DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-34

August 16, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Connor, D.O.
Lead Interpreting Physician
The Imaging Center
7631 W. Jefferson Blvd.
Fort Wayne, IN 46804

Dear Dr. Connor:

We are writing you because on August 1, 2002, your facility was inspected by a representative of the State of Indiana acting on behalf of the Food & Drug Administration (FDA). The inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 recent inspection at your facility revealed the following Repeat Level 2 findings:

1) There was no documentation available to verify that your radiologic technologist [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units (CEU's) in the previous 36 month period. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a) (2) (iii).
2) There was no documentation available to verify that your radiologic technologist [redacted] met the continuing education requirement of having taught or completed at least 15 CEU's in the previous 36 month period. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(2)(iii).

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed) which your facility received at the close of the inspection. These problems are identified as Repeat Level 2 because they identify a failure to meet

significant MQSA requirements and indicate failure by your facility to implement permanent correction of problems found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of the law which may result in FDA initiating regulatory action without further informal 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, seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against performing further mammography.

In addition, your response should address the Level 2 and Repeat Level 3 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 and Repeat Level 3 findings are:

1) There were inadequate procedures written for the collection and resolution of consumer complaints. This is in violation of Title 21 Code of Federal Regulations § 900.12 (h).
2) Phantom image quality control (QC) records were missing at least 2 weeks, but less than 4 weeks, for the [redacted] mammography system. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e)(2).
3) There was no documentation available to verify that radiologic technologist [redacted] met the alternative initial training requirement of having training specific to mammography as required under the interim regulations. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(2)(ii).
4) There was no documentation available to verify that radiologic technologist [redacted] met the continuing experience requirement of having performed at least 200 mammographic examinations in the previous 24 month period. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(2)(iv).
5) The darkroom fog density was measured in the darkroom to be [redacted] optical density units. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e)(4)(i).

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Repeat Level 2, Level 2 and Repeat Level 3 violations noted in this letter;

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

- the sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

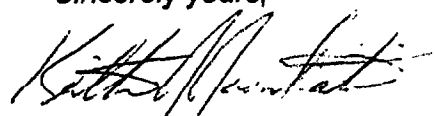
Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy of your response to the State of Indiana radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

There are many FDA requirements pertaining to mammography. This letter only concerns the findings of your recent 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.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,



Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)