DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 Eighth Street, N.E.
Atlanta, Georgia 30309

June 5, 2002

VIA FEDERAL EXPRESS

Mary Scott Soo, M.D.
Chief of Breast Imaging
Duke University
General Internal Medicine Clinic/Mammography
3024 Pickett Road
Durham, NC 27707

Inspection ID: 1929300009

WARNING LETTER
(02-ATL-28)

Dear Dr. Soo:

Your facility was inspected on May 8, 2002, by a representative of the North Carolina Department of Environment & Natural Resources (DENR), Division of Radiation Protection, acting on behalf of the United States Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

- 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, [redacted] located in the mammography room.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 2, because it identifies a failure to meet a significant MQSA requirement in 21 CFR § 900.12 (e)(8). This was a repeat finding from the previous inspection of your facility on April 26, 2001.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA imposing regulatory sanctions. These sanctions 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 the federal mammography standards, or suspending or revoking your facility's FDA certificate.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days after receiving this letter:

- the specific steps you have taken to correct the violation 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 recordkeeping procedures, if the noncompliance relates 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 corrections will be completed. Please send the original copy of your response to: Serene A. Kimel, Compliance Officer, U.S. Food and Drug Administration, 60 8th St., NE, Atlanta, GA 30309. You should also send a copy of your response to the North Carolina DENR, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609-7221 and to Thomas Clarida, U.S. Food and Drug Administration, 5701 Executive Center Drive, Suite 104, Charlotte, NC 28212.

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

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704-344-6116.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District