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