Food and Drug Administration
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

June 3, 2002

VIA FEDERAL EXPRESS

Carl Nash, M.D.
Mammography Supervisor
Morehead Memorial Hospital
117 East Kings Highway
Eden, NC 27288

Inspection ID: 1582380006

WARNING LETTER
(02-ATL-27)

Dear Dr. Nash:

Your facility was inspected on 4/29/02 by a representative of the North Carolina Department of Environment & Natural Resources (DENR), Division of Radiation Protection, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Mammography Quality Standards Act of 1992 (MQSA) and with the Quality Standards for Mammography governing radiologic technologists, as specified in Title 21, Code of Federal Regulations (C.F.R.), Part 900.12, as follows:

- Your facility failed to produce documents verifying that the [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body.

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 1, because it identifies a failure to meet a significant MQSA requirement, specified in 42 U.S.C. § 263b(f)(1)(C) and 21 C.F.R. § section 900.12(a)(2)(i).

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 statutory sanctions without further notice to you. These sanctions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC) and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek 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 or to seek suspension or revocation of 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 all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;

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 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 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

Cc: [redacted]