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DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

November 16, 1999

via Federal Express

MQSA Facility ID: 150391
Inspection ID: 1503910006
FDA Reference #: 2951899

James E. Yamasaki, M.D.
Chief Radiologist
Central Medical Clinic
321 North Kuakini, Suite 201
Honolulu, Hawaii 96817

Dear Dr. Yamasaki,

We are writing to you because on September 24, 1999, your facility was inspected by a representative of the State of Hawaii, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography procedures performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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 finding at your facility, which represent departures from Title 21, Code of Federal Regulations (CFR), Part 900.

Level 1: Phantom quality control records were missing for four consecutive weeks, during May 1999, for unit 2, [REDACTED], located in room Mammo. The requirement is to perform this test at least weekly. {21CFR§900.12(e)(2)}

The specific problem noted above appeared on your initial MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

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.

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:

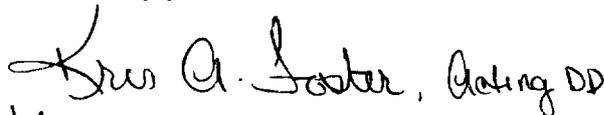
- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; 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:

John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel)
510-337-6702 (fax)

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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. John M. Doucette at 510-337-6793 or 781-729-5700.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District Office

cc:

Russell Takata, Supervisor, Radiation Branch
Lynn Nakasone, MQSA Inspector (2039)
Pamela A. Wilcox-Buchalla, R.N., M.B.A.