



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1b05d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

August 6, 2001

via Federal Express

MQSA Facility ID: 124222
Inspection ID: 1242220006

FDA Reference #: 2951761

Jerry Wood, Radiology Manager
Mendocino Coast District Hospital
700 River Drive
Fort Bragg, CA 95437

Dear Jerry Wood:

We are writing to you because on July 16, 2001, your facility was inspected by a representative of the State of California, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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:

- Level 1: Processor QC records were missing at least 5 consecutive days for processor 0000000001, [REDACTED] room Mammo at site Mendocino Coast District Hospital

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.

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 taking regulatory action without further notice to you. 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, assessing 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, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, there were Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: Processor QC records in the month of 05/2001 were missing for at least 10% but less than 30% of operating days, for processor 0000000001, [REDACTED] room Mammo at site Mendocino Coast District Hospital5
- Level 2: Failed to produce documents verifying that the radiologic technologist [REDACTED] (8.5 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months

We acknowledge your faxed response dated July 30, 2001. Your response appears to adequately address the Level 1 and the first of the two Level 2 findings above. However, the response does not address the issue regarding the failure of the radiologic technologist to meet the continuing education requirement. Please provide a response to this office in writing within 15 days on the steps you have taken to correct this finding.

Please submit your response to:

Russell A. Campbell, Compliance Officer
San Francisco District
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

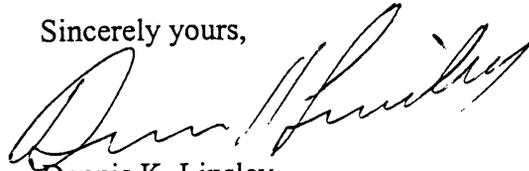
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography 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>.

Letter to Jerry Wood
Mendocino Coast District Hospital

Page 3
August 6, 2001

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell, Compliance Officer, at (510) 337-6861.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is written in a cursive style with a large, looping initial "D".

Dennis K. Linsley
District Director