DEPARTMENT OF HEALTH AND HUMAN SERVICES

93169

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

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

March 22, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Reference: Warning Letter SEA 02-37
Inspection ID: 1165330008

Stephan Imbriaco, Administrator
Highline Community Hospital
16259 Sylvester Road, SW
Seattle, Washington 98166

WARNING LETTER

Dear Mr. Imbriaco:

We are writing to you because on March 6, 2002, your facility was inspected by Bill Van Pelt, a representative of the State of Washington, acting on 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 findings at your facility:

1. There is no system in place to provide timely lay summaries to patients, including those with assessments of "suspicious" or "highly suggestive of malignancy" who should be notified of these results as soon as possible.

2. Phantom QC records were missing for at least four weeks for each of the following X-ray units: unit 3, model HFX Plus, manufactured by Fisher Imaging Corporation; units 4 and 5, models 800, manufactured by General Electric Co. (GE Medical Systems).

3. Processor QC records for the month of November 2001, were missing for at least 30% of operating days and for at least 5 consecutive days, for the Kodak, RP X-OMAT M6B, 6AN, 6AW processor.

4. There was no documentation verifying that the interpreting physician, [redacted], met the initial requirement of holding a valid State license to practice medicine.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement. 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.

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

1. A medical outcomes audit was not performed annually on the disposition of all positive mammograms for all interpreting physicians, collectively and individually, at your facility.

2. A medical outcomes audit was not performed for any cases of breast cancer among those women imaged at the facility that subsequently become known to the facility.

3. There was no documentation verifying that the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in a 36 month period were met by the interpreting physicians, [redacted] (11 CME's in 36 months), or [redacted] (12 CME's in 36 months).

4. Corrective actions for processor QC failures were not documented on at least one occasion for the Kodak RP X-OMAT M6B, 6AN, 6AW processor.

5. Mammograms were processed using the Kodak RP X-OMAT M6B,6AN,6AW processor when it was out of limits on at least 2 but less than 5 days in March and May 2001.

6. Corrective action before further exams, for a phantom background optical density outside the allowable regulatory limits, was not documented for unit 4, model 800, manufactured by General Electric Co. (GE Medical Systems).

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 U.S. Food & Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

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

Sincerely,

Kristen B. Rees

for Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.

CC: [redacted]