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

May 10, 2000

WARNING LETTERxc: HFI-35
DWA**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 33

Kevin Hayden
Chief Administrative Officer
Dean Health System, Inc.
1808 W. Beltline Highway
Madison, Wisconsin 53713

Dear Mr. Hayden:

On April 25, 2000, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your Riverview Clinic—Division of Dean Medical Center, Inc., Janesville, WI, facility (FDA mammography certificate no. 194662). 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 findings were documented at your facility:

Level 1 Non-Compliances:

1. Phantom QC records were missing for eight weeks for the  mammographic system located in room EG17.
2. Phantom QC records were missing for eight weeks for the  mammographic system located in room EG16 (G43).

(Evaluation criteria for the above two items: number of weeks missed during worst 12-week time interval.)

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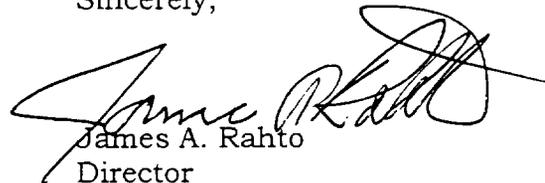
Kevin Hayden
May 10, 2000

Please submit your response to Radiological Health Specialist Thomas W. Garvin, 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/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,


James A. Rahto
Director
Minneapolis District

TWG/ccl

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

Priscilla F. Butler
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