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**PURGED** LTK

March 6, 2001

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 01 - 36

Glen Erickson  
Chief Executive Officer  
Central Minnesota Diagnostic, Inc.  
150 Tenth Street NW  
Milaca, Minnesota 56353

Dear Mr. Erickson:

On January 25-26, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mobile mammography facilities (FDA certificates #112268, 192112, 222406). All three MQSA certificates list Central Minnesota Diagnostic, Inc., c/o Fairview Northland Regional Hospital, 911 Northland Drive, Princeton, MN 55371, as the site address. Data was collected at the Princeton, MN, site and eight additional remote sites that are visited by your mobile vans. These inspections reveal serious regulatory problems involving the mammography at your facilities.

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. Based on the documentation your site presented at the time of the inspection the following non-compliances were documented at your facility:

Level 1 Non-Compliance:

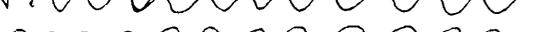
1. The system to communicate mammography results to patients is inadequate. The system in place reportedly does not provide a timely lay summary to all patients. (Affected: All three certificates; repeat non-compliance for #222406).

Level 2 Non-Compliance:

2. Your complaint handling system is inadequate. Your written policy lacks one or more of the required elements. Your manager at the Princeton site

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acknowledged knowing about a complaint from a patient not receiving a timely lay letter. FDA deems that such a complaint meets the definition of "serious." The complaint and its resolution were reportedly not documented. (Affected: All three certificates; repeat non-compliance for #222406.)

3. The corrective actions for film processor QC failures were not documented at the following sites:
  - A.) Princeton, MN 
  - B.) Elk River, MN 
  - C.) Lino Lakes, MN 
  - D.) Milaca, MN 
  - E.) Zimmerman, MN 
  - F.) Sandstone, MN 
4. The organization of QC records is such that the inspector could not accurately verify that the "performance verification test" was conducted after each move for the mobile units. (Affected: Cited under FDA certificate #112268, a.k.a. Mobile "1" or Mobile "A," but relates to all three certificates.)
5. Corrective action before future exams for a failing phantom image score, a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for:
  - A.)  unit certified under #112268 (Mobile "1" / Mobile "A")
  - B.)  unit certified under #192112 (Mobile "2" / Mobile "B")
6. The medical physicist's survey for all three FDA certificates is incomplete because the system artifact test was not completed for all remotely located film processors.

Note: Under the Quality Standards, a qualified physicist must complete the artifact test. Because your operation uses remotely located film processors, the physicist would have to visit each remote location. To reduce the burden of this requirement you may wish to submit a request (under Title 21, Code of Federal Regulations, Part 900.18 [21 CFR 900.18]) for an Alternative to the Quality Standard (Alternative Standard). Such a request may propose that the test films be generated by remotely located staff and then forwarded to the physicist for review. Other alternative methods may also be proposed. Approval of an alternate standard is required prior to its implementation.

7. Your system to collect medical outcome data from positive mammograms (e.g. biopsy results) is inadequate. If the patient chooses to have a biopsy at a site other than those under your direct control, reportedly no attempt is made to learn the results of that biopsy. (Affected: All three certificates.)

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Repeat Level 3 Non-Compliance:

8. The QA program is inadequate because various elements (designation of personnel responsibilities and defined QC test procedures) are either missing, incomplete, or inaccurate. (Affected: All three certificates; repeat Level 3 non-compliance for certificate #222406.)

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because of the repeat Level 1 non-compliance, FDA would like to meet with you or your representative to review how you plan to correct the non-compliances noted in this letter. We have scheduled the meeting for 2:30 p.m. on Tuesday, March 13, 2001, at the FDA Minneapolis District office located at 240 Hennepin Avenue, Minneapolis, MN. If you should have further questions about the meeting you may contact Compliance Officer Timothy Philips at (612) 334-4100 ext. 192.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the 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, or each day of failure to substantially comply with, the 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 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the 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.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI. 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain

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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/index.html>.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,



Cheryl A. Bigham  
Acting Director  
Minneapolis District

TWG/ccl

7/14

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