

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

In the Matter of)
)
ECUMED HEALTH GROUP)
a corporation,)

ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY

and)

AMADOR REYES,)
JUAN C. CARRAI,)
RICHARD W. STONE, M.D., and)
ERLINDA E. ENRIQUEZ, M.D.,)
individuals.)

FDA Docket: 2004H-0322)

PARTIAL SUMMARY DECISION

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), brought this action for administrative civil money penalties against Respondents Ecumed Health Group, Inc., Amador Reyes, Juan C. Carrai, Richard W. Stone, M.D., and Erlinda E. Enriquez, M.D., alleging violations of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b.

On June 10, 2005, Complainant filed its Motion For Partial Summary Decision (Complainant's Motion) moving for partial summary decision on the issue of Respondents' liability for these violations. Pursuant to 21 C.F.R. § 17.17(a) Respondents had 30 days in which to respond to Complainant's Motion. No responses have been filed.

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Consideration of the Complainant's Motion and the record of this proceeding lead to the following findings of fact and conclusions of law:

FINDINGS OF FACT

During all relevant times:

1. Respondent Ecumed Health Group, Inc. (EHG), was a corporation organized under the laws of the State of Florida and was doing business at 687 East 9th Street, Hialeah, Florida 33010. See Answer of EHG and Amador Reyes (hereafter, "EHG/Reyes Answer") ¶ 2; Florida Uniform Business Report for year 2001, 2002, and 2003 (hereafter, "FL Business Reports"), attached as Ex. G-C; Joint Stipulation (Joint Stip.; filed May 20, 2005) ¶¶ 1 and 2. EHG owned and operated a mammography facility within the meaning of 42 U.S.C. § 263b(a)(3). See EHG/Reyes Answer ¶ 2; Joint Stip. ¶ 2.

2. Respondent Amador Reyes was the president and a co-owner of EHG. See EHG/Reyes Answer ¶ 2; Joint Stip. ¶ 3; FL Business Reports. Mr. Reyes ran the administrative operations of the firm and was in charge of establishing new accounts. See Declaration of D. Janneth Caycedo (Caycedo Decl.; Attached as Ex. G-B to Complainant's Motion) ¶ 11 and attachment G-B(5) thereto. As president and co-owner of EHG, Mr. Reyes was the most responsible person at the firm, and thus, was responsible

for all operational decisions. See Answer of Respondent Carrai (hereafter, "Carrai Answer") ¶ 4.

3. Respondent Juan C. Carrai was the vice-president and co-owner of EHG, as well as the registered radiologic technician. See Carrai Answer ¶ 5; Joint Stip. ¶ 4. Mr. Carrai has admitted that he had authority over all mammography and x-ray operations conducted at EHG. See Carrai Answer ¶ 5; Joint Stip. ¶ 4.

4. Respondent Richard W. Stone, M.D., was the Lead Interpreting Physician, within the meaning of 21 C.F.R. § 900.12(d)(1)(ii), at EHG from on or about October 30, 2000, through January 31, 2002. See Answer of Respondent Dr. Stone ¶ 6; Joint Stip. ¶ 5. As Lead Interpreting Physician, Dr. Stone was responsible for ensuring that the clinical image quality of the mammograms at EHG was adequate. Dr. Stone also read and interpreted mammograms for EHG until at least July 8, 2002. See Declaration of Michael P. Divine (Divine Decl.; Attached as Ex. G-A to Complainant's Motion) ¶ 28; Caycedo Decl. ¶ 8 and Ex. G-B(2), (3), (6), and (7) attached thereto.

5. Respondent Erlinda E. Enriquez, M.D., was the Lead Interpreting Physician, within the meaning of 21 C.F.R. § 900.12(d)(1)(ii), at EHG from on or about September 19, 2002 through May 6, 2003. See Joint Stip. ¶ 6. As Lead Interpreting Physician, Dr. Enriquez was responsible for ensuring adequate

clinical image quality at EHG. Dr. Enriquez also read and interpreted mammograms for EHG throughout the relevant period of time. See Divine Decl. ¶ 28; Caycedo Decl. ¶ 8 and Ex. G-B(2), (3), (6), and (7) attached thereto.

6. FDA issued a provisional MQSA certificate to EHG on June 13, 2001. See Divine Decl. ¶ 11 and Ex. G-A(1) attached thereto; Joint Stip. ¶ 7. The provisional certificate allowed EHG to perform mammography while conducting additional testing in order to obtain full MQSA certification of its facility. See Divine Decl. ¶¶ 11 and 12 and Ex. G-A(1), (2), and (3) attached thereto. The provisional certificate expired on December 8, 2001. Id.; Joint Stip. ¶ 8. This expiration date was clearly indicated on the provisional certificate. See Divine Decl. ¶ 12 and Ex. G-A(2) attached thereto.

7. By letter dated September 14, 2001, ACR notified Respondents that EHG's provisional certificate would soon expire. See Divine Decl. ¶ 13 and Ex. G-A(4) attached thereto; Joint Stip. ¶ 10. The letter explained that EHG could not legally conduct mammography examinations once EHG's provisional MQSA certificate expired. See Divine Decl. ¶ 13 and Ex. G-A(4) attached thereto; Joint Stip. ¶ 10. It further explained that, if EHG conducted mammography examinations without being certified, EHG could be subject to sanctions or fines by FDA.

See Divine Decl. ¶ 13 and Ex. G-A(4) attached thereto; Joint Stip. ¶ 10.

8. FDA also notified Respondents in a letter dated November 1, 2001, that EHG's provisional MQSA certificate would expire on December 8, 2001, unless it was reinstated. See Divine Decl. ¶ 14 and Ex. G-A(5) attached thereto; Joint Stip. ¶ 11. The letter also advised that EHG could not perform mammography services once EHG's MQSA certificate expired. See Divine Decl. ¶ 14 and Ex. G-A(5) attached thereto; Joint Stip. ¶ 11.

9. By letter dated November 14, 2001, ACR informed EHG that it failed to qualify for full accreditation as a mammography facility because ACR's examination of EHG's clinical image quality testing showed that it did not comply with ACR's standards. See Divine Decl. ¶ 16 and Ex. G-A(7) attached thereto; Joint Stip. ¶ 13. The letter also reminded Respondents that they may not lawfully conduct mammography examinations after the firm's provisional MQSA certificate expired. See Divine Decl. ¶ 16 and Ex. G-A(7) attached thereto; Joint Stip. ¶ 13.

10. EHG's provisional MQSA certificate expired on December 8, 2001. See Divine Decl. ¶ 17 and Ex. G-A(2) attached thereto; Joint Stip. ¶ 14. On December 12, 2001, EHG appealed ACR's decision denying accreditation for its failure to meet the ACR's

standards for clinical image quality. See Divine Decl. ¶ 18 and Ex. G-A(8) attached thereto; Joint Stip. ¶ 15. Respondent Dr. Stone signed this appeal, in his capacity as Supervising Radiologist, and dated December 7, 2001. See Divine Decl. ¶ 18 and Ex. G-A(8) attached thereto; Joint Stip. ¶ 15.

11. By letter dated January 4, 2002, ACR informed Respondents that it had denied their appeal. See Divine Decl. ¶ 19 and Ex. G-A(9) attached thereto; Joint Stip. ¶ 16. ACR again found that it could not accredit EHG's mammography unit due to one or more deficiencies. See Divine Decl. ¶ 19 and Ex. G-A(9) attached thereto; Joint Stip. ¶ 16. The letter advised EHG that it had failed to comply with ACR's standards for clinical image quality. See Divine Decl. ¶ 19 and Ex. G-A(9) attached thereto; Joint Stip. ¶ 16. The letter also stated that EHG had to apply for provisional reinstatement in order to provided mammography services. See Divine Decl. ¶ 19 and Ex. G-A(9) attached thereto; Joint Stip. ¶ 16.

12. On October 14, 2002, ACR received from EHG an application to reinstate certification of its mammography unit. See Divine Decl. ¶ 20 and Ex. G-A(10) attached thereto. The application has several different sections, including, but not limited to, information regarding EHG's radiologist, the MQSA Information Release Authorization (hereafter, "the Release

Authorization"), and the Mammography Survey Agreement. Id.; see also, Joint Stip. ¶ 17.

13. The section of the application that called for the identity of, and information about, the radiologist, identified and provided information about Respondent Dr. Enriquez. Id. The end of this section contains the signature of Respondent Dr. Enriquez, dated September 19, 2002. Id.

14. The Release Authorization authorized ACR to submit to FDA information about EHG that it gave to ACR. Id. The Release Authorization contains the signature of Respondent Dr. Enriquez, as Supervising Radiologist and Lead Interpreting Physician, dated September 19, 2002. See Divine Decl. ¶ 20 and Ex. G-A(10) attached thereto.

15. The Mammography Survey Agreement is a document that a facility uses to request that the ACR survey the quality of the facility's mammography service. Id. As a condition of receiving the requested survey, the Lead Interpreting Physician and the facility agree to numerous obligations, including, but not limited to: (a) providing, in a timely manner, all materials, including clinical images, phantom images, and other information necessary to evaluate mammography services for accreditation purposes, and (b) ensuring that the facility's quality assurance procedures and all other accreditation criteria are met and will continue to be complied with during

the accreditation period. Id. The Mammography Survey Agreement contains the signatures of Respondent Dr. Erlinda Enriquez (as Lead Interpreting Physician), dated September 19, 2002, and Respondent Juan Carrai (as President/CEO of EHG), dated September 20, 2002. Id.

16. On May 5, 2003, ACR received a summary of the Quality Control Tests of EHG's mammography unit that were performed by EHG's medical physicist on April 29, 2003. See Divine Decl. ¶ 21 and Ex. G-A(11) attached thereto. The tests completed the required information that EHG needed to submit to ACR to obtain provisional certification. Id.

17. When EHG completed its application for reinstatement, ACR notified FDA that EHG's application was complete for review and that EHG was eligible for provisional reinstatement. Id.

¶ 22. Thereafter, on May 7, 2003, FDA issued an interim notice to EHG. See Divine Decl. ¶ 22 and Ex. G-A(12) attached thereto; Joint Stip. ¶ 18. This interim notice served as EHG's certification to conduct mammography services until it received a provisional certificate. See Divine Decl. ¶ 22 and Ex. G-A(12) attached thereto; Joint Stip. ¶ 18.

18. In a letter to Respondent Dr. Enriquez, dated May 9, 2003, FDA issued a provisional MQSA certificate to EHG. See Divine Decl. ¶ 23 and Ex. G-A(13) attached thereto; Joint Stip. ¶ 19. This MQSA certificate had an expiration date of November

6, 2003, which was clearly indicated on the certificate. See Divine Decl. ¶ 23 and Ex. G-A(13) attached thereto; Joint Stip. ¶ 19. Therefore, between and including December 9, 2001, and May 6, 2003, EHG was not certified by the FDA to perform mammography.¹ See Divine Decl. ¶ 24 and Ex. G-A(14) attached thereto.

19. On April 23 and 24, 2003, FDA and the State of Florida conducted a joint, unannounced inspection of EHG. See Caycedo Decl. ¶ 5. The purpose of FDA's inspection was to determine whether EHG had performed mammography without a valid MQSA certificate. Id. During this inspection, Respondent Reyes told the FDA investigator, D. Janneth Caycedo, that EHG was not performing mammography. Id. ¶ 6 and Ex. G-B(1) attached hereto. Ms. Caycedo then asked to see a list of patients for that day, April 23, 2003. Id. While Mr. Reyes went to retrieve a printout of the patient log for that day, Ms. Caycedo observed a patient log sitting on top of a secretary's table. Id. ¶ 7. Ms. Caycedo requested to see it, and found that it was a log for all examinations performed during the month of April. See

¹ Mr. Carrai incorrectly asserted in his affidavit that, after the December 8, 2001 expiration of EHG's provisional MQSA certificate, EHG received another provisional MQSA certificate, which expired in June 2002. See Caycedo Decl. ¶ 8 and Ex. G-B(2) attached thereto. Complainant searched its files and confirmed that between and including December 9, 2001, and May 6, 2003, FDA did not issue a mammography certificate to EHG. See Divine Decl. ¶ 24 and Ex. G-A(14) attached thereto.

Caycedo Decl. ¶ 7. This log included many appointments for mammograms. Id.

20. When Mr. Reyes returned, Ms. Caycedo showed Mr. Reyes the log for all examinations done during April 2003. Id. Mr. Reyes then instructed Ms. Caycedo to speak with Respondent Carrai. Id.

21. Ms. Caycedo spoke with Respondent Carrai. In a signed affidavit, Respondent Carrai stated that he performed mammography and that EHG was presently conducting mammography without a certificate. See Caycedo Decl. ¶ 8 and Ex. G-B(2) attached thereto. He also stated that the mammograms were read and interpreted by Dr. Stone and Dr. Enriquez. Id. Respondent Carrai gave Ms. Caycedo photocopies of EHG's patient logs covering January 2003 through April 2003. See Caycedo Decl. ¶ 9 and Ex. G-B(3) attached thereto showing that EHG conducted mammography between January 2003 and April 2003.

22. In June 2003, FDA again visited EHG. See Caycedo Decl. ¶ 11 and Ex. G-B(4) attached thereto. During this visit, FDA Investigator Caycedo requested copies of EHG's patient log for 2002, the mammography examinations that corresponded to each patient entry for 2002, and all mammography reports that corresponded to the patient logs between and including January 2003 to April 2003. Id. Respondent Reyes provided copies of these documents to Ms. Caycedo. See Caycedo Decl. ¶ 12 and Ex.

G-B(5) and Ex. G-B(6) and (7), which are attached thereto showing that EHG conducted mammography between and including January 2002 and April 2003.

23. The patient logs and mammography reports for 2002 and January 2003 through April 2003 show that EHG conducted at least 1201 mammography examinations between and including January 7, 2002, and April 23, 2003, during the period when EHG was not certified by FDA to conduct mammography examinations. See Divine Decl. ¶¶ 24, 27, and 28 and Ex. G-A(14) attached thereto; Caycedo Decl. ¶¶ 9, 12, and 13 and Ex. G-B(3), (6), and (7) attached thereto.

CONCLUSIONS OF LAW

24. Under the regulations governing this action, "a party may move . . . for a summary decision on any issue in the hearing." 21 C.F.R. § 17.17(a). The Presiding Officer "shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue of material fact and that the party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b).

25. Furthermore, where "a motion for summary decision is made and supported as provided in [21 C.F.R. § 17.17], a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions;" it must

submit affidavits or other responses that "set forth specific facts showing that there is a genuine issue of material fact for the hearing." 21 C.F.R. § 17.17(c).

26. The MQSA became effective on October 1, 1994. Id. It was enacted to establish uniform mammography standards and a certification process to ensure that only those mammography facilities providing high quality mammograms would remain in operation. See 62 Fed. Reg. 55852 (Oct. 28, 1997).

27. Under the MQSA, no mammography facility may conduct a mammography examination or procedure unless it possesses an effective certificate that has been issued or renewed under the MQSA. 42 U.S.C. § 263b(b)(1).

28. In order to obtain or renew a certificate, the MQSA, and its implementing regulations, require a facility to apply to, and be accredited by, an FDA-approved accreditation body.² 42 U.S.C. § 263b(d)(1)(A)(iv); 21 C.F.R. §§ 900.11(a) and (b). Once FDA receives notification of the accreditation body's decision to accredit a facility, FDA may issue a certificate to

² FDA designates and approves private agencies to evaluate the performances of mammography facilities and to accredit or re-accredit those facilities that meet certain standards. In this case, the American College of Radiology ("ACR") has met the requirements of FDA's regulations for a mammography accreditation. Therefore, the ACR is designated and approved by FDA to accredit facilities to be eligible to perform screening or diagnostic mammography services.

the facility or renew the facility's existing certificate. 21 C.F.R. § 900.11(b)(ii).

29. Where a previously certified facility has allowed its certificate to expire or has been refused a renewal, the facility may apply to an accreditation body to have its certificate reinstated. See 21 C.F.R. § 900.11(c). A facility applying for reinstatement must submit to an accreditation body, among other things, a mammography corrective action plan ("CAP") that details how the facility has corrected the deficiencies that led to the lapse of its certificate. See 21 C.F.R. § 900.11(c)(1)(iii).

30. At the time it submits its application for accreditation, a facility is also required to submit an evaluation of its mammography equipment that demonstrates that the facility's equipment complies with the requirements in 21 C.F.R. § 900.12(e). See 21 C.F.R. § 900.4(e)(1)(i). The Lead Interpreting Physician is responsible for ensuring that a facility's mammography equipment complies with 21 C.F.R. § 900.12(e). See 21 C.F.R. § 900.12(d)(1)(i).

31. FDA may issue a provisional certificate to the facility once the accreditation body notifies FDA that the facility has corrected, or is in the process of correcting, the deficiencies that led to the lapse of its certificate. See 42 U.S.C. § 263b(c)(2); 21 C.F.R. § 900.11(c)(2).

32. Once a facility receives a provisional certificate, it may lawfully perform mammography services while completing the requirements of certification. See 21 C.F.R. § 900.11(c)(3). However, a provisional certificate can only be effective for up to six (6) months from the date of issuance. See 21 C.F.R. § 900.11(b)(2)(ii). A facility may not conduct mammography unless the facility prominently displays the provisional certificate in its facility. 42 U.S.C. § 263b(b)(1)(B)(iii).

33. No genuine issue of material fact exists as to whether Respondents EHG, Amador Reyes, Juan C. Carrai, Richard W. Stone, M.D., and Erlinda E. Enriquez, M.D. violated, or aided and abetted in violations of, the MQSA.

34. The undisputed facts show that:

(a) Respondent EHG was not certified under the MQSA between and including December 9, 2001, until May 6, 2003, during which time EHG performed mammography examinations in violation of 42 U.S.C. § 263b(b)(1). Furthermore, EHG conducted at least 1201 mammography examinations between and including January 7, 2002, and April 23, 2003, while EHG was not certified, in violation of 42 U.S.C. § 263b(b)(1). Thus, as a corporation, EHG is, as a matter of law, liable for 1202 violations of the MQSA;

(b) Amador Reyes and Juan C. Carrai, as co-owners of the facility and most responsible individuals at EHG, are, as a matter of law, responsible for the same violations; and

(c) Respondents Richard Stone, M.D., and Erlinda E. Enriquez, M.D., aided and abetted in EHG's MQSA violations. Dr. Stone and Dr. Enriquez clearly knew that EHG did not have the required certification; yet, Dr. Stone and Dr. Enriquez conducted, read, and/or interpreted at least 126 and 616 mammography examinations, respectively, while EHG was uncertified. Therefore, as a matter of law, Dr. Stone and Dr. Enriquez are liable for aiding and abetting EHG in 126 and 616 violations of the MQSA, respectively.

A. ECUMED HEALTH GROUP

1. Failure to Obtain a Certificate

35. Under 42 U.S.C. § 263b(h) (3) (A), FDA may assess civil money penalties for the "failure to obtain a certificate as required by" 42 U.S.C. § 263b(b).

36. The MQSA places the responsibility for obtaining a certificate upon the owner or lessee of the facility, or an authorized agent to either. 42 U.S.C. § 263b(d) (1).

37. EHG was the owner and operator of the EHG facility.

38. EHG failed to obtain a certificate for the period between and including December 9, 2001, until May 6, 2003, during which time EHG performed mammography in violation of 42 U.S.C. § 263b(b) (1). Therefore, EHG is liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A).

2. Performance of 1201 Uncertified Mammography Examinations

39. Under 42 U.S.C. § 263b(h) (3) (D), FDA may assess civil money penalties in an amount not to exceed \$10,000 for each violation of, or for aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate.

40. Between and including January 7, 2002, and April 23, 2003, EHG's owners and employees conducted at least 1201 mammography examinations while it was not certified, in violation of 42 U.S.C. § 263b(b) (1). Therefore, EHG is liable for 1201 violations of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (D).

41. Accordingly, EHG is liable for a total of 1202 violations of the MQSA.

B. AMADOR REYES AND JUAN C. CARRAI

42. Respondents Amador Reyes and Juan C. Carrai, as the owners and most responsible individuals at EHG, are each liable, as a matter of law, for 1202 violations of the MQSA for performing mammography examinations without a certificate.

43. It is well established that responsible corporate officers are individually liable for violations of public health legislation. See United States v. Dotterweich, 320 U.S. 277, 285 (1943); United States v. Park, 421 U.S. 658, 672 (1975);

United States v. Hodges X-Ray, Inc., 759 F.2d 557, 560 (6th Cir. 1985).

44. Accordingly, a corporate officer who is in a position to prevent or correct violations of statutes affecting public health is personally responsible for such violations. See Park, 421 U.S. at 673-74.

45. Amador Reyes and Juan Carrai, by virtue of their positions and responsibilities, had the authority to prevent and correct EHG's violations of the MQSA. Amador Reyes was the president and a co-owner of EHG. Juan Carrai was the vice-president and a co-owner of EHG, as well as the registered radiologic technician. Additionally, Mr. Carrai has admitted to having authority over all mammography operations and to personally conducting mammography.

46. By virtue of their positions as president and vice-president, and as co-owners of the facility, Respondents Reyes and Carrai had the ability to prevent EHG from performing uncertified mammography examinations in violation of 42 U.S.C. § 263b(b)(1).

47. The failure of Respondents Reyes and Carrai to prevent these violations cause each of them to be liable for: (a) one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate, and (b) 1201 violations of

the MQSA, pursuant to 42 U.S.C. § 263b(h) (3) (D), for conducting 1201 uncertified mammography examinations.

C. RICHARD W. STONE, M.D., AND ERLINDA E. ENRIQUEZ, M.D.

48. FDA may assess civil money penalties for each violation of, or for each aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate. 42 U.S.C. § 263b(h) (3) (D).

49. A person is liable as an aider and abettor if (1) the underlying violation was committed by a principal; (2) the person knew of the violation; and (3) the person participated or assisted in the execution of the violation. Cf. United States v. Keene, 341 F.3d 78, 84 (1st Cir. 2003); United States v. Davis, 306 F.3d 398, 401 (6th Cir. 2002); United States v. Hunt, 272 F.3d 488, 493 (7th Cir. 2001) (all interpreting "aiding and abetting" under 18 U.S.C. § 2, which makes it punishable as a principal one who aids or abets the commission of a federal offense).

50. Respondents Dr. Richard Stone and Dr. Erlinda Enriquez aided and abetted EHG in conducting 126 and 616 mammography examinations, respectively, while EHG was uncertified.

51. EHG conducted at least 1201 mammography examinations without a valid certificate, in violation of 42 U.S.C. 263b(b) (1). EHG, as a principal, thereby violated the MQSA.

52. Respondents Dr. Stone and Dr. Enriquez had knowledge of EHG's violations. Dr. Stone, as Lead Interpreting Physician, was notified by at least two letters from the ACR and FDA, dated September 14, 2001, and November 1, 2001, of the impending December 8, 2001 expiration of EHG's provisional MQSA certificate. See Divine Decl. ¶¶ 13 and 14 and Ex. G-A(4) and (5) attached thereto. After EHG's certificate expired, Dr. Stone signed an appeal, on December 7, 2001, of an adverse determination by ACR. On December 4, 2002, Dr. Stone received ACR's denial of that appeal. Therefore, on and after January 7, 2002, Respondent Dr. Stone clearly knew or should have known that EHG was not certified to perform mammography under the MQSA.

53. Dr. Enriquez, during her tenure as Lead Interpreting Physician, signed several documents on September 19, 2002, that made up EHG's application for reinstatement. By signing these documents, Dr. Enriquez must have known that EHG was required to be certified under the MQSA and that it was in need of certification. Therefore, on and after September 19, 2002, Respondent Dr. Enriquez knew or should have known that EHG was not certified to perform mammography under the MQSA.

54. Respondents Dr. Stone and Dr. Enriquez participated and assisted in performing uncertified mammography examinations. Dr. Stone read and interpreted the mammograms from at least 126

of the uncertified examinations that were performed on and after January 7, 2002 and before May 6, 2003. Dr. Enriquez read and interpreted the mammograms from 616 of the uncertified examinations that were performed on and after September 19, 2002, and before May 6, 2003.

55. Accordingly, Respondent Dr. Stone aided and abetted EHG in conducting 126 mammography examinations, and Respondent Dr. Enriquez aided and abetted EHG in conducting 616 examinations, all in violation of 42 U.S.C. § 263b(b) (1). Therefore, pursuant to 42 U.S.C. § 263b(h) (3) (D), Respondents Dr. Stone and Dr. Enriquez are liable for aiding and abetting in 126 and 616 violations of the MQSA, respectively.

Accordingly, it is ORDERED, that Complainant's Motion For Partial Summary Decision is GRANTED;

It is further ORDERED: that Respondents Ecumed Health Group, Inc., Amador Reyes, and Juan C. Carrai are each liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A);

That Respondents Ecumed Health Group, Amador Reyes, and Juan C. Carrai are each liable for 1201 violations of the MQSA, pursuant to 42 U.S.C. § 263b(h) (3) (D);

That Respondents Ecumed Health Group, Amador Reyes, and Juan C. Carrai are therefore each liable for 1202 violations of the MQSA;

That Respondent Richard Stone, M.D., is liable for aiding and abetting EHG in conducting 126 mammography examinations in violation of the MQSA, pursuant to 42 U.S.C. § 263b(h) (3) (D); and

That Respondent Erlinda Enriquez, M.D., is liable for aiding and abetting EHG in conducting 616 mammography examinations in violation of the MQSA, pursuant to 42 U.S.C. § 263b(h) (3) (D).

And it is Further ORDERED that the remainder of the hearing schedule (as set forth in the Order of April 19, 2005) continues in effect limited to the issues of the amount of the penalties to be imposed and any mitigating circumstances, as provided in 21 C.F.R. § 17.34.

Dated this 13th day of July, 2005.

/s/Daniel J. Davidson
DANIEL J. DAVIDSON
Administrative Law Judge
U.S. Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857