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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

April 7, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warning Letter SEA 03-16

Re: MQSA Inspection ID Number 1606550008

Terry Fletchall, CEO
Santiam Memorial Hospital
1401 North Tenth Avenue
Stayton, Oregon 97383

WARNING LETTER

Dear Mr. Fletchall:

On February 12, 2003, a representative of the State of Oregon, acting on behalf of the Food and Drug Administration ("FDA"), inspected your facility at 1401 North Tenth Avenue, Stayton, Oregon. This inspection revealed serious regulatory problems 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.

This inspection revealed violations of MQSA at your facility. The violations were noted on the MQSA Facility Inspection Report (*"Important Information about your Mammography Quality Standards Act (MQSA) Inspection"*) that the inspector left with Valerie Young, Director of Radiology, at your facility at the close of the inspection on February 12, 2003. The following Level 1 findings were noted:

1) Daily quality control testing was not performed for the [redacted] or [redacted] processor for the period of January 28-31, 2002, and February 1, 4-8, 11-15, 2002. 21 C.F.R. § 900.12(e). In fact, processor quality control could not be performed because the only sensitometer and densitometer for this processor had been sent out of the facility for calibration.

2) Weekly phantom quality control testing was not performed for X-Ray Unit 2, [redacted], in the Mammo Room, during the following weeks: January 28-February 1, 2002; February 4-8, 2002; and February 11-15, 2002. 21 C.F.R. § 900.12(e)(2).

The following Level 2 findings were noted:

1) Infection control procedures to be followed for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials are inadequate. Your procedure does not describe the specific infection control product '[redacted] and its proper use, including that the contact time of ten minutes is necessary for disinfection. The current method is to spray the product on and immediately wipe off. In addition, there is no documentation as to when disinfection was performed. 21 C.F.R. § 900.12 (e)(13).

2) Appropriate corrective action was not performed before further exams for a failing phantom image score for X-Ray Unit 2, [redacted], in the Mammo Room. Corrective action taken was not in accordance with the equipment manufacturer's requirements. 21 C.F.R. § 900.12 (e)(8).

3) The current annual medical physicist's survey report was conducted approximately 15 months and three weeks after the previous survey report for X-Ray Unit 2, [redacted], in the Mammo Room, when 21 C.F.R. § 900.12(e)(9) requires such surveys to be conducted at least once a year. In addition, the medical physicist determined that the light to x-ray field was misaligned and required servicing as soon as possible. There is no documentation that the realignment was ever accomplished.

Because these violations 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
- seeking a court injunction against your facility

see 42 U.S.C. §§ 263b(h) through (j)

You should respond in writing to FDA within fifteen (15) working days from the date you receive 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**)

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 also send a copy of your response to:

Robert Rapcinski, State of Oregon Health Services, Radiation Protection Services, 800 Northeast Oregon Street, Suite 260, Portland, Oregon 97232.

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: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Robert Rapcinski
State of Oregon Health Services
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