DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-31

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 9, 2002

Ms. Julia Bokuniewicz
Diagnostic Center Manager
Romeo Plank Diagnostic Center
46591 Romeo Plank Road, Suite 135
Macomb, MI 48044

Dear Ms. Bokuniewicz:

Your facility was inspected on June 17, 2002 by a representative of the U.S. Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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:

1. Clinical images submitted to the American College of Radiology (ACR) as part of the reaccredidation application for one (1) study representing dense breasts (predominance of glandular tissue) had not been interpreted by a qualified interpreting physician prior to submission to the ACR. This is in violation of Title 21 Code of Federal Regulations § 900.4 (c) (4).

2. There was no written medical report for the results of the mammographic exam conducted on 12/10/2002 and submitted to the ACR as part of the reaccredidation application. This is in violation of Title 21 Code of Federal Regulations § 900.12 (c) (1).

3. There was no summary of the mammography exam, for the exam conducted on 12/10/2002 and submitted to the ACR as part of the reaccredidation application, written in lay terms and sent to the patient within 30 days of the examination. This is in violation of Title 21 Code of Federal Regulations § 900.12 (c) (2).

4. There was no written report for the results of the mammographic exam conducted on 12/10/2002 and submitted to the ACR as part of the reaccredidation

application, sent to a referring health care provider within 30 days of the examination. This is in violation of Title 21 Code of Federal Regulations § 900.12 (c)(3).

These problems are identified as Level 1 because they represent a failure to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law that may result in FDA initiating regulatory action without informal 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, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against performing further mammography. (See 42 U.S.C. §§ 263b(h)-(j)).

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 will take to **correct** all of the violations noted in this letter, any reason that corrective action has not been taken, and the time within which any steps not yet taken will be complete;

- 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

- documentation showing that correction is complete including, if the findings relate to quality control or other records, sample records that demonstrate proper record keeping procedures, **(Note: Patient names or identification should be deleted from any copies submitted)**.

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food and Drug Administration
1560 East Jefferson Avenue
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a state from enforcing its own state mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent state requirements, if any. You should also send a copy of your

response to the state of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional state requirements in your response.

There are many FDA requirements pertaining to mammography. This letter only concerns the findings of your recent 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/cdrh/mammography.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 ext. 155.

Sincerely yours,

John P. Dempster
for Joann M. Givens
District Director
Detroit District Office

Cc: [redacted]