STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

FLORIDA PERFUSION SOCIETY and FLORIDA HOSPITAL ASSOCIATION, Petitioners, vs. BOARD OF CLINICAL LABORATORY PERSONNEL, Respondent, and FLORIDA COALITION OF PROFESSIONAL LABORATORY ORGANIZATIONS, INC., Intervenor.	)	CASE NO. 94-5968RP
FLORIDA SOCIETY OF PATHOLOGISTS and LOUIS S. McCANN, JR., M.D., Petitioners, vs. BOARD OF CLINICAL LABORATORY PERSONNEL, Respondent.	)	CASE NO. 94-5969RP
FLORIDA LEAGUE OF HOSPITALS, INC., Petitioner, vs. BOARD OF CLINICAL LABORATORY PERSONNEL, Respondent, and FLORIDA COALITION OF PROFESSIONAL LABORATORY ORGANIZATIONS,INC, Intervenor.	)	CASE NO. 94-5970RP

FINAL ORDER

Pursuant to notice, the above matters were heard before the Division of Administrative Hearings by its assigned Hearing Officer, Donald R. Alexander, on November 23, 1994, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUE

The issue is whether proposed rules 590-2.002, 590-3.003, 590-5.001, 590-5.002, 590-5.006, 590-9.002, 590-9.004, 590-10.004 and 590-13.006 are an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

These cases began on October 21, 1994, when three petitions were filed challenging the validity of certain proposed rules in Chapters 590-2, 59O-3, 59O-5, 59O-6, 59O-9, 59O-10 and 59O-13, Florida Administrative Code. The first petition was filed on behalf of the Florida Perfusion Society, Florida Hospital Association, Mallinckrodt Sensor Systems, Inc., i-Stat Corporation and Boehringer Mannheim Diagnostics and was assigned Case No. 94-5968RP. The second petition was filed by the Florida Society of Pathologists, Dr. Louis S. McCann, Jr, and Dr. Timothy M. Kilpatrik and was assigned Case No. 94-5969RP. The last petition was filed on behalf of the Florida League of Hospitals, Inc. and was assigned Case No. 94-5970RP. The rules being challenged were proposed for adoption by respondent, Board of Clinical Laboratory Personnel. After being reviewed for legal sufficiency, the petitions were assigned to the undersigned Hearing Officer on October 31, 1994.

By notice of hearing dated October 31, 1994, the final hearing was scheduled on November 23, 1994, in Tallahassee, Florida. The same notice consolidated the three cases on the hearing officer's own motion.

Prior to hearing, and based upon a motion filed by respondent, Mallinckrodt Sensor Systems, Inc., i-Stat Corporation, and Boehringer Mannheim Corporation were dismissed as parties in Case No. 94-5968RP on the ground they lacked standing to file a petition. In addition, Dr. Timothy M. Kilpatrik voluntarily withdrew as a petitioner in Case No. 94-5969RP. Finally, the Florida Coalition of Professional Laboratory Organizations, Inc. was authorized to intervene in Case Nos. 94-5968RP and 94-5970RP.

As in relevant here, on November 10, 1994, respondent published a notice of change in the Florida Administrative Weekly wherein it proposed to change the first sentence of proposed rule 59O-3.003(3)(e) and to add a sentence after the first sentence in the first paragraph of proposed rule 59O-5.006. Those changes have been considered by the undersigned in resolving this dispute.

At final hearing, petitioners in Case No. 94-5968RP presented the testimony of Mark Orangio, a clinical perfusionist and accepted as an expert in that area; Karen Brzys, a consultant and accepted as an expert in alternate site testing regulations; Dr. Michael Groves, a manager for i-Stat Corporation; and Barbara Foley, director of government affairs for the Florida Hospital Association. Also, it offered FPS exhibits 1-10. All exhibits were received in evidence. In addition, a request for official recognition of five documents has been granted. Petitioners in Case No. 94-5969RP presented the testimony of Dr. Louis S. McCann, Jr. and Dr. Richard Essman, both pathologists and accepted as experts in pathology and the directorship of clinical laboratories. Petitioner in Case No. 94-5970RP offered FLH exhibit 1 which was received in evidence. That exhibit is the deposition of its vice-president, Belita Moreton. Respondent presented the testimony of George Mavros, a clinical laboratory supervisor and chairman of the Board of Clinical Laboratory Personnel. Also, it offered respondent's exhibits 1-3. All exhibits were received in evidence. Intervenor adopted the evidence submitted by respondent.

The transcript of hearing (three volumes) was filed on January 31, 1995. Proposed findings of fact and conclusions of law were filed by the parties on February 15, 1995. A ruling on each proposed finding has been made in the Appendix attached to this Final Order.

FINDINGS OF FACT

Based upon all of the evidence, the following findings of fact are determined:

A. Background

1. These cases arose after respondent, Board of Clinical Laboratory Personnel (Board), published in the Florida Administrative Weekly its notice of intent to adopt certain revisions in Chapters 59O-2, 59O-3, 59O-5, 59O-6, 59O-9, 59O-10 and 59O-13, Florida Administrative Code. The proposed rules deal with the subject of alternate site testing within the state.

2. The Board was created by the legislature in 1992 to regulate clinical laboratory personnel. Its authority and duties are set forth in Part IV of Chapter 483, Florida Statutes. The Board's purpose is to ensure the protection of public health, safety, and welfare through the regulation of clinical laboratory personnel. To this end, the Board is required by law to prescribe minimal qualifications for clinical laboratory personnel.

3. Alternate site testing is any "laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory." It can only exist in a hospital under the direct supervision of the central clinical laboratory and its clinical laboratory director. The alternate site laboratory does the same type of testing as does the central laboratory but it uses different equipment. Alternate site testing is performed using ten to twelve instruments specifically designed for that purpose, and which specifically incorporate safeguards to prevent misuse or misinterpretation.

4. Clinical laboratory personnel are persons who perform clinical laboratory examinations on specimans derived from the human body for the purpose of delineating information for the diagnosis, management and treatment of patients. There are four classes of clinical laboratory personnel, namely, technician, technologist, supervisor and director. Within the category of technician are various specialty categories including clinical chemistry, hematology, immunohematology, histology, radioassay, serology, microbiology, exclusive use and alternate site.

5. In general terms, the proposed rules define an alternate site technician, set forth the curriculum requirements for training programs for alternate site technicians, state the minimum standards for licensure as an alternate site technician, prescribe the initial licensure and renewal fees for alternate site technicians, set forth the scope of practice for all clinical laboratory personnel, and enumerate the responsibilities of alternate site technicians including limits on tests that can be performed with this type of licensure. These rules were adopted after various workshops, public meetings and member conference calls were conducted by the Board in 1993 and 1994.

6. As clarified by a more definite statement, petitioners in Case No. 94-5968RP, Florida Perfusion Society (FPS) and Florida Hospital Association (FHA), contend that all or parts of proposed rules 590-2.002, 590-3.003, 590-5.006, 590-9.002, 590-9.004, 590-10.004 and 590-13.006 are invalid on the grounds (a) the Board exceeded its rulemaking authority, (b) the rules are arbitrary and capricious, and (c) the rules contravene the law being implemented.

7. Petitioners in Case No. 94-5969RP, Florida Society of Pathologists (FSP) and Dr. Louis S. McCann, Jr., have challenged proposed rules 590-5.001 and 590-5.002 on the grounds the two rules contravene the statutes being implemented and are arbitrary and capricious.

8. Petitioner in Case No. 94-5970RP, Florida League of Hospitals (FLH), has challenged the validity of all the proposed rules on the ground the Board has exceeded its rulemaking authority. In addition, it has challenged Rules 590-2.002(7), 590-5.006(2), 590-9.002(4), 590-9.004(7) and 590-13.006 on the ground they contravene the statutes being implemented.

9. Intervenor, Florida Coalition of Professional Laboratory Organizations, Inc., is a nonprofit corporation representing twelve organizations who represent the interests of laboratory professionals licensed under Part IV of Chapter 483, Florida Statutes. It supports the challenged rules and is aligned with the Board in these proceedings.

B. Standing

10. Respondent has stipulated to the standing of the FSP, a professional association of pathologists, and Dr. McCann, its president-elect, and thus there is no dispute that those petitioners are substantially affected by the proposed rules.

11. FPS is a statewide professional medical society representing professional cardiovascular perfusionists in Florida. Perfusionists are principally known for the safe operation and maintenance of the heart-lung machine in open heart surgery. The FPS currently has more than one hundred members, most of whom are actively engaged in the practice of perfusion.

12. The purpose of the FPS is to promote perfusion education and clinical expertise and to address the professional interests of perfusionists on issues affecting the profession, including representation before governmental bodies.

13. Perfusionists are regularly required to perform the type of tests that are performed at alternate sites as part of their profession. The proposed rules would directly regulate their practice. In addition, a substantial number of FPS members would be affected by the proposed rules because they would be required to obtain a license as a laboratory professional in order to continue practicing using alternate test sites, or to use alternate test sites in the future. As such, they are substantially affected by the proposed rules.

14. The FHA is a statewide, nonprofit trade association representing all types of hospitals in the state. As of August 1994, or three months before the hearing, it had 233 institutional members (licensed hospitals), plus various organizational and individual members. Its purpose is to serve its members by developing and promoting programs and services that will enhance their ability to provide comprehensive, efficient, high quality health care to the people of Florida. The association also represents its members at the state and national levels in providing an effective health care system.

15. Only hospitals with clinical laboratories can have alternate site laboratories where alternate site technicians would be employed. The number of institutional members having clinical laboratories is not of record nor is the number of hospitals who plan to operate alternate site laboratories. Even so, it may be reasonably inferred that at least some of the hospitals provide clinical laboratory services in their facilities and, in the future, they intend to provide alternate site testing. Because the proposed rules require medical professionals already licensed or certified to obtain an additional license, limit the professionals who can provide these services, and impose regulatory and financial requirements on the provision of those services, the institutional members of the FHA are substantially affected by these proceedings. Moreover, because the proposed rules impose new training requirements on medical personnel, the hospitals who employ such individuals would be required to absorb the cost of training these employees and providing coverage for their duties while they are being trained. In these respects, they are further impacted by the rules.

16. The FLH is a trade association comprised of seventy-six for-profit hospitals. Of its seventy-six members, seventy-three have clinical laboratories. Because the proposed rules limit the categories of hospital personnel who could be licensed as alternate site testing technicians and restrict the tests that these licensees can perform, the FLH is substantially affected by the proposed rules.

C. Legislative History of Alternate Site Testing

17. In 1993, the Florida Legislature adopted Chapter 93-178, Laws of Florida. That act specifically provided for the implementation of alternate site testing in Florida. The section relating to alternate site testing, which has been codified as Subsection 483.051(9), Florida Statutes, provides as follows:

> (9) Alternate Site Testing.- The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping requirements. Alternate-site testing locations must register when the clinical laboratory applies to renew its license. For purposes of this subsection, the term "alternate-site testing" means any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

(emphasis added)

18. The bill which became Chapter 93-178, Laws of Florida, originated as PCB 93-01 of the House Committee on Health Care. It was later filed as House Bill 2071 (HB 2071), Medical Tests and Procedures/Sunset. The overall purpose of the bill was to review provisions of Part I of Chapter 483 related to clinical laboratories, which was scheduled for sunset review under Section 11.61, Florida Statutes. The original version of PCB 93-01, dated January 28, 1993, had no provisions relating to alternate site testing.

19. During consideration of the bill on February 3, 1993, the House Committee on Health Care amended PCB 93-01 to provide for rulemaking by the Board. Specifically, the amendment stated that "(t)he board shall adopt rules for alternate site testing to be performed under the supervision of clinical laboratory director." However, the authority for the Board to adopt rules was subsequently removed from the bill by amendment on the House floor on March 23, 1993.

20. The House bill was then considered by the Senate, which amended the House bill on March 31, 1993. The amendment was a "strike everything after the enacting clause" amendment. In effect, the amendment substituted all new bill language in place of the House bill, while retaining the bill number of HB 2071. The alternate site testing language substituted was identical to the bill that had been considered in the Senate as SB 156, which, among other things, added subsection 483.051(9), relating to alternate site testing. This provision gave rulemaking authority to the Agency for Health Care Administration (ACHA) "in consultation with the Board of Clinical Laboratory Personnel."

21. The Senate passed the amended bill and this version was returned to the House. The House then passed HB 2071 as it had been amended and passed in the Senate (with two amendments not related to alternate site testing). The Senate then concurred in the final House version. The amendment relating to subsection 483.051(9) (on alternate site testing) remained intact and eventually became the current Subsection 483.051(9), Florida Statutes.

22. Subsection 483.051(9), as adopted, specifically delegates the rulemaking authority for alternate site testing to AHCA. That provision calls for "consultation" with the Board, but does not give the Board any rulemaking authority.

23. The Board had a designated member, George Mavros, who represented the Board during the legislative session. Initially, the Board recognized ACHA's exclusive rulemaking authority in a report from its legislative liason and in discussions with affected public at its regularly scheduled meetings. That position was reiterated in an official letter to a representative of an affected organization from the Board's chairman. The chairman was specifically authorized to speak for the Board, and the letter reflected the official position of the Board at that time.

24. In its discussions and letters, the Board specifically stated that the newly adopted statute did not give the Board rulemaking authority. Such public statements and letters are evidence of the Board's contemporaneous construction of the statute that it had no authority to adopt rules governing alternate site testing. Since that time, however, the Board has taken an opposing position, that is, that it has authority to adopt rules pertaining to alternate site testing requirements, and the rules under challenge are the end product of this changed position.

25. The statute authorizing AHCA to adopt rules is clear on its face and unambiguous. Moreover, the legislative history reveals that during the 1993 session the legislature specifically considered the delegation of rulemaking authority to the Board in an early version of the bill. The provision giving specific rulemaking authority to the Board was deleted by later action of the same legislature. The final version of the bill contains a delegation of rulemaking authority to AHCA and omits any delegation to the Board. This is clear evidence that the legislature considered giving rulemaking authority to the Board, and instead evinced a clear intent to give exclusive rulemaking authority to AHCA.

26. The legislature cannot be said to have simply forgotton the authority of the Board. Subsection 483.051(9) specifically sets forth the Board's role as a consultant. If the legislature had intended to "split" the rulemaking authority for alternate site testing between the Board and AHCA, it would not have specifically set out a different role in the statute. The legislative

staff analyses of the bill support these findings. The staff analyses of subsection 483.051(9) refer solely to AHCA when referencing rulemaking authority for alternate site testing. Therefore, the Board did not have statutory authority to adopt the rules. For the reasons given in the conclusions of law portion of this order, the statutes which the Board relies upon for its rulemaking authority are not deemed to be controlling or relevant.

D. Are the Challenged Rules Invalid for Other Reasons?

27. Nothwithstanding the above findings, and solely for the sake of judicial economy in the event an appeal is taken by any party, additional findings are made relative to each of the challenged rules. In making these findings, it is noted that where new grounds for invalidating a rule have been raised for the first time in a party's proposed order, they have been disregarded as being untimely. Further, where a party has not addressed a previously raised ground in its proposed order, the undersigned has assumed that ground has been abandoned. Where a party speaks to a rule in general terms, and not a specific part thereof, and the undersigned is unable to discern which part of the rule is being attacked, that contention has been disregarded.

a. Rule 59O-2.002(7)

28. The first challenged rule is 59O-2.002(7), which defines the term "technician in the specialty of Alternate Site Testing" as follows:

> (7) Technician in the specialty of Alternate Site Testing means a person qualified to be a technician in the specialty of alternate site testing pursuant to the rules of the Board who under the general supervision of a laboratory director, supervisor or technologist may perform specific testing authorized by the Agency pursuant to rule chapter 59A-7 and the Board pursuant to rule chapter 59O-13 in a hospital based alternate site testing environment approved by the Agency pursuant to section 483.051(9), F. S. and whose practice is limited to an alternate site testing environment.

The Board had cited Subsections 483.805(4) and 483.811(3) and (4), Florida Statutes, as the specific authority for adopting the rule while Subsections 483.803 and 483.811(3) and (4), Florida Statutes, are cited as the laws being implemented.

29. Besides leveling the broad charge that the Board lacks statutory authority to adopt the rule, a contention already decided in their favor, petitioners FPS and FHA contend that the rule is arbitrary and capricious because it sets up an impossible condition for qualifying as an alternate site technician since necessary related rules in Chapter 59A-7 have never been adopted by AHCA.

30. In order for the proposed rule to become operable, AHCA must first adopt amendments to its Chapter 59A-7, which pertain to alternate site testing laboratories. Also, AHCA must approve a "hospital based alternative site testing environment" in which such tests can take place. At the time of hearing, a draft of new proposed rules 59A-7.034 and 59A-7.035 was being circulated by AHCA, but had not yet been adopted. Even so, the fact that the

Board's rule is contingent on further rules being adopted by another agency does not render the rule arbitrary or capricious. The contention is accordingly rejected.

(b) Rule 59O-3.003(3)(e)

31. This rule sets out the proposed requirements for training for individuals performing specific alternate site tests. As modified by the notice of change published in the Florida Administrative Weekly on November 10, 1994, the challenged portion of the rule now provides the following training requirements:

> (e) Notwithstanding all other provisions of rule chapter 59O-3.003, the only requirements for training in the specialty of Alternate Site Testing shall be 4 contact hours of instruction per test system with an additional 0.5 contact hour of instruction for each analyte above 8 analytes performed on the same test system. The contact hours of instruction shall be by a Board approved continuing education provider approved pursuant to rule chapter 59O-11 which shall include as a minimum instruction in the tasks defined as follows:
>
> * * *
>
> The terms "analyte" and "test system," which are the guages on which training is measured, are not defined anywhere in the Board's rules.

32. Besides the argument that the Board lacks statutory authority to adopt the rule, petitioners FPS and FHA contend the proposed rule is arbitrary and capricious in that the requirements are excessive and inflexible. They also contend that the rule contravenes the provisions of Subsection 455.201(4), Florida Statutes, which prohibits a regulatory board from adopting "unreasonably restrictive and extraordinary standards" for a given profession.

33. In proposing the number of hours of training for alternate site testing, the Board relied mainly upon its own members' expertise and judgment. It also relied on public comment given at a Board meeting on August 7, 1993, including testimony from a manufacturer's representative. Finally, it relied upon a training and certification program manual by i-Stat Corporation, a manufacturer of equipment used in clinical laboratories, and on other unspecified "documents and manuals." It did not conduct any surveys of professional literature or other outside services, nor did its staff conduct any research on the subject.

34. Initially, it is noted that the proposed rule gives no consideration to the relative levels of medical training and education in the various professions regulated by the rules, even though that can affect how much training time is needed. For some professionals, such as an ICU nurse or emergency physician nurse, four hours of training is excessive, based on approved manufacturer's training protocol. By providing uniform instruction for all professionals, regardless of their prior training, and without any factual basis for doing so, the Board acted in an arbitrary manner.

35. In arriving at the number of hours of instruction required for each test system, the Board relied in part on the testimony of a manufacturer's

representative (Mallinckrodt) given at the August 7, 1993 meeting. A review of his comments, however, reveals that the representative recommended far fewer hours of instruction than is provided for in the rule. Moreover, in prescribing four hours training per test system, the Board relied primarily on its own judgment rather than on technical material submitted by other affected persons. Likewise, the basis for the additional 0.5 hours per analyte over eight analytes was not grounded on empirical data. Indeed, analytes and test systems are not even defined in the rule. Given these shortcomings, it cannot be said that the requirements of the rule are based on facts or logic. The rule is accordingly deemed to be arbitrary and capricious. Given this finding, it is unnecessary to reach the issue of whether the rule contravenes Subsection 455.201(4), Florida Statutes, by providing unreasonable and restrictive standards.

(c) Rule 59O-5.001(1)(b), (2)(a), and (2)(b)

36. This rule prescribes the educational requirements for the director of a clinical laboratory. Under current standards (rule 10D-41.067), a director must be a physician or a doctoral scientist. By its rule, the Board proposes to allow a person with a master's degree to become licensed as a clinical laboratory director. The challenged portions of the rule read as follows:

> (1) Education. An applicant shall meet one of the following education requirements:
> * * *
> (b) Have a master's degree in clinical laboratory science, one of the specialty areas, or one of the chemical or biological sciences.
> (2) Experience. An applicant who qualifies pursuant to rule 59O-5.001(1) shall meet one of the following requirements:
> (a) Have full time pertinent clinical laboratory experience in an approved laboratory subsequent to receipt of the relevant degree as follows:
> * * *
> 2. If qualifying under rule 59O-5.001(b), 8 years of experience.
> * * *

37. Petitioners FSP and Dr. McCann generally contend the foregoing rule contravenes Section 483.800, Florida Statutes, and is arbitrary and capricious in that it allows untrained persons to become laboratory directors.

38. All state clinical laboratories and their personnel are subject to federal regulation under the federal Clinical Laboratory Improvement Act (CLIA). Regulations promulgated thereunder classify clinical laboratories based on the complexity of the tests performed. The three category of tests are waived, moderately complex and highly complex. Laboratories performing waived tests, or those that are simple and pose no risk to the public, are not regulated by CLIA while those performing moderate to highly complex testing must meet CLIA's minimum requirements for quality control, quality assurance and personnel.

39. CLIA regulations link personnel requirements with the complexity of testing. The requirements for moderate and highly complex testing personnel are defined separately and are significantly different. Those facilities providing only moderately complex testing may use directors having both master's level and bachelor's level degrees. In recognition of both the sophistication of highly complex tests and the broad scope of a laboratory director's duties and

responsibilities, however, CLIA regulations require directors of clinical laboratories performing any highly complex testing whatsoever to be either physicians or doctoral scientists. It is noted that hospital laboratories and independent laboratories perform highly complex testing, and that any hospital laboratory, including rural hospitals, providing full service functions will perform highly complex testing.

40. Under CLIA regulations, laboratories which perform highly complex testing allow the director to reapportion performance of responsibilities to persons having less qualifications. The overall responsibility, however, rests with the director, and the regulations do not allow a master's level individual to direct the clinical laboratory performing highly complex testing, or to delegate responsibilities to a more qualified individual.

41. The proposed rule would allow master's degree scientists to direct laboratories performing highly complex testing so long as that individual hired a "co-director" who was a physician or a doctoral scientist. Under this arrangement, the co-director would be left with only those responsibilities that the lesser qualified master's level director called upon him or her to perform. In this respect, the proposed rule is at variance with federal regulations. While the Board justifies this change on the ground a study shows a shortage of various professionals in the rural hospital setting, the study itself was not introduced into evidence. Moreover, the rule would apply to all hospitals, whether rural or not.

42. Even though the proposed rule is inconsistent with CLIA, in its filing with the Joint Administrative Procedures Committee, the Board represented that "(t)here is no ascertainable parallel federal rule or standard with which to make a comparison." It is reasonable to infer that this response was given so that the Board would not have to give an explanation of the rule's inconsistency with CLIA.

43. Although the Board had a wide range of input regarding this rule, it failed to address a number of valid concerns raised by the opponents. Because of the nature of the testing involved in laboratories performing highly complex testing, severe injury or even death can result from an incorrect test result being reported by one of the clinical laboratory personnel. It is esential, therefore, that clinical laboratories performing highly complex testing be directed by the most competent and trained personnel. This goal is not attained in the proposed rule. The appointment of a lesser qualified person would also mean that a director would not be able to perform all work functions in the laboratory, something current directors can now perform. Further, the proposed allocation of responsibilities would place virtually all of the professional liability on the "co-director" (physician or doctoral scientist) even though the co-director does not "direct" the laboratory. Finally, even though a laboratory can be licensed by specialty, this does not eliminate the above concerns since a specialty is not limited to moderately complex testing.

44. Given the lack of a factual basis or logic to support the rule as presently proposed, subsections (1)(b), (2)(a) and (2)(b) of rule 59O-5.001 are deemed to be arbitrary and capricious and are thus invalid. These portions of the rule also contravene Section 483.800, Florida Statutes, which requires, among other things, the "licensure of clinical laboratory personnel who meet minimum requirements for safe practice."

(d) Rule 590-5.006

45. This rule sets forth the educational requirements necessary for the specific types of licensure and certification for clinical laboratory personnel. As modified by the Board on November 10, 1994, the rule now reads as follows:

59O-5.006 Technician in the Specialty of Alternate Site Testing.

Those persons licensed as a director, supervisor, technologist or technician pursuant to part IV of chapter 483, F.S., can work in the specialty of alternate site testing without additional licensure or certification. Persons only performing waived tests as defined in section 483.041(9), F. S. in a laboratory holding a certificate of exemption pursuant to section 483.106, F. S., are not required to be licensed and need not meet these requirements. Persons certified only under this rule shall not perform testing beyond that defined in rule 590-13.006. Persons who perform testing defined in rule 590-13.006 at alternate testing sites as defined in section 483.051(9), F.S., shall meet the requirements of rule 590-5.006(1), (2) and (3) as follows:

(1) Education.

(a) Have a high school diploma or its equivalent and

(b) Have completed 4 contact hours of HIV/AIDS continuing education pursuant to rule chapter 59O-11.

(2) Training. For purposes of this rule the term "licensed" requires a full permanent license not a temporary license. An applicant who qualifies under the education requirements of rule 59O-5.006(1) shall in addition meet one of the following requirements:

(a) Is licensed as a registered nurse pursuant to chapter 464, F. S.

(b) Is licensed as a radiologic technologist pursuant to chapter 468, part IV, F. S.

(c) Is licensed as a respiratory therapist or as a respiratory care practitioner certified to perform critical care services pursuant to chapter 468, part V, F. S.

(d) Is a perfusionist certified by the American Board of Cardiovascular Perfusion-ists.

(3) Additional Training. An applicant who qualifies under the education requirements of rule 590-5.066(1) and the training requirements of rule 590.006(2) shall in addition meet one of the following requirements:

(a) Have successfully completed a Board approved Clinical Laboratory Personnel Technician training program in general laboratory practice principles pursuant to rule 590-3.003(3)(d).

(b) Have successfully completed alternate

site testing training for each test the applicant will be performing which provides instruction in all subject matter areas of rule 590-3.003(3)(e). After completing the training, the applicant shall submit verification from the laboratory director that the applicant has successfully completed the alternate site testing training.

(c) Have received instruction in all subject matter areas of rule 590-3.003(3)(d) or (e) while enrolled in a program leading to licensure under chapters 464, 468, part IV, or 468, part V, F. S., or certification by the Board of Cardiovascular Perfusionists and shall submit verification from the program director of such instruction.

46. Although a number of grounds for invalidating the rule were raised in the initial petitions, in their joint proposed order, the FPS, FHA and FLH have limited their grounds to four: (a) the Board was arbitrary and capricious in limiting the application of the rule to five professions; (b) the Board did not comply with Section 455.201, Florida Statutes; (c) the proposed rule contravenes Section 468.351(2), Florida Statutes, by making the terms of the rule applicable to respiratory therapists and respiratory care practitioners, and (d) the Board was arbitrary and capricious by requiring training for waived tests. The allegation regarding the validity of the requirement in subsection (1)(b) for HIV/AIDS continuing education training has been disregarded as being untimely.

47. The rule applies to respiratory therapists and respiratory care practitioners even though Subsection 468.351(2), Florida Statutes, which governs the practice of those professions, clearly provides that "it is the intent of the Legislature that personnel certified or registered pursuant to this part shall be exempt from the licensure provisions of chapter 483." There is no basis in the record for the Board's contention that the exemption in subsection 468.351(2) applies only to blood gas testing, and no others. Given this lack of support for that limitation, the rule contravenes the provisions of the cited statute, and paragraph (2)(c) is deemed to be invalid.

48. The contention is also made that the Board selected the remaining three classes of professions (registered nurses, radiologic technologists and perfusionists) without any justification. Although the Board contended it studied the type of training and education received by these professions, there is no evidence of such a discussion in the Board records, nor is there evidence that rules regarding education and training of other professions were ever presented to all of the Board members. Further, there is no evidence that the Board ever considered other professionals of equal medical educational background. While the Board did receive information from the American Board of Cardiovascular Perfusionists regarding the certification requirements for that organization, that by itself is an insufficient factual basis to justify the limitation imposed by the rule. Under these circumstances, it cannot be said that the remainder of the rule is supported by facts or logic.

49. Petitioners further contend that the rule contravenes the provisions of Subsection 455.201(4), Florida Statutes, which makes it unlawful for the Board to "create unreasonably restrictive and extraordinary standards that deter qualified persons from entering the various professions." Since the Board acted arbitrarily and capriciously in limiting the approved professions that are

subject to the rule, it is found that the proposed rule creates unreasonably restrictive and extraordinary standards for the profession.

50. Finally, by modification to the rule on November 10, 1994, the Board added the following sentence in the first paragraph: "Persons only performing waived tests as defined in section 483.041(9), F. S., in a laboratory holding a certificate of exemption pursuant to section 483.106, F. S., are not required to be licensed and need not meet these requirements." In order to obtain a certificate of exemption, a laboratory must be engaged only in waived tests. These are tests that are relatively simple and pose little risk of harm to the public. Petitioners complain that, while providing this exception to training for waived tests at laboratories holding a certificate of exemption, the Board did not remove the requirement for training for waived tests performed at alternate site testing facilities, and thus the rule is arbitrary. Under the proposed rule, any person performing waived tests, who later becomes certified to perform a moderately complex test, must receive additional training in the waived test as well. While the Board suggests that a hospital can avoid this double training by setting up multiple laboratories in the same location, it failed to provide any justification for this excessive testing. The challenged sentence is accordingly deemed to be arbitrary.

(e) Rules 59O-9.002(4) 59O-9.004(7)

51. These two proposed rules levy a $20 fee for the initial and renewal certification of alternate site testing technicians, respectively.

52. In its petition, the FLH contended that the Board lacked statutory authority to adopt both rules, a contention already resolved in petitioner's favor. In its posthearing filing, however, it argues for the first time that the rules are arbitrary and capricious. This contention has accordingly been rejected as not being timely.

53. The FPS and FHA have similarly contended that rule 59O-9.004(7) is invalid on the ground the agency lacks statutory authority to adopt the rule. They also contend for the first time that the rule is arbitrary. This untimely allegation has been disregarded.

(f) Rule 59O-10.004

54. This proposed rule sets forth minimum standards that all laboratory professionals must meet. At issue here are the requirements that all clinical laboratory personnel provide the following services:

> (14) Process aliquots or components of specimens for analysis according to the type of specimen and procedure to be performed.
>
> * * *
>
> (18) Recognize output signals and observations and convert them to prescribed units for recording and reporting.
>
> * * *

55. In their initial petition, as clarified by a more definite statement, FPS and FHA contended the Board exceeded its rulemaking authority by including professionals engaged in alternate site testing as clinical laboratory personnel subject to Board regulations, a ground already discussed. In their proposed order, petitioners have added the contention that the rule is vague because it

contradicts the terms of another rule. Because this newly raised ground is untimely, it has been disregarded.

(g) Rule 59O-13.006

56. The final rule being challenged describes the responsibilities of alternate site testing technicians. Among other things, the rule prescribes the tests that the technicians can perform. The specific portions of the rule which are being challenged read as follows:

> (1) Alternate Site Testing Technican shall:
>
> * * *
>
> (b) Perform only tests from the following list provided the requirements of Rule 59O-13.006 have been met:
>
> 1. Tests designated as waived pursuant to 42 CFR 493.15, incorporated by reference.
>
> * * *
>
> 3. Tests designated as moderately complex pursuant to 42 CFR 493.10 and 42 CFR 493.17 which employ whole blood and require no pre-analytical, analytical or post-analytical specimen or reagent manipulation, treatment, extraction, separation or other processing of any kind and must employ an automated single, closed, dry or electrochemical sensor reagent system. The instrumentation shall provide for instrument calibration without any operator adjustment. Post analytical instrument output signals must be directly reportable in the correct units of measure-measure without need for data conversion or other manipulation. Electronic instrumen-tation must have a mechanism whereby the operator is alerted when patient results exceed reportable limits and when internal or external quality control or calibration is not acceptable. Such results shall not be used for the diagnosis, treatment, management or monitoring of patients and shall be validated through the central laboratory. Validation shall be documented at the alternate test site.
>
> * * *
>
> (j) When affixing the name or signature to any laboratory record or patient report, indicate the professional status by adding the designation "ASTT" to designate Alternate Site Testing Technician immediately following the name or signature if holding a current Florida certificate. The holder of temporary certification must use the designation "GASTT" to designate Graduate Alternate Site Testing Technician until such time as certification is granted by the Board.
>
> * * *
>
> The specific authority for adopting the rule

is Subsection 483.805(4), Florida Statutes, while the laws being implemented are Sections 483.800, 483.813 and 483.825, Florida Statutes.

57. Although a number of grounds for invalidating the rule were raised in the petitions filed by the FLH, FPS and FHA, these grounds have been narrowed in their joint proposed order. As to the newly raised contention that certain parts of the rule, including subparagraph (1)(b)3., are vague, this contention has been disregarded as not being timely. Similarly, the argument that subparagraph (1)(b)3. contravenes the provisions of Subsection 455.201(4), Florida Statutes, was not specifically pled by any party. Likewise, the assertion that paragraph (1)(a) is invalid because its effectiveness is dependent on other rules being enacted has been rejected as being untimely. Since no other viable claim has been raised, the rule is deemed to be invalid on the single ground that the agency has exceeded its rulemaking authority.

CONCLUSIONS OF LAW

58. The Division of Administrative Hearings has jurisdiction of the subject matter and the parties hereto pursuant to Subsections 120.54(4) and 120.57(1), Florida Statutes.

59. As the parties challenging the proposed rules, petitioners have the burden of proving by a preponderance of the evidence that the challenged rules are an invalid exercise of delegated legislative authority. Agrico Chemical Company v. Department of Environmental Regulation, 365 So.2d 759, 763 (Fla. 1st DCA 1978).

60. Subsection 120.52(9), Florida Statutes, defines an invalid exercise of authority as follows:

> "Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the legislature.
>
> The same statute goes on to provide that a proposed rule is invalid if:
>
> (a) The agency has materially failed to follow the applicable rulemaking procedures set forth in s. 120.54;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(7);
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(7);
>
> (d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency; or
>
> (e) The rule is arbitrary or capricious.

61. Respondent contends that FPS, FHA and FLH have failed to prove standing to bring these actions. Trade and professional associations are, of course, accorded standing to represent the interests of their injured members. Florida Home Builders Ass'n v. Department of Labor and Employment Security, 412 So.2d 351, 352-53 (Fla. 1982). To do so, the association must demonstrate that

a substantial number of its members, although not necessarily a majority, are substantially affected by the challenged rule, that the subject matter of the rule is within the association's general scope of interest and activity, and that the relief requested is of the type appropriate for an association to receive on behalf of its members. Florida League of Cities, Inc. v. Department of Environmental Regulation, 603 So.2d 1363, 1366 (Fla. 1st DCA 1992). Importantly, a failure by the association to allege a specific number of members affected by the proposed action is not fatal. Federation of Mobile Home Owners of Florida, Inc. v. Department of Business Regulation, 479 So.2d 252, 254 (Fla. 2d DCA 1985). Further, "(i)t is not necessary to elaborate how each member would be personally affected by the proposed rule" so long as a substantial portion of the association's members will be regulated by the rule. Fla. League of Cities at 1367; Coalition of Mental Health Professionals v. Department of Professional Regulation, 546 So.2d 27, 28 (Fla. 1st DCA 1989).

62. The previously established facts show that FPS, FHA and FLH are statewide professional associations representing perfusionists who work in, and hospitals that operate, clinical laboratories, that the proposed rules will regulate the staffing of the laboratories in licensed clinical laboratories, that the three organizations are charged with the responsibility of representing their respective members on such issues, and the relief requested is the type of relief appropriate for an association to receive on behalf of its members. This being so, it is concluded that the FPS, FHA and FLH have standing to bring this action. The standing of petitioners FSP and Dr. McCann has not been questioned.

63. Even if the argument could be made that petitioners FHA and FLH are not directly regulated by the rules, the hospitals cannot operate their respective licensed clinical laboratories in the absence of clinical laboratory personnel who are licensed by the Board. In this further respect, they are substantially affected by the proposed rules.

64. To resolve the issue of whether the Board lacks statutory authority to adopt the rules, a review of several provisions within Chapter 483, Florida Statutes, is required. Initially, it is noted that Subsection 483.051(9), Florida Statutes, provides in relevant part that

> (t)he agency (AHCA), in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: . . . a protocol of implementation including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate site testing; minimum training and education requirements for those who will perform alternate site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; . . . and recordkeeping requirements. (emphasis added)

Here, the statute unambiguously gives the rulemaking authority relating to alternate site testing to the Agency for Health Care Administration. This

conclusion is supported by the fact that the law is specific to alternate site testing, and it was adopted more recently than the statutory authority relied upon by the Board for its rulemaking authority.

65. Although the clear statement by the legislature should be sufficient to determine that the Board lacks authority to adopt the rules, the Board's interpretation to the contrary raises ambiguities that require analysis of the legislative history to discern legislative intent. Reference to legislative history confirms that the legislature considered and rejected rulemaking authority by the Board on the subject and that the intent of the legislature was that AHCA would have exclusive rulemaking authority.

66. Notwithstanding the clear mandate of the legislature, the Board nonetheless contends that authority to adopt the rules is found in various parts of Part IV of Chapter 483, Florida Statutes. More specifically, it argues that authority to adopt rules 59O-2.002, 59O-10.004 and 59O-13.006 derives from Subsection 483.805(4), Florida Statutes, which authorizes the Board "to adopt such rules not inconsistent with law as may be necessary to carry out the duties and authority conferred upon the board by this part." It is well settled, however, that a general grant of rulemaking authority does not authorize an agency to adopt rules outside of that specifically given to that agency. State Dept. of Insurance v. Insurance Services Office, 434 So.2d 908 (Fla. 1st DCA 1983). In fact, the limitation of this authority [in s. 483.805(4)] to Part IV of Chapter 483 can be seen as more limiting than a general grant of rulemaking authority.

67. The Board also cites Subsection 483.811(2), Florida Statutes, as authority to adopt rule 59O-3.003. That subsection authorizes the Board to adopt "rules relating to curriculum" for laboratory personnel. However, Subsection 483.051(9), Florida Statutes, specifically states that alternate site testing is "not limited to laboratory professionals."

68. The Board next relies upon Subsection 483.807(1), Florida Statutes, as authority for adopting rules 59O-9.002 and 59-9.004. That subsection authorizes the Board to establish fees for application, examinations and licensure under Part IV of Chapter 483. If the Board is authorized to establish a licensure category, it would also have the authority to impose fees. However, the authority for a new licensure category must exist before this provision can be effected. Here, there are no authorizing statutes referred to by the Board as authority for it to regulate alternate site testing.

69. The Board has also cited Subsection 483.811(3), Florida Statutes, as authority for adopting rules 59O-2.002, 59O-3.003 and 59O-5.006. That section, however, applies to the adoption of rules relating to exclusive use (physician's office) laboratories and is not applicable to alternate site testing which by definition is limited to the administrative supervision of a hospital.

70. Finally, the Board relies upon Subsection 483.811(4), Florida Statutes, as authority for adopting rule 59O-2.002. That subsection authorizes the Board to "approve training programs for laboratory techicians in a hospital or clinical laboratory." It also requires that "any person who completes a training program must pass, before licensure, an examination by the department." The statute does not, however, contain authorization for the Board to adopt rules establishing a new licensure category.

71. In summary, the elements that the Board attempts to regulate in its rules include: "tests to be performed" (59O-13.006); "who will perform the

tests" [59O-5.006(2)]; "minimum training and education requirements for those who will perform alternate site testing" (59O-3.003, 59O-5.006); "such as documented training, licensure, certification or other medical professional background not limited to laboratory professionals" (59O-5.006); "documented inservice training as well as initial and ongoing competency validation" (59O-3.003(a), 59O-9.004); and "recordkeeping requirements" (59O-13.006). Because the Board's rules essentially track the elements that the legislature directed AHCA to adopt, it must be concluded that the Board exceeded its rulemaking authority in proposing to adopt the rules. For this reason, the challenged rules are an invalid exercise of delegated legislative authority.

72. If petitioners had simply filed a motion for summary final order on this dispositive legal issue, considerable resources expended in prosecuting these cases could have been saved. However, the cases proceeded to final hearing, and evidence was presented on the numerous other grounds raised by the parties. Although this presents an unnecessary laborious task, for the sake of judicial economy in the event an appeal is taken, further conclusions are made with respect to the individual rules being challenged.

73. The remaining contentions are that the rules are either arbitrary or capricious, or that in some respect they contravene the law being implemented. Case law instructs us that a proposed rule is arbitrary only if it is not supported by facts and logic. On the other hand, a proposed rule is capricious if it is taken without thought and reason. Agrico at 763. Also relevant here is the proposition that in making a factual record to support a rule, an agency cannot rely on "literature" or other unspecified documents that are not made a part of the record. Ameraquatic, Inc. et al v. State, Dept. of Natural Resources, 20 F. L. W. D366, D369 (Fla. 1st DCA, February 7, 1995). At the same time, an agency cannot enlarge, modify or contravene the provisions of a statute, and a rule which purports to do so constitutes an invalid exercise of delegated legislative authority. See, e. g., Cataract Surgery Center v. Health Care Cost Containment Board, 581 So.2d 1359 (Fla. 1st DCA 1991). Finally, a hearing officer cannot adjudicate claims on matters not timely raised by the parties. Compare Agency for Health Care Administration v. Principal Nursing Services, Inc., 20 F. L. W. D492 (Fla. 1st DCA, February 24, 1995)(improper for hearing officer to determine the validity of a rule not specifically alleged to be invalid in the initial petition).

74. Assuming for the sake of argument only that the Board has authority to promulgate the rules, the undersigned rejects the contention that proposed rule 59O-2.002(7) is invalid because it is arbitrary and capricious. Simply because a rule's operation is contingent on the adoption of other rules is not a ground to invalidate a rule. A second contention that the rule is vague and fails to establish adequate standards for agency discretion has been rejected as being untimely raised.

75. Because rule 59O-3.003(3) lacks an adequate factual basis, as more specifically described in findings of fact 33-35, it is concluded that the rule is arbitrary, and it is therefore an invalid exercise of delegated legislative authority.

76. In a similar vein, given the lack of a factual basis for rules 59O-5.001(1)(b), (2)(a), and (2)(b), as further explained in findings of fact 38-43, these portions of the rule are deemed to be arbitrary and are thus an invalid exercise of delegated legislative authority.

77. By making respiratory therapists and respiratory care practitioners subject to the requirements of rule 59O-5.006, in contravention of Subsection 468.351(2), Florida Statutes, rule 59O-5.006(2)(c) is deemed to be an invalid exercise of delegated legislative authority. Further, there is a lack of facts or logic to support the Board's decision to include only three classes of professions within the terms of the rule. Accordingly, the remainder of the rule is deemed to be arbitrary and thus invalid. It is also concluded that the same rule is invalid on the ground it contravenes the provisions of Subsection 455.201(4), Florida Statutes, by creating unreasonable restrictions and standards on qualified professions. Finally, the second sentence in the first paragraph of the rule is deemed to be arbitrary and thus an invalid exercise of delegated legislative authority.

78. Finally, the contention that proposed rules 59O-9.002(4), 59O-9.004(7), 59O-10.004 and 59-13.006 are invalid for other reasons has been rejected since the grounds were not timely raised.

Based on the foregoing findings of fact and conclusions of law, it is

ORDERED that proposed rules 59-2.002(7), 59-3.003, 59O-5.001(1)(b), (2)(a) and (2)(b), 59O-5.006, 59O-9.002(4), 59O-9.004(7), 59O-10.004 and 59O-13.006 are declared to be an invalid exercise of delegated legislative authority on the ground the agency exceeded its rulemaking authority.

DONE AND ORDERED this 8th day of March, 1995, in Tallahassee, Florida.

DONALD R. ALEXANDER
Hearing Officer
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-1550
(904) 488-9675

Filed with the Clerk of the
Division of Administrative Hearings
this 8th day of March, 1995.

APPENDIX TO FINAL ORDER

Petitioners FPS, FHA, and FLH:

1-2. Partially accepted in finding of fact 3.
3. Rejected as being irrelevant.
4. Rejected as being unnecessary.
5-21. Partially accepted in findings of fact 10-16.
22-36. Partially accepted in findings of fact 17-26.
37-39. Partially accepted in findings of fact 28-30.
40-47. Partially accepted in findings of fact 31-35.
48-55. Partially accepted in findings of fact 45-50.
56-58. Partially accepted in findings of fact 51-53.
59. Partially accepted in findings of fact 54 and 55.
60-71. Partially accepted in findings of fact 56 and 57.

Petitioners FSP and McCann:

1-37. Partially accepted in findings of fact 36-44.

Respondent:

1. Partially accepted in finding of fact 14.
2. Partially accepted in findings of fact 11 and 12.
3. Partially accepted in finding of fact 16.
4. Partially accepted in finding of fact 10.
5. Partially accepted in findings of fact 2 and 9.
6-13. Partially accepted in findings of fact 10-16.
14. Partially accepted in finding of fact 2.
15. Partially accepted in finding of fact 4.
16. Partially accepted in finding of fact 3.
17-18. Partially accepted in findings of fact 5, 33 and 35.
19. Covered in preliminary statement.
20-24. Rejected as being unnecessary.
25. Partially accepted in finding of fact 43.
26. Partially accepted in finding of fact 35.
27. Partially accepted in finding of fact 36.
28-31. Partially accepted in findings of fact 38-44.
32. Partially accepted in findings of fact 28-30.
33-34. Partially accepted in findings of fact 31-35.
35-36. Partially accepted in findings of fact 45-50.
37. Partially accepted in findings of fact 51-53.
38. Partially accepted in finding of fact 54.
39. Partially accepted in finding of fact 56-57.

Note - Where a proposed finding has been partially accepted, the remainder has been rejected as being unnecessary for a resolution of the issues, irrelvant, cumulative, subordinate, not supported by the evidence, or a conclusion of law.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate procedure. Such proceedings are commenced by filing one copy of a notice of appeal with the agency clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the district court of appeal in the appellate district where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.

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DISTRICT COURT OPINION

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IN THE DISTRICT COURT OF APPEAL
FIRST DISTRICT, STATE OF FLORIDA

BOARD OF CLINICAL LABORATORY PERSONNEL,

Appellant,

vs.

FLORIDA PERFUSION SOCIETY, et al.,

Appellee.
_____/

NOT FINAL UNTIL TIME EXPIRES TO FILE MOTION FOR REHEARING AND DISPOSITION THEREOF IF FILED.

CASE NO. 95-1196
DOAH CASE NO. 94-5968RP

Opinion filed January 28, 1997.

An appeal from an order of the Division of Administrative Hearings.

Robert A. Butterworth, Attorney General, and Claire D. Dryfuss, Assistant Attorney General, Tallahassee, for Appellant.

Carol A. Forthman of Cobb, Cole & Bell, Tallahassee, for Appellees Florida Hospital Association and Florida Perfusion Society; Harold F.X. Purnell of Rutledge, Ecenia, Underwood, Purnell & Hoffman, P.A., Tallahassee, for Appellees Florida Society of Pathologists and Louis S. McCann, Jr.

PER CURIAM.

AFFIRMED.

BARFIELD, C. J., HAHN and DAVIS, JJ., CONCUR