



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m49651n
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 6, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-10

James F. Kadlec, M.D.
Women's Diagnostic Center at Enumclaw Community Hospital
1450 Battersby Avenue
PO Box 218
Enumclaw, Washington 98022

Re: Inspection # 1626510006

WARNING LETTER

Dear Dr. Kadlec:

We are writing to you because on October 30, 2000, a representative of the State of Washington, Scott Mantyla, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. 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 two level 1 findings at your facility:

1. Phantom QC records were missing for 12 weeks for unit 3, _____ room Mammo;
2. Mammograms were processed in processor _____ room Mammo at site Women's Diagnostic Center, when it was out of limits on 12 days.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

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 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

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comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

Three Level 2 findings were found and these were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 3, _____, room Mammo;
2. Corrective actions for processor QC failures were not documented at least once for processor _____, room Mammo at site Women's Diagnostic Center,
3. The time period between the previous and current surveys for x-ray unit 3, _____ exceeds 14 months.

A letter dated November 24, 2000, from Ms. Roberta Dutcher, Administrative Manager Imaging Services, responding to these Level 1 and 2 findings was received. Based on this response, your facility has now met the annual MQSA inspection requirement. The corrective actions you have implemented will be evaluated during your next inspection.

If you chose to respond further to these findings, 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