



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
FAX: 425-483-4996

September 14, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-99

Leon T. Davis, M.D.
Okanogan Douglas District Hospital
Radiology Department
703 NW Second Street
Brewster, Washington 98812

RE: Inspection ID - 1290150007

WARNING LETTER

Dear Dr. Davis:

We are writing to you because on July 26, 2000, a representative of the State of Washington, Kelly Cameron, 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. Please excuse the delay in responding to this inspection.

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 QC records were missing 5 out of 16 days of operation in January 2000. Processor QC records missing 31%, for processor 0000000001, [REDACTED] room Main at site Okanogan Douglas District Hospital.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

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

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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.

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). *

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:

- 4 of 5 random reports reviewed did not contain an assessment category for site Okanogan Douglas District Hospital.
- Processor QC records were missing 3 consecutive days for processor 0000000001 [REDACTED] room Main at site Okanogan Douglas District Hospital.
- Corrective action for a failing image score (before further exams) was not documented for unit 1, [REDACTED] room Mammo.

Please submit your response to Thomas S. Piekarski, Compliance Officer, at the above mailing address.

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,


for Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.