



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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

WARNING LETTER  
2001-DT-01

October 11, 2000

Joseph Painter, M.D.  
Medical Director  
Hillsdale Community Health Center  
168 S. Howell Street  
Hillsdale, Michigan 49266

Dear Dr. Painter:

We are writing you because on October 3, 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. Processor QC records were missing for [REDACTED] consecutive days.
2. Processor QC records were missing for [REDACTED] out of [REDACTED] days of operation ([REDACTED]) during the month of September, 2000.

The above Level 1 findings related to your facility's processor QC records is attributable to improper settings being used on your automated scanning densitometer. Improper readings resulted in erroneous mid-density and density difference results. These erroneous data therefore invalidated the Q.C. data for the film processor.

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 represent 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 onsite 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.

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 violations 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 & Drug Administration  
1560 East Jefferson Ave.  
Detroit, MI 48207

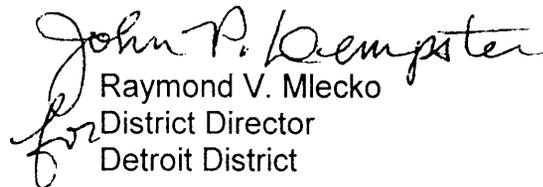
Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should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

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,

  
for Raymond V. Mlecko  
District Director  
Detroit District

Enclosures: a/s