DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 24, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warning Letter SEA 03-02
Re: MQSA Inspection ID Number 1793820008

Kim Howe
Radiology Supervisor
St. Joseph Medical Center
1717 South "J" Street
P.O. Box 2197
Tacoma, WA 98401-2197

WARNING LETTER

Dear Ms. Howe:

On October 8, 2002, a representative of the State of Washington, acting on behalf of the Food and Drug Administration ("FDA"), inspected your facility: Gig Harbor Medical Clinic, 6401 Kimball Drive, Gig Harbor, Washington. This inspection revealed a serious regulatory problem regarding the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code ("U.S.C."), your facility must meet specific requirements to practice mammography. These requirements help to protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed a violation of the MQSA at your facility. This violation was noted on the MQSA Facility Inspection Report (*"Important Information about your Mammography Quality Standards Act (MQSA) Inspection"*) that the inspector left with Tina Rodriguez, Staff Technologist, at your facility at the close of the inspection on October 8, 2002. The following Level 1 finding was noted:

Your facility does not have adequate procedures to ensure that results of assessments that are "suspicious" or "highly suggestive of malignancy" are communicated to patients as soon as possible. 21 C.F.R. § 900.12(c)(2)

Because this violation may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- seeking civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementation of those steps;

3. sample records that demonstrate proper record keeping procedures. **Note: patient names and other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.**

Your response also should address the actions you have taken to correct the following objectionable conditions observed during our recent inspection. These Level 2 findings are:

1. Procedures for infection control are inadequate in that they do not reflect the recommendations of the x-ray unit manufacturer. 21 C.F.R. § 900.12 (e)(13)

2. There was no documentation verifying that the interpreting physician, [redacted] met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months. 21 C.F.R. § 900.12(a)(1)(ii)

Please submit your response to this letter to:

U.S. Food & Drug Administration, Attention Lisa M. Althar, Compliance Officer, 22201 23rd Drive Southeast, Bothell, Washington 98021-4421, 425-483-4940 (phone) and 425-483-4760 (fax).

Please send a copy of your response to:

State of Washington
Radiation Control Office
2409 East Valley Street
Seattle, Washington 98112

There are many requirements applicable to mammography facilities. This letter pertains only to findings related to the recent inspection of your facility and does not necessarily address other obligations you may 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/cdrh/mammography/index.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, you may contact Lisa M. Althar, Compliance Officer, at 425-483-4940.

Sincerely yours,

Charles M. Breen
District Director

cc: [redacted]

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