DEPARTMENT OF HEALTH AND HUMAN SERVICES

93809

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

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

January 23, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warning Letter SEA 03-12

Re: MQSA Inspection ID Number 1834000010 – Curry General Hospital
MQSA Inspection ID Number 2280750001 – Brookings Clinic

Virginia Hochberg, CEO
Hospital Administrator
Curry General Hospital
94220 Fourth Street
Gold Beach, Oregon 97444

WARNING LETTER

Dear Ms. Hochberg:

On December 10, 2002, a representative of the State of Oregon, acting on behalf of the Food and Drug Administration ("FDA"), inspected your facilities at Curry General Hospital, 94220 Fourth Street, Gold Beach, Oregon, and Brookings Clinic, 412 Alder Street, Brookings, Oregon. These inspections revealed serious regulatory problems regarding the conduct of mammography at your facilities. 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 facilities 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.

These inspections revealed violations of MQSA at your facilities. The violations were noted on the MQSA Facility Inspection Reports (*"Important Information about your Mammography Quality Standards Act (MQSA) Inspection"*) that the inspector left with Aaron Robbins, Chief Technologist, at your facilities at the close of the inspections on December 10, 2002. The following Level 1 finding was noted:

Your facility utilized a film processor, [redacted], in the Darkroom at Curry General Hospital, to develop mammograms for at least five days when the processor was out of limits. The source of the problem was not identified and corrective actions were not taken during that time. 21 C.F.R. § 900.12(e)(8). This processor is used to develop mammograms for both Curry General Hospital and Brookings Clinic.

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
- seeking a court injunction against your facility

see 42 U.S.C. §§ 263b(h) through (j)

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

1. Corrective action was not documented before performing further exams after the mammography system Unit 2, [redacted] in the Hospital Mammo Room, Curry General Hospital, failed the density test at least once. 21 C.F.R. § 900.12 (e)(8).

2. Corrective actions were not documented when the fixer retention test was not performed at the required interval for the mammography film processor [redacted] in the Darkroom at Curry General Hospital. This processor is used to develop mammograms for both Curry General Hospital and Brookings Clinic. 21 C.F.R. § 900.12 (e)(8).

3. The medical audit and outcome analysis was not made for each individual interpreting physician who interprets for both Curry General Hospital and Brookings Clinic. 21 C.F.R. § 900.12(f)(1).

4. There was no documentation verifying that radiologic technologist [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in the last 36 months. 21 C.F.R. § 900.12(a)(2)(iii).

5. There is no designated interpreting physician to review the medical outcomes audit data for Curry General Hospital or Brookings Clinic. 21 C.F.R. § 900.12(f)(3).

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**)

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

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