



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

August 25, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-33

Georgian Smith, M.D.
University of Washington Medical Center
Roosevelt II Radiology
4245 Roosevelt Way N.E. (XB-45)
Seattle, Washington 98105

WARNING LETTER

RE: Inspection ID - 2072900004

Dear Dr. Smith:

We are writing to you because on August 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 University of Washington Medical Center Roosevelt II Radiology because there is no system in place to communicate serious or highly suggestive cases immediately.

Level 2: There is no written procedure for infection control at site University of Washington Medical Center Roosevelt II Radiology.

Level 2: There was no designated reviewing interpreting physician for site University of Washington Medical Center Roosevelt II Radiology.

Level 2: The measured fog density is equal to 0.53 for darkroom E-313 at site University of Washington Medical Center Roosevelt II Radiology.

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Level 2: Corrective actions for processor QC failures were not documented at least once for processor [REDACTED], room E313 at site University of Washington Medical Center Roosevelt II Radiology.

Level 2: There is no written procedure for handling consumer complaints at site University of Washington Medical Center Roosevelt II 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).

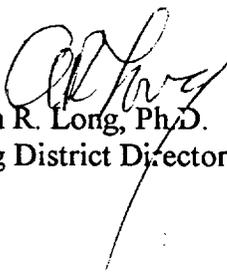
Please submit your response to Richard S. Andros, Compliance Officer, Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021.

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>.

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If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Richard S. Andros at (425) 483-4980.

Sincerely yours,



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

copy: Bill VanPelt
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Seattle, Washington 98112

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