DEPARTMENT OF HEALTH & HUMAN SERVICES

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WARNING LETTER
2002-DT-36

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

August 22, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Allen Gillespie, M.D.
Chairman
Southside OB/GYN, P.C.
8051 S. Emerson Avenue, Suite 400
Indianapolis, IN 46237

Dear Dr. Gillespie:

On July 24, 2002, a representative of the Indoor and Radiologic Health program of the Indiana State Department of Health inspected your mammography facility on behalf of the Food and Drug Administration (FDA). The inspector found violations of the Mammography Quality Standards Act of 1992 (MQSA), as amended, 42 U.S.C. § 263b, and implementing regulations promulgated by FDA, 21 C.F.R. Part 900. These violations are described in a Facility Inspection Report (FIR), a copy of which the inspector provided to your facility at the end of the inspection. Another copy of the FIR is enclosed with this letter for your reference.

Level 1 Findings

The inspector found that your facility has failed to conduct phantom image quality control testing and to maintain records of such testing. FDA regulations require facilities with screen-film mammography systems to perform image quality evaluation tests using an FDA-approved phantom at least weekly. 21 C.F.R. § 900.12(e). They also require such facilities to maintain and update records of quality control testing, including records of phantom image testing. 21 C.F.R. § 900.12(d)(2). Phantom image quality control testing records for your [redacted] mammography x-ray system were found to be missing for five weeks in which your facility was conducting mammography. This suggests that your facility is not maintaining required records and/or is not conducting the required quality control testing.

The absence of phantom image testing records is a Level 1 finding. Under FDA's three-tiered system for classifying MQSA inspection findings, Level 1 findings are the most serious. They indicate a failure to meet a key MQSA requirement that seriously threatens the quality of mammography services performed at the facility. FDA focuses its enforcement resources on facilities with Level 1 findings.

Level 2 Findings

The inspection also revealed the following Level 2 findings, indicating violations of other significant mammography quality requirements:

1. Your facility failed to produce documentation demonstrating that corrective action was taken to address quality control failures of your primary processor. FDA regulations provide that if a processor falls outside of quality control action limits, the facility must identify the source of the problem and take corrective action. They also require the facility to maintain quality control records, including records relating to corrective action. 21 C.F.R. § 900.12(d)(2), (e)(8).

2. Mammograms were processed in your [redacted] mammography film processor on two days when the processor was outside of acceptable control limits, in violation of 21 C.F.R. § 900.12(e)(8)(ii).

3. Your [redacted]. x-ray system failed required quality control tests or exhibited values outside of allowable limits, but your facility failed to document that corrective action was taken before the system was used in further exams. FDA regulations require corrective action to address quality control deficiencies and maintenance of records that such action was taken. 21 C.F.R. § 900.12(d)(2), (e)(8).

4. Your facility failed to produce documentation verifying that radiologic technologist [redacted] taught or completed at least 15 continuing education units in mammography within the previous 36 month period, as required by 21 C.F.R. § 900.12(a)(2)(iii). Similarly, your facility could not demonstrate that [redacted] fulfilled the continuing experience requirement set forth in 21 C.F.R. § 900.12(a)(2)(iv).

Level 3 Findings

The inspection also revealed the following Level 3 violations which remain uncorrected since your last inspection.

1. Quality control for your [redacted] mammography film processor was not adequate because the fixer retention test was not conducted at the frequency required by 21 C.F.R. § 900.12(e)(3).

2. The film-screen contact test was not conducted as frequently as required by 21 C.F.R. § 900.12(e)(4).

3. The darkroom fog quality control test was also not conducted at the frequency required by 21 C.F.R. § 900.12 (e)(4).

Action

FDA has legal authority to take action against your facility to assure compliance with the MQSA and FDA's implementing regulations. The MQSA authorizes FDA to impose one or more sanctions on mammography facilities found to be out of compliance. These sanctions include directed plans of correction, payment for the cost of onsite monitoring, patient notification, civil money penalties, suspension or revocation of a facility's mammography certificate and injunctive relief. 42 U.S.C. § 263b(h)-(j). FDA is also authorized to require a mammography facility to provide information for review by an entity designated by the agency to help determine whether the facility is in compliance with Part 900. 21 C.F.R. § 900.12(j). This is known as "additional mammography review."

Based on the inspectional findings described in this letter, FDA has determined that your facility should be subjected to additional mammography review. The entity designated by FDA for this purpose is the American College of Radiology (ACR). The ACR will contact you regarding the selection of films for their review. If FDA determines that the quality of mammography performed at your facility was so inconsistent with the MQSA and FDA regulations as to present a significant risk to individual or public health, FDA regulations authorize us to require your facility to notify patients and their referring physicians of the deficiencies presenting such risk and other relevant information.

In addition, you should immediately address the findings from your facility's July 24, 2002 inspection. Please describe to this office in writing within fifteen working days from the date you receive this letter (1) the specific steps you have taken to correct the violations, and (2) each step your facility is taking to prevent the recurrence of these violations. Please include with your response examples of records demonstrating that your facility has corrected the record keeping violations described above. Please assure that the records you submit do not bear patient names or other patient identifiers.

This letter only concerns the findings of your July 24, 2002 inspection. It does not address other obligations you have under the MQSA or any other federal law. Nor does it address state law requirements. Nothing in the MQSA or FDA regulations precludes a State from enforcing its own mammography laws and regulations, which may be more stringent than the MQSA. When you plan your corrective actions, therefore, you should consider not only the MQSA, but also any applicable state requirements. You may choose to address both the MQSA and state requirements in your response.

Please submit your response to:

Mr. David M. Kaszubski
Director, Compliance Branch
Food and Drug Administration
1560 East Jefferson Avenue
Detroit, MI 48207-3179

You should send a copy of your response to the Indoor and Radiologic Health program of the Indiana State Department of Health.

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; <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 x 155.

Sincerely yours,

for Joann M. Givens
District Director
Detroit District Office

Enclosure