



DEPARTMENT OF HEALTH & HUMAN SERVICES

m403/n

New York District

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

July 31, 2000

WARNING LETTER NYK 2000-88

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Irene Krisztinicz, M.D.
Amherst Radiology
777 Maple Road
Williamsville, New York 14221

RE: Facility ID Number 211003

Dear Dr. Krisztinicz:

Your facility was inspected on July 13, 2000 by a representative of the New York State Department of Health, 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:

- *The system to communicate results is not adequate because there is no system in place to provide timely lay summaries.*

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; obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- *Corrective actions for processor QC failures were not documented at least once for the [REDACTED] processor.*
- *Mammograms were processed in the [REDACTED] processor when it was out of limits on four days.*
- *Processor QC records were missing for three consecutive days.*
- *Processor QC records were missing three out of 21 days of operation or 14% of the time in the month of January 2000.*
- *Corrective action for a failing image score was not documented before further exams were performed on the [REDACTED] mammography unit.*
- *One of nine reports reviewed at random did not contain an assessment category.*
- *There was no designated reviewing interpreting physician.*

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 these violations and 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, Olympic Towers, Suite 100, Buffalo, New York 14202.

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,


Brenda J. Holman
District Director

Amherst Radiology
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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
584 Delaware Avenue
Buffalo, New York 14202