



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
FAX: 425-483-4996

March 6, 2002

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Reference: Warning Letter SEA 02-34
Inspection ID: 2105340006

Carol Devaney, Hospital Administrator
Manilaq Health Center
Fifth & Grizzley
Post Office Box 43
Kotzebue, Alaska 99752

WARNING LETTER

Dear Ms. Devaney:

We are writing to you because on February 20, 2002, your facility was inspected by Clyde E. Pearce, a representative of the State of Alaska, 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:

There is no system in place to communicate assessments of either "suspicious" or "highly suggestive of malignancy" to each patient as soon as possible after the mammographic examination.

The specific problems 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. There is no physician designated who has the general responsibility of ensuring that the quality assurance program meets all of the MQSA requirements.
2. The facility failed to produce documentation verifying that the medical physicist [REDACTED], met the *continuing experience* requirement of having surveyed at least 2 mammography facilities and a total of at least 6 mammography units in 24 months. Also, there was no documentation that he had met the *continuing education* requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.
3. Documentation verifying that the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months was not available for radiologic technologists [REDACTED] (6 CEU's in 36 months) and [REDACTED] (13 CEU's in 36 months).

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).*

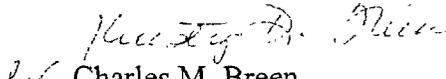
Please submit your response to U.S. Food & Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

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.

Carol Devaney, Hospital Administrator
Manilaq Health Center, Kotzebue, Alaska
Warning Letter SEA 02-34

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

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

CC: