IN THE SUPREME COURT OF FLORIDA

CASE NO. SC16-1752

JOHN GOODMAN,

Petitioner,

v.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT,

Respondent.
_____/

L.T. CASE NOS.
4D14-3263
Div. Admin. Hearing No. 14-1918RX

APPENDIX TO PETITIONER'S INITIAL BRIEF ON THE MERITS

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DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA
FOURTH DISTRICT

JOHN GOODMAN,
Appellant,

v.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT,
Appellee.

No. 4D14-3263

[May 25, 2016]

Appeal from the Florida Division of Administrative Hearings; L.T. Case No. 14-1918RX.

Jane Kreusler-Walsh and Stephanie L. Serafin of Kreusler-Walsh, Compiani & Vargas, P.A., West Palm Beach; Brian A. Newman of Pennington, P.A., Tallahassee; and Elizabeth L. Parker of Law Office of Elizabeth Parker, P.A., Palm Beach Gardens; for appellant.

Ann Marie Johnson, Tallahassee, for appellee.

FORST, J.

Appellant John Goodman was involved in a vehicular collision that resulted in the death of another individual. Appellant's blood was drawn after the accident for blood alcohol testing, pursuant to Florida's implied consent statutes. *See* §§ 316.1932-34, Fla. Stat. (2010). Ultimately, Appellant was charged with DUI Manslaughter/Failed to Render Aid and Vehicular Homicide/Failed to Give Information or Render Aid. As part of his defense, Appellant moved to exclude the blood alcohol test results, challenging Florida Administrative Code Rules 11D-8.012 and 11D-8.013 and the authority of the Florida Department of Law Enforcement ("FDLE") to promulgate these rules relating to the collection and labeling of blood for blood alcohol content testing. The trial court deferred ruling on the motion and transferred this issue to the Florida Division of Administrative Hearings, under the doctrine of primary jurisdiction.[1] An administrative

[1] "The doctrine of primary jurisdiction dictates that when a party seeks to invoke the original jurisdiction of a trial court by asserting an issue which is beyond the ordinary experience of judges and juries, but within an administrative agency's

law judge ("ALJ") held an evidentiary hearing and dismissed Appellant's petition, finding that the challenged rules were valid exercises of delegated legislative authority, i.e., FDLE has the authority to govern the collection of blood and that Rule 11D-8.012 and Rule 11D-8.013 are valid exercises of agency rulemaking that ensure reliable blood alcohol test results.

Subsequently, the trial court denied Appellant's motion to exclude the blood test results. Appellant was ultimately convicted of the above-noted charges and sentenced.[2]

Appellant now appeals the ALJ's order and raises three issues: (1) the FDLE lacked delegated authority to promulgate the rules at issue; (2) Rule 11D-8.012 constitutes an invalid exercise of delegated legislative authority because it fails to establish standards for the method by which blood is collected for chemical analysis; and (3) Rule 11D-8.013 constitutes an invalid exercise of delegated legislative authority because it fails to incorporate a process to identify and/or exclude unreliable blood samples from the testing process. We affirm the first issue without further comment. *See State v. Bender*, 382 So. 2d 697, 699 (Fla. 1980) (finding that the pertinent statutes "direct law enforcement to use only approved techniques and methods . . . to ensure reliable scientific evidence for use in future court proceedings . . . ."). We write to explain our reasons for affirming on the other two challenges to the rules.

BACKGROUND

As noted above, Appellant challenges the legitimacy and sufficiency of two FDLE regulations: Rules 11D-8.012 and 11D-8.013. These regulations govern the collection and storage of blood samples for the FDLE's blood alcohol testing program, as well as regulate those persons qualified to test the samples. Rule 8.012 specifies a number of steps that must be taken during the blood collection and testing process, including, *inter alia*, that the skin must be cleansed with a non-alcohol antiseptic before collection, that the samples "must be collected in a glass evacuation tube that contains a preservative," that "the tube must be inverted several times" and labelled properly, and that the samples must be refrigerated if they are stored for more than seven days. However, the rule does not set standards either for the type and size of needle to be used or the tourniquet application protocol to be followed in the collection of a blood sample for

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special competence, the court should refrain from exercising its jurisdiction over that issue until such time as the issue has been ruled upon by the agency." *Flo-Sun, Inc. v. Kirk*, 783 So. 2d 1029, 1036-37 (Fla. 2001).

[2] Appellant's appeal of his conviction and sentence is proceeding separately.

testing. Rule 8.013 lays out the requirements for a Florida blood analyst permit, and further sets forth the blood alcohol testing analytical procedures. This rule fails to explicitly require the analysts to screen for and reject compromised blood samples, or to document irregularities in the tested samples.

These deficiencies, Appellant argues, render the regulatory scheme insufficient to ensure the reliability of the blood alcohol test results. However, as described below, Appellant's argument is an overbroad solution in search of a problem that does not exist.

ANALYSIS

A. Challenge to Rule 11D-8.012

"In an appeal from final administrative action, this court reviews the administrative agency's findings of fact to determine whether they are supported by competent, substantial evidence." *Dorcely v. State Dep't of Bus. & Prof. Regulation*, 22 So. 3d 834, 836 (Fla. 4th DCA 2009). "We review the agency's conclusions of law de novo." *Id.* In a challenge to an existing rule, the burden is on the petitioner to demonstrate that the rule is invalid. *See* § 120.56(3)(a), Fla. Stat. (2010); *State Dep't of Children & Family Servs. v. I.B.*, 891 So. 2d 1168, 1171 (Fla. 1st DCA 2005).

By law, persons accepting drivers' licenses in the state are deemed to consent to testing of their blood alcohol content. § 316.1932(1)(a)1.a., Fla. Stat. (2010). The "underlying purpose of the implied consent law . . . 'is to ensure reliable scientific evidence for use in future court proceedings and to protect the health of those persons being tested . . . .'" *State v. Miles*, 775 So. 2d 950, 953 (Fla. 2000) (emphasis omitted) (quoting *Bender*, 382 So. 2d at 699). Furthermore, compliance with the FDLE regulations gives rise to various statutory presumptions for use in court proceedings. When a regulation fails to meet the purposes of the implied consent program, however, the statutory presumptions do not apply. *See id.* at 953-55 (holding that failure to require proper preservation of blood samples rendered a prior version of Rule 8.102 "inadequate and inconsistent with the purpose of the implied consent law as it relates to ensuring the reliability of test results. As such, the State [was] not entitled to the presumptions of impairment associated with the implied consent statutory scheme.").

Appellant argues that Rule 8.012 is invalid for failure to specify a required needle size for drawing blood. Specifically, he alleges that his blood was drawn using a twenty-five gauge butterfly needle, rather than a

"standard" twenty-one gauge straight needle. A twenty-five gauge needle is narrower than a twenty-one, and, unlike a straight needle, which injects blood directly into the vial, a butterfly needle delivers blood to the collection vial via a small length of rubber tubing. Although the standard kits used by law enforcement contain the twenty-one gauge straight needles, the twenty-five gauge butterfly needles can be useful for certain patients.

At the proceedings below, the administrative law judge heard testimony from seven expert witnesses, all of whom opined on the relative effectiveness of this deviation in needle size and type and/or the effectiveness of the procedures in place under the current regulations. The testimony established that the use of a smaller butterfly needle to draw a suspect's blood can have several effects on a blood sample, such as increased blood clotting or hemolysis (the release of the contents of red blood cells into the surrounding plasma).[3] Experts for both parties testified, and the administrative law judge found, that the use of a smaller needle is more likely to cause blood to clot in the delivery from the donor to the test tube in which the blood will be stored (at which point anti-coagulation measures are employed to prevent new or further coagulation). However, because the administrative law judge found that an accurate result being obtained from clotted blood was not "inevitably precluded," he determined that Rule 11D-8.102 was valid.

Although the testimony presented at the hearing was subject to multiple conclusions on this point, there was sufficient evidence in the record to support the ALJ's findings of fact as to the effect of clotting on the accuracy of blood testing. First, the testimony was clear that a smaller needle can increase clotting, and that clotting can affect the accuracy of a blood alcohol test. However, one expert testified that it is still possible to get an accurate result from testing a properly prepared sample even after clotting had occurred because the clot does not add or subtract anything from the blood that would affect the test.[4] He referred to this homogenization process as "[v]ery easy" and testified that a clotted sample is neither "contaminated" nor necessarily an unreliable input into the

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[3] On appeal, Appellant has focused his arguments with respect to Rule 8.012 solely on the increase in clotting caused by a smaller needle and deficient tourniquet usage.

[4] *See also* Derrick J. Pounder & Alan Wayne Jones, *Post-Mortem Alcohol — Aspects of Interpretation, in* FORENSIC ISSUES IN ALCOHOL TESTING 65, 66 (Steven B. Karch ed. 2008) ("The presence of blood clots will not necessarily have a negative influence on the accuracy of the blood alcohol analysis using headspace gas chromatography.").

scientific analysis. Further testimony revealed that homogenization was necessary only with larger clots, because "small clots . . . would have no affect [sic] on the blood alcohol test." These large clots would be easily noticeable, based on the testimony that grossly clotted blood would be difficult to move through the needles or pipettes. Regardless of the size of the clot, testimony also revealed that standard practice is to "mix[ ] the sample" prior to testing, in order to avoid problems such as those created by clots.

The takeaway point from this expert's testimony is that "a sample collected using a 25-gauge butterfly needle [is] valid for blood alcohol determination using headspace gas chromatography" so long as proper procedures are followed, and that Rule 8.012 is not invalid for failure to specify a required needle size for drawing blood. *See State v. Friedrich*, 681 So. 2d 1157, 1161-63 (Fla. 5th DCA 1996) (finding that, so long as the Intoxilyzer breath tests were made in substantial compliance with the applicable statutes and rules and the results of the tests "are sufficiently reliable so as to be generally acceptable in the scientific community," the court could not "say FDLE is remiss for not adopting rules or protocols in this regard"). Thus, the testimony established that clotting is notably different than the flaws caused by the lack of refrigeration in *Miles*, which could not be rectified after the fact. *Miles*, 775 So. 2d at 954-55. This testimony was sufficient for the ALJ to find that clotting, even when increased by the use of a smaller butterfly needle, does not inherently render blood alcohol testing inaccurate, as there were commonly known and utilized curative procedures.

B. Challenge to Rule 11D-8.013

Appellant also argues that Rule 8.013 improperly fails to require the screening, removal, or documentation of flawed blood samples. FDLE responds, and we agree, that Appellant has not established that the Rule has failed to ensure the accuracy of the blood testing program. The Rule itself, titled "Blood Alcohol Permit — Analyst," sets out criteria to apply for a permit to conduct blood alcohol analyses, including submission of an application providing "[a] complete description of proposed analytical procedure(s) to be used in determining blood alcohol level." The applicant's "proposed analytical procedures" are then reviewed by the Department.

Appellant called two witnesses who actually conducted blood tests for the Palm Beach County Sheriff's Office. Both testified that they routinely documented any irregularities in blood samples. Another expert, who had analyzed thousands of blood samples, stated that he always made written

documentation if a sample was clotted and required analysts working under him to do the same. That second expert, who was in fact the person who tested Appellant's blood in this case, specifically stated that "any time a sample is clotted, it is documented on the analyst's case file and is also reported . . . [a]s additional remarks under the conclusions."[5] Yet another expert testified that in his tens-of-thousands of samples tested, he always noted when a sample was clotted, but had also always been able to properly test the blood after making that notation. This testimony supports FDLE's contention, both below and on appeal, that Rule 8.013 is not meant to be the only source of guidance for analysts, but is instead meant to supplement and reinforce sound scientific principles and laboratory practices. It also supports the ALJ's conclusion that "analysts routinely examine and document the condition of samples as a matter of standard laboratory practice [and the] omission of such a requirement does not provide a basis to invalidate [Rule 8.013]."

Any attempt by FDLE to regulate for *every* possible contingency that may arise in the collection or testing processes would swiftly devolve into a hopeless endeavor and serve only to expand the Department's regulations to epic lengths.[6] Furthermore, such over-regulation would run the risk of locking in today's current scientific methodology, preventing the evolution and improvement of the system. It would also deprive both the State and criminal defendants of the expertise and discretion of the analysts, as their training and practical experience is necessary to properly address the wide variety of factual scenarios that may arise.[7] For instance,

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[5] Appellant has failed to provide a copy of his report as part of the record on appeal. We therefore do not know whether Appellant's blood was in fact clotted.

[6] No other state appears to have regulated to the extent that Appellant argues Florida must. Appellant has not provided, and we have failed to locate, a single rule across the country that regulates the exact size of needle that must be used. Instead, the rules simply provide general guidance clearly intended to be supplemented by standard best practices and medical knowledge. *See, e.g.,* Miss. Admin. Code 31-5-2:1750.000 et seq. (2016) (adopting rules regulating blood collection without specifying a particular needle size to be used); § 577.029, Mo. Rev. Stat. (2016) (requiring use of a "previously unused and sterile needle"); Mont. Admin. R. 23.4.220 (2016) (adopting rule with similar requirements to FDLE rule); N.H. Code Admin. R. Saf-C 6402.02 (2016) (same); Ohio Admin. Code 3701-53-05 (2016) (requiring blood to be drawn "with a sterile dry needle"). With regards to the screening of blood, we have found only one state—Maine—which specifically requires analysts to document clots found in testing samples. *See* 10-144 Ch. 270 Me. Code. R. § B(3)(e) (2016).

[7] *See* Edward J. Imwinkelried, *Some Preliminary Thoughts on the Wisdom of Governmental Prohibition or Regulation of Employee Urinalysis Testing*, 11 Nova L. Rev. 563, 596-97 (1987) (calling for government regulation of laboratories, but

we would be loath to require the FDLE to mandate a single, one-size-fit-all needle choice for blood collection, as the unique facts of each case may require a different choice. This determination is best left for the trained professionals on the ground, as are many of the choices made in the testing laboratories across the State. The rules at issue, when combined with basic laboratory practices, are sufficient to protect the safety and interests of the court system and defendants alike. *See Wissel v. State*, 691 So. 2d 507, 507-08 (Fla. 2d DCA 1997) (holding "that procedures that are implicit and incidental to procedures otherwise explicitly provided for in a properly adopted rule or regulation do not require further codification by a further adopted rule or regulation [and] to hold otherwise belies statutory intent . . . ." and that such an argument, "based on the lack of a rule or regulation to cover every step of the testing procedures . . . is not only speculative and theoretical, but also hyper-technical.").

CONCLUSION

Appellant has failed to show that Rules 8.012 and 8.013 do not ensure the accuracy of the blood testing program. The ALJ's and trial court's determinations that these rules adequately protect the reliability and consistency of blood testing were supported by competent evidence in the record on appeal. For these reasons, we affirm the administrative law judge's order.

Affirmed.

WARNER and STEVENSON, JJ., concur.

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Not final until disposition of timely filed motion for rehearing.

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only going so far as to argue that the laboratories should themselves establish specific internal quality control procedures based on more general regulations).

DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA
FOURTH DISTRICT

JOHN GOODMAN,
Appellant,

v.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT,
Appellee.

No. 4D14-3263

[August 24, 2016]

Appeal from the Florida Division of Administrative Hearings; L.T. Case No. 14-1918RX.

Jane Kreusler-Walsh and Stephanie L. Serafin of Kreusler-Walsh, Compiani & Vargas, P.A., West Palm Beach; Brian A. Newman of Pennington, P.A., Tallahassee; and Elizabeth L. Parker of Law Office of Elizabeth Parker, P.A., West Palm Beach; for appellant.

Ann Marie Johnson, Tallahassee, for appellee.

ON MOTION FOR REHEARING AND CERTIFICATION OF QUESTIONS OF GREAT PUBLIC IMPORTANCE

PER CURIAM.

We deny Appellant's motion for rehearing. We grant Appellant's June 28, 2016 Motion for Certification of Questions of Great Public Importance and certify the following questions to the Florida Supreme Court:

> (1) ARE THE CURRENT RULES OF THE FLORIDA DEPARTMENT OF LAW ENFORCEMENT (FDLE) INADEQUATE UNDER STATE v. MILES, 775 So. 2d 950 (Fla. 2000), FOR PURPORTEDLY FAILING TO SUFFICIENTLY REGULATE PROPER BLOOD DRAW PROCEDURES, AS WELL AS THE HOMOGENIZATION PROCESS TO "CURE" A CLOTTED BLOOD SAMPLE?
>
> (2) ARE THE PRESENT RULES SIMILARLY INADEQUATE FOR FAILING TO SPECIFICALLY REGULATE THE WORK OF

ANALYSTS IN SCREENING BLOOD SAMPLES, DOCUMENTING IRREGULARITIES, AND REJECTING UNFIT SAMPLES?

WARNER and FORST, JJ., concur.

GERBER, J., concurs with the denial of the motion for rehearing, and dissents from the granting of the motion for certification of questions of great public importance.

* * *

CHAPTER 11D-8
IMPLIED CONSENT PROGRAM

11D-8.002 Definitions.

(1) Acceptable Range – the results of alcohol reference solutions and dry gas standard analyses which fall within the following ranges at each alcohol vapor concentration: 0.05 g/210L range is 0.045 to 0.055 g/210L; 0.08 g/210L range is 0.075 to 0.085 g/210L; 0.20 g/210L range is 0.190 to 0.210 g/210L; or the Alcohol Reference Solution gas chromatographic results which fall within the following ranges: 0.0605 g/100mL range is 0.0586 to 0.0623 g/100mL; 0.0968 g/100 mL range is 0.0938 to 0.0997 g/100mL; 0.2420 g/100mL range is 0.2347 to 0.2492 g/100mL.

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

(3) Acetone Stock Solution – a mixture of acetone and distilled or deionized water provided by the Department.

(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.

(5) Agency Inspection – the periodic testing of the calibration and operation of a breath test instrument, including all required preventive maintenance, in accordance with Rule 11D-8.006, F.A.C., and performed by a person authorized by the Department.

(6) Agency Inspector – a person who has been issued an Agency Inspector permit by the Department.

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

(8) Alcohol Free Test – a result of 0.000 g/210L when using distilled or deionized water.

(9) Alcohol Reference Solution – a standard used to verify the calibration of a breath test instrument consisting of a mixture of alcohol and distilled or deionized water that will produce a known alcohol vapor concentration at a specific temperature.

(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.

(12) Approved Breath Alcohol Test – a minimum of two samples of breath collected within fifteen minutes of each other, analyzed using an approved breath test instrument, producing two results within 0.020 g/210L, and reported as the breath alcohol level. If the results of the first and second samples are more than 0.020 g/210L apart, a third sample shall be analyzed. Refusal or failure to provide the required number of valid breath samples constitutes a refusal to submit to the breath test. Notwithstanding the foregoing sentence, the result(s) obtained, if proved to be reliable, shall be acceptable as a valid breath alcohol level.

(13) Authorized Repair Facility – the Department, the breath test instrument manufacturer, an entity authorized by the breath test instrument manufacturer to service and repair such breath test instrument.

(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).

(16) Breath Alcohol Level – the alcohol concentration by weight in a person's breath based upon grams of alcohol per 210 liters of breath (g/210L).

(17) Breath Test Instructor – a person who has been issued a Breath Test Instructor Certification by the Criminal Justice Standards and Training Commission.

(18) Breath Test Operator – a person who has been issued a Breath Test Operator permit by the Department.

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

(20) Dry Gas Standard – a standard consisting of a mixture of alcohol and gas which produces a known alcohol vapor concentration used to verify the calibration of a breath test instrument.

(21) Evidentiary Breath Test Instrument – a breath test instrument approved by the Department under Rule 11D-8.003, F.A.C., and used primarily to conduct alcohol breath tests pursuant to Florida law.

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

(23) Mouth Alcohol Solution – a mixture of alcohol and distilled or deionized water provided by the Department.

(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.

(25) Reference Sample Device – a device, also known as a simulator, that produces a known vapor concentration by the passage of air through a liquid.

(26) Target Concentration – a gas chromatographic result equivalent to the following known alcohol vapor concentrations of alcohol reference solution: for 0.05 g/210L the target concentration is 0.0605 g/100mL; for 0.08 g/210L the target concentration is 0.0968 g/100mL; for 0.20 g/210L the target concentration is 0.2420 g/100mL.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 316.1933(2)(b), 316.1934(3), 322.63(3)(a), (b), 327.352(1)(b)3. FS. Law Implemented 316.1932(1)(b)2., 316.1933(2)(b), 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.353(2), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-6-99, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

11D-8.003 Approval of Breath Test Methods and Instruments.

(1) The Department has approved the following method(s) for evidentiary breath testing: Infrared Light Test, also known as Infrared Light Absorption Test.

(2) The Department approves breath test methods and new instrumentation to ensure the accuracy and reliability of breath test results. The Department has approved the following breath test instrumentation for evidentiary use: CMI, Inc. Intoxilyzer 5000 Series – including any or all instruments using one of the following programs: 5000 Basic Software Program; Florida Software Program; R-Software Program; and CMI, Inc. Intoxilyzer 8000 using software evaluated by the Department in accordance with Instrument Evaluation Procedures FDLE/ATP Form 34 – Rev. March 2004.

(3) The Department has approved the following options for use with Intoxilyzer 5000 Series instruments: keyboard; simulator recirculation; sample capture; pressure switch setting at no less than two inches and no more than six inches of water.

(4) A Department inspection performed in accordance with Rule 11D-8.004, F.A.C., validates the approval, accuracy and reliability of an evidentiary breath test instrument.

(5) The Department shall conduct evaluations for approval of new instrumentation under subsection (2) in accordance with Instrument Evaluation Procedures FDLE/ATP Form 34 – Rev. March 2004.

(6) The availability or approval of new instruments, software, options or modifications does not negate the approval status of previously approved instruments, software, options or modifications.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), (b), 327.352(1)(b)3. FS. Law Implemented 316.1932(1)(b)2., 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04.

11D-8.0035 Approval of Alcohol Reference Solution and Sources.

(1) The Department shall approve a source of alcohol reference solution for use by agencies in the State of Florida. The source approved by the Department shall be an entity that manufactures alcohol reference solutions and meets the following requirements:

(a) The source must prepare alcohol reference solution, and be capable of producing a minimum batch volume of 800 bottles, each containing at least 500 milliliters, to produce the following vapor alcohol concentrations: 0.05 g/210L, 0.08 g/210L, and 0.20g/210L;

(b) The source must have performed and documented tests that demonstrate that the alcohol reference solutions are reliable for at least two years from the date of manufacture.

(2) The Department shall approve each lot of alcohol reference solution prior to distribution for use in Florida.

(a) The Department shall determine the alcohol concentration in a minimum of ten (10) sample bottles of each lot of alcohol reference solution using gas chromatography or other scientifically accepted method. Duplicate analyses will be performed on each sample bottle of alcohol reference solution. All analysis results shall fall within the alcohol reference solution acceptable range.

(b) The Department shall notify the source that the approved lots may be distributed for use in Florida, and shall issue a Certificate of Assurance, FDLE/ATP Form 32 – Rev. March 2001.

(3) Alcohol reference solution lots approved by the Department shall be used in agency or Department inspections within two (2) years of the date of manufacture.

(4) Approval analyses of alcohol reference solution lots shall be based on requirements and procedures in effect at the time such lots are submitted for approval. No post-approval analysis is required for previously approved alcohol reference solution lots.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3., (d) FS. Law Implemented 316.1932(1)(b)2., 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.354(3) FS. History–New 7-6-99, Amended 7-29-01, 12-9-04.

11D-8.0036 Approval of Dry Gas Standards Source.

(1) The Department shall approve a source of dry gas standards for use by agencies in the State of Florida. The source approved by the Department shall be an entity that manufactures dry gas standards and meets the following requirements:

(a) The source must produce dry gas standards which are traceable to the National Institute of Standards and Technology.

(b) Each dry gas standard lot produced by the source must be certified by the source as to its contents and alcohol vapor concentration.

(c) The source must be capable of producing a minimum of 300 cylinders of dry gas standard during a thirty day period at an alcohol vapor concentration of 0.08 g/210L.

(d) The source must have performed and documented tests that demonstrate that the source's dry gas standards are reliable for at least two years from the date of manufacture.

(2) Dry gas standard cylinders produced by the approved source must not be used beyond the expiration date.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), (b), 327.352(1)(b)3. FS. Law Implemented 316.1932(1)(b)2., 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.354(3) FS. History–New 11-5-02, Amended 12-9-04.

11D-8.004 Department Inspection and Registration of Breath Test Instruments.

(1) The Department shall register and inspect a breath test instrument prior to such instrument being initially placed into evidentiary use by an agency. The inspection validates the instrument's approval for evidentiary use, and the registration denotes an instrument approved pursuant to these rules and shall reflect the registration date, the owner of the instrument, the instrument serial number, the manufacturer, and the model designation.

(2) Registered breath test instruments shall be inspected by the Department at least once each calendar year, and must be accessible to the Department for inspection. Any evidentiary breath test instrument returned from an authorized repair facility shall be inspected by the Department prior to being placed in evidentiary use. The inspection validates the instrument's approval for evidentiary use.

(3) Department inspections shall be conducted in accordance with Department Inspection Procedures FDLE/ATP Form 35 – Rev. August 2005 for the Intoxilyzer 5000 Series, or Department Inspection Procedures – Intoxilyzer 8000 FDLE/ATP Form 36 – Rev. August 2005 for the Intoxilyzer 8000; and the results reported on FDLE/ATP Form 26 – Department Inspection Report – Rev. March 2004 for the Intoxilyzer 5000 Series, or FDLE/ATP Form 41 – Department Inspection Report – Intoxilyzer 8000 – Rev. August 2005 for the Intoxilyzer 8000.

(4) Department Inspectors shall be employed by the Department to register evidentiary breath test instruments, to conduct inspections and maintenance of breath test instruments and related equipment and facilities, to conduct and monitor training classes, and to otherwise ensure compliance with Chapter 11D-8, F.A.C.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3. FS. Law Implemented 316.1932(1)(b)2., 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

11D-8.006 Agency Inspection of Breath Test Instruments.

(1) Evidentiary breath test instruments shall be inspected by an agency inspector at least once each calendar month. The agency inspection shall be conducted in accordance with Agency Inspection Procedures FDLE/ATP Form 16 – Rev. March 2004 for the Intoxilyzer 5000 Series, or Agency Inspection Procedures – Intoxilyzer 8000 FDLE/ATP Form 39 – Rev. August 2005 for the Intoxilyzer 8000; and the results reported on FDLE/ATP Form 24 – Agency Inspection Report – Rev. March 2001 for the Intoxilyzer 5000 Series, or FDLE/ATP Form 40 – Agency Inspection Report – Intoxilyzer 8000 – March 2004 for the Intoxilyzer 8000.

(2) Whenever an agency relocates an Intoxilyzer 5000 evidentiary breath test instrument for use at another facility, an agency inspection shall be conducted prior to the instrument's removal, and another inspection shall be conducted prior to the instrument's use for evidentiary breath testing at the new facility. A mobile testing unit is considered an agency facility.

(3) Whenever an instrument is taken out of evidentiary use, the agency shall conduct an agency inspection. The agency shall also conduct an agency inspection prior to returning an instrument to evidentiary use.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3. FS. Law Implemented 316.1932(1)(b)2., 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

11D-8.007 Approved Breath Test Instruments – Access, Facility Requirements, Observation Period, and Operational Procedures.

(1) Evidentiary breath test instruments shall only be accessible to a person issued a valid permit by the Department and to persons authorized by a permit holder. This section does not prohibit agencies from sending an instrument to an authorized repair facility. Only authorized repair facilities are authorized to remove the top cover of an Intoxilyzer 8000 evidentiary breath test instrument.

(2) The instrument will be located in a secured environment which limits access to authorized persons described in subsection (1), and will be kept clean and dry. All breath test facilities, equipment and supplies are subject to inspection by the Department.

(3) The breath test operator, agency inspector, arresting officer, or person designated by the permit holder shall reasonably ensure that the subject has not taken anything by mouth or has not regurgitated for at least twenty (20) minutes before administering the test. This provision shall not be construed to otherwise require an additional twenty (20) minute observation period before the administering of a subsequent sample.

(4) When operating an Intoxilyzer 5000 Series instrument, a breath test operator shall conduct a breath test in accordance with, and shall record the results on, the Breath Test Results Affidavit FDLE/ATP Form 14 – Rev. March 2002. When operating an Intoxilyzer 8000 instrument, a breath test operator shall conduct a breath test in accordance with Operational Procedures – Intoxilyzer 8000 FDLE/ATP Form 37 – Rev. August 2005, and the results of the test shall be recorded on the Breath Alcohol Test Affidavit – Intoxilyzer 8000 FDLE/ATP Form 38 – March 2004.

(5) Each agency shall record all breath tests conducted on a particular Intoxilyzer 5000 Series evidentiary breath test instrument on the Breath Test Log FDLE/ATP Form 13 – Effective January 1997. The breath test log shall be reviewed each calendar month by an agency inspector to ensure that the information is properly recorded and that all necessary corrections are made. The agency inspector's signature on the breath test log shall signify compliance with this section.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3. FS. Law Implemented 316.1932(1)(b)2., 316.1934(3), 322.63(3)(b), 327.352(1)(e), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

11D-8.0075 Agency Retention of Records.

(1) Each agency shall maintain the following records for at least three years from the last entry date: agency inspection reports and agency inspection print cards, breath test logs, and breath test instrument repair records. The breath test instrument registration

shall be retained by an agency for at least three years after the instrument is removed from evidentiary use. Dry gas standard certificates of analysis shall be retained by an agency for at least three years after receipt.

(2) The above records shall be accessible to the Department upon request. At least once each calendar month each agency shall electronically transmit to the Department all breath tests conducted on that agency's Intoxilyzer 8000 evidentiary breath test instruments.

(3) The purpose of this section is solely for regulatory and administrative use, and any violation of this section shall not affect the admissibility, validity or reliability of breath test results.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3. FS. Law Implemented 322.63(3), 327.354(3) FS. History–New 7-29-01, Amended 11-5-02, 12-9-04.

11D-8.008 Breath Test Operator and Agency Inspector.

(1) Qualifications for Breath Test Operator Permit – An applicant for a breath test operator permit must meet the following qualifications:

(a) Eighteen (18) years of age or older;

(b) High school diploma or its equivalent;

(c) Present employment by an agency, or the Department;

(d) Successful completion of the basic Breath Test Operator Course approved by the Criminal Justice Standards and Training Commission. Successful completion shall require obtaining a passing score of at least 80% on a written examination, and demonstrating proficiency by:

1. Properly operating an approved breath test instrument in accordance with the applicable procedures for such instrument;

2. Properly completing the required forms.

(e) Submit to the Department a complete written application upon successful completion of the breath test operator course, but no later than ninety days after completion.

(2) Qualifications for Agency Inspector Permit – An applicant for an agency inspector permit must meet the following qualifications:

(a) Has been issued a breath test operator permit by the Department valid at the time that the application is submitted;

(b) Successfully completes the basic Agency Inspector Course approved by the Criminal Justice Standards and Training Commission. Successful completion shall require a passing score of at least 80% on a written examination and a demonstration of proficiency by:

1. Proper inspection of an approved breath test instrument in accordance with the procedures for such instrument;

2. Proper completion of all required forms.

(c) Submits to the Department a complete written application upon successful completion of the agency inspector course, but no later than ninety days after completion.

(d) Present employment by an agency or the Department.

(3) Breath Test Operators and Agency Inspectors must satisfy continuing education requirements in order to maintain valid permits. Continuing education requires successful completion of the applicable Commission-approved Renewal Course by June 30 following the fourth permit anniversary date, and during each subsequent four-year cycle. Successful completion of the Commission-approved Agency Inspector Course or Agency Inspector Renewal Course also satisfies an Agency Inspector's breath test operator continuing education requirements.

(4) Any Breath Test Operator or Agency Inspector who fails to satisfy the continuing education requirements shall not perform any duties authorized by the permit until successful completion of the applicable renewal course.

(5) Permits to conduct breath tests and inspect breath test instruments issued pursuant to former Rule 11D-8.008, F.A.C., shall remain valid until such permits expire or otherwise become invalid in accordance with those rules.

(6) Agency Inspectors are responsible for compliance with Chapter 11D-8, F.A.C., rules governing agency custody, care, and inspection of breath test instruments and related records.

(7) Any breath test operator or agency inspector who fails to successfully complete the Commission-approved renewal course shall not perform any duties authorized by the permit until successful completion of the Commission-approved basic course.

(8) Members of the Department's Alcohol Testing Program who instruct Commission-approved breath test courses may use such course instruction to satisfy their continuing education requirements under this section.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3. FS. Law Implemented 316.1934(3), 322.63(3)(b), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

11D-8.010 Qualifications for Instructors.

(1) Persons who conduct breath test training courses must have a valid Breath Test Instructor certification issued by the Criminal Justice Standards and Training Commission, and such persons shall be deemed permitted by the Department to conduct breath test training courses.

(2) Unless exempted by the Commission, at least once every four years each breath test instructor must successfully complete the Commission-approved breath test instructor certification renewal course in order to remain qualified for a breath test instructor certification. Successful completion of the Commission-approved breath test instructor certification course or breath test instructor certification renewal course satisfies that person's agency inspector and breath test operator continuing education requirements. Each breath test instructor must also successfully complete all Department breath test instructor update courses.

(3) Breath test instructors must adhere to and comply with the approved curricula and related forms when teaching Commission or Department approved courses and processing related documentation.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 327.352(1)(b)3. FS. Law Implemented 316.1934(3), 322.63(3)(b), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04.

11D-8.011 Approval of Blood Alcohol Test Methods.

The Department approves the following test methods for determining blood alcohol level:

(1) Alcohol Dehydrogenase (Enzymatic).

(2) Gas Chromatography.

Rulemaking 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. History–New 10-31-93.

11D-8.012 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.

Rulemaking 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. History–New 10-31-93, Amended 7-29-01.

11D-8.013 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.

Rulemaking 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. History–New 10-31-93, Amended 4-1-94, 2-1-95, 1-1-97, 11-5-02, 12-9-04.

11D-8.014 Blood Alcohol Permit – Analyst: Renewal.

(1) Permits to conduct blood alcohol analyses shall remain valid until otherwise suspended or revoked by the Department. In order to remain qualified for such permit, an analyst must satisfactorily determine the blood alcohol level of at least 2 proficiency samples provided by the Department semiannually. 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.

(2) Upon notification by the Department that an analyst has failed to satisfactorily determine the blood alcohol level on any set of proficiency samples, the analyst shall be required to satisfactorily determine the blood alcohol level of a second set of five proficiency samples provided by the Department.

(3) Upon notification by the Department that an analyst has failed to satisfactorily determine the blood alcohol level on a second set of proficiency samples, the analyst shall not perform any duties authorized by the analyst's permit until the analyst satisfactorily determines the blood alcohol level of a subsequent set of proficiency samples provided by the Department. This section shall not preclude the Department from taking further action in accordance with Rule 11D-8.015, F.A.C.

(4) Failure to satisfactorily determine the blood alcohol level of any 4 sets of proficiency samples provided by the Department within a 12-month period shall result in revocation of the blood analyst permit.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 322.63(3)(a), 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)(e), 327.353(2), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 11-5-02, 5-29-14.

11D-8.015 Denial, Revocation, and Suspension of Permits.

(1) Notwithstanding an applicant's qualifications, the Department shall deny an application for an original permit where the applicant:

(a) Fails to meet the permit qualifications under these rules.

(b) Has been convicted of any of the following offenses in any federal or state court:

1. Any felony;

2. Any misdemeanor involving perjury, false statements or falsification of records;

3. Criminal conviction for any violation of Chapter 893, F.S.;

4. Driving under the influence of alcoholic beverages or drugs during the five years prior to submitting the application;

5. Leaving the scene of a crash involving death or serious bodily injury.

(c) Knowingly performing the duties of a breath test operator, agency inspector, breath test instructor, or analyst without a valid applicable permit.

(d) Had the permit previously revoked under subsection (3) below.

(2) The Department is authorized to suspend any permit for any of the following reasons:

(a) Failure to prepare and maintain breath or blood testing records as required by these rules.

(b) Failure to continue to meet the qualifications for such permit.

(c) Any violation of these rules, or aiding and abetting any violation of these rules.

(3) The Department is authorized to revoke any permit for any of the following reasons:

(a) Knowingly making a false statement or providing false information on any agency document or on any document required by these rules.

(b) Knowingly making a false statement or providing false information on any application for permit submitted to the Department.

(c) Being convicted after issuance of the permit of any of the following offenses in any federal or state court:

1. Any felony;

2. Any misdemeanor involving perjury, false statements or falsification of records;

3. Driving under the influence of alcoholic beverages or drugs;

4. Leaving the scene of a crash involving death or serious bodily injury;

5. Any criminal violation of Chapter 893, F.S.

(d) Performing the duties of a breath test operator, agency inspector, or analyst with knowledge that the applicable permit is suspended or in violation of continuing education requirements.

(e) Having had the permit previously suspended for any violation of these rules.

(4) The Department is authorized to require a breath test operator, agency inspector, breath test instructor, or analyst who violates any of these rules to attend additional training or education related to their certification or permit.

(5) The Department is authorized to invalidate the registration of any evidential instrument for a violation of any rule relating to the use, custody and care of such instrument.

(6) All permits and registrations which have been suspended, revoked or invalidated must be surrendered to the Department upon demand.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 316.1933(2)(b), 316.1934(3), 322.63(3)(a), (b), 327.352(1)(b)3. FS. Law Implemented 316.1933(2)(b), 316.1934(3), 322.63(3)(b), 327.353(2), 327.354(3) FS. History–New 10-31-93, Amended 1-1-97, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

11D-8.016 Administrative Hearings.

All proceedings concerning the revocation, suspension, or denial of permits shall be conducted in accordance with Chapter 120, F.S., and the Florida Administrative Code.

Rulemaking 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), 327.353(2), 327.354(3) FS. History–New 10-31-93, Amended 7-29-01.

11D-8.017 Forms.

The following forms referenced in these rules are hereby incorporated by reference:

FDLE/ATP Form 13 – Breath Test Log – Effective January 1997.
FDLE/ATP Form 14 – Breath Test Result Affidavit – Revised March 2002.
FDLE/ATP Form 16 – Agency Inspection Procedures – Revised March 2004.
FDLE/ATP Form 24 – Agency Inspection Report – Revised March 2001.
FDLE/ATP Form 26 – Department Inspection Report – Revised March 2004.
FDLE/ATP Form 32 – Certificate of Assurance – Revised March 2001.
FDLE/ATP Form 34 – Instrument Evaluation Procedures – Revised March 2004.
FDLE/ATP Form 35 – Department Inspection Procedures – Revised August 2005.
FDLE/ATP Form 36 – Department Inspection Procedures – Intoxilyzer 8000 – Revised August 2005.
FDLE/ATP Form 37 – Operational Procedures – Intoxilyzer 8000 – Revised August 2005.
FDLE/ATP Form 38 – Breath Alcohol Test Affidavit – Intoxilyzer 8000 – March 2004.
FDLE/ATP Form 39 – Agency Inspection Procedures – Intoxilyzer 8000 – Revised August 2005.
FDLE/ATP Form 40 – Agency Inspection Report – Intoxilyzer 8000 – March 2004.
FDLE/ATP Form 41 – Department Inspection Report – Intoxilyzer 8000 – Revised August 2005.

These forms may be obtained by contacting the Florida Department of Law Enforcement, Alcohol Testing Program, P. O. Box 1489, Tallahassee, Florida 32302. Agencies will be provided blank forms upon request and without cost for their alcohol testing program use.

Rulemaking Authority 316.1932(1)(a)2., (f)1., 316.1933(2)(b), 316.1934(3), 322.63(3)(a), (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)(e), 327.353(2)(b), 327.354(3) FS. History–New 10-31-93, Amended 2-1-95, 1-1-97, 7-29-01, 11-5-02, 12-9-04, 3-27-06.

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

For Petitioner: Brian A. Newman, Esquire
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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

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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.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 5th day of December, 2016, I will electronically file the foregoing with the Clerk of Court using the Florida Courts E-Filing Portal, which will then send a copy of such filing to:

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