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

October 15, 2001

**WARNING LETTER**

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

**Refer to MIN 02 - 10**

Glen A. Grady  
Administrator and Chief Executive Officer  
Neillsville Memorial Medical Center, Inc.  
216 Sunset Place  
Neillsville, Wisconsin 54456

Dear Mr. Grady:

We are writing to you because on September 5, 2001, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility (FDA Certificate #182345).

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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 Non-Compliance:**

1. The system to communicate results is inadequate for the Neillsville Memorial Medical Center, Inc. site because there is no system in place to provide timely written lay summaries for all patients, regardless of their mammography assessment category.

Reportedly, patients with positive mammograms are only provided a verbal (rather than a written) summary.

Note: A lay summary of an "addendum" or "comparison" report sent to the health care provider (or self-referred patient) must be provided to all patients even if there is no change in the final assessment category or recommended

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course of action. For the specific case where there is no significant change in the report, a simple statement that the comparison has been performed and that there is no overall change would satisfy the requirement. If the "addendum" merely stated that the referring health care provider had been notified of the results of the patient's examination, the lay summary could be a simple statement informing the patient of that fact.

Level 2 Non-Compliances:

2. Corrective actions for processor QC failures were not documented at least once for mammography film processor (..  Room = Darkroom).
3. Medical audit and outcome analysis was not done separately for each individual at the Neillsville Memorial Medical Center, Inc. site.

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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 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 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

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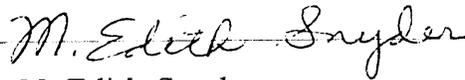
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Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general 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 phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

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M. Edith Snyder  
Acting Director  
Minneapolis District



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xc:   
Lead Interpreting Radiologist  
Neillsville Memorial Medical Center, Inc.  
216 Sunset Place  
Neillsville, WI 54456

Paul Schmidt  
Chief, Radiation Protection Unit  
State of Wisconsin  
P.O. Box 2659  
Madison, WI 53701-2659

Priscilla F. Butler  
Director, Breast Imaging Accreditation Programs  
American College of Radiology  
1891 Preston White Drive  
Reston, VA 20191