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**PURGED** *PK*

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

December 20, 1999

xc: HFI-35  
DWA

**WARNING LETTER**

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

**Refer to MIN 00 - 12**

George Petry  
President  
Shared Medical Technology  
202 West Newton  
Rice Lake, Wisconsin 54868

Dear Mr. Petry:

On December 2, 1999, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility at 1239 Payne Avenue, St. Paul, MN (ID# 220667). This 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. Based on the documentation your site presented at the time of the inspection the following Level 1 and Level 2 findings were documented at your facility:

**Level 1 Non-Compliance:**

1. Based on information obtained from one of the remote sites that your mobile van visits *~~~~~* your system to communicate lay summaries to patients is inadequate. Reportedly, only those patients that could not be contacted verbally were being sent lay summaries. Written lay summaries must be sent to all patients within 30 days.

**Level 2 Non-Compliances:**

2. There is no written procedure for handling consumer complaints at site Shared Medical Technology MOBILE @ Payne Avenue Medical Associates.



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- 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, FDA, 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 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 call Mr. Garvin at (414) 771-7167 x 12.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

TWG/ccl

*ed*  
xc: Sue McClanahan  
Supervisor, Section of Radiation Control  
Minnesota Department of Health  
P.O. Box 64975  
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