

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

\_\_\_\_\_)  
In the Matter of )  
 )  
ECUMED HEALTH GROUP ) ADMINISTRATIVE COMPLAINT  
a corporation, ) FOR CIVIL MONEY PENALTY  
 )  
and )  
 )  
AMADOR REYES, ) FDA Docket: 2004H-0322  
JUAN C. CARRAI, )  
RICHARD W. STONE, M.D., and )  
ERLINDA E. ENRIQUEZ, M.D., )  
individuals. )  
\_\_\_\_\_)

JOINT STIPULATION

In this Civil Money Penalties action under 21 C.F.R. Part 17 for alleged violations of the Mammography Quality Standards Act ("MQSA"), 42 U.S.C. § 263b, Complainant, the Center for Devices and Radiological Health ("CDRH"), Food and Drug Administration ("FDA"), and Respondents Ecumed Health Group ("EHG"), Amador Reyes, Juan C. Carrai, Richard W. Stone, M.D., and Erlinda E. Enriquez, M.D., hereby jointly stipulate and agree that at all relevant times:

1. EHG was a corporation organized under the laws of the state of Florida.
2. EHG was engaged in the business of conducting mammography examinations, and it owned and operated a

2004H-0322

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mammography facility that did business at 687 East 9th Street, Hialeah, Florida 33010.

3. Respondent Amador Reyes was the president and co-owner of EHG.

4. Respondent Juan C. Carrai was the vice-president and co-owner of EHG, as well as the registered radiologic technician. Mr. Carrai admitted in his "Answer and Affirmative Defenses of Juan C. Carrai" that he had authority over all mammography and x-ray operations conducted at EHG.

5. Respondent Richard W. Stone, M.D., was the Lead Interpreting Physician at EHG from October 30, 2000, through at least January 31, 2002.

6. Respondent Erlinda E. Enriquez, M.D., was the Lead Interpreting Physician at EHG from at least September 11, 2002, through May 6, 2003.

7. In a letter signed by John L. McCrohan, CDRH, FDA, that was addressed to Respondent Dr. Richard Stone at Ecumed Health Group, 687 E. 9 St., Hialeah, FL 33010, dated June 13, 2001 (hereafter, "the June 2001 letter"), FDA stated that it was issuing a six-month provisional mammography certificate (hereafter, "the provisional certificate") to EHG. The letter advised that "while [EHG's] application is in progress," the provisional certificate "certifies [EHG] as a lawful provider of mammography services . . . ."

8. The June 2001 letter also stated that it contained several enclosures, including the provisional certificate and the "Mammography Quality Standards Act Six-Month Provisional Certificate Fact Sheet." The provisional mammography certificate had an expiration date of December 8, 2001; this expiration date was indicated on the provisional certificate.

9. By letter dated June 11, 2001, the American College of Radiology ("ACR") issued testing materials to EHG for its mammography unit.

10. In a letter from Priscilla F. Butler, ACR, that was addressed to Respondent Dr. Richard Stone at Ecumed Health Group, 687 E. 9 St., Hialeah, FL 33010, dated September 14, 2001, ACR advised that EHG's certificate would soon expire. The letter explained that EHG could not legally conduct mammography if EHG's MQSA certificate expired. The letter also explained that, without such certification, EHG could be subject to sanctions or fines by FDA.

11. In a letter signed by CAPT John L. McCrohan, CDRH, FDA, that was addressed to Respondent Dr. Richard Stone at Ecumed Health Group, 687 E. 9 St., Hialeah, FL 33010, dated November 1, 2001 (hereafter "the November 2001 FDA letter"), FDA advised that EHG's MQSA certificate would expire on December 8, 2001. This letter also stated that EHG could not perform mammography services once EHG's MQSA certificate expired.

Furthermore, the letter offered two options if the facility wanted to continue its mammography services: (a) apply for reinstatement, or (b) apply for a 90-day extension of mammography operations under the provisional certificate.

12. Enclosed with the November 2001 letter was a copy of the "Mammography Quality Standards Act Expiration of Certificate (Provisional) Fact Sheet." This document is attached hereto as Exhibit A-1.

13. In a letter signed by Judy M. Destouet, ACR, that was addressed to Respondent Dr. Richard Stone at Ecumed Health Group, 687 E. 9 St., Hialeah, FL 33010, dated November 14, 2001, ACR advised that EHG's mammography unit could not be accredited due to one or more deficiencies. According to this letter, EHG failed to qualify for accreditation because ACR's examination of EHG's clinical image quality testing showed that EHG's mammography unit failed to comply with ACR's standards for clinical image quality. The letter also stated that mammography could not be lawfully conducted once the firm's MQSA certificate expired.

14. EHG's certificate expired on December 8, 2001.

15. On December 12, 2001, ACR received an appeal of the November 14, 2001 ACR letter denying EHG accreditation for the failure of the mammography unit to meet the ACR's standards for clinical image quality. This appeal was dated December 7, 2001,

and contains a signature that reads "Richard Stone." This signature appears over the title "Signature of Supervising Radiologist."

16. In a letter signed by Judy M. Destouet, ACR, that was addressed to Respondent Dr. Richard Stone at Ecumed Health Group, 687 E. 9 St., Hialeah, FL 33010, dated January 4, 2002, ACR denied EHG's appeal. ACR again found that it could not accredit EHG's mammography unit due to one or more deficiencies. The letter advised that EHG's mammography unit failed to comply with ACR's standards for clinical image quality. The letter also stated that for EHG to provide mammography services, it must apply for provisional reinstatement.

17. On or after September 20, 2002, EHG sent to ACR an application for reinstatement for its mammography unit. The application has several different sections, including, but not limited to the Mammography Survey Agreement. The Mammography Survey Agreement is attached hereto as Exhibit A-2.

18. On May 6, 2003, ACR notified FDA that EHG's application was successfully complete for review, and that EHG was eligible for provisional reinstatement. Therefore, on May 7, 2003, FDA issued an interim notice to Janet Labrada at Ecumed Health Group, 687 E. 9 St., Hialeah, FL 33010. This interim notice served as EHG's certification to conduct mammography services until it received a provisional certificate.

19. In a letter to Respondent Dr. Erlinda Enriquez at Ecumed Health Group, 687 E. 9 St., Hialeah, Florida 33010, dated May 9, 2003, FDA issued a MQSA provisional certificate to EHG. This MQSA certificate had an expiration date of November 6, 2003.

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Respectfully Stipulated to by,



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May 20<sup>th</sup>, 2005



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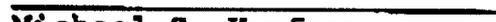
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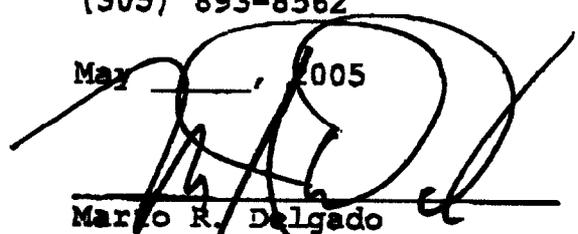
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CERTIFICATE OF SERVICE

I certify under the penalty of perjury that on this 20th day of May, 2005, I served a copy of this Joint Stipulation via facsimile and regular U.S. mail on the following:

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