



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

April 19, 2000

**WARNING LETTER NYK 2000-66**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Roger Soricelli, Senior Vice President  
Genesee Memorial Hospital  
127 North Street  
Batavia, New York 14020

RE: Facility ID: 113746

Dear Mr. Soricelli:

Your facility was inspected on April 13, 2000 by a representative of the New York State Dept. of Health, acting in 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.

- *Phantom QC records were missing for 10 weeks. Specifically, the weeks of May 3, May 10, and the eight weeks from May 24 to July 12, 1999, were missing.*

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 significant MQSA requirements.

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 finding that was listed on the inspection report provided at the close of the inspection. The Level 2 finding is:

- *The phantom QC is not adequate because the image is not taken at the clinical setting.*

It is necessary for you to act on these matters 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, including supporting documentation.
- Each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection 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, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,



Brenda J. Holman  
District Director



cc: Priscilla F. Butler, M.S.  
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