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4. The system to communicate results is not adequate for Oak Point Clinic because the system provides timely lay summaries only to those patients with assessment categories associated with normal mammograms.

Level 2 Non-Compliances:

5. There is no written procedure for handling mammography consumer complaints in accordance with Title 21, Code of Federal Regulation, (CFR) Part 900.12(h)(1)(2)(3)(4).
6. There is no written procedure for mammography infection control in accordance with 21 CFR 900.12(e)(13)(i), (ii), and (iii).

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 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

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