4-0297

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

FLORIDA ASSOCIATION OF BLOOD BANKS, a non-profit corporation,	)	
Petitioner,	)	
vs.	)	CASE NO. 96-4335RP
STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION, BOARD OF CLINICAL LABORATORY PERSONNEL,	)	
Respondent.	)	

FINAL ORDER

Pursuant to notice this cause came on for final hearing before P. Michael Ruff duly designated Administrative Law Judge in Tallahassee, Florida on October 23, 1996. The appearances were as follows:

APPEARANCES

For Petitioner: Thomas J. Guilday, Esquire
Rex D. Ware, Esquire
Huey, Guilday and Tucker, P.A.
Post Office Box 1794
Tallahassee, Florida 32302

For Respondent: Edwin A. Bayo, Esquire
Office of the Attorney General
The Capitol, Plaza Level 01
Tallahassee, Florida 32399-1050

STATEMENT OF THE ISSUES

The issues to be resolved in this case concern whether Proposed Rules 59O-3.002, 59O-5.003, 59O-3.003, 59O-5.004, and

590-7.001, Florida Administrative Code, which substantially revise and replace existing provisions of the same rules are invalid on the basis that they are allegedly an invalid exercise of delegated legislative authority for reasons set forth more fully in Section 120.52(8), Florida Statutes.

PRELIMINARY STATEMENT

This matter arose upon the filing of a Petition for Administrative Determination of Invalidity of the above-referenced, proposed rules. The Petitioner, in the Petition filed on September 13, 1996, alleged that the proposed rules in essence were invalid for the reason referenced above. The cause was ultimately assigned to the undersigned Administrative Law Judge and came on for hearing as noticed.

The final hearing was held on October 23, 1996. The Respondent presented testimony of Patricia Johns, Ph.D. in support of the validity of the proposed rules. The Petitioner provided testimony of Jane Dariotis, Alice Barr, and Michael Pratt. Additionally, the Petitioner offered three (3) exhibits which were admitted into evidence.

Upon conclusion of the hearing the Petitioner and Respondent elected to file proposed final orders after the filing of a transcript of the proceedings. Ultimately, after extensions were agreed upon and granted, those proposed final orders were timely filed.

FINDINGS OF FACT

1. The Respondent, Agency for Health Care Administration, is an agency of the State of Florida charged with administering licensing of clinical laboratory personnel in pertinent part. This responsibility was formerly that of the Department of Health and Rehabilitative Services.

2. The Florida Association of Blood Banks, the Petitioner, is a non-profit organization made up of community blood banks throughout the state of Florida. The organization represents the interest of individual member physicians, technicians, technologists and other health care workers who work in blood banks, hospitals, community blood banks, and blood centers throughout the state as well as institutional blood banks and transfusion services.

3. The association is organized to assure good blood banking practices in the state of Florida in order to improve safety of the blood supply in the state for the public. Both the individual and institutional memberships of the association are affected by the proposed rule in terms of both institutional community blood centers and individual technicians and technologists working in blood centers because changes to licensure provisions will make employment more difficult and otherwise make qualified staff prospectively ineligible for employment and thus make it more difficult for blood banking entities in hiring qualified personnel.

4. Hospital-based blood banks which perform transfusion services will also be impacted because changes in the proposed rules may disqualify certain technologists and technicians from working in blood banks, may increase costs and make it more difficult for these blood banks to replace qualified staff. It has not been shown that the changes will improve the safety or quality of health care provided.

5. The proposed rules will impose education and training programs which are not adequate for the specialized procedures performed by the blood banks, thus making licensure more difficult. They will provide less qualified applicants.

6. The Petitioner has demonstrated that it represents the interests of its institutional and individual members and that a substantial number of those members will be affected by the proposed rules. The rules are within the scope of interest which the Petitioner/association was organized and is operated to protect.

7. Clinical laboratory personnel are defined to include technologists and technicians who perform or are responsible for performing laboratory test procedures. This definition includes personnel in blood banks performing laboratory test procedures but does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists or persons employed by the clinical laboratory to perform manual pre-testing duties, clerical personnel or those with other administrative responsibilities.

8. Clinical laboratory personnel and blood banks currently

perform test procedures in the field of immunohematology and the current specialization of blood banking.

9. All laboratories must comply with the conditions imposed under the Federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). Those regulations appear at 42 Code of Federal Regulation Section 493.1, et. seq. The CLIA regulations, however, do not relate to licensure of laboratory personnel themselves. CLIA imposes specific qualifications and requirements for individuals who perform "high complexity testing." Compliance with these regulations requires that each individual performing such testing "possess a current license issued by the state in which the laboratory is located as well as certain other requirements which are discussed herein." The CLIA rules provide detailed and specific regulations concerning performance of laboratory test procedures.

10. The proposed rules at issue substantially modify the existing laboratory personnel rules and eliminate the specialty designation in blood banking. The following proposed rules delete the specialty designation in blood banking:

> A. The specialty designation of blood banking is deleted from the provision pertaining to general requirements of clinical laboratory personnel training programs (Fla. Admin. Code R. 59)-3.001);
>
> B. The specialty designation in blood banking is deleted from clinical laboratory personnel training programs (Fla. Admin. Code R. 59O-3.003);
>
> C. The licensing procedure for technologists with a specialty in blood banking is deleted (Fla. Admin. Code R. 59O-5.004); and

D. The licensing procedure for technicians with a specialty in blood banking is deleted (Fla. Admin. Code R. 590-5.004); and

E. Provisions providing for licensure examinations for the specialty in blood banking are deleted (Fla. Admin. Code R. 590-7.001).

11. Substantial changes are made in technician and technologist training and experience requirements. These changes include:

A. Education and training requirements for licensure as a technician are changed from 400 hours of instruction in a designated specialty under the existing rules to a minimum of one year of integrated instruction covering all categories, including categories of clinical chemistry, hematology, immunohematology, microbiology and serology immunology. (Fla. Admin. Code R. 590-3.001(6)(1)).

B. Experience requirements for licensure as a technologist are changed from 400 hours of training and experience in a designated specialty (no longer including blood banking) to five years of pertinent clinical laboratory experience with one year of experience in each category for which licensure is sought (Fla. Admin. Code R. 590-5.003(1)(g)). Alternatively, three years of pertinent clinical laboratory experience of which one year shall be in the category for which licensure is sought for an applicant with a baccalaureate degree.

12. The laboratory personnel licensure rules have been in existence for a substantial period of time but until recently did not provide for a specialty designation in blood banking. Because of new laboratory tests for specific diseases which were imposed on blood banks pursuant to federal regulation issued by the Federal Food and Drug Administration and the need for specially trained personnel in order to perform these tests, a

task force was formed in 1988 and 1989 to work with the Department of Health and Rehabilitative Services to develop a blood banking specialty under the laboratory personnel rules. This specialty was created by rules adopted in May of 1995. The specialization was intended to focus training in specific areas of work in blood banks in order to ensure that laboratory personnel working in blood banks complied with controlling federal regulations.

13. A comprehensive examination for this blood banking specialty was developed and adopted by rule in December of 1995. See Rule 59O-7.001, Florida Administrative Code. The examination was administered for the first time in September of 1996.

14. The proposed rules were published in the August 23, 1996, Florida Administrative Weekly. The agency offered no testimony or evidence that any change in circumstances that occurred with respect to licensure of laboratory personnel in the specialization of blood banking. Further no evidence was offered that any difficulty had been created in maintaining the blood banking specialization. There was no evidence of the existence of any problem with respect to specialized training and educational requirements for licensed technologists and technicians. To the contrary, the evidence indicates that failure to provide specialized education for training in blood banks would create significant problems for blood banks and their personnel.

15. The agency offered several reasons for the proposed changes at the hearing. These included the agency's desire to

minimize proliferation of specialties; a desire to make licensure dependent upon the discipline related to the particular laboratory test procedures performed and a desire to make the state regulatory scheme consistent with CLIA.

16. The proposed rules limit the categories in which training and education are provided for licensure to certain limited categories. These are the categories of Chemistry, Hematology, Immunohematology, Microbiology, and Serology/Immunology. The department contends that these categories of tests are "disciplines" while blood banking is not. It maintains that the categories of Histology, Radioassay and Blood Gas Analysis are also disciplines. (See Proposed Rules 590-3.003(2)(a)(b)(c) and (d), Florida Administrative Code). However, each of these areas involves performance of one or more test procedures from a specialty category. Thus these categories are no more discrete "disciplines" than is blood banking.

17. The agency contends that while immunohematology is synonymous with blood banking, the "donor processing" aspect of blood banking is not a disciplined-based specialty and should therefore be deleted.

18. The disciplines which the department intends to recognize in its proposed rules are Chemistry, Hematology, Immunohematology, Microbiology, and Serology/Immunology, as well as Histology, Radioassay, and Blood Gas Analysis. Except for Radioassay and Blood Bas Analysis these categories are based upon laboratory tests proficiency standards described in the federal regulatory scheme known as CLIA. CLIA regulations contains

specific proficiency standards for tests performed in these general categories. A blood bank performs a limited number of tests in each category, to wit, Immunology (42 CFR Section 493.027), Routine Chemistry (42 CFR Section 493.931), Syphilis Serology (42 CFR Section 493.923), Hemotology (42 CFR Section 493.941), and Immunohematology (42 CFR Section 493.959). Each CLIA category includes numerous tests within the category. While CLIA does not provide for personnel standards, the proficiency tests' standards are the basis upon which personnel are licensed in the various specialty categories.

19. While clinical laboratory procedures are utilized to assist in the diagnosis and treatment of disease, blood is considered a product. Thus standards for performing clinical laboratory test procedures and testing blood are different. For this reason CLIA provides specific standards respecting the activities of blood banks. These provisions includes standards concerning the operation of a transfusion service and blood bank pursuant to standards of immunohematology (42 CFR Section 493.1271), standards governing immunohematological collection, processing dating periods, labeling and distribution of blood and blood products (42 CFR Section 493.1273), standards for blood and blood products storage (42 CFR Section 493.1275), standards for the provision of testing (42 CFR Section 493.1279), standards for the retention of samples of transfused blood (42 CFR Section 493.1283), and standards for the investigation of transfusion reactions (42 CFR Section 493.1285).

20. The CLIA standards incorporate provisions of 21 CFR Section 640 and 21 CFR Part 606, pertaining to blood and blood product collection, processing and distribution. Pertinent regulations adopted by the Food and Drug Administration Act provide comprehensive regulatory requirements controlling the manner, method and procedures of a blood bank in collecting, testing, processing, and storing blood. See generally 21 CFR Section 640.1 through Section 640.56. Additionally, other provisions of the Act provide extensive regulation pursuant to provision of good manufacturing practices for blood and blood components. See 21 CFR Section 606.3 through Section 606.17. Thus, these regulations provide the primary regulation of the performance of laboratory procedures by blood bank personnel. They are the focus of a blood bank training and education program. The blood bank specialty examination provided for by the existing rules which the department proposes to delete, incorporates applicable provisions of the above-described federal regulations. The preponderant evidence does not demonstrate that the agency considered the import of the CLIA and Food and Drug Administration provisions in proposing to delete the blood bank specialization.

21. A blood bank performs a limited number of test procedures in a number of different categories. These include a single Serology test (Syphilis), two Immunology tests (HIV and hepatitis), a single Chemistry test (ALT), several Hemotology procedures and several Immunohematology test procedures. Although CLIA provides proficiency standards for many laboratory

test procedures in each category, a blood bank performs only the specific procedures identified by FDA regulations. The FDA regulations, previously referred to, specify the methodology and manner of performing these specific tests.

22. Performance of these test procedures in a blood bank is fundamentally different than that which occurs in a general laboratory. In a general laboratory, personnel are trained to perform a multiple of tests and to interpret the results for purposes of diagnosis. It is essential that personnel be able to interpret tests and determine if additional tests are required. No FDA regulations control the performance of these test procedures. Rather, CLIA describes general proficiency standards for performance of each specialty and sub-specialty tests procedures. (See 42 CFR Section 493.812 through Section 493.865; 42 CFR Section 493.909 through Section 493.959). These performance standards provide the basis for education and training in the licensure of personnel. However, blood banks provide specific training in the performance of test procedures required by CLIA and the FDA. This type of training is not available in a general medical technologist program nor in a training program which was not provided by a blood bank.

23. In proposing rules deleting the blood bank specialty, the agency has admitted that it did not consider the import of any of the federal regulations, described above, pertaining to blood banks, nor did it consider the provisions of CLIA pertaining to unique standards and procedures applied to blood banks in adopting personnel training and licensure provisions.

Further, although the agency acknowledges that the training and educational programs necessary for training laboratory personnel licensed and employed in blood banks would require inclusion of the relevant federal regulations, the deletion of the blood banking specialty would effectively delete education and training under these provisions.

24. Part of the agency's justification for the proposed rules was to assure consistency between the provisions of CLIA and the clinical laboratory personnel rules. However, representatives of the department admitted that the proposed rules regarding training programs for licensure were not consistent with CLIA and in fact, would exceed the CLIA requirements. The specific provision of CLIA pertaining to experience and training at issue provides as follows:

> Section 493.1489 Standard: Testing Personnel Qualifications
>
> Each individual performing high complexity testing must:
>
> A. Possess a current license issued by the state in which the laboratory is located, if such licensing is required; and
>
> B. Meet one of the following requirements:
>
> * * *
>
> (2)(B) have laboratory training that includes either of the following:
>
> * * *
>
> (2) At least three months documented laboratory training in each specialty in which the individual performs high complexity testing.

25. This provision is consistent with existing rule provisions which require 400 clock hours of pertinent clinical laboratory experience in each specialty for which licensure is sought. (See Rules 59)-5.003(2)(a)1, Florida Administrative Code). Additionally, this provision in CLIA is consistent with clinical laboratory training programs for the technicians which require a minimum of 400 clock hours of instruction in each specialty (See Rule 590-3.003(3), Florida Administrative Code, Rule 59)-5.004(2)(b), Florida Administrative Code). The proposed rules, however, delete these provisions and instead require participation in a one year educational program for each specialty in which licensure is sought or one year of experience in each category for which licensure is sought. (See Proposed Rule 590-3.001(6)(1) and 590-5.003(1)(g), Florida Administrative Code).

26. Change of the experience and training requirement of 400 hours (approximately three months) to one year represents a substantial departure from the CLIA requirements. The agency offered no preponderant evidence explaining the reason for the departure. Moreover, such an inconsistency contradicts one of the stated goals expressed by the agency - to make the personnel standards consistent with CLIA.

27. Change of the experience and training requirements from 400 hours to one year would impose unnecessary and unreasonable requirements in training blood bank personnel. A blood bank performs only a limited number of tests in several categories. Training for each procedure is based upon federal regulatory

requirements imposed by CLIA and the FDA. Thus, training of laboratory personnel to perform a wide array of tests in each category as proposed is unnecessary, costly and counterproductive.

28. For personnel employed with broad-based designations, the blood bank is forced to provide additional specialized education and training because of the unique nature of the test procedures performed. Thus, 400 hours of training in each specialty in which tests are to be performed in a blood bank setting (rather than one year) appears to be a reasonable allocation of time.

29. Training programs have been established which provide training in each specialty consistent with these requirements and which have been approved by the state as recently as in the last year. Adoption of the longer training and experience requirements in the proposed rules would result in more difficult recruitment of qualified personnel, will increase personnel costs and will not produce more qualified, competent personnel.

30. The agency offered as justification for the change the fact that under the existing regulatory scheme, a high school graduate who obtained 400 hours of education and/or training could qualify as a technician. Although the agency appears to imply that something is wrong with this standard, it offered no evidence or testimony that such individuals would be ill-equipped or ill-trained to perform laboratory test procedures for which they had been thus trained.

31. The effect of the proposed change as it would apply to personnel employed by a blood bank would be, in many instances, to change the education and experience requirements from 400 hours in the specialty licensure obtained to one year in each specialty. Thus, in a blood bank in which personnel were employed to perform limited testing in each of four different areas, a minimum of four years of experience and/or training would be required. These are significant and substantial changes from the requirements of the present rules.

32. The agency has suggested that there is no interest in the blood banking designation because no one is currently designated in that specialty. However, it is apparent that the examination for this specialty has only recently been developed and the first examination was only given in September of 1996, approximately one month after the agency proposed the rules at issue which would delete that specialty. Even though it was not well-advertised, sixty-two people took the blood bank examination, including ten who took only the blood bank specialty. There was evidence that there are many individuals who are interested in taking the examination and making application for the blood bank licensure designation.

CONCLUSIONS OF LAW

33. The Division of Administrative Hearings has jurisdiction of the subject matter of and the parties to this proceeding. Section 120.56(1), Florida Statutes.

34. The Petitioner has established that it has standing to challenge the proposed rules. Elimination of the blood bank

specialization designation and training requirements provided for under the existing rules would have a direct, adverse impact upon the association's members. The association represents those adversely impacted members and established that the subject matter of the proposed rule comes within the scope of interests the association was organized to protect. Thus, the Petitioner has standing. See Florida Home Builders v. Dept. of Labor, 412 So. 2d 351 (Fla. 1982); Dept. of Professional Regulation v. Fla. Dental Hygienists Assn., 612 So. 2d 646 (Fla. 1st DCA 1993).

35. The Respondent agency licenses clinical laboratories pursuant to Section 483.057, Florida Statutes, et. seq., and clinical laboratory personnel pursuant to Section 483.800, et. seq., Florida Statutes. Clinical laboratories are defined as laboratories

> Where examinations are performed on material or specimens taken from the human body to provide information or materials for use in the diagnosis, prevention or treatment of a disease or the assessment of a medical condition.

Section 483.041(2), Florida Statutes.

36. The legislature has determined that protection of the public and individual health requires the licensure of clinical laboratories which meet certain "minimum standards and safeguards consistent with the federal law." (Emphasis supplied). See Section 483.021, Florida Statutes. The agency is granted authority to adopt rules and regulations regarding performance of examination of specimens which comply with the Federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and the federal rules adopted thereunder. See Section 483.051(2)(a),

Florida Statutes.

37. In order to protect the public health, safety, and welfare the agency has been delegated authority to license clinical laboratory personnel and is authorized to license personnel who meet the minimum requirements for safe practice and established training programs. Section 483.800, et. seq., Florida Statutes. The performance of clinical laboratory examinations or reports requires licensure. Section 483.813, Florida Statutes. The Board of clinical laboratory personnel is authorized to establish for licensure "minimal qualifications for clinical laboratory personnel." (Emphasis supplied). Section 483.823, Florida Statutes.

38. Whether or not a blood bank or blood banking is a separate discipline, as comprehended by the agency, it is clearly apparent that different standards, regulatory provisions, training, and educational requirements are required. Moreover, it is clear that CLIA and regulations promulgated by the FDA mandate a special category for blood banks.

39. A substantially affected person may seek an administrative determination of the invalidity of the proposed rule. Section 120.56(2)(a), Florida Statutes. The petition filed by the Florida Association of Blood Banks (FABB) describes with particularity the objections to the proposed rule and the reason that the proposed rule is an invalid exercise of delegated legislative authority. Additionally, the Petitioner provided substantial evidence that the proposed rules are, under the circumstances, unreasonable and not attended by logic and reason.

Therefore, under Section 120.56(2)(a), Florida Statutes (1996), the agency has the burden of establishing that the proposed rules are not an invalid exercise of delegated legislative authority as to the objections raised. The specific provision of Section 120.56(2)(a), Florida Statutes, provides as follows:

* * *

> The agency then has the burden to prove that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised. The Administrative Law Judge may declare the proposed rule wholly or partially invalid. Section 120.56(2)(a), Florida Statutes.

40. The above-cited provisions of Section 120.56(2), Florida Statutes, became effective on October 1, 1996. Thus, the effective date of this statutes is after the date that the agency proposed these rules. The proposed rules were published in the Florida Administrative Weekly, on August 23, 1996. The petition was filed on September 13, 1996. However, the hearing was held on October 23, 1996. Thus, an issue exists as to whether the newly adopted provisions regarding the placement of the burden of proof apply to these proceedings.

41. As a matter of general law, a statute affecting the burden of proof is inherently procedural. 49 Fla. Jur. 2d Section 108. Even in the absence of clear legislative intent, a procedural rule may be abrogated retroactively under the general provision that no one has a vested right to a given mode of procedure. Moreover, the First District Court of Appeal has recently considered this issue in an analogous situation

involving other October, 1996 amendments to Chapter 120. In Life Care Centers of America v. Sawgrass Care Center, ___ So. 2d ___, 821 FLW 2487 (Fla. 1st DCA November 21, 1996), Judge Benton applied retroactively amendments to Section 120.59(2), Florida Statutes, pertaining to findings of fact. In addressing the issue of retroactive application of statutory changes, the court cited general principles stating:

> In general, a rule [of statutory construction] is that a substantive statute will not operate retrospectively absent clear legislative intent to the contrary, but that a procedural or remedial statute is to operate retrospectively. Additionally, `statutes that relate only to procedure or remedy generally apply to all pending cases.' Id. at 2488.

42. The court noted that "procedure within an administrative agency is subject to statutory regulation." Thus, the court applied the amended statute. The same result applies here. Newly enacted Section 120.56(2), Florida Statutes, shifts the burden of proof to the agency.

43. Having concluded that the agency carries the burden of proof in establishing that the proposed rule is not an invalid exercise of delegated legislative authority, it must be determined what showing the agency was required to make.

44. Section 120.52(8) Florida Statutes, defines an invalid exercise of delegated legislative authority as action which goes beyond the powers, functions and duties delegated by the Legislature. In accordance with this provision a proposed or

existing rule is an invalid exercise of delegated legislative authority if any one of the following bases for invalidity, raised generally or specifically in the petition, exists:

> a. The Agency has materially failed to follow the applicable rule making procedures or requirements set forth in this chapter;
>
> b. The Agency has exceeded its grant of rule making authority, citation to which is required by Section 120.54(3)(a)1, Florida Statutes.;
>
> c. The rule enlarges, modifies or contravenes the specific provisions of law implemented, citation to which is required by Section 120.54(3)(a)1, Florida Statutes.;
>
> * * *
>
> e. The rule is arbitrary or capricious;
>
> f. The rule is not supported by competent, substantial evidence; or
>
> g. The rule imposes regulatory costs on a regulated person, county or city which can be reduced by adoption of less costly alternatives that substantially accomplish the statutory objectives.

45. Application of the burden of proof requirements of Section 120.56(2), Florida Statutes, to this definition logically requires the agency to establish by a preponderance of the evidence that the proposed rules satisfy the above elements. Moreover, the rulemaking authority of the agency is additionally circumscribed by the general principle stated in Section 120.52(8), Florida Statutes, to the effect that the agency's powers extend no further than the particular powers and duties conferred by statute. The agency has no authority to adopt rules only because they are "reasonably related to the purpose of

enabling legislation and [are] not arbitrary or capricious." The proposed rules are invalid in a number of respects.

46. As specific authority for adoption of the proposed rules the agency cited Section 483.805(4), Florida Statutes and Section 483.811(2)(3), Florida Statutes. Section 483.805(4), Florida Statutes, merely embodies the board's authority to approve curricula in schools and colleges offering education and training leading toward application for licensure under this part. Thus, it is not applicable to the dispute at issue here. The other provisions relied upon are Section 483.811(2)(3) Florida Statutes, which authorize the board to adopt rules for training programs and licensure as follows:

> Section 483.811
>
> (2) The Board shall adopt rules for training programs, including but not limited to, rules related to curriculum, educational objectives, evaluation procedures, personnel license requirements, pre-entry educational requirements and length of clinical training.
>
> (3) The Board shall adopt rules for the licensure, education and training of personnel in laboratories operated pursuant to Section 483.035 based upon and not exceeding the standards contained in the Federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder . . .

47. Because the agency in essence conceded that the proposed rules are inconsistent with and in excess of the standards of CLIA, the Department argued that Section 483.811(3) Florida Statutes, did not apply because laboratories operated pursuant to Section 483.035, Florida Statutes, are "exclusive use laboratories" and not at issue here. If this is true then the

Department has failed to cite any specific statutory authority for the rules it seeks to implement. If it relies on Section 483.811(3) Florida Statutes, then the proposed rules clearly contravene that cited statute in that they are admittedly inconsistent with CLIA.

48. A provision not cited by the agency, Section 483.823, Florida Statutes, appears to provide authority for the Board to prescribe the qualifications for clinical laboratory personnel licensure. This section provides:

> Section 483.823
>
> The Board shall prescribe minimal qualifications for clinical laboratory personnel and shall issue a license to any person that meets the minimum qualifications and who demonstrates that he possesses the character, training and ability to qualify in those areas for which the license is sought. (Emphasis supplied)

49. It is noteworthy that this statute provides that the Board's authority is limited to establishing minimal qualifications. It should also be noted that the declaration of policy and statement of purpose for the regulation of clinical laboratories generally provides as follows:

> The protection of public and individual health requires licensure of clinical laboratories and the meeting of certain minimum standards, as well as certain other necessary safeguards as authorized by this part. The Legislature intends that, in keeping with federal law and regulations, clinical laboratories regardless of location, size or type, meet appropriate standards. (Emphasis supplied)

The agency has no statutory authority to adopt other than minimal standards for personnel licensure. It is apparent from the intent of the statute that any standard adopted should be consistent with the requirements of CLIA. Moreover, this was the stated purpose given by the agency in justifying the proposed rules. Thus, as to the disputed rules, the agency has proposed rules which are more than minimal and are inconsistent with CLIA. Thus, it has exceeded its statutory authority and has proposed rules which modify or contravene the enabling legislation.

50. In order to determine whether a rule is arbitrary or capricious, it must be determined whether the proposed rule is supported by fact or logic or is undertaken without thought or reason. Dravo Basic Materials Company, Inc. v. State Department of Transportation, 602 So. 2d 632 (Fla. 2d DCA 1992). The agency admittedly failed to consider the impact of many federal regulations which are applicable to personnel performing procedures in a blood bank. Thus, the has failed to establish that it has acted with sufficient fact or logic as a basis for the proposed rules and it is concluded that the disputed rules were undertaken without sufficient thought or reason. This is especially so in light of the fact that the agency had enacted the existing rules, effective December of 1995, which provided for the "blood banking specialty", presumably enacted with logical thought, reason, fact-gathering and consideration of related federal regulations. Indeed the rationale and fact-gathering process underlying the existing rules began as far back as the 1988 convening of the "task force" which assisted in

formulation of the existing rules up to their 1995 enactment. Now only a few short months later the agency has embarked on a rather singular course reversal in proposing the rules at issue, which delete the blood banking specialty before prospective licensees can even sit for the first examination administered under the rules which became effective in December of 1995. That first examination was administered in September of 1996 and some months previously the rulemaking process for the proposed rules, deleting the specialty to which the examination related, was inaugurated and the proposed rules were noticed on August 23, 1996.

51. The agency bears the burden of establishing by competent evidence the validity of the proposed rules. Even if it be assumed that the agency established some evidence in support of the rules it has not established by a preponderance of the evidence the proposed rules' validity.

52. The Petitioner has established by a preponderance of the evidence that the existing rule framework which provided for the specialty in blood bank designation and training and educational requirements consistent with CLIA standards were developed based upon legitimate concerns and problems unique to blood banks and blood banking. There is no dispute that laboratory testing of blood is performed pursuant to controlling federal regulation and standards referenced above. It is self-evident that personnel should be trained, educated and licensed pursuant to these regulations. The existing rules included examinations focused on these topics. This was the reason that

the blood bank specialty was adopted in the first place. The agency now seeks to delete these provisions, without apparently considering the impact of the changes nor providing a cogent explanation for its abrupt, rapid change in direction in this area of regulation.

53. It is presumed that the existing rules are valid. The agency offered no persuasive evidence that the existing rules were arbitrary, capricious, based upon flawed rationale or different circumstances when adopted in December of 1995. In now proposing repeal of those same rules and adoption of new rules without any change in the organic statutory authority or other preponderantly proven change in circumstances, the agency should have to provide some persuasive rationale justifying elimination of the presumed valid existing provisions. The agency has failed to establish that the existing rules are arbitrary, capricious or without reason. Moreover, it has offered no credible explanation as to why the existing rules should be repealed and replaced with a new and contrary regulatory scheme. The proposed discarding the existing rules only a few months after their enactment, when the enabling statutory basis for them, including the agency's statutory charge to adopt minimal standards for licensure, in a manner in keeping with federal law has not changed, renders the proposed rule enactment to be arbitrary and in contravention of its rulemaking authority and the specific provisions of law implemented.

54. It is thus been established that, to the extent that the proposed rules eliminate the blood bank specialization and

revise training and educational time periods, the agency has failed to establish that the proposed rules are not an invalid exercise of delegated legislative authority. Accordingly, it therefore

ORDERED that, in consideration of the above findings of fact, conclusions of law, the evidence of record, the candor and demeanor of the witnesses, and the pleadings and arguments of the parties that the following proposed rules are invalid exercises of delegated legislative authority, to wit: Proposed Rule 59O-3.001(6)(1), Florida Administrative Code; Proposed Rule 59O-3.003(2)(a), Florida Administrative Code; Proposed Rule 59O-5.003(1)(c) and (g) Florida Administrative Code; Proposed Rule 59O-5.004(3) Florida Administrative Code; Proposed Rule 59O-7.001, Florida Administrative Code.

DONE and ORDERED this 2nd day of April, 1997, in Tallahassee, Leon County, Florida.

R. MICHAEL RUFF
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 2nd day of April, 1997.

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NOTICE OF RIGHT TO APPEAL

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 the 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.