



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

Telephone: 425-486-8788
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August 29, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA-00-94

John T. Burke, M.D.
North Cascade Family Physicians
1320 E. Division Street
Mt. Vernon, Washington 98274

RE: Inspection ID: 2117630005

WARNING LETTER

Dear Dr. Burke:

We are writing to you because on July 16, 1996, Bill Van Pelt, a representative of the State of Washington, 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 level 1 finding at your facility:

The communication of results is not adequate for North Cascade Family Physicians because there is no system in place to provide timely lay summaries, and there is no system in place to communicate serious or highly suggestive cases as soon as possible.

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

John T. Burke, M.D.
North Cascade Family Physicians, Mt. Vernon, Washington
Re: Warning Letter SEA-00-94
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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 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, telephone number 800-838-7715 or through the Internet at <http://www/fda.gov>.

Sincerely,



Charles M. Breen
District Director

Cc: Bill Van Pelt
Washington State Radiation Control
2409 E. Valley Street
Seattle, Washington 98112

Priscilla F. Butler, M.S.
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