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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-02-28

February 11, 2002

FACILITY ID # 144428

Jim Cruckshank, Administrator
University Hospital and Medical Center
7201 North University Drive
Tamarac, Florida 33321

Dear Mr. Cruckshank:

We are writing to you because on January 8, 2002 a representative of the State of FL, acting in behalf of the Food and Drug Administration (FDA) inspected your facility. 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 REPEAT level 2 violation(s) at your facility.

Level 2 – REPEAT: Your facility failed to produce documents verifying that the interpreting physicians [REDACTED], [REDACTED], and [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

Additionally, the medical audit and outcome analysis was not performed annually at your site.

A finding is considered a repeat finding, if the same type of violation was cited during the previous inspection, whether or not the finding is associated with the same piece of equipment (x-ray unit, processor, darkroom) or the same personnel in any given category.

The specific problem(s) noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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.

We have received and reviewed your letter dated January 23, 2002 signed by Jacqui Cotterall, Managing Director, and find that your firm's response addresses our concerns for the most part. The response, however, does not address the events that led up to these repeat violations. It is necessary for you to act on this matter immediately and establish procedures to assure this deficiency is not repeated.

Please submit your response to Timothy J. Couzins, Compliance Officer, U.S. Food & Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

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 D. Janneth Caycedo, Consumer Safety Officer, Food and Drug Administration, Boca Raton Resident Post, 1499 W. Palmetto Park Road, Ste. 110, Boca Raton, FL 33486 or call 561-338-5236, ext 23.

Sincerely yours,



Emma R. Singleton
Director, Florida District