



Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell WA 98041-3012

November 14, 1996

VIA FEDERAL EXPRESS

Telephone: 206-486-8788
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In reply refer to Warning Letter SEA 97-04

Ann Grundell, Technical Manager
Women's Health Imaging
12911 120th Avenue NE, Suite E-10
Kirkland, Washington 98034

WARNING LETTER

Dear Ms. Grundell:

Your facility was inspected on November 8, 1996, (inspection ID 1957680002) by a representative of the State of Washington radiation control program, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. The interpreting physician is unqualified to interpret mammograms due to the lack of both board certification from any of the approved boards and two months full-time training in the interpretation of mammograms: [REDACTED]

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

2. The interpreting physician did not meet the continuing experience requirement, i.e. interpreting an average of 40 patient examinations per month over a 24 month period preceding the date of the completion of initial requirement: [REDACTED]
3. The interpreting physician does not have the initial training of 40 hours of continuing medical education in mammography: [REDACTED]
4. The interpreting physician's initial experience was

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inadequate (reading and interpreting mammograms from the
examinations of at least 240 patients in 6 months):
~~_____~~

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 and regulations under the Act. The specific violation noted in this letter and in the printed summary of test results and the inspection observations issued at the close of the inspection may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography. You are responsible for investigating and determining the causes of the violations from the quality standards.

You should take prompt action to correct these deficiencies. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. A facility may be subject to civil money penalties up to \$10,000 for each failure to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to comply with the Standards. Continuation of any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

You should be advised that FDA regulations do not prevent enforcement of requirements under State laws and regulations. In some cases, State requirements may be more stringent than requirements under FDA regulations. You may receive a letter or notification from the State advising you of this fact. When conducting corrective action, you should take into consideration the more stringent State requirements, if any.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. In your response, you must also respond to the items on your printout. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. If your response includes equipment test results, please include equipment settings (including technique factors), raw test data, and calculated final results, where appropriate. If the noncompliances found relate to quality control or other records, example records showing complaint record keeping should be included with your submission (patient