



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

October 5, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2000-04

Alan B. Greenfield, M.D.
Medical Director
Rockaway Open MRI and Diagnostic Imaging
114-04 Beach Channel Drive
Rockaway Beach, NY 11694

Facility ID: 223551

Dear Dr. Greenfield:

Your facility was inspected on August 31, 2000 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. 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 Level 1 finding at your facility:

- *The medical physicist, [REDACTED] did not have a Masters degree or higher in a physical science, with 20 semester hours in physics.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

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 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, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

Rockaway Open MRI and Diagnostic Imaging
Warning Letter NYK-2000-04

There were also Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings were:

- (1) There is no written procedure for handling consumer complaints at your facility.***
- (2) There is no written procedure for infection control at your facility.***
- (3) As an interpreting physician, you did not meet the requirement of having initial experience in mammography by having read or interpreted 240 patient examinations in a 6 month period.***
- (4) As an interpreting physician, you did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.***
- (5) As an interpreting physician, you did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.***

It is necessary for you to act on these matters 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 to correct the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's

Rockaway Open MRI and Diagnostic Imaging
Warning Letter NYK-2000-04

requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert L. Hart". The signature is written in a cursive style with a large, prominent "R" and "H".

Robert L. Hart
Acting District Director
New York District

Rockaway Open MRI and Diagnostic Imaging
Warning Letter NYK-2000-04

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: Dorothy Pender
New York City Department of Health
Bureau of Radiological Health
2 Lafayette Street
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cc: Abraham Thomas
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