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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

March 4, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: MQSA Inspection I.D.: #185553
FEI: #1000521780

Charles M. Paccinnini
Facility Manager
Canal Radiology Associates, P.C.
212 Canal Street / Suite #206
New York, New York 10013

Re: NYK-2004-06

Dear Mr. Paccinnini:

On August 20, 2003, a representative of the State of New York, acting on behalf of the Food & Drug Administration (FDA), inspected your facility Canal Radiology Associates, P.C. This inspection revealed serious problems involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that Inspector, Ceferina Ramos, mailed to your facility on August 22, 2003.

The violations noted are identified below:

Level 1:

Phantom QC records were missing for at least four (4) weeks (01/03 to 04/03 no films; month of 05/03 no films and no charting done) for Unit #2, [redacted] ELIT, located in the Mammography Room at the site [See 21 CFR 900.12(e)(2)].

Level 2:

The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow such procedures when they were required at the site Canal Radiology Associates, P.C. [See 21 CFR 900.12(h)].

You failed to comply with the requirements for quality assurance mammography medical outcomes auditing [See 21 CFR 900.12(f)]. Specifically, your facility did not follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's report, individually and collectively for all interpreting physicians at your facility.

On August 22, 2003, we received your facility's response to the MQSA Facility Inspection Report. Your response was inadequate in that: (1) your facility's own charting indicated that all 13 phantom films failed due to substandard object scores. (Our review of these same films showed that only 10 of the 13 images failed with 1 passing and 2 found to be border line. However, for most of the films the images failed for a different object than that specified by your facility); (2) with respect to the complaint handling procedures, our review of the procedures submitted revealed that they failed to include directives to provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

On January 29, 2004, a representative of the FDA performed an MQSA follow-up inspection of your facility. This MQSA follow-up inspection revealed that your facility failed to correct the violations identified below. In addition, this inspection revealed new violations, which are also listed below:

Level 1:

Mammograms were processed in processor #0000000001, [redacted] located in the Mammography Room at the site when it was out of limits for at least five (5) days (08/27/03 to 08/31/03) [See 21 CFR 900.12(e)(1) & (8)].

Level 2 (*repeat*):

Phantom QC records were missing for at least two (2) weeks (11/24/03 to 12/15/03), but less than four (4) weeks for Unit #2, [redacted] ELIT, located in the Mammography Room at the site [See 21 CFR 900.12(e)(2)] (***REPEAT***).

Level 2:

The Phantom Image score (using an FDA – Approved Mammography Phantom) is at least two (2) masses, but less than three (3) masses for Unit #2, [redacted] ELIT, located in the Mammography Room at the site [See 21 CFR 900.12(e)(2)(iii)].

The Phantom Image score (using an FDA – Approved Mammography Phantom) is at least three (3) fibers, but less than four (4) fibers for Unit #2, [redacted] ELIT, located in the Mammography Room at the site [See 21 CFR 900.12(e)(2)(iii)].

Corrective action for processor QC failures were not documented at least once for processor #0000000001 [redacted] located in the Mammography Room at the site [See 21 CFR 900.12(e)(8)(ii)].

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for Unit #2, [redacted] ELIT, located in the Mammography Room at the site [See 21 CFR 900.12(e)(8)(ii)].

Level 3 (*repeat*):

The QA program is inadequate at the site because of the missing and/or incomplete item listed: [See 21 CFR 900.12(d)(1)] (***REPEAT***)

- Personnel Responsibilities

The fixer retention QC is not adequate for processor #0000000001, [redacted] at the site because of the following: [See 21 CFR 900.12(e)(3)(i)] (***REPEAT***)

- The fixer retention QC tests were not done at the required frequency, as noted for the main processor used from 11/26/03 to 12/05/03 without testing fixer retention.

The compression device QC is not adequate for Unit #2, [redacted] ELIT, located in the Mammography Room at the site [See 21 CFR 900.12(e)(4)(iii)] ***(REPEAT)***.

- The QC tests on 01/17/03, 06/19/03 & 10/16/03, were not done at the required frequency and under automatic mode as required by MQSA.

Because the continued failure to resolve these violations may be indicative 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 up to $10,000 for each failure to substantially comply with the 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)-(j) and CFR 900.12(j)***.

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should address the findings listed above and 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 implementing those steps; and
3. the sample records that demonstrate proper record keeping procedures.

NOTE: ***Patient names and/or any other information that would likely reveal the patient's identity should be deleted from any copies of records you submit to the agency.***

Please submit your written response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, New York District, 158 – 15 Liberty Avenue, Jamaica, New York 11433 – 1034.

Please submit a copy of your response to this letter to:

Dorothy Pender
New York City Department of Health
Bureau of Radiological Health
2 Lafayette Street / 11th Floor
New York, New York 10007

Finally, you should understand that there are many requirements pertaining to mammography operations. This letter pertains only to violations related to the recent inspection of your facility 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 & 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 additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Arthur S. Williams, Jr., Compliance Officer, at (718)/662-5568.

Sincerely yours,

Jerome G. Woyshner
District Director
New York District