DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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-10

CERTIFIED MAIL
RETURN RECEIPT REQUEST

March 4, 2003

Ms. Lanelle Brooks
Diagnostic Imaging Supervisor
DMC Health Centers – East Jefferson
10201 E. Jefferson
Detroit, MI 48214

Dear Ms. Brooks:

We are writing you because on February 7, 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 that your facility failed to comply with the Mammography Quality Standards Act of 1992 (MQSA) and certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The recent inspection at your facility covered the quality assurance/quality control and personnel qualification records since your previous inspection at the 9221 E. Jefferson Ave. location through the date of inspection at your current location. The inspection revealed the following Level 1 findings:

1. Daily processor quality control tests were missing for at least 30% of the operating days during the month of October at your current location. This included at least 5 consecutive days where there were no processor quality control records. This is in violation of Title 21 Code of Federal Regulations § 900.12(d)(2). See also 21 CFR § 900.12(e)(1).

2. Phantom image quality control records were missing for at least 4 weeks while patients were receiving mammograms at the 9221 E. Jefferson location. This is in violation of Title 21 C.F.R. § 900.12(d)(2). See also 21 CFR § 900.12(e)(2).

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These violations are identified as Level 1 because they identify a failure by your facility to meet significant MQSA requirements.

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and they represent violations of law that 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, suspending or revoking of your facility's FDA certificate or obtaining a court injunction against performing further mammography.

In addition, you should address the following Level 2 violations that were listed on the inspection report provided to your staff at the conclusion of the inspection:

1. The darkroom fog level was measured to be 0.14 optical density units (O.D.) at your current location. This is in violation of Title 21 C.F.R. § 900.12 (e)(4)(i).

2. Phantom image quality control records were missing for at least 2 weeks while patients were receiving mammograms at your current location. This is in violation of Title 21 C.F.R. § 900.12(d)(2). See also 21 CFR § 900.12(e)(2).

3. There was no documentation available to verify that technologist [redacted] met the continuing experience requirement of having performed a minimum of 200 mammography exams in the previous 24 month period. This is in violation of Title 21 C.F.R. § 900.12(a)(4). See also 21 CFR § 900.12 (a)(2)(iv)(A).

4. There was no documentation available to verify that medical physicist [redacted] met the continuing experience requirement of having surveyed at least 2 mammography facilities and a total of at least 6 mammography units in the previous 24 month period. This is in violation of Title 21 C.F.R. § 900.12(a)(4). See also 21 CFR § 900.12(a)(3)(iii)(B).

5. One (1) of eight (8) random medical reports reviewed did not contain an acceptable assessment category. This is in violation of Title 21 C.F.R. § 900.12 (c)(1).

It is necessary for you to act on this matter immediately. It is your responsibility to ensure adherence to each requirement of the MQSA and FDA's regulations.

You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

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).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed. 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

Enclosures: MQSA Facility Inspection Report