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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER

NWE- 22 -03W

July 29, 2003

VIA FEDERAL EXPRESS

Re: MQSA Inspection ID # 2237430004

Newton E. Kendig II, M.D.
Medical Director
Department of Justice
Federal Bureau of Prisons
320 First Street, NW
Washington, D.C. 20534

Dear Dr. Kendig:

We are writing to you because on June 24, 2003, the mammography facility at the Federal Correctional Institution located at 33 1/2 Pembroke Road, Danbury, CT, was inspected by a representative of the Food and Drug Administration (FDA). This inspection revealed a serious problem involving the conduct of mammography at that facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b, and the regulations set forth in Title 21, Code of Federal Regulations (CFR), Part 900, the facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following violations of the MQSA at the facility. These violations were noted on the MQSA Facility Inspection Report as Level 1 and Repeat Level 2 findings:

Quality Standards-Equipment- 21 CFR 900.12(e)

Level 1: Processor QC records in the month of November, 2002 were missing for at least 30% of operating days, for the [redacted] processor in the

darkroom. Your records showed that mammography was performed on three days in November and that processor QC was only done one of those days. [21 CFR 900.12(e)(1)]

Quality Standards-Medical Records and Mammography Reports-21 CFR 900.12(c)

Repeat Level 2: Three (3) of five (5) random reports reviewed did not contain an acceptable assessment category for site Federal Correctional Institution. [21 CFR 900.12(c)(1)(iv)]

The specific problems noted above appeared on the MQSA Facility Inspection Report issued to the FCI Danbury Health Services Administrator at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility. A Repeat Level 2 finding indicates a failure to meet a significant MQSA requirement and a failure by the facility to implement permanent correction of problems found during the previous inspection.

In addition, there were Level 2 and Repeat Level 3 findings listed on the inspection report provided to the FCI Danbury Health Systems Administrator at the close of the inspection. A Level 2 and Repeat Level 3 finding indicate that the inspector found one or more deviations from MQSA standards that may compromise the quality of mammography services offered by the facility (or indicate a failure to meet an MQSA requirement and a failure by the facility to implement permanent correction of problems found during the previous inspection). These Level 2 and Repeat Level 3 findings are:

Quality Standards-Equipment-21 CFR 900.12(e)

Level 2: Processor QC records were missing at least two (2) but less than five (5) consecutive days for the [redacted] processor in the darkroom; [21 CFR 900.12(e)(1)]

Quality Standards-Personnel-21 CFR 900.12(a)

Level 2: Failed to produce documents verifying that the interpreting physician [redacted]

met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months (0 CME's in 36 months); [21 CFR 900.12(a)(1)(ii)(B)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted]

met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months (0 CME's in 36 months); [21 CFR 900.12(a)(1)(ii)(B)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted]

met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months (0 CME's in 36 months); [21 CFR 900.12(a)(1)(ii)(B)]

Quality Standards-Equipment-21 CFR 900.12(e)

Level 2: 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 the [redacted] unit in the X-ray room; [21 CFR 900.12(e)(8)(ii)]

Quality Standards-Equipment-21 CFR 900.12(e)

Repeat Level 3: The fixer retention QC is not adequate for the [redacted] processor in the darkroom because the fixer retention QC tests were not done at the required frequency. [21 CFR 900.12(e)(3)]

Because these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography at the FCI Danbury mammography facility, they represent serious violations of the law that may result in FDA initiating regulatory action. These actions include, but are not limited to, the following: requiring the facility to undergo an Additional Mammography Review; placing the facility under a Directed Plan of Correction; charging the 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, the MQSA standards; seeking suspension or revocation of the facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 USC §§ 263b(h)-(j) and 21 CFR § 900.12(j).

Before initiating any enforcement action against the facility, FDA may need to perform a follow-up inspection of your facility to determine whether these problems have been corrected.

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 to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

- the specific steps your facility has taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

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

Please submit your response to M. Patricia Murphy, Compliance Officer, at U.S. Food and Drug Administration, One Montvale Avenue, 4th floor, Stoneham, MA 02180.

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.

If you have specific questions about mammography facility requirements, you may contact Michael Leal, MQSA Auditor. If you have specific questions concerning this matter, please contact Ms. Murphy at 781-596-7758.

Sincerely yours,

Gail T. Costello
New England
District Director