



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3396

01-BLT-19

February 23, 2001

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Dr. Mannachanallur R. Ramakrishanan, Radiologist  
Wellmont Lonesome Pine Hospital  
1990 Holton Avenue East  
Big Stone Gap, Virginia 24219

Dear Dr. Ramakrishanan:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on February 13, 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:

- **During 12 processing days in June 2000, your facility processed mammograms when your mammography processor was out of limits.**

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.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation 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.

M. R. Ramakrishnan, M.D.  
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In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to perform corrective actions at least once for processor Quality Control failures by your mammography processor.**
- **Your facility failed to perform corrective action before further patient exams for phantom image test scores performed on your [REDACTED] mammography machine that fell outside of preset parameters.**
- **Radiologic Technologist [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.**
- **Radiologic Technologist [REDACTED] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.**

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 the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

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 technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,



Lee Bowers  
Director, Baltimore District