



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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-17

April 06, 2000

Ms. Carrie J. Voegtle
Director of Ambulatory Services
Providence Medical Center Farmington Hills
30055 Northwestern Highway
Farmington Hills, MI 48334

Dear Ms. Voegtle:

We are writing you because on March 28, 2000, your facility was inspected by a representative of the State of Michigan, acting in behalf of the Food & Drug Administration (FDA). The 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 (MQSA), 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 findings at your facility:

1. During the month of July, 1999, mammograms were processed during 20 days of operation without processor QC records to show that your film processor was operating in a state of control. The 20 days of operation is the sum total days of operation for that month.
2. In addition to the above, a review of the processor QC records revealed that processor QC records were missing for 31 consecutive days. This occurred during the months of June and July, 1999.

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

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they present a violation of 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 MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should also address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. The Level 2 findings are:

1. Mammograms were processed on four (4) days when the processor QC data available showed it to be out of limits.
2. Corrective action was not taken, when the mammography phantom image was out of limits, before further exams were performed.

The Food and Drug Administration approved an alternative standard to sensitometric-densitometric testing of processor performance on October 18, 1999 retroactive to April 28, 1999. The alternative standard allows facilities to use phantom image measurements as processor performance criteria when a sensitometer is not available for a period not to exceed two (2) weeks.

Your facility exceeded the allowable time period for this alternative standard by approximately six (6) weeks. In addition, your facility took no action when data from this alternative standard was outside of control limits. I have also enclosed a copy of this policy that has been widely distributed to all certified mammography facilities and interested parties and is also available on the FDA web site.

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 to correct the Level 1 and Level 2 violation noted in this letter;
- 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

- 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.)

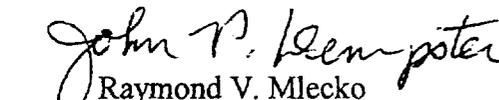
Please submit your response to: Mr. David M. Kaszubski
Director, Compliance Branch
U.S. Food and Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

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 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.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under 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/dmgrp.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,


Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s