DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

CIN–03-19031

October 15, 2003

Sent by Federal Express

Dr. Antonio Motta
Medical Director
Kaiser Permanente –East
12301 Snow Rd.
Parma, OH 44130

RE: Facility MQSA I.D. #: 221837
Cleveland Heights Medical Center
10 Severance Circle
Cleveland Heights, OH 44118

Dear Dr. Motta:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility (Cleveland Heights Medical Center, 10 Severance Circle, Cleveland Heights, OH 44118) on September 8, 2003. This inspection revealed a serious regulatory problem involving the mammography at your 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 (C.F.R.), Part 900, 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 Level 1 finding at your facility (identified on your inspection report):

Medical records and mammography reports – *Communication of mammography results to the patients* (21 C.F.R. § 900.12(c)(2))

Your records revealed that your facility failed to provide lay summary letters to patients that included the results of each mammography examination written in lay terms within 30 days of the examinations. During the inspection, there were at least three patient film records waiting for comparison films whose mammography examination dates had been more than 30 days. The mammography records indicated the following examination dates: July 29, August 5 & 6, 2003. Your facility failed to ensure that these mammograms are interpreted and results are communicated to the patients within thirty days of the date of examinations. Your facility failed to follow your own Mammography Policy/Procedure which states: " In the event that outside

comparison images must be obtained, a letter of results is sent within 30 days of the mammogram."

The inspection also revealed the following Level 2 violation at your facility (identified on your inspection report):

Quality Assurance – *Equipment* (21 CFR 900.12(e)(8)(ii)(A), *as required in 21 CFR 900.12(e)(2)(ii)*)

Your 2003 phantom quality control record revealed on July 8, 2003, the background density was charted outside the allowable regulatory limit and your facility failed to document corrective action taken before further mammography exams.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law that may result in FDA initiating regulatory action. 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 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 your facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 USC §§ 263b(h) through (j) of the MQSA). Before initiating any enforcement action against you, FDA may perform a follow-up inspection of your facility to determine whether these problems have been corrected. FDA assesses fees for MQSA inspections, including follow-up inspections 42 USC 263b(r).

It is necessary to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. The specific steps you have taken to correct the violations noted in this letter; and

2. Each step your facility is taking **to prevent the recurrence** of similar violations.

Please also provide the following in answering this letter: (Note: Patient names or patient social security numbers should be deleted from any copies submitted)

1. A copy of your corrected written procedure for communication of mammography results ensuring that patients will receive a lay summary letter within 30 days of mammography examinations. The written procedure shall also include communication of "Suspicious" and Highly suggestive of malignancy" mammography results to the patients as soon as possible (normally within three to five days) from the date of examination. The written procedures shall cover all mammography results for patients with or without comparison films. Also, include a copy of sample lay summary letters for each final assessment categories.

2. A copy of your written procedure for documentation of corrective actions when the phantom QC parameter(s) is operating out of limits.

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Ms. Terri Eckert
Ohio Department of Health
Radiological Technology Section
161 South High St., Suite 400
Akron, OH 44308-1616

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.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138.

Sincerely yours,

Carol A. Heppe
District Director
Cincinnati District Office

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OH/TEckert

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Program
American College of Radiology
1891 Preston White Dr.
Reston, VA 20191