DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

g32184

WARNING LETTER

Certified Mail
Return Receipt Requested

April 30, 2002

Azam M. Khan
President and Chief Executive Officer
Arizona Institute of Medicine & Surgery
3636 Stockton Hill Road
Kingman, AZ 86401-0514

W/L Number: 38 - 02
Inspection ID. 1917180007
CFN: 20-30,200
FEI: 1000519331

Dear Mr. Khan:

We are writing to you because on March 29, 2002, your facility was inspected by a representative of the State of Arizona acting on behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 42 U.S.C. § 263b (MQSA), 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:

- Level 1: Processor quality control (QC) records, for processor #1 (a [redacted] machine, model [redacted] with this unit located in mammography room number 1) were missing for thirteen (13) days during the month of October 2001 and mammography examinations were performed on patients during those days. This is a violation of Title 21 Code of Federal Regulations section 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 [redacted] machine, model [redacted]) which is located in mammography room number 1. This is a violation of Title 21 Code of Federal Regulations section 900.12(d)(2) and 900.12(e)(1).

- Level 1: Phantom QC records were missing for the weeks of June 18th, July 23rd, August 6th, August 13th, and August 20th of the year 2001for unit #2 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in the mammography room. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(2).

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), 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.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: Not all positive mammograms were entered in the tracking system. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 2: There were no examples of, nor attempts, to get biopsy results. No biopsies have been logged, whatsoever, since the year 1999. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 2: Medical audit and outcome analysis was not performed annually. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(2).

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

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 received 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 (including technique factors), raw test data, and calculated final results, where appropriate; and

- please provide 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 submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to 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 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov

If you have 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 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director