



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

July 22, 1998

WARNING LETTER BUF 98-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Chandler Ralph, CEO
Adirondack Medical Center - Lake Placid
Church Street
Lake Placid, New York 12946

RE: Facility ID Number 214171

Dear Ms. Ralph:

Your facility was inspected on June 18, 1998 by a representative of the New York State Department 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 a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

The number of masses scored in the phantom image was 0.5 and did not meet the required number. The minimum number required for masses is 3.

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 presents a violations 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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In addition, there was a Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 noncompliance is:

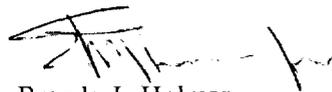
The number of fibrils scored in the phantom image was 3.5 and did not meet the required number. The minimum number required for fibrils is 4.

We hereby acknowledge receipt of a response dated June 24, 1998, from Jan Vize, LRT(R)(M). Ms. Vize submitted to us an explanation including service reports from the processor company, and a new phantom image film. Our evaluation of this material is that it satisfies correction of the above two cited conditions, and it appears your facility now meets its MQSA obligations. However, policy dictates you be advised formally of the conditions via this Warning Letter.

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>.

If you have specific questions about the mammography deficiencies found during the inspection of your facility, you may contact Murray L. Kurzman, Radiation Programs Manager, at 516/921-2035. If you have questions about Compliance issues related to the inspectional findings, contact James M. Kewley, Compliance Officer, at the above address, or by telephone at 716/551-4461, extension 3128.

Sincerely,



Brenda J. Holman
District Director

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cc: Pamela A. Wilcox-Buchalla, RN, MBA
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