



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M3060N

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 00-07

Neil F. Schneider, M.D.  
Summit Radiology  
861 Poplar Place South  
Seattle, Washington 98144

WARNING LETTER

RE: Inspection ID - 1709440005

Dear Dr. Schneider:

We are writing to you because on October 4, 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: The system to communicate results is not adequate for site Summit Radiology because:

- There is no system in place to provide timely medical reports;
- There is no system in place to provide timely lay summaries;
- There is no system in place to communicate serious or highly suggestive cases immediately.

Level 2: 10 of 10 random reports reviewed did not contain an assessment category for site: Summit Radiology

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

Level 2: The measured fog density is equal to 0.1 for darkroom darkroom at site: Summit Radiology.

**Level 2:** There is no written procedure for handling consumer complaints at site: Summit Radiology.

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 \$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 23<sup>rd</sup> 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