



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3047n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94602-7070
Telephone: 510/327-6700

VIA FEDERAL EXPRESS

June 23, 2000

Our Reference No. 2952779

Mr. Keith Miyashiro
Director of Imaging Services
Straub Clinic - Mililani
95-1249 Meheula Parkway, #C2
Mililani, HI 96789

WARNING LETTER

Dear Mr. Miyashiro:

We are writing you because on March 17, 2000, representatives of the State of Hawaii inspected your facility. The State of Hawaii Department of Health referred this matter to the Food and Drug Administration because the 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 finding at your firm:

21 CFR part 900.11(a) Requirements for Certification

After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart.

Straub Clinic - Mililani performed mammography without a valid certificate from September 23, 1999 until March 16, 2000.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law

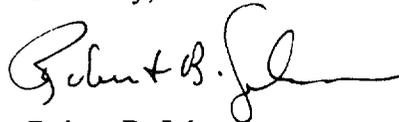
which may result in FDA taking regulatory actions without further notice to you. These actions include, but are not limited to, assessing civil money penalties up to \$10,000 or obtaining a court injunction against further mammography.

We acknowledge that your facility has applied for accreditation and is currently operating under an Interim Notice. This letter serves as documentation of the violation stipulated above.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to the issue of the performance of mammography under a valid FDA MQSA certificate 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 Russell A. Campbell, Compliance Office, San Francisco District, 1431 Harbor Bay Parkway, Alameda, CA 94502 (tel.: 510-337-6861).

Sincerely,



Robert B. Johnson
Acting Director
San Francisco District

cc: Jon Grimes
President and Chief Executive Officer
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Russell S. Takata, Supervisor, Radiation Section
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