



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m3059n

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

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

October 13, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-08

Karen Rochelle, M.D.
Breast Care Center Sedro-Woolley
1971 Highway 20
Sedro-Woolley, Washington 98284

WARNING LETTER

RE: Inspection ID - 1641940005

Dear Dr. Rochelle:

We are writing to you because on October 5, 1999, your facility was inspected by a representative of the State of Washington, acting in 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 and level 2 findings at your facility:

Level 1: Phantom QC records were missing for 4 weeks for unit 2, [REDACTED] room Mammo Room.

Level 2: The time period between the previous and current surveys for x-ray unit 2, [REDACTED] exceeds 14 months.

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

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

Karen Rochelle, M.D.
Breast Care Center Sedro-Woolley, WA
Page 2

\$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.

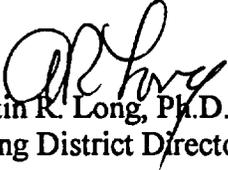
It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- 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 Richard S. Andros, Compliance Officer, Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021.

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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

Sincerely yours,


Austin R. Long, Ph.D.
Acting District Director

copy: Bill Van Pelt
WA Department of Health
X-ray Protection
2409 East Valley
Seattle, Washington 98112

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091