



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

g1554d

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

July 25, 2001

WARNING LETTER NYK 2001-102

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Irene L. Krisztinic, M.D.
Amherst Radiology
777 Maple Road, Suite 3
Williamsville, New York 14221

RE: Facility ID Number 211003

Dear Dr. Krisztinic:

Your facility was inspected on July 18, 2001 by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems 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 repeat Level 2 finding at your facility:

- ***Failure to document corrective action for a failing phantom image score, or a phantom background optical density or density difference outside the allowable regulatory limits before further exams.***

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 repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and it indicates a failure by your facility to implement permanent correction of a problem found during your previous inspection.

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.

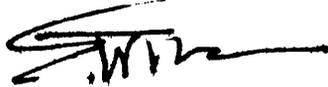
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It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct this violation and to prevent the recurrence of similar violations. Your response should include documents that demonstrate proper record keeping.

Please submit your response to the above issue to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone (716) 551-4461 ext. 3117.

Finally, you should understand 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 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>.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. W. Thomas', with a long horizontal flourish extending to the right.

Edward W. Thomas
Acting District Director

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

cc: Gerald O'Connor
New York State Department of Health
Flanigan Square
Room 530
547 River Street
Troy, NY 12180

cc: Barbara Ignatz
NYS Department of Health
Western Regional Office
584 Delaware Avenue
Buffalo, New York 14202