



November 5, 1997

WARNING LETTER
CHI-2-98

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Nicola L. Chiaradonna, M.D.
Springfield Imaging &
Diagnostic Center
319 East Madison
Suite G
Springfield, IL 62701

Dear Dr. Chiaradonna:

Your facility was initially inspected on July 24, 1997. This inspection was closed on October 14, 1997, after you failed to respond to the inspector's repeated request for additional personnel documentation. The inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12.

Your "MQSA Facility Inspection Report", which was subsequently mailed to you by the FDA Inspector, listed a Level 1 noncompliance finding. Level 1 findings are the most serious type of MQSA violations. They may be symptomatic of serious underlying problems that could compromise the quality of a mammography program. The following Level 1 noncompliance was found at your facility:

- Dr. [REDACTED] did not have the required documentation to show that [REDACTED] was either certified by an approved board or that [REDACTED] had received two months of full-time training in the interpretation of mammograms.

The following Level 2 noncompliance finding was also listed on your "MQSA Facility Inspection Report":

- Dr. [REDACTED] did not have documentation to show that [REDACTED] had met the initial experience requirement of interpreting mammograms from the examinations of at least 240 patients in a six month period.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, the FDA may, without further notice, initiate regulatory action. Under MQSA, the FDA may:

- * impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- * suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- * seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

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 action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify the FDA in writing of:

- * 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 noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Note that the two Level 3 noncompliant items listed on your "MQSA Facility Inspection Report" must also be corrected; however, a written response is not required. Future inspections of your facility will verify that corrective action has been taken for each of these.

Please send the original of your response to:

Rachel T. Evans, Biomedical Engineer
Food and Drug Administration
300 South Riverside Plaza
Suite 550 South
Chicago, IL 60606

page 3

Also, send a copy of your response to:

Mr. Donald Agnew, Health Physicist
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Evans at (312) 353-5863, x-123.

Sincerely,

RSI

Raymond V. Mlecko
District Director
Chicago District

cc: Mr. Donald Agnew, Health Physicist
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704