DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Telephone: 425-486-8788
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August 7, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Reference: Warning Letter SEA 02-58
Inspection ID: 1413900009

Ms. Ginny Prentice, RT, MQSA Supervisor
TRA Medical Imaging Centers – Tacoma
2202 S. Cedar Street, Suite 200
Tacoma, Washington 98405

WARNING LETTER

Dear Ms. Prentice:

We are writing to you because on July 25, 2002, your facility was inspected by Mark Radonich, a representative of the State of Washington, 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:

Processor quality control records for the Kodak, X-OMAT, M35 processor, were missing for at least 30% of operating days, including at least 5 consecutive days, for the period of November 7-17, 2001 [see 21 CFR § 900.12(e)].

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 serious 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, the 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 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. Phantom QC records for units 5-8 (each identified as Lorad Medical Systems Inc., MIV x-ray units) were missing for the following periods of time [see 21 CFR § 900.12(e)(2)(iii)]:

   Room 1 (unit 8) - November 21, 2001; December 31, 2001 to January 4, 2002; and April 8 – 12, 2002.
   Room 2 (unit 6) - December 31, 2001 to January 4, 2002; and April 8 – 12, 2002.
   Room 3 (unit 5) - December 31, 2001 to January 4, 2002; January 21-25, 2002; and May 27 to June 1, 2002.
   Room 4 (unit 7) - December 31, 2001 to January 4, 2002; and January 21-25, 2002.

2. There was no documentation verifying that radiologic technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations during the 24 months preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two [see 21 CFR § 900.12(a)(2)(iv)(A)].

3. Corrective actions for QC failures of the M35 processor were not documented when the sensitometer was unavailable November 7-17, 2001 [see 21 CFR § 900.12(e)].

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 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.
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