

Page Two

Carol M. Fruetel

June 5, 1998

Level 2

3. The measured darkroom fog exceeded 0.05 (the measured fog level was 0.13), Room = @DRS DX PL.
4. Processor QC: 99 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing (month of January):  M35 or M35A-M, Room Id= @B'VILE F.
5. Processor QC: 75 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing (month of May): , Room Id= @DRS DX PL.
6. Interpreting physicians  did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months.
7. Interpreting physicians  did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of five credits/year).
8. Interpreting physicians  did not meet the initial training requirement of having 40 hours of continuing medical education in mammography.
9. Interpreting physicians  did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in six months.
10. Your medical physicist  did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year).

Page Three

Carol M. Fruetel
June 5, 1998

Level 3

11. For item listed below, QC records/charts were present but reflected that the listed tests were not conducted at the proper frequency.

Compression: 

12. Processor QC: Corrective actions for processor (QC) failures were not documented on at least one occasion:  90, Room Id=@DRS DX PL.
13. Mammograms were processed at least once with the medium density or density difference or base+fog out of control:  M35 or M35A-M, Room Id=@B'VILE F.
14. Mammograms were processed at least once with the medium density or density difference or base+fog out of control:  90, Room Id=@DRS DX PL.
15. Documentation was missing from the quality assurance (QA) program, regarding Personnel Responsibilities.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's 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, FDA may, without further notice, initiate regulatory action. Under MQSA, 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.

Page Four

Carol M. Fruetel

June 5, 1998

- 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 FDA in writing of:

- * the specific steps you have taken to correct all of the Level 1 and Level 2 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 non-compliances 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.

Please send the original copy of your response to:

Thomas W. Garvin
Radiological Health Specialist
Food and Drug Administration
2675 N. Mayfair Road, Suite 200
Milwaukee, WI 53226-1305

Page Five

Carol M. Fruetel
June 5, 1998

Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. 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 Mr. Garvin at (414)771-7167 ext. 12.

Sincerely,



James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Judith A. Ball
Manager, Section of Radiation Control
MN Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975