



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region D1429B

Telephone (973) 331-2907

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

February 17, 1998

WARNING LETTER

RELEASE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Aguirre Imaging Newark
ATTN: Dr. Olga Aguirre
40 Ferry Street
Newark, New Jersey 07105

REVIEWED BY RLB 2/25/98
C.O. DATE

FILE NO.: 98-NWJ-16
Inspection ID NO.: 199885003

Dear Dr. Aguirre:

Your facility was inspected on January 26, 1998, by a representative from the State of New Jersey Bureau of Radiological Health, Radiation Control Program acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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 level 1 finding at your facility:

1. Interpreting physician, [REDACTED] was not licensed by a State to practice medicine because of an expired New Jersey medical license.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further 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, assessing 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, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 and Level 3 repeat noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 and Level 3 repeat noncompliances are:

2. The [REDACTED] film processor was deviating significantly from expected performance measures (speed of 82 for extended processing).
3. For the month of October, 99 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) for the [REDACTED] Processor QC chart were missing.
4. The radiologic technologist, [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3 year period (average of 5 credits/year).
5. Quality Control records/charts were not present for Screen Film Contact and for compression on the [REDACTED] mammography system.

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 receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and

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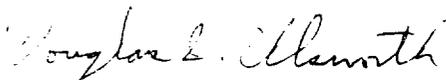
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

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.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may 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 more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Larry Rourk, Regional Radiological Health Representative at (410) 962-3591 ext 119.

Sincerely,


DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

cc: Radiation Protection Programs
Department of Environmental Protection and Energy
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