



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 31992d

Telephone (973) 526-6007

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

November 7, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Satish Shah, MD
Supervisory Radiologist
Community Radiology, P.A.
434 New Jersey Avenue
Absecon, New Jersey 08201

FILE NO.: 02-NWJ-09
Inspection ID NO.: 1077550011

Dear Dr. Shah:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on September 21, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

- Your facility's processor and mammography machine failed to pass two phantom image tests performed by the inspector on the date of your inspection. Both phantom images failed for mass artifacts.

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 a Level 1 finding because it identifies a failure to comply with a significant MQSA requirement.

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In addition, the following Level 2 finding was listed on the inspection report provided to you at the close of the inspection:

- Corrective actions before further exams for weekly phantom image scores that fell outside the allowable regulatory limits were not documented for your facility's mammography unit.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations of the law that 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.

You must act on this matter immediately. Please explain or provide to this office in writing within 15 working days from the date that you receive 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, if the findings relate to quality control or other records.

In addition, we have discussed these findings from your MQSA inspection with your accreditation body, the American College of Radiology (ACR). After an assessment of the serious problems currently present at your facility, we have determined that the quality of mammography may have been severely affected by these conditions. Therefore, we request that you undergo Additional Mammography Review (AMR) by the ACR.

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Since we have discussed your facility problems with the ACR, they are aware of our request that you undergo an AMR. Your facility is responsible for the payment of the costs to the accreditation body for the AMR and that the accreditation body may require a portion or all of this payment prior to the start of the AMR.

You should contact the following individual at the ACR for more information on the AMR at your facility:

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Once the AMR has been completed, the ACR should submit a detailed report to the FDA on the review, and we will provide you with a copy at that time. This report would usually include the total number of examinations evaluated by the physician(s), a list of examinations with films showing image quality problems that may need to be repeated, and an overall assessment by the reviewing physician(s) of the quality of mammography from August 1, 2000 to October 20, 2000.

If the AMR indicates that clinical image problems exist that represent a risk to health, FDA may request that your facility submit a proposed plan for patient notification, including a draft letter to referring physicians and/or patients which would be subject to approval by the FDA.

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 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>.

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If you have any specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591 x159.

Sincerely,

Edward H. Wilkows, Gov
Douglas I. Ellsworth
District Director
New Jersey District Office

cc:

RLB/