DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g373d

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

WARNING LETTER

December 5, 2002

Certified Mail
Return Receipt Requested

Howard Berger, M.D.
President and Chief Executive Officer
Desert Advanced Imaging Center
2601 East Taquitz Canyon Way
Palm Springs, CA 92262-7015

W/L Number: 12 - 03
Inspection ID: n/a
CFN: 20-32,627
FEI: 3003809057
FACTS: 15738-0

Dear Dr. Berger:

On October 2, 2002, our Consumer Safety Officer/Senior MQSA Auditor inspected your facility. This inspection revealed serious problems involving the conduct of mammography at your facility noted above. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code, your facility must meet specific requirements to practice mammography. These requirements help to protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA and associated regulations at your facility. Our MQSA Auditor explained these violations to Ms [redacted] (Director of Quality Assurance at the facility's parent firm of RadNet Management, Inc.) in a telephone conversation prior to leaving the facility at the close of the inspection, as Ms Foster was not physically present during the inspection. The inspection revealed one Level 1 and seven Level 2 findings at your facility:

Level 1 - The system to communicate results is not adequate because there is no system in place to provide timely lay summaries to all patients within thirty (30) days of their examinations. Specifically, we substantiated a consumer's complaint that the patient's results were not made available to her (as of September 25, 2002), even though her examination occurred on July 25, 2002. Your Standard Operating Procedure in the Policy and Procedure Manual does not indicate that the results will be sent out within thirty (30) days. This is a violation of Title 21, Code of Federal Regulations, section 900.12(c)(2).

Level 2 - Not all positive mammograms were entered in the tracking system. Specifically, while the patients were included in the tracking log for the year 2001, the examination date and the assessment category was not indicated after October 31, 2001. This is a violation of Title 21, Code of Federal Regulations, section 900.12(f)(1).

Level 2 – Four (4) reports reviewed did not contain an acceptable assessment category. Specifically, the physician's use of the word "incomplete" alone does not explain what was discussed in the Findings section of that respective report. Additionally, one report is confusing in that the physician states that s/he needs additional views or comparison films, but then merely recommends a follow-up examination in one (1) year. This is a violation of Title 21, Code of Federal Regulations, section 900.12(c)(1).

Level 2 - There were no examples of nor attempts to get biopsy results. Specifically, following up on a biopsy would be impossible since the category reference, for the patient, is unknown. This is a violation of Title 21, Code of Federal Regulations, section 900.12(f)(1).

Level 2 – The facility failed to produce documents verifying that the interpreting physician, Dr. [redacted], met the initial experience requirement of having interpreted or multi-read two hundred forty (240) mammograms in six (6) months. This is a violation of Title 21, Code of Federal Regulations, section 900.12(a)(1)(i)(D).

Level 2 – The facility failed to produce documents verifying that the interpreting physician, Dr. [redacted], met the initial requirement of having forty (40) hours of medical education in mammography prior to April 28, 1999. This is a violation of Title 21, Code of Federal Regulations, section 900.12(a)(1)(C). We acknowledge that the physician does fall under the exemption found in section 900.12(a)(1)(iii) (i.e., the requirement of forty (40) hours of medical education in mammography under the interim regulations applies, rather than the current requirement of 60 hours).

Level 2 – The facility failed to produce documents verifying that the interpreting physician, Dr. [redacted], met the initial experience requirement of having interpreted or multi-read two hundred forty (240) mammograms in six (6) months. This is a violation of Title 21, Code of Federal Regulations, section 900.12(a)(1)(i)(D).

Level 2 – The facility failed to produce documents verifying that the interpreting physician, Dr. [redacted], met the initial requirement of having forty (40) hours of medical education in mammography prior to April 28, 1999. This is a violation of Title 21, Code of Federal Regulations, section 900.12(a)(1)(C). We acknowledge that the physician does fall under the exemption found in section 900.12(a)(1)(iii) (i.e., the requirement of forty (40) hours of medical education in mammography under the interim regulations applies, rather than the current requirement of 60 hours).

Because these violations may be symptomatic 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 of 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
- seeking a court injunction against your facility.

See Title 42, United States Code, Sections 263b(h)-(j) and Title 21, Code of Federal Regulations, Section 900.12(j).

You should respond, in writing, to FDA within fifteen (15) working days from the date you received this letter. Your response should 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 implementation of those steps; and,

3. sample records that demonstrate proper record keeping procedures.
   Note: patient names and other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.

Further, in accordance with Title 21 Code of Federal Regulations section 900.12(a)(1)(iv), interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall re-establish their qualifications before resuming the independent interpretation of mammograms. Please provide written assurance that the two aforementioned interpreting physicians are now fully qualified to independently interpret mammograms or are not independently interpreting mammograms pending their re-qualifications or are no longer under your employ.

re: Desert Advanced Imaging Center
re: Warning Letter number 12 - 03

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

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, U. S. 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 this letter, 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