HFE-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –14187-02

July 17, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Michael Lileas
President
Salem Internal Medicine & Radiology
564 East Second St.
Salem, OH 44450

Facility I.D.#: 223291

Dear Dr. Lileas:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on June 26, 2002. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b, and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 findings at your facility (identified on your inspection report):

Medical records and mammography reports – *Communication of mammography results* (21C.F.R. § 900.12 (c)(2))

1. Your records revealed that your facility failed to provide lay summary letters on the results of each of the mammography examinations to patients that were called back for a follow-up mammography examination.

   During the inspection, the inspector observed your records and found that at least three patients were called back for a follow-up mammography exam and the results of the follow-up mammography were not provided to the patients in lay summaries.

2. Your written procedure for communication of mammography results to the patients covering "Suspicious" and "Highly suggestive for malignancy" cases is not adequate.

During the inspection, the inspector observed that your facility's written procedure is inadequate for communication of mammography results to the patients with serious cases. The inspector observed that your facility used the following language for results of serious cases: "Interpretation of your exam indicates the need for additional follow-up." Your facility sample serious case letter does not indicate the actual result with wording such as: "Interpretation of your exam indicates an abnormal finding. Please contact this office for further consultation with your referring physician."

In addition, we found other areas where your facility failed to comply that were listed as Level 2 findings on your inspection report:

Personnel Requirements- ***Interpreting physicians*** **(21 C.F.R. § 900.12(a)(1)(iii)(A)&(B))**

1. Your facility failed to produce documents verifying that [redacted] **and** [redacted], interpreting physicians who performed interpretation of mammograms at your facility, meet the initial requirement of having forty (40) hours of training in mammography prior to April 28, 1999. During the inspection of your facility, your staff could not provide any records regarding the initial mammography education requirements of [redacted]

2. Your facility failed to produce documents verifying that [redacted], an interpreting physician who performed interpretation of mammograms at your facility, meets the initial experience requirement of having interpreted or multi-read 240 mammograms in any six month period during the last two years of diagnostic radiology residency. During the inspection of your facility, your staff could not provide any records regarding the initial mammography experience requirement of [redacted]

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law that may result in FDA imposing statutory actions. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the MQSA Standards, suspension or revocation of your facility's FDA certificate, or a court injunction against performing further mammography (see 42 USC §§ 263b(h) through (j) of the MQSA).

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

- The specific steps you have taken to correct the violations noted in this letter; and

- Each step your facility is taking **to prevent the recurrence** of similar violations.

Please also provide the following in answering this letter: (Note: Patient names or patient social security numbers should be deleted from any copies submitted)

- A copy of your corrected written procedure for communication of mammography results. The written procedures shall cover mammography results for follow-up patients and for patients with "Suspicious" and "Highly suggestive of malignancy" results. Also include a copy of a lay summary letter for each result.

- Copies of the appropriate documents covering the initial education and experience requirements for the interpreting physicians.

- Please submit your response to:

  Mr. R. Terry Bolen
  MQSA Compliance Officer
  Food & Drug Administration
  6751 Steger Drive
  Cincinnati, OH 45237-3097
  FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Mr. Dwight Leeseberg
Ohio Department of Health
Radiological Technology Section
161 South High St., Suite 400
Akron, OH 44308-1616

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to certain 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.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138.

Sincerely yours,

Deborah A. Grelle
Acting District Director
Cincinnati District Office

c.
OH/DWLeeseberg

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