DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2003-DT-14

April 28, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Anita T. Craig
Mammography Coordinator
Northland Radiology/Seven Mile
15521 West Seven Mile Road
Detroit, MI 48235

Dear Ms. Craig:

We are writing you because on April 11, 2003, your facility was inspected by a representative of the State of Michigan acting on behalf of the Food & Drug Administration (FDA). The inspection revealed a serious compromise in the quality of the mammography services offered by 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 recent inspection at your facility revealed the following Level 1 finding:

1. The phantom image score, using FDA approved phantom, was scored as having less than 2 masses after subtracting for any mass-like image artifacts. This is in violation of Title 21 Code of Federal Regulations (C.F.R.) § 900.12(e)(2)(iii).

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

Since this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional regulatory action.

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, seeking to suspend or revoke your facility's FDA certificate, or seeking a court injunction against performing further mammography.

In addition, you should also address the following Level 2 finding that was listed on the inspection report provided to you at the close of the inspection:

1. The phantom image score, using an FDA approved phantom, was scored as having at least 3 fibers but less than 4 fibers after subtraction for any fiber-like artifacts. This is in violation of 21 C.F.R. § 900.12(e)(2)(iii).

Based on this information, we have asked the American College of Radiology (ACR) to conduct an Additional Mammography Review (AMR) of mammograms performed by your facility during a three (3) month period prior to the inspection. The ACR will contact you regarding the selection of films for their review. You may be required to reimburse the ACR for the cost of this AMR. If this review shows that the clinical image quality of mammograms during this time has been compromised and may present a serious risk to human health, we may require that you notify patients and their referring physicians of this problem. We have enclosed a copy of the relevant FDA regulation at Title 21 C.F.R. § 900.12(j) as a reference.

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 receive this letter:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- the sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (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 & Drug Administration
300 River Place, Suite 5900
Detroit, MI 48207

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 313-393-8156.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)