DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

October 30, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Harshad Patel
Chief Executive Officer
AP Diagnostic Imaging, Inc.
1692 Oak Tree Road, Suite 25
Edison, New Jersey 08820

FILE NO.: 03-NWJ-01
Inspection ID NO.: 2277750001

Dear Mr. Patel:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on September 16, 2002. This inspection revealed serious regulatory problems involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA) 42 U.S.C. 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violations of Section 354(f) of the Act [42 U.S.C. 263b(f)], at your facility (identified as Level 1):

- **Processor Quality Control (QC) records were missing for at least 30% of operating days in December 2001 for Processor 1 [redacted]. [See 21 CFR 900.12(e)(1)]**

- **Phantom QC records were missing for 7 weeks for Unit 1, [redacted] mammography unit. [See 21 CFR 900.12(e)(2).] Phantom quality control testing records were missing for the following weeks:**

October 21-27, 2001
November 11-17, 2001
November 18-24, 2001
November 25 - December 01, 2001
December 2-8, 2001
December 9-15, 2001
December 16-22, 2001

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems were identified as Level 1 findings because they identify a failure to comply with significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems, they could compromise the quality of mammography at your facility. They represent serious violations of the law which may result in FDA initiating regulatory action without informal notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography (see Sections 354(h) - (j) of the Act, 42 U.S.C. 263b(h) - (j)).

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. A Level 2 finding indicates that the facility's performance is generally acceptable. However, the inspector did find one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility. These Level 2 findings are:

- **Your facility failed to have adequate procedures for infection control. [See 21 CFR 900.12(e)(13)]**

- **Your facility failed to have adequate procedures for collecting and resolving consumer complaints. [See 21 CFR 900.12(h)]**

- **Corrective actions for Processor QC failures were not documented at least once for Processor 1 ([redacted]). [See 21 CFR 900.12(e)(8)(ii)]**

- **Your facility failed to establish a background optical density operating limit of at least 1.20 for a phantom image test performed on 11/10/01 for Unit 1, [redacted]. [See 21 CFR 900.12(e)(2)(i)]**

- **Your facility failed to have a physicist survey completed within 14 months of the previous survey. The last survey was conducted on 5/4/2001. [See 21 CFR 900(e)(9)(i)]**

- **Your facility failed to produce documentation verifying that [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months. [See 21 CFR900.12(a)(1)(ii)(A)]**

- **Your facility failed to produce documentation verifying that radiologic technologists [redacted], and [redacted] met the continuing education requirement of having completed 15 continuing education units in mammography in 36 months. [See 21 CFR 900.12(a)(2)(iii)(A)]**

- **Your facility failed to produce documentation verifying that radiologic technologists [redacted], and [redacted] met the continuing experience requirement of having performed 200 mammography examinations in a 24-month period. [See 21 CFR 900.12(a)(2)(iv)(A)]**

- **[redacted] of five random reports reviewed did not contain an acceptable assessment category. [See 21 CFR 900.12(c)(1)(iv)]**

- **[redacted] of five random reports reviewed did not have the identification of a qualified interpreting physician. [See 21 CFR 900.12(c)(1)(iii)]**

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during the inspection 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.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District Office

cc: Judy Odonovich, MQSA Inspector
State of New Jersey
Department of Environmental Protection
P.O. Box 415
Trenton, New Jersey 08625

Ramona Chambus, Supervisor, MQSA
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