DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

Certified Mail
Return Receipt Requested

September 23, 2003

Donald B. Yellow
Radiology Supervisor
Chinle Comprehensive Health Care Facility
Highway 191 @ Hospital Turnoff
Chinle, AZ 86503

W/L Number: 52 - 03
Inspection ID: 2273960002
FEI: 3003811281
FACTS: 19003-0

Dear Mr. Yellow:

On July 28, 2003, a representative of the U. S. Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector left with you, or your representative, at your facility at the close of the inspection. The violations are again identified below:

Level 1: Mammograms were processed in processor #1 (a Kodak machine; model "other"), which is located in the mammography darkroom, when it was out of limits on January 8-10, 16, 19-23, 27-28, and 30 of 2003. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(1).

Level 1: Processor quality control (QC) records in the months of October, November, and December 2002 were missing for at least thirty percent (30%) of operating days for processor #1 (a Kodak machine; model "other") which is located in the mammography darkroom. This is a violation of Title 21 Code of Federal Regulations sections 900.12(d)(2) and 900.12(e)(1).

Level 1: Processor QC records were missing at least five (5) consecutive days for processor #1 (a Kodak machine; model "other") which is located in the mammography darkroom. This is a violation of Title 21 Code of Federal Regulations sections 900.12(d)(2) and 900.12(e)(1).

Level 1: Phantom QC records were missing from October 2002 through January 2003 and from May 30 to June 13 of 2003 and from June 20 to July 2 of 2003 for unit #1 (a General Electric Company [GE Medical Systems]; model: DMR; serial number: 314316BU1) which is located in mammography room number 3A41. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(2).

Level 2: Corrective actions for processor QC failures were not documented at least once for processor #1 (a Kodak machine; model "other") which is located in the mammography darkroom. For example, Medium Density was out of control on January 19, 2003, January 28, 2003, and January 30, 2003, and Density Difference was out of control on January 8-10,16 , 20-23, and 27 and 28 of 2003, yet there was no indication of what corrective action(s) had been taken and documented. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(3)(ii).

Level 2: Corrective action before further exams (for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits) was not documented for unit #1 (a General Electric Company [GE Medical Systems]; model DMR; serial number 314316BU1) which is located in mammography room number 3A41. This is a violation of Title 21 Code of Federal Regulations sections 900.12(e)(8)(ii) and 900.12(d)(2).

You have failed to respond to the MQSA Facility Inspection Report as requested in the document "Important Information about your MQSA Inspection".

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction (DPC)
- charging your facility for the cost of on-site monitoring
- seeking 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
- seeking to suspend or revoke your facility's FDA certificate

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond, in writing, to FDA within fifteen (15) working days from the date you received this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. equipment settings (including technique factors), raw test data, and calculated final results;

4. sample records that demonstrate proper record keeping procedures.

Note: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies of records you submit to us.

Please submit your response to this letter to:

Scott A. Goff
Compliance Officer (Mammography)
U.S. Food & Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Please send a copy of your response to:

Shanna Farish
Supervisor
State of Arizona
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040-2968

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility 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, U. S. Food and Drug Administration, P.O. Box

re: Chinle Comprehensive Health Care Facility
re: Warning Letter Number 52 - 03

6057, Columbia, MD 21045-6057 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-608-4433.

Sincerely yours,

Alonza E. Cruse
District Director

cc:

Shanna Farish
Supervisor
State of Arizona
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040-2968

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