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**PURGED** RAK

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

April 27, 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 27

Thomas Holets  
Chief Executive Officer  
Aspen Medical Clinic  
1020 Bandana Boulevard West  
St. Paul, Minnesota 55108

Re: ID 2033980004

Dear Mr. Holets:

We are writing to you because on March 17, 1999, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA) inspected your Bloomington facility. This inspection revealed a serious regulatory problem involving the mammography performed 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 and Level 2 findings at your facility:

Level 1

1. Based on the documentation your site supplied during the inspection, radiologic technologist  did not meet the requirement of being licensed by a State or certified by an FDA-recognized board.

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- Note: If [redacted] was performing mammography (at any site) on or before March 17, 1996, also submit her CEUs documenting that she has earned at least 15 credits in the period March 17, 1996 - March 17, 1999.

### Level 2

2. Based on the documentation your site supplied during the inspection, interpreting physician [redacted] did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a six month period).
3. Based on the documentation your site supplied during the inspection, interpreting physicians [redacted] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.
4. Based on the documentation your site supplied during the inspection, radiologic technologist [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.
5. Based on the documentation your site supplied during the inspection, interpreting physicians ([redacted]) did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period.

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

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

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each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA, 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; and

each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to Tom 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 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 more specific questions about mammography facility requirements or about the content of this letter please feel free to contact Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

TWG/ccl

xc: Judith A. Ball  
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Minnesota Department of Health  
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