

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

JOHN GOODMAN,

Petitioner,

vs.

Case No. 14-1918RX

FLORIDA DEPARTMENT OF
LAW ENFORCEMENT,

Respondent.

FINAL ORDER

An administrative hearing was held June 10 and 11, 2014, in Tallahassee, Florida, before Administrative Law Judge (ALJ) William F. Quattlebaum, Division of Administrative Hearings.

APPEARANCES

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STATEMENT OF THE ISSUE

The issue in this case is whether Florida Administrative Code Rules 11D-8.012 and 11D-8.013 are invalid exercises of delegated legislative authority.

PRELIMINARY STATEMENT

On April 24, 2014, John Goodman (Petitioner) filed a Petition to Determine the Invalidity of an Existing Rule pursuant to section 120.56(3), Florida Statutes (2013).^{1/}

On April 25, 2014, a Notice of Hearing was issued scheduling the administrative hearing to commence on May 23, 2014. On April 30, 2014, the Respondent filed an Agreed Motion for Continuance, and the hearing was rescheduled for June 10 through 12, 2014.

On June 6, 2014, the parties filed a Joint Pre-Hearing Stipulation containing a statement of admitted facts. The stipulated facts have been adopted and are incorporated herein.

At the hearing, the Petitioner presented the testimony of four witnesses and had Exhibits 2 through 7 and 16 through 18 admitted into evidence. The Respondent presented the testimony of two witnesses and had Exhibits 7 and 8 admitted into evidence.

The Transcript of the hearing was filed on June 30, 2014. On July 10, 2014, the parties filed proposed final orders that have been considered in the preparation of this Final Order.

Although rule 11D-8.011 approves both gas chromatography and alcohol dehydrogenase (enzymatic) analytical methods for blood alcohol testing and rule 11D-8.013 references both methods, no forensic laboratory in Florida conducts blood alcohol testing by the enzymatic method, and the Findings of Fact set forth herein are applicable only to gas chromatography headspace analysis.

FINDINGS OF FACT

1. The Petitioner has been charged with "DUI Manslaughter/Failed to Render Aid" and "Vehicular Homicide/Failed to Give Information or Render Aid" in Palm Beach County, Circuit Court Case No. 502010CF005829AXXXMB.

2. The prosecution in the criminal case intends to offer the results of a blood alcohol test performed on blood collected from the Petitioner as evidence at the trial.

3. The Petitioner has moved to exclude the blood alcohol test results from the trial based, in part, on the method used to collect his blood for forensic testing.

4. The Respondent is the state agency responsible for implementing the "Implied Consent" blood alcohol testing program, including the adoption of rules. The Respondent has adopted such rules which are set forth in Florida Administrative Code Chapter 11D-8.

5. The Petitioner has asserted that the Respondent's "Implied Consent" rules are insufficient to ensure the scientific

reliability of the blood alcohol test results to be offered against him in the criminal trial.

6. On March 21, 2014, the circuit court judge presiding in the criminal trial entered an Order Granting State's Motion to Invoke the Doctrine of Primary Jurisdiction, which specifically directed the Petitioner to file a petition challenging rule 11D-8.012 with the Division of Administrative Hearings.

7. On April 24, 2014, the Petitioner filed a Petition to Determine the Invalidity of an Existing Rule, challenging rules 11D-8.012 and 11D-8.013 as invalid exercises of delegated legislative authority.

8. The parties stipulated that the Petitioner is substantially affected by, and has standing to challenge the validity of, rules 11D-8.012 and 11D-8.013.

9. Rule 11D-8.002 provides the following relevant definitions:

(2) Accuracy - the nearness of a measurement to a known concentration.

* * *

(4) Agency - a law enforcement agency other than the Department, or an entity which conducts breath tests or submits blood samples for alcohol testing pursuant to these rules, or a civilian entity performing such duties on behalf of a law enforcement agency.

* * *

(7) Alcohol - ethyl alcohol, also known as ethanol.

* * *

(10) Analyst - a person who has been issued a permit by the Department to conduct blood alcohol analyses.

(11) Approved Blood Alcohol Test - the analyses of two separate portions of the same blood sample using a Department-approved blood alcohol test method and a Department-approved procedure, with results within 0.010 grams of alcohol per 100 milliliters of blood (g/100mL), and reported as the blood alcohol level.

* * *

(14) Blood - whole blood.

(15) Blood Alcohol Level - the alcohol concentration by weight in a person's blood based upon grams of alcohol per 100 milliliters of blood (g/100mL).

* * *

(19) Department - the Florida Department of Law Enforcement.

* * *

(22) Methods - types of alcohol analyses approved by the Department to conduct chemical or physical tests of blood or breath.

* * *

(24) Permit - when issued by the Department, certifies that the holder has met all necessary qualifications, remains in full compliance with these rules and is

authorized to perform all related duties. A permit is issued only to a qualified applicant and remains valid and in full effect until determined otherwise by the Department.

Rule 11D-8.012

10. The Petitioner has asserted that rule 11D-8.012 is an invalid exercise of delegated legislative authority because the rule does not establish a venipuncture procedure regulating needle gauge and tourniquet usage by which blood is obtained for the purpose of performing a blood alcohol test. At the same time, the Petitioner asserts, and the Respondent agrees, that the Respondent lacks statutory authority to adopt such a rule.

11. Rule 11D-8.012 provides as follows:

Blood Samples - Labeling and Collection.

(1) Before collecting a sample of blood, the skin puncture area must be cleansed with an antiseptic that does not contain alcohol.

(2) Blood samples must be collected in a glass evacuation tube that contains a preservative such as sodium fluoride and an anticoagulant such as potassium oxalate or EDTA (ethylenediaminetetraacetic acid). Compliance with this section can be established by the stopper or label on the collection tube, documentation from the manufacturer or distributor, or other evidence.

(3) Immediately after collection, the tube must be inverted several times to mix the blood with the preservative and anticoagulant.

(4) Blood collection tubes must be labeled with the following information: name of person tested, date and time sample was collected, and initials of the person who collected the sample.

(5) Blood samples need not be refrigerated if submitted for analysis within seven (7) days of collection, or during transportation, examination or analysis. Blood samples must be otherwise refrigerated, except that refrigeration is not required subsequent to the initial analysis.

(6) Blood samples must be hand-delivered or mailed for initial analysis within thirty days of collection, and must be initially analyzed within sixty days of receipt by the facility conducting the analysis. Blood samples which are not hand-delivered must be sent by priority mail, overnight delivery service, or other equivalent delivery service.

(7) Notwithstanding any requirements in Chapter 11D-8, F.A.C., any blood analysis results obtained, if proved to be reliable, shall be acceptable as a valid blood alcohol level.

Specific Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3., (d) FS.
Law Implemented 316.1933(2)(b), 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.353(2), 327.354(3) FS.

12. Commercially available kits, generally containing glass evacuation tubes, a non-alcohol skin wipe, and a 21-gauge needle assembly, may be used to collect samples for blood alcohol testing. The Respondent's rules do not require usage of such

kits, and the components of the kits are commonly available where blood collection is performed.

13. The Legislature identified the persons authorized to collect samples for blood alcohol testing in section 316.1933(2)(a), Florida Statutes, which states as follows:

Only a physician, certified paramedic, registered nurse, licensed practical nurse, other personnel authorized by a hospital to draw blood, or duly licensed clinical laboratory director, supervisor, technologist, or technician, acting at the request of a law enforcement officer, may withdraw blood for the purpose of determining the alcoholic content thereof or the presence of chemical substances or controlled substances therein. However, the failure of a law enforcement officer to request the withdrawal of blood shall not affect the admissibility of a test of blood withdrawn for medical purposes.

14. The Petitioner asserts that the gauge of the needle used to puncture a vein for blood collection and improper application of a tourniquet during the collection process can result in "hemolysis" of blood and an inaccurate blood alcohol test result.

15. As noted above, rule 11D-8.002(14) defines "blood" to mean "whole blood."

16. Whole blood is comprised of four components, including white cells, red cells, platelets, and plasma.

17. Hemolysis is the release of the contents of red blood cells (hemoglobin) into blood plasma.

18. Hemolysis can occur from a variety of causes, including, but not limited to, the manner of collection (regardless of the gauge of the needle used to puncture the vein), improper agitation of a sample in the collection tube, and storage of a sample.

19. All blood alcohol testing performed by forensic laboratories in Florida is conducted through "gas chromatography headspace analysis."

20. Extensive testimony was presented at the hearing as to the process of gas chromatography headspace analysis. The reliability and accuracy of the gas chromatography headspace analysis process is not at issue in this proceeding.

21. Gas chromatography headspace analysis involves the removal and testing of a subsample of the blood sample contained in a collection tube.

22. A subsample taken from a sample that exhibits hemolysis contains all of the components present at the time of collection and is whole blood.

23. The evidence fails to establish that hemolysis alters the concentration of alcohol within a subsample taken from a sample of whole blood.

24. The evidence fails to establish that hemolysis affects the results of a blood alcohol test performed on whole blood by gas chromatography headspace analysis.

Rule 11D-8.013

25. Rule 11D-8.013 governs the issuance of permits to analysts conducting blood alcohol tests, including a requirement that analysts define the method and procedures to be followed in conducting the tests.

26. The Petitioner has asserted that the rule is an invalid exercise of delegated legislative authority because the rule does not explicitly require analysts performing a blood alcohol test to identify and/or exclude an "unreliable" blood sample from the testing process. Essentially, the Petitioner argues that samples exhibiting hemolysis or coagulation should not be analyzed for alcohol content.

27. Rule 11D-8.013 provides as follows:

Blood Alcohol Permit - Analyst.

(1) The application for a permit to determine the alcohol level of a blood sample shall be made on a form provided by the Department and shall include the following information:

- (a) Name and address of applicant;
- (b) A copy of state license if licensed, or college transcript;
- (c) Name and address of employer and laboratory facility where applicant performs analyses;
- (d) Identify at least one Agency for which blood analyses are to be performed pursuant to Chapters 316, 322, and 327, F.S.; and,

(e) A complete description of proposed analytical procedure(s) to be used in determining blood alcohol level.

(2) Qualifications for blood analyst permit - To qualify, the applicant must meet all of the following requirements:

(a) Department approval of analytical procedure(s). All proposed analytical procedures will be reviewed and a determination of approval will be made by the Department;

(b) Satisfactory determination of blood alcohol level in five proficiency samples provided by the Department using the proposed analytical procedure. Satisfactory determination shall be made by reporting results for blood alcohol proficiency samples within the acceptable range for the samples. For blood alcohol testing, acceptable ranges shall mean the calculated proficiency sample mean + or - 3 standard deviations iterated twice. The mean and standard deviations will be calculated using the results reported by the analysts and reference laboratories;

(c) Identify at least one Agency for which blood analyses are to be performed pursuant to Chapters 316, 322, and 327, F.S.; and,

(d) Meet one of the following:

1. Possess a clinical laboratory license in clinical chemistry as a technologist, supervisor or director, under Chapter 483, F.S.; or

2. Be a licensed physician pursuant to Chapter 458, F.S.; or

3. Complete a minimum of 60 semester credit hours or equivalent of college, at least 15 semester hours of which must be in college chemistry.

(3) The department shall approve gas chromatographic analytical procedures and enzymatic analytical procedures based on alcohol dehydrogenase which meet the following requirements:

(a) Includes the approved method used and a description of the method, and the equipment, reagents, standards, and controls used;

(b) Uses commercially-prepared standards and controls certified by the manufacturer, or laboratory-prepared standards and controls verified using gas chromatography against certified standards. For commercially-prepared standards and controls, the manufacturer, lot number and expiration date must be documented for each sample or group of samples being analyzed. For laboratory-prepared standards and controls, date, person preparing the solution, method of preparation and verification must be documented;

(c) A statement of the concentration range over which the procedure is calibrated. The calibration curve must be linear over the stated range;

(d) Uses a new or existing calibration curve. The new calibration curve must be generated using at least three (3) standards: one at 0.05 g/100mL or less, one between 0.05 and 0.20 g/100mL (inclusive) and one at 0.20 g/100mL or higher, and must be verified using a minimum of two (2) controls, one at 0.05 g/100mL or less and one at 0.20g/100mL or higher. The existing calibration curve must be verified using a minimum of two (2) controls, one at 0.05 g/100mL or less and one at 0.20g/100mL or higher;

(e) Includes the analysis of an alcohol-free control, and the analysis of a whole blood or serum control. The whole blood or

serum control may be used to satisfy the control requirement(s) in paragraph (d);

(f) A gas chromatographic analytical procedure must discriminate between methanol, ethanol, acetone and isopropanol and employ an internal standard technique;

(g) An enzymatic analytical procedure based on alcohol dehydrogenase must use the procedure recommended by the instrument manufacturer/test kit vendor for whole blood alcohol analysis, and the enzyme used must have sufficient selectivity to provide negligible cross-reactivity towards methanol, acetone and isopropanol.

(4) The permit shall be issued by the Department for a specific method and procedure. Any substantial change to the method, analytical procedure, or laboratory facility must receive prior approval by the Department before being used to determine the blood alcohol level of a sample submitted by an agency. The Department shall determine what constitutes a substantial change.

(5) An analyst shall only use a Department-approved procedure to determine the blood alcohol level of samples submitted by an agency. Approval of blood alcohol analysis methods and procedures shall be based on rule requirements in effect at the time they were submitted for approval.

Specific Authority 316.1932(1)(a)2., (f)1., 316.1933(2)(b), 316.1934(3) 322.63(3)(b), 327.352(1)(b)3. FS.

Law Implemented 316.1932(1)(b), 316.1933(2)(b), 316.1934(3), 322.63(3)(b), 327.352(1)(b), (e), 327.353(2), 327.354(3) FS.

28. Analysts submit the procedures referenced in the rule in the form of written "standard operating procedures" (SOP)

filed with the Respondent. No SOP was admitted into the record of the hearing.

29. As set forth above, the evidence fails to establish that hemolysis affects the results of a blood alcohol test performed on whole blood by gas chromatography headspace analysis. A subsample taken from a sample that exhibits hemolysis contains all of the components present at the time of collection and is whole blood. Accordingly, the evidence fails to establish that a sample exhibiting hemolysis should be excluded from testing.

30. Notwithstanding the requirement in rule 11D-8.012 that glass evacuation tubes containing a preservative and an anticoagulant be used in the collection process, a collection tube containing a blood sample submitted for testing can, on occasion, include coagulated blood.

31. Coagulation can occur for a variety of reasons, including the type of needle used in the collection process or the failure to mix the sample properly with the anticoagulant contained in the tube.

32. Rule 11D-8.002(15) defines "blood alcohol level" as "the alcohol concentration by weight in a person's blood based upon grams of alcohol per 100 milliliters of blood (g/100mL)."

33. The entire sample in a collection tube containing a portion of coagulated blood contains all of the components that

were present in the "whole blood" of the subject from whom the blood was collected. However, coagulation causes some of the blood components to solidify.

34. Alcohol (ethanol) is water-soluble. Coagulation alters the ratio of liquid to solid in the sample and can increase the concentration of alcohol in the liquid portion of the sample.

35. The evidence fails to establish that the mere presence of coagulation inevitably precludes the withdrawal of a subsample that properly reflects the components of the whole blood contained in the collection tube.

36. Because gas chromatography headspace analysis uses a subsample of the liquid portion of the sample, the accuracy of the blood alcohol level reported by the subsample is related to the degree of coagulation present in the sample.

CONCLUSIONS OF LAW

37. The Division of Administrative Hearings has jurisdiction over the parties to and subject matter of this proceeding. § 120.56, Fla. Stat.

38. This case commenced on the filing by the Petitioner of a Petition to Determine the Invalidity of an Existing Rule pursuant to section 120.56(3), which provides as follows:

CHALLENGING EXISTING RULES; SPECIAL
PROVISIONS. -

(a) A substantially affected person may seek an administrative determination of the

invalidity of an existing rule at any time during the existence of the rule. The petitioner has a burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised.

(b) The administrative law judge may declare all or part of a rule invalid. The rule or part thereof declared invalid shall become void when the time for filing an appeal expires. The agency whose rule has been declared invalid in whole or part shall give notice of the decision in the Florida Administrative Register in the first available issue after the rule has become void.

39. The Petitioner has asserted that rules 11D-8.012 and 11D-8.013 are invalid exercises of delegated legislative authority. To the extent that the parties have attempted to raise issues beyond whether the referenced rules are invalid exercises of delegated legislative authority, such issues are outside the scope of this proceeding and have not been considered.

40. Section 120.52(8) provides the following relevant definition:

“Invalid exercise of delegated legislative authority” means action that goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:

(a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;

(b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;

(c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or

(f) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to

extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

41. In a challenge to an existing agency rule, the Petitioner has the burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised. § 120.56(3)(a), Fla. Stat.

Rule 11D-8.012

42. The Petitioner has asserted that rule 11D-8.012 is an invalid exercise of delegated legislative authority because the rule does not establish a specific venipuncture procedure by which blood is obtained for the purpose of performing a blood alcohol test.

43. The Respondent has not proposed rules that would regulate needle gauge and tourniquet usage, and both parties agree that the Respondent lacks statutory authority to adopt such rules. The issue of whether the Respondent has the authority to adopt such rules is outside the scope of this proceeding.

44. The omission from the rule of a requirement related to needle gauge and tourniquet usage is of no material consequence. The evidence fails to establish that hemolysis alters the concentration of alcohol in blood tested through gas chromatography headspace analysis. Accordingly, the evidence fails to provide a basis to invalidate rule 11D-8.012.

45. This Final Order does not address the alleged impact of hemolysis on the results of blood alcohol testing through the enzymatic analytical procedure because there is no evidence that any forensic laboratory in Florida utilizes such a procedure.

Rule 11D-8.013

46. The Petitioner has asserted that rule 11D-8.013 is an invalid exercise of delegated legislative authority because the rule does not explicitly require an analyst to identify, document, and exclude "unreliable" blood samples from the testing process.

47. Because the evidence fails to establish that hemolysis impacts the measurement of blood alcohol levels, the omission from the rule of a requirement to exclude samples exhibiting hemolysis from testing does not provide a basis to invalidate the rule.

48. The evidence presented at the hearing establishes that analysts routinely examine and document the condition of samples as a matter of standard laboratory practice. The omission of such a requirement does not provide a basis to invalidate the rule.

49. The evidence establishes that coagulation in a sample may result in elevation of the blood alcohol level reported by a subsample subjected to gas chromatography headspace analysis. However, the accuracy of a blood alcohol test report derived from

a sample that exhibits coagulation depends on whether the subsample taken from the sample is an appropriate representation of the components of the whole blood contained in the collection tube. The evidence fails to establish that the mere presence of coagulated blood in a sample inherently precludes the withdrawal of an appropriate subsample.

50. It should be noted that a rule requiring exclusion from testing of all samples exhibiting any level of coagulation could result in the denial of potentially exculpatory evidence to an individual whose test results were measured at 0.05 or less, despite some degree of coagulation having been present in the individual's sample. See § 316.1934(2)(a), Fla. Stat.

51. The Respondent's rules require that blood alcohol tests be conducted using "whole blood." Reference to the assorted statutes implemented by, and identified herein with, the challenged rules clearly demonstrate that blood alcohol tests are to be performed "substantially in accordance" with the Respondent's rules. Determination of whether a blood alcohol test was performed "substantially in accordance" with the Respondent's rules requires a case-specific inquiry and is an issue within the jurisdiction of a trial court. The omission of a requirement to exclude such samples from testing fails to provide a basis to invalidate rule 11D-8.013.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that the Petition filed by the Petitioner in this case pursuant to section 120.56(3), Florida Statutes, and seeking a determination that Florida Administrative Code Rules 11D-8.012 and 11D-8.013 are invalid exercises of delegated legislative authority, is hereby DISMISSED.

DONE AND ORDERED this 30th day of July, 2014, in Tallahassee, Leon County, Florida.

William F. Quattlebaum

WILLIAM F. QUATTLEBAUM
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
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this 30th day of July, 2014.

ENDNOTE

^{1/} Unless otherwise noted, all statutory references are to Florida Statutes (2013).

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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 the original notice of administrative appeal with the agency clerk of the Division of Administrative Hearings within 30 days of rendition of the order to be reviewed, and a copy of the notice, accompanied by any filing fees prescribed by law, with the clerk of the District Court of Appeal in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law.