



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91760d  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

September 21, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Reference: Warning Letter SEA 01-87  
Inspection ID: 1211600007

Mr. Moe Chaudry, Administrator  
Lower Umpqua Hospital  
600 Ranch Road  
Reedsport, Oregon 97467

**WARNING LETTER**

Dear Mr. Chaudry:

We are writing to you because on September 13, 2001, your facility was inspected by Robert Ropcinski, a representative of the State of Oregon, acting on 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:

Phantom QC records were missing for at least 4 weeks for unit 2, [REDACTED], [REDACTED], OTH, mammography room.

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, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

Mr. Moe Chaudry, Administrator  
Lower Umpqua Hospital, Reedsport, Oregon  
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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;
- each step your facility is taking to prevent the recurrence of similar violations;
- 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 U.S. Food & Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23<sup>rd</sup> Drive, SE, Bothell, Washington 98021-4421.

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, Maryland 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

Sincerely,



Charles M. Breen  
District Director

\*This note is not applicable for letters that also address patient notification.

CC: Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
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1891 Preston White Drive  
Reston, Virginia 20191

Mr. Moe Chaudry, Administrator  
Lower Umpqua Hospital, Reedsport, Oregon  
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J. Robert Rapcinski  
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