DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-63

September 20, 2002

FACILITY ID # 103598

Jodi Galbato, Vice President
Boca Radiology Associates
1590 NW 10th Avenue Suite 202
Boca Raton, Florida 33486

Dear Ms. Galbato:

We are writing to you because on August 21, 2002 a representative of the State of Florida, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 **repeat** violations at your facility:

Your facility failed to conduct a medical physicist's survey for x-ray unit 2, [redacted] (mammo room 3) within the last 14 months per 21 CFR 900.12(d)(1)(iii). The previous inspection of your facility dated August 23, 2001 also revealed that a physicist's survey for x-ray unit 3, [redacted] (mammo room 2), was not conducted within the prior 14 months.

Important Note Regarding Repeat Findings: An observation marked **repeat** indicates that the finding or violation was cited during the previous inspection and is, therefore, a repeat finding. A finding is considered a repeat finding if the same type of violation was cited during the previous inspection, whether or not the finding is associated with the same piece of equipment (x-ray unit, processor, or darkroom) or the same personnel in a given category.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection on August 21, 2002. Because these conditions may be symptomatic of serious underlying problems that

could compromise the quality of mammography at your facility, they represent a violation of the law that may result in FDA initiating regulatory action without informal notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction, 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, the MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against performing further mammography. (See 42 U.S.C. §§ 263b(h)-(j)).

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 or will take to correct all of the violations noted in this letter, any reason that corrective action has not been taken, and the time within which any steps not yet taken will be complete;

- 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

- documentation showing that correction is complete including, if the findings relate to quality control or other records, sample records that demonstrate proper record keeping procedures, (**Note: Patient names or identification should be deleted from any copies submitted**).

Please submit your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

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 actions, you should consider the more stringent state requirements, if any. You should also send a copy of your response to the state of Florida radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional state requirements in your response.

There are many FDA requirements pertaining to mammography. This letter only concerns the findings of your recent 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 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please contact D. Janneth Caycedo, Boca Resident Post, Food and Drug Administration, Interstate Plaza, 1499 W. Palmetto Park Rd., Ste. 110, Boca Raton, Florida 33486, telephone no. (561) 338-5236, ext. 23.

Sincerely,

for Emma R. Singleton
Director, Florida District