DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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June 17, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Reference: Warning Letter SEA 02-50
Inspection ID: 1208160009

Mr. William R. Hunter, R.T., Radiology Administrator
Livingston Memorial Hospital
504 S. 13th Street
Livingston, Montana 59047

WARNING LETTER

Dear Mr. Hunter:

We are writing to you because on May 28, 2002, your facility was inspected by Warren Freier, a representative of the State of North Dakota, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations (CFR), Part 900, 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 2 findings at your facility:

1. Corrective action before further examination was not documented for a phantom background optical density outside the allowable regulatory limits for unit 2, manufactured by Instrumentarium Imaging Corp. [see 21 CFR 900.11(e)]. The incidents occurred on July 31 and August 10, 2001. This is a repeat finding.

2. Mammograms were processed in the Kodak, RP X-OMAT M6B, 6AN, 6AW processor when it was out of limits on at least two but less than five days (July 12 and September 26, 2001). [see 21 CFR 900.11(e)]. This is a repeat finding.

3. Two of five random reports reviewed did not contain an acceptable assessment category [see 21 CFR 900.11(c)(2)].

4. Your facility failed to perform the medical outcomes analysis and audit to include a correlation of pathology results with each interpreting physician's mammography report. Additionally, the audit analysis was not performed at a frequency of at least once every twelve months [see 21 CFR 900.11(f)].

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law that may result in FDA imposing statutory sanctions. These sanctions include, but are not limited to, placing your facility under a Directed Plan of Correction and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the MQSA Standards; suspension or revocation of your facility's FDA certificate; or to seek a court injunction against further mammography (see sections 263b(h) through (j) of the MQSA).

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 received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: patient names or identification should be deleted from any copies submitted unless the findings also relate to patient notification).

Please submit your response to the U.S. Food & Drug Administration, Attention - Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

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 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,

Charles M. Breen
District Director

CC: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
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American College of Radiology
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