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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161
FAX: 404-253-1202

October 15, 2002

VIA FEDERAL EXPRESS

Elaine Murtha
Director of Imaging Services
The Outer Banks Hospital
4800 S. Croatan Highway
Nags Head, NC 27959

Inspection ID: 2196340004

WARNING LETTER
(03-ATL-03)

Dear Ms. Murtha:

Your facility was inspected on September 26, 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 a serious regulatory problem involving the mammography services at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, 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 recent inspection at your facility revealed the following Level 1 and Level 2 findings:

Level 1 Noncompliance:

- The system to communicate results is not adequate in that there is no system in place to provide timely lay summaries. Lay reports are not given for "incomplete" assessments; and patients return for additional images sometimes more than 30 days later. [21 CFR § 900.12(c)(2)]

Level 2 Noncompliance:

- Your facility has not specified adequate procedures to be followed for infection control or did not follow them when required. [21 CFR § 900.12 (e)(13)]

- Your facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required. [21CFR § 900.12 (h)]

- The phantom QC is not adequate for Unit #2 [redacted] located in the mammography room because the image was not taken at clinical setting. [21 CFR § 900.12 (e)(2)]

- The medical physicist's survey for x-ray unit #2, described above, is incomplete because the following tests were inadequate or not done:
  -No AEC performance-reproducibility (numerical results were not given).
  -No AEC performance capability (Test was not done for 2, 4, and 6 cm phantom thicknesses at typical kVp(s) (numerical results were not given). [21 CFR §900.12 (e)(9)]

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because these conditions 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, placing 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;
- 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 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 findings related to the 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/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,

Barbara A. Wood, Acting Director
Atlanta District

Cc: [redacted]