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.

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