

HFI-35

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124363

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

March 12, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Fitzgerald, President/CEO
American Radiology Services
1838 Green Tree Road, Suite 450
Baltimore, Maryland 21208

Inspection ID #1654800010

Dear Mr. Fitzgerald:

The following American Radiology site was inspected on February 20 and 24, 1998 (Facility Inspection Report enclosed) by representatives of the Food and Drug Administration (FDA) as a follow-up to a Warning Letter (copy enclosed) issued by the FDA on January 16, 1998:

American Radiology Services
404 Eastern Boulevard
Baltimore, Maryland 21221

Under a United States federal law--the Mammography Quality Standards Act of 1992--your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography.

The previous annual inspection, conducted by the State of Maryland's Radiological Health Department on November 12, 1997, revealed serious regulatory problems with your mammography practice. These observations were listed in the aforementioned Warning Letter. The most serious deviations include the following:

- * A copy of Dr. [REDACTED] license to practice medicine was not on file at the facility.
- * A medical physicist survey had not been completed during the previous 14 months.

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- * Seventy-five percent of the data points for processor quality control for the month of September 1997 were missing.

Ms. Cindy Almony's, Regional Operations Manager, January 26, 1998 response to our letter was inadequate. The response did not supply documentation of the physicist survey, documentation proving that Dr. [REDACTED] had read an average of 40 patient exams in mammography over the last 24 months, and documentation of continuing education credits in mammography equaling 15 credits over the previous three years for several of the facility's radiologists. The response to the missing data points for processor quality control for the month of September 1997 was, "This center only performs Mammography three days per week. The processor QA was performed on the days that we performed exams...."

A second letter was sent to the attention of Ms. Almony at American Radiology Services on February 5, 1998, requesting the missing documentation and copies of patient logs and processor quality control data for the month of September. American Radiology Services was given until February 12, 1998 to respond to this letter. On February 16, 1998, Ms. Michelle Wineke left a message on the voice mail of FDA Investigator Lori Holmquist, stating that she was calling on behalf of Cindy Almony, and that their response to our second letter would be sent by FedEx that same day. It was, therefore, due to arrive at our office on February 17, 1998. When the response had not arrived by Friday, February 20, 1998, a phone call was made to Ms. Wineke by Investigator Holmquist. This call was not returned.

Because American Radiology Services' response to our first letter was unacceptable, and there was no reply to our second letter, the Regional Radiological Health Representative authorized an unannounced follow-up inspection. Investigators Lori Holmquist and Elizabeth Laudig conducted the inspection over a 2-day period on February 20 and 24, 1998. This inspection revealed continuing deviations from MQSA standards that could compromise the quality of mammography services offered by your facility. We request that you respond to the following observations made during the follow-up inspection. (Not all of these issues are listed on the enclosed inspection report.) The deviations are as follows:

1. Processor Quality Control (QC) data points were missing.

American Radiology Services was cited for missing data points for processor QC at the close of the inspection in November. The highest percentage of missing data points occurred in September 1997, when 75% of the data points were missing. During the follow-up inspection in February, the facility's patient log was compared to the processing control chart. There were 15 days in the month of September when this facility processed mammograms. On six of these days, processor QC strips were run through the processor and charted. Twenty-six patient exams were processed on days when no processor QC was done.

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Along with the month of September 1997, the investigators reviewed processor QC data for the months following the inspection, specifically November 1997 through February 1998. December was the only month in which processor QC strips were run and charted for every day mammography films were run. Of the three and a half months reviewed, QC strips were not run and charted five times. Twenty-two patient exams were processed on days when no processor QC was done.

In your response, please provide the procedures that have been or will be taken to ensure that processor Quality Control is performed every day that mammography films are processed.

2. **Dr. [REDACTED] did not meet the requirement of having completed a minimum of 15 credits in mammography over a 3-year period.**

MQSA requires radiologists to obtain 15 hours of continuing education in mammography over a 3-year period. American Radiology Services was cited for Dr. [REDACTED] failure to meet this requirement during the November 1997 inspection. He was given a 90-day grace period in which to earn the required credits, which ended on February 12, 1998. American Radiology Services has not submitted documentation to this office of the required number of credits. Therefore, Dr. [REDACTED] must cease the independent interpretation of mammograms.

In your response, please provide the procedures that your office will institute to disqualify radiologists who earn less than the required continuing education credits from performing mammography.

Please note that beginning in October 1998, personnel not meeting the continuing education requirements will not be legally qualified to perform mammography from the date the violation is discovered until they have earned the required credits.

3. **There was no medical audit system in place to track positive mammograms.**

During the follow-up inspection in February, the facility's office manager stated that no one had told her how to follow up positives, and that she would ask if she ever had a positive reading. She also stated that there was no statistical analysis of films read.

In your response, please describe the procedures that will be used for the Medical Audit System (tracking the results of positive mammograms).

4. **Mr. George Kuehnl was designated as the Regional Manager of this facility by Ms. Almony and is, therefore, responsible for reviewing mammography quality control documentation. However, he does not have any background in mammography.**

In your response, please provide documentation of the steps that will be taken to ensure that adequate reviews of your quality control program will be conducted. Also, address how quality control problems will be identified and corrected.

5. **Fog test optical density results documented in September, November, and December 1997, and in January 1998, were ten times the allowed limit, yet no corrective action was taken by the facility, nor did peer review discover the problem.**

Results of the last four fog tests were as follows: .33 - September 1997; .40 - November 1997; .33 - December 1997; and .32 - January 1998. The action limit for fog is **0.04** optical density difference. The films for these tests were reviewed. There was no fog present on any of the test dates. A technologist for the facility could not tell the investigators the pass/fail limits for the fog test. The technologist also stated that she exposed one side of the film to darkroom light for three minutes. The ACR Mammography Quality Control Manual states that the film is to be exposed to two minutes of darkroom light. (The physicist survey conducted in November 1997 noted the problem. Still, no corrective action was taken.)

In your response, please describe what procedures have been taken to ensure the dark room fog test is conducted correctly and that facility deficiencies identified in the physicist report are corrected.

6. **Ms. [REDACTED] removed the quality control binder from the facility in early January and did not return it until the second day of the follow-up inspection.**

Ms. [REDACTED] returned the binder on February 24, 1998. Fixer retention analysis was not conducted, and phantom image test results were not recorded during the time Ms. [REDACTED] had the binder. These failures resulted in two Level 3 findings. Please address this issue. Is it the normal practice of your firm to remove quality control documents from facilities for extended periods of time? In your response, state the procedures you will use to ensure that all required quality control tests are conducted at the proper intervals.

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7. **This facility was cited for failure to have standard operating procedures for personnel responsibilities and equipment use and maintenance during the November 1997 inspection. These areas were still not adequately addressed and were cited again during the February follow-up inspection.**

In your response, please provide copies of those procedures that identify the responsibilities of the radiologists, physicists, quality control manager, and any other staff who has responsibilities related to mammography at this facility. Also, provide documentation that a copy of the operators manual for the X-ray system has been obtained/ordered.

Because the aforementioned conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice. 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, MQSA 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 fifteen (15) working days from the date you receive 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 (include 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. (Note: Patient names or identification should be deleted from any copies submitted.)

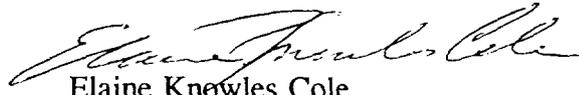
Please send the original copy of your response to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, Attn: Scott J. MacIntire, Compliance Officer. Also, send a copy to the State Radiation Control Office that conducted the inspection referenced in this letter.

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Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspections and does not necessarily address other obligations you may have under the law. You may obtain general information regarding all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have more specific questions concerning mammography facility requirements or about the contents of this letter, please contact Elizabeth A. Laudig at (410) 962-3591, Ext. 159.

Sincerely,


Elaine Knowles Cole
District Director

Enclosures