QC is not adequate for unit {unit number}, room {room name or number} because [Compr. QC inadeq]:

- QC was not done at the required frequency [§900.12(e)(4)(iii) & (d)(2)].
- Corrective action (before further exams) was not documented at least once [§900.12(e)(4)(iii), (e)(8)(ii), & (d)(2)].

The medical physicist's survey for x-ray unit {unit number}, room {room name or number} is incomplete because the following tests were inadequate or not done [§900.12(e)(9) & (d)(2); Incomplete survey - 3]

- 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) & (d)(2); No c/a @ ph.recom].

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. The Policy Guidance Help System usually spells out the specific criteria FDA will use to evaluate whether a facility complies with a specific section of the regulations. You should consult these criteria when evaluating a response.

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 medical records, the corrective action might include changes to procedures. These procedures would specify what steps must be taken to prepare the records correctly and assure that reports and letters are provided within appropriate time frames. In the case of mammography reports, the facility should provide sample reporting formats to demonstrate that required information is included.
8. Other areas where revised procedures usually need to be sent to FDA include medical outcomes audit, consumer complaints, and infection control.
9. For level 1 observations for a mammography x-ray unit, the unit 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.
10. For level 1 observation(s) for an interpreting physician, the facility must provide documentation that the physician is licensed and is board certified or had two/three months training in mammography. Usually these physicians are able to provide documentation to the facility. However, if the facility cannot provide documentation, you should refer to Attachment G for a possible AMR.

**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/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.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: DMQRP routinely scans MPRIS Web for inspection observations under A and B above and may follow up with districts regarding these observations. Level 1 phantom image scores are very rare. For this reason, each score must be verified using the procedure outlined in Appendix 3 of the MQSA inspection procedures. For level 1 observations for interpreting physicians, most facilities will be able to produce documentation to show that the physician is qualified. For licensure, level 1 observations are almost always cited for missing documentation or expired licenses. Facilities are usually able to produce the license or documentation that the physician has renewed his or her license. If the facility is cited for a physician not having board certification or two/three months training in mammography, it usually is able to produce the documentation. For guidance for using AMR for these observations, go to the Policy Guidance Help System at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.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

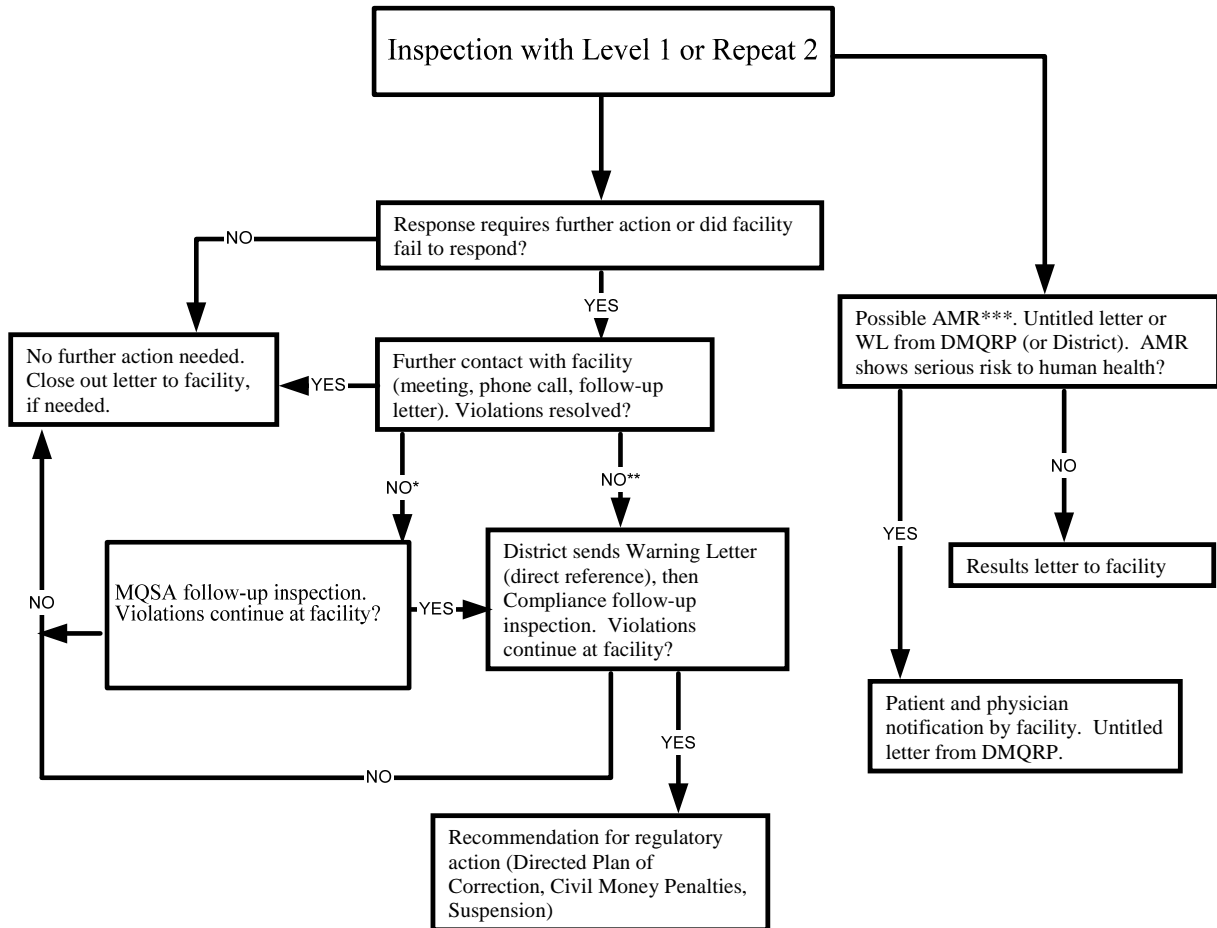
If a facility had performed mammography without a certificate for at least 90 days, FDA may require AMR.

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.**

### 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) and (a)(4)].

*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) and (d)(2)].

*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) and (a)(4)].

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:

Penny Butler, Senior Director  
Breast Imaging Accreditation Programs  
American College of Radiology  
1891 Preston White Drive  
Reston, Virginia 20191-4397

If the facility is accredited by the State of Arkansas:

Melinda Davis  
Mammography Accreditation Program  
Radiation Control Section  
Division of Health  
Arkansas Department of Health  
4815 W. Markham, Slot 30  
Little Rock, Arkansas 72205-3867

bcc:

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:  
(district office)

Attachment K

### Sample Inspection Report

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

---

MQSA Facility Inspection Report  
Inspection ID: 1234560014  
FEI: 1000111111  
Inspection Date: 05/28/2008  
Print Date: 06/02/2008 15:47

Facility:  
Rockstone Radiology, P.C.  
5588 Western Hills Road  
Suite A  
Rockstone, NY 12345

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

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

Most Responsible Individual:  
Martin J. Chuzzlewit, M.D.  
Director, Radiology Services  
Phone: (315) 555-2000

Lead Interpreting Physician: MARTIN CHUZZLEWIT

[Equipment Test Results]

Unit number: 3  
Room name or number: Rm 2  
X-Ray unit still in use? Yes  
Manufacturer - model: Acme Medical Systems Inc. - MARK V  
Medical physicist's survey date: 02/05/2008  
Dose value (mrad) reported: 169.6  
C/A taken before resuming clinical use?:  
Image receptor type: Film Screen

X-Ray Tests:

Phantom Image 1  
Number of fibers = 4  
Number of speck groups = 3.5  
Number of masses = 4

Unit number: 5

Room name or number: Rm 1  
X-Ray unit still in use? Yes  
Manufacturer - model: Acme Medical Systems Inc. - MARK V  
Medical physicist's survey date: 02/05/2008

Post Inspection Report Page 1 Inspection: 1234560014  
Printed: 6/2/2008 3:47:15 PM FEI: 1000111111

POST INSPECTION REPORT

Unit number: 5  
Room name or number: Rm 1  
Dose value (mrad) reported: 167  
C/A taken before resuming clinical use?:  
Image receptor type: Film Screen

X-Ray Tests:

Phantom Image 1  
Number of fibers = 5  
Number of speck groups = 3  
Number of masses = 4

[Processor STEP Test]

Processor number: 2 Processing Speed = 107 (Normal)  
Manufacturer: Acme Site: Rockstone Radiology, P.C.  
Model: 2500 Room: Mammography

[Darkroom Fog Test]

Room: Darkroom Fog OD = 0  
Site: Rockstone Radiology, P.C. [List of Observations]

Noncompliance Level: 1

Phantom QC records were missing for at least 4 weeks for unit 5, Acme Medical Systems Inc. MARK V Rm 1

Failed to produce documents verifying that the radiologic technologist CLARA PEGGOTTY met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body

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 Rockstone 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 Rockstone 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]

3.9.2 Phantom Image QC

No phantom image tests were performed during the week of January 7 through the week of February 18

Post Inspection Report  
Printed: 6/2/2008 3:47:15 PM

Page 2

Inspection: 1234560014  
FEI: 1000111111

POST INSPECTION REPORT

3.11.2 Technologists

Clara Peggotty's ARRT card has expired and the facility indicated that she had failed to renew it

3.9.1 S-F Processor Performance QC

Processor QC was out of limits on the following dates without documented corrective action: 1/8/08, 1/9/08, & 1/22/08

3.10 Survey Report

The previous survey report was dated 12/6/06

3.9.4 Repeat Analysis QC

No documentation was found to indicate that the facility investigated the increase of the repeat rate from 4% for the 1/9/08 analysis to 9% for the 4/14/08 analysis

Post Inspection Report  
Printed: 6/2/2008 3:47:15 PM

Page 3

Inspection: 1234560014  
FEI: 1000111111

POST INSPECTION REPORT

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Inspection conducted by: CHARLES DICKENS (I1000)

Name of state or district office: FDA

Address: Food and Drug Administration  
New York District  
PO Box 30000  
New York, NY 10000

Telephone: (800) 123-4567

Signature of inspector: \_\_\_\_\_

This inspection report was given to Martin J. Chuzzlewit, M.D.  
Director, Radiology Services on 6/2/2008 at the close of the inspection.

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](http://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: [http://www.fda.gov/Radiation-](http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm)

[EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm](http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.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 \$1,144 is charged for a follow-up inspection.

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

- Facility ID number (from your FDA certificate).

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

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

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

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

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

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

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

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



- For personnel qualification issues, documentation showing that the person(s) actually met the requirement(s) or what steps the facility has or will take to address the problem.
- **The steps taken to prevent the reoccurrence of the problem(s). This should include having the facility's most responsible individual discuss these problems with the lead interpreting physician and other staff about these problems. You should consider changes to your standard operating procedures, management practices, oversight for the quality assurance program, and recordkeeping to assure that future inspections are free from adverse observations. A detailed explanation of any changes should be included in your response.**

*If your report identified at least one Level 2 or repeat Level 3 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 \$1,144 is charged for a follow-up inspection.

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

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

*If your report identified at least one Level 3 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 – 7/8/2009

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.

Attachment N

### MPRIS Web

MPRIS Web is the primary application for accessing and updating data in MPRIS relating to mammography facilities. While the FISS application, which is only used to enter data during inspections and is only installed on inspection laptops provided to inspectors, MPRIS Web has wider availability. In addition to MQSA inspectors, DMQRP has provided access to compliance officers, RRHRs, and others within the field with a need to access and update data regarding facility inspections.

**Home Page** (<https://192.168.163.14:4443/MPRISWeb/user/login.jsp>)

The MPRIS Web home page has two main columns titled Latest News and MPRIS Documents. Latest News includes recent emails sent to inspectors. MPRIS Documents are other inspector-related documents, such as updates on software releases for FISS and MPRIS Web and the MQSA inspection procedures.

#### Search Tab

In the upper left-hand corner of the every screen in MPRIS Web is the Search tab (see Figure 1) which can be used to search for specific facilities or inspections. You should use the search by the Facility ID if you know the number and need to find information on a specific facility. The Advanced Search and Inspection Search allow for broader searches for facilities or inspections. For example, the Inspection Search tab can be used to find all inspections within the district in the last six months with a level 1 inspection observation. These searches also allow the data to be exported in either PDF or Excel formats.



Figure 1

**Facility Information**

If you select a specific facility using the search capability, you will pull up basic information including the expiration date of the facility’s certificate and the date of the last inspection (see Figure 2).

The screenshot shows a web interface for facility information. At the top, there are search fields for 'Facility ID' and 'AB ID'. Below these, a search box labeled 'Enter Facility ID:' contains a text input field and a 'Search' button. The main content area displays the following details:

- Facility ID:** [Redacted]
- AB ID:** [Redacted]
- Certification Status:** Certified
- Certificate Expiration:** 11/06/2008
- Accreditation Body:** [American College of Radiology]
- Accreditation Status:** Accredited
- Last Inspection Date:** 06/20/2008

Below the details is a navigation bar with tabs: Facility (selected), Certification, Units, and Inspections. A 'View Facility Information History' link is present. A 'View In Excel' button is located in the top right corner.

**Facility Information**

Facility ID: [Redacted]      **Accreditation Contact**      **Inspection Contact**

Name: [Redacted]      Name: [Redacted]

M.D. [Redacted]      Title: Technologist

Title: [Redacted]      Company: [Redacted]

Company: [Redacted]

Type: Private Practice – Radiology

Figure 2

From the Facility Information screen, you can also access information on inspections by clicking on the Inspections tab which will pull up the Inspection History with a list of inspections (see Figure 3).

The screenshot shows the 'Inspection History' screen. It features a navigation bar with tabs: Facility, Certification, Units, Inspections (selected), Compliance Case, and Billing. A 'View In Excel' button is in the top right corner.

**Inspection History**

Inspection ID	Inspection Type	Inspection Date	Locked?	Unit Count	Inspector ID/Name	Inspection Status
0010	Annual Inspection	06/20/2008	N	1	[Redacted]	Open
0009	Annual Inspection	06/29/2007	N	1	[Redacted]	Closed
0008	Annual Inspection	06/27/2006	N	1	[Redacted]	Closed
0007	Annual Inspection	06/03/2005	N	1	[Redacted]	Closed
0006	Annual Inspection	06/11/2004	N	1	[Redacted]	Closed
0005	Annual Inspection	06/13/2003	N	1	[Redacted]	Closed

Figure 3

You can then click on any of the inspections in the left-hand column, which will put up Inspection Details including a list of the inspection observations (see Figure 4)

The screenshot shows the 'Inspections' tab selected in the navigation menu. Below the menu are several links: [View Inspection History](#), [View Noncompliance](#), [View Correspondence](#), [Post Inspection Report](#), [Inspection Detail Report](#), [Warning Letter](#), and [Final Letter](#).

**Inspection Details**

Inspection Status: Closed	Inspector ID: _____	Final Response Adequate Date: 07/23/2008
Inspection Type: Annual Inspection	Inspector Name: _____	Inspection Closed Date: 07/23/2008
Inspection ID: _____	Inspection Date: 02/20/2008	Download Date: 02/07/2008
Unit Count: 1	Next Response Due Date: 09/12/2008	First Upload Date: 02/20/2008
		Last Upload Date: 02/20/2008

**Noncompliances** [View In Excel](#)

Level	Repeat	Status	Noncompliance Code	Noncompliance Description
1	N	Resolved	Proc. QC consec d	Processor QC records were missing at least 5 consecutive days for processor PROCESSOR 1, _____ or _____ room DARKROOM 1 at site _____ Hospital
1	N	Resolved	Proc. out of limits	Mammograms were processed in processor PROCESSOR 1, _____, room DARKROOM 1 at site _____ Hospital, when it was out of limits on at least 5 days
1	N	Resolved	Proc. QC miss.%	Processor QC records in the month of 08/2007 were missing for at least 30% of operating days, for processor PROCESSOR 1 _____ room _____

Figure 4

**Updating MPRIS Web – Corrective Actions for Inspection Observations**

In the section entitled Compliance Information (section C of the Cover Page), it states that field personnel are responsible for updating MPRIS Web regarding corrective actions and correspondence for inspection observations (i.e., noncompliances). In Figure 4 above, one of the choices is Add Correspondence which provides districts with data on contacts to or from a facility (letters, phone calls, etc.). By clicking on Add Correspondence, users will pull up the screen shown in Figure 5 below.



**Add Correspondence**

An asterisk (\*) denotes a mandatory field

**Correspondence Details**

\*Sent Date: 05/22/2008  
 Received Date:  
 Reviewed Date:  
 \*Next Response Due Date: 07/12/2008

\*Initiator: FDA  
 \*Correspondence Type: Letter  
 \*Contact Person:

**Remarks**

Asked for most recent phantom QC chart

**Noncompliance List**

Noncompliance Code	Noncompliance Description	Level	*Related <input type="checkbox"/>	Resolved <input type="checkbox"/>
Ph. QC missing	Phantom QC records were missing for at least 4 weeks for unit 4, room Rm. 217	1	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ph. QC missing	Phantom QC records were missing for at least 4 weeks for unit 6, DMR+, room Rm 225	1	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Figure 5

For the typical inspection, the facility will send a letter to the district which provides sufficient documentation that the facility has corrected all of the noncompliances. In this case, the user:

- will enter the date of the letter under Sent Date
- choose “FAC” under Initiator of the letter (the facility)
- enter the Contact Person which may be the signer of the letter or the person indentified in the letter as the contact
- check off the Related and Resolved boxes at the top of these columns to indicate the letter relates to all of the noncompliances and that they have been corrected

You should select “Final Response” as the Correspondence Type. Since entering information into the Remarks block is mandatory, entering “Response adequate” should be sufficient.

For some inspections, FDA may need to contact the facility. In the example in Figure 5 above, the user has entered information on a letter the district sent requesting additional information. Since the related noncompliances aren’t resolved, the user has indicated that the noncompliances are related to the letter, but are still unresolved. The Correspondence Type choices include Letter, E-Mail, Fax, Telephone Call,

Warning Letter, Final Response, and Other. The Remarks field is mandatory so a short explanation of why additional contact was needed should be entered. For example, the user may enter correspondence data regarding a phone call to the facility and enter “Called facility since it failed to respond to the inspection observations”. Once the facility finally submits an adequate response to the district, this final communication should be entered as “Final Response”

### **Tracking resolution of noncompliances in MPRISweb**

DMQRP routinely monitors the resolution of inspection noncompliances by using the following MPRISweb reports:

- Noncompliance Response Pending Report
- Noncompliance Response Overdue Report

Noncompliances will show up in the pending report after upload and will show up in the overdue report after about seven weeks if no correspondence is entered for the inspection.

### **Time frames for closing out noncompliances**

Typically, the vast majority of inspections can be closed out after review of the initial response. In these cases, the only correspondence entered would be this initial response from the facility and the adequate response letter (see Attachment J of CP 7385.014).

In some cases, the facility fails to provide an adequate response or does not respond. In these cases, add additional correspondence information to MPRISweb regarding follow-up contacts to and from the facility. Where there are problems with the initial response, noncompliances may take longer than seven weeks to resolve. If correspondence data is entered, the next response due date is reset to prevent the inspection from showing up in the overdue report.

Based on our experience, only under unusual circumstances should noncompliances in MPRISweb remain unresolved more than 90 days after the inspection. While it is possible to reset the next response due date for inspections without entering additional correspondence information, we discourage that approach. If noncompliances cannot be resolved quickly, you should periodically enter correspondence data regarding contacts with the facility to indicate that you are actively working to resolve the noncompliances.

### **Inspections where further action is needed**

There may be situations where a facility is being considered for further action, such as a follow-up inspection or regulatory action. In these and similar cases, the situation has escalated to the point that the original noncompliances should be closed out. For these situations, you should:

1. enter correspondence data under Other
2. check on the Resolved block for the noncompliance(s)



3. enter an explanation in the Remarks section

Some examples for information in Remarks would be “Follow-up inspection planned for 6/5/2009,” “Recommendation for additional mammography review being prepared,” and “possible fraud at facility referred to OCI for investigation.”

### Locked inspections

When a facility has a new annual inspection and the previous inspection has unresolved noncompliances, the prior inspection will be locked against updates to these noncompliances. A locked inspection can only be unlocked by contacting MPRIS Computer Support at [computersupport@cdrh.fda.gov](mailto:computersupport@cdrh.fda.gov).

### Reports Tab

By clicking the Reports Tab, you can access a number of useful database reports. Below are some of the more useful reports to districts. These reports allow the user to view the report information online or export the information in either Acrobat PDF or Microsoft Excel formats.

- **Inspection History Report:** The Inspection History Report contains facility, inspector, inspection and noncompliance information for inspections of a specified facility or conducted by a specified inspector(s). In addition, users can view data for all inspections conducted in a state, region or nationwide, during the specified date range. NOTE: This report can produce very large result sets and will take a long time to run if the search criteria are too large.
- **Noncompliance Inspection Report:** This report lists all of the facilities issued a particular noncompliance.
- **Facility Count Report:** This report shows a count of certified facilities, grouped by certificate type and accreditation body.
- **Facility Expiration Warning Report:** This report provides a list of facilities with a certification expiration date that is 90 days, 120 days, 180 days or less from the date specified.
- **State Contract Scorecard Report:** This report provides data for negotiating annual inspection contracts with the States. Microsoft Excel is required to run this report.
- **State Inspection Contract Performance Monitor Report:** This report provides state contract information, number of facilities in each state, number of contract inspections completed contract year-to-date, and number of available facilities inspected contract year-to-date. Microsoft Excel is required to run this report.
- **Audit, Federal, and VHA Inspections Report:** This report lists all audit, federal, and VHA inspections. Microsoft Excel is required to run this report.
- **Elapsed Time between Inspections Report:** This report gives the elapsed time, in days, between the two most recent inspections for all facilities within the specified State or nationwide. CAUTION: This report can take a long time to run, especially for nationwide.
- **Facilities Not Inspected in the last Fourteen Months:** This report displays all new facilities that are overdue for inspection (exceeded 14 months since certification) but have never been

inspected, and or facilities that have had a previous inspection but not one in the 14 months since they became certified. By default, when selecting All Facilities, results are sorted first by region.

- **Inspection Summary Report:** This report provides the fiscal year to date numbers of certified facilities, inspections conducted, and inspectors by State and Region with inspection performance goals by State and a statistical summary of noncompliant facilities. Microsoft Excel is required to run this report.
- **Inspections by Selected Inspector(s) Report:** This report displays the inspection ID and date, facility name, city and state of all inspections conducted by the selected inspector(s) in a state, region or nationwide during the specified date range. NOTE: This report can produce very large result sets and will take a long time to run if the search criteria are too large.
- **VHA Facility Inspections Report:** This report gives a list of the Veterans Administration Hospital (VHA) facilities that were inspected during a specified date range.
- **Inspection History Report (FOIA):** The Inspection History Report (FOIA) contains facility, inspector, inspection and noncompliance information for inspections at a specified facility; inspections conducted by a specified inspector(s); or for all inspections conducted in a state, region or nationwide, during the specified date range. The data is produced in a pre-redacted format that can be released under the Freedom of Information Act. NOTE: This report can produce very large result sets and will take a long time to run if the search criteria are too large.
- **Level One and Level Two Status Report:** This report shows the current compliance status vis-à-vis correspondence with the FDA, for facilities who received level one or level two noncompliances within the date range specified.
- **Noncompliance Response Overdue Report:** This report consists of the facilities that have not responded to a noncompliance by the response due date. The report displays the facility ID and name, inspector ID, response due date, number of days overdue, level of noncompliance, and the noncompliance code.
- **Noncompliance Response Pending Report:** This report consists of the facilities that have not responded to a noncompliance. The report displays the facility ID and name, inspector ID, response due date, number of days overdue, level of noncompliance, and the noncompliance code.