STATE OF FLORIDA
FLORIDA DEPARTMENT OF HEALTH

Division of Disease Control and Health Protection

Bureau of Public Health Laboratories

REQUEST FOR APPLICATION

RFA # 18-006

Environmental Laboratory Assessments

Environmental Laboratory Certification Program
Florida Department of Health
1217 Pearl Street
Jacksonville, Florida 32202

Vendor Name_____

Vendor Mailing Address_____

City-State-Zip_____

Telephone Number_____

Email Address_____

Federal Employer Identification Number (FEID)_____

Authorized Signature (Manual)_____

Authorized Signature (Typed) and Title_____

This is not a competitive solicitation subject to the notice or challenge provisions of section 120.57(3), Florida Statutes.

NOTE: THE RECEIPT OF SUBMISSION IN RESPONSE TO THIS RFA DOES NOT IMPLY OR GUARANTEE THAT ANY ONE OR ALL APPLICANTS WILL BE AWARDED A CONTRACT WITH THE FLORIDA DEPARTMENT OF HEALTH.

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TIMELINE
DOH RFA 18-006

EVENT	DUE DATE	LOCATION
RFA Advertised – Released	December 14, 2018	Vendor Bid System: http://vbs.dms.state.fl.us/vbs/main_menu Florida Department of Health Grant Funding http://www.floridahealth.gov/about-the-department-of-health/about-us/administrative-funding-opportunities/index.html
Non-Mandatory Pre-Application Conference	December 21, 2018 At 10:00 AM EST	**Florida Department of Health 4052 Esplanade Way, Room 301 Tallahassee, FL 32399-3265 Or Via Conference Call @** (888) 670-3525 Conference Code 6207714911#
Questions submitted in writing.	Prior to 5:00 PM EST January 14, 2019	Submit to: Florida Department of Health Attention*:* *Vanessa Soto Contreras* 1217 Pearl Street Jacksonville, FL 32202 Email: vanessa.sotocontreras@flhealth.gov
Answers to Questions Anticipated Date	February 18, 2019	Posted electronically via the following Internet site: http://vbs.dms.state.fl.us/vbs/main_menu
Sealed Applications/ Replies Due and Opened	**Must be received PRIOR to: 3:00 PM EST** March,11, 2019	Submit to: Florida Department of Health Attention*: Vanessa Soto Contreras* 1217 Pearl Street Jacksonville, FL 32202
Anticipated Evaluation of Applications	Beginning March 29, 2019	Individual Evaluation of applications
Anticipated Posting of Intent to Award	April 5, 2019	Vendor bid system: http://vbs.dms.state.fl.us/vbs/main_menu Florida Department of Health Grant Funding http://www.floridahealth.gov/about-the-department-of-health/about-us/administrative-funding-opportunities/index.html

SECTION 1.0 INTRODUCTORY MATERIALS

1.1 Statement of Purpose

The purpose of this Request for Applications (RFA) is to solicit applications from parties with the ability to provide on-site assessments of environmental testing laboratories for the purpose of determining the laboratories' compliance with applicable laws and regulations. The Department seeks to qualify multiple parties through this solicitation to allow choice for the laboratories seeking this service and reduce costs through competitive market forces.

1.2 Term

The term of any contract resulting from this solicitation will be for three years, beginning on July 1, 2019 and ending on June 30, 2022.

1.3 Definitions

Accreditation Body: *Authoritative body that performs accreditation or certification of environmental testing laboratories.*

Analyte: *A substance, organism, physical parameter, or chemical constituent that is being measured with a method, and in this context, for which certification is offered.*

Assessor: *Person assigned by or on behalf of an accreditation body to perform, alone or as part of an assessment team, an assessment of a laboratory to determine its capability and capacity for meeting certification or accreditation requirements by examining the records and other physical evidence for each one of the Fields of Accreditation for which certification has been requested. Assessors may also be subcontractors of the accreditation body.*

Assessment: *Process undertaken by or on behalf of an accreditation body to assess the competence of a laboratory based on particular standards, regulations, certified test methods, and other normative documents and for defined Fields of Accreditation.*

Accreditation: *Third-party attestation related to an environmental testing laboratory conveying formal demonstration of its competence to carry out specific tasks related to the conduct of the testing for which it holds certification. Also, the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards.*

Applicant: *Person, group, or entity submitting an application to this RFA.*

Application: *An Applicant's entire submittal to the RFA.*

Certification Application: *Form DH 1762, "Application for Certification of Environmental Testing Laboratories," December 2016 adopted by reference in 64E-1.102(1), Florida Administrative Code.* Application form and 64E-1 are found at: http://www.doh.state.fl.us/lab/EnvLabCert/WaterCert.htm

Certification: *Regulatory recognition given to a laboratory that meets minimum quality standards and analytical performance standards.*

Corrective Action Plan (Plan of Correction): *The actions taken to eliminate the causes of an existing deficiency, nonconformity, defect or other undesirable situation in order to prevent recurrence.*

Deficiency: *An assessment conclusion referenced to a laboratory certification standard and supported by objective evidence that identifies a deviation from a laboratory certification standard requirement*.

Department: *The Florida Department of Health*

Fields of Accreditation: *Those matrix, method, and analyte combinations for which certification is offered.*

Internal Audit: *A systematic evaluation conducted by an organization on itself to determine the conformance to quantitative and qualitative specifications of some operational function or activity.*

Matrix: *The substrate of a test sample further defined in this context for certification purposes as:*

> **Drinking Water Matrix***: Any aqueous sample that has been designated a potable or potential potable water source.*
>
> **Non-Potable Water Matrix**: *Any aqueous sample excluded from the definition of Drinking Water matrix. Includes source water, groundwater, effluents, water treatment chemicals, and Toxicity Characteristic Leaching Procedure-(T*CLP) *or other extracts.*
>
> **Solid and Chemical Materials Matrix**: *Includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.*
>
> **Biological Tissue Matrix***: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples will be grouped according to origin.*
>
> **Air and Emissions Matrix:** *Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.*

The National Environmental Laboratory Accreditation Conference (NELAC) Institute (TNI): *A non-profit organization of state and federal officials formed to establish and promote mutually acceptable performance standards for the operation of environmental laboratories.*

National Environmental Laboratory Accreditation Program (NELAP): *A national accreditation program developed by TNI for environmental laboratories.*

Provider: *The entity to which a contract has been awarded, by the Department, in accordance with an application submitted in response to this RFA.*

Standard Operating Procedure (SOP): *A written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.*

SECTION 2.0 TECHNICAL SPECIFICATIONS

2.1 Scope of Service

Providers will conduct periodic on-site assessments of environmental testing laboratories seeking certification by the Department's Environmental Laboratory Certification Program for determining the laboratories' compliance with applicable laws and regulations. After receipt and processing of an application for initial or additional certification or for renewal of annual certification, the Department will provide the laboratory a list of approved Providers. The laboratory will select a provider to perform the on-site assessment for that application, or to perform the laboratory's biannual on-site assessment that is required by Florida law. When Provider notifies the Department of a pending inspection, the Department will forward the application information to Provider for review and use in its assessment of the laboratory.

2.2 Programmatic Authority

Provider must comply with all applicable Federal and state laws, regulations, action transmittals, program instructions, review guides, and similar documentation related to the following:

a. Chapters 119, 120, and 403, Florida Statutes.
b. Florida Administrative Code Chapter 64E-1.
c. Title 40 Code of Federal Regulations, Part 141 and Part 143.

2.3 Major Program Goals

The Department is responsible for certifying competent and qualified drinking water and environmental testing laboratories. The Department's goal is to establish contracts for the certification application process of on-site assessment of laboratory facilities, management, personnel, quality systems, and analytical activities at competitive rates that will be used by the laboratory facilities seeking certification.

2.4 Applicants will provide to the Department:

2.4.1 Verification of its assessors' credentials including, but not limited to college transcripts, certifications, and training records. These records must show explicit conformance to TNI Standard EL-V2M1-2009 and EL-V2M3-2009 and Chapter III, Sections 4.1 and 4.2 of the United States Environmental Protection Agency's (EPA) Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition. http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two

In addition to meeting education and training requirements above, the assessors will also have the following attributes:

2.4.1.1 Be familiar with the relevant regulations, certification procedures, and certification requirements;

2.4.1.2 Have a thorough knowledge of the relevant assessment methods and assessment documents;

2.4.1.3 Be thoroughly familiar with the various forms of records (hardcopy and electronic) used by environmental laboratories;

2.4.1.4 Be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;

2.4.1.5 Have a working knowledge and be conversant with the specific tests or types of tests for which the certification is sought and, where relevant, with the associated sampling and preservation procedures;

2.4.1.6 Be able to communicate effectively, both orally and in writing;

2.4.1.7 Exhibit sound judgment and appropriate conduct when performing duties associated with any contract awarded through this solicitation.

2.4.2 A signed statement certifying that no conflict of interest exists between the Applicant and the client laboratories and provide any supporting information as required by the Department.

2.4.3 A proposed staffing plan for technical, administrative, and clerical support.

2.4.4 Copies of at least two on-site assessment reports issued for assessments conducted previously by each assessor. All information identifying the subject laboratory should be removed or redacted prior to submittal.

2.4.5 Copies of documentation of assessor's review and conclusions regarding the laboratory's Corrective Action Plan for deficiencies cited in the on-site assessment reports submitted in response to section 3.4 paragraph c.

2.4.6 Documentation for each assessor attesting as to whether or not they have ever been investigated by any state or federal Inspectors General or other investigatory entities within the last seven years and indicating whether the allegations were substantiated.

2.4.7 Documentation for each assessor attesting that they are not, or within the previous two years, has been employed by or under contract to any laboratory certified by the Department. A person that has worked for the lab (i.e., a direct employee), cannot do assessments two years from the date of ending their employment.

2.5 Experience

Applicants are required to submit with their applications, contact information for three entities that have received services from the applicant that are similar to those requested in this solicitation. The Department reserves the right to contact any and all entities to verify the information provided. The Department will make only two attempts to contact each entity.

2.6 Responsive and Responsible

The Applicants will complete and submit the following mandatory information or documents as a part of their application. Any application which does not include the following will be deemed non- responsive and will not be considered for evaluation and award:

2.6.1 Title Page
2.6.2 Attachment I - Experience Form
2.6.3 Attachment III - Cost Application
2.6.4 Attachment IV- Required Certifications
2.6.5 Attachment VII- Applicant Certification Regarding Scrutinized Companies List Form

2.7 Evaluation of Application

Each application will be evaluated based on the criteria outlined in Attachment II. Evaluation sheets will be used by the Evaluation Team to determine if the Applicant meets the criteria. The Department reserves the right to accept or reject any and all applications, or separable portions thereof, and to waive any minor irregularity, technicality, or omission if the Department determines that doing so will serve the State's best interests. The Department may reject any response not submitted in the manner specified by the solicitation documents. **A minimum score of 75 (average score from among all evaluators on the Evaluation Team) will be required to be considered a Provider under this RFA.**

2.8 Description of Approach to Performing Task

2.8.1 The application will include a section to provide insight into the Applicant's approach to providing the services as specified in this solicitation. Applicants will address all areas of work within the Task List, Section 5.4. Applicants' technical approach will demonstrate a thorough understanding and insight into this project. At a minimum, this section should address:

2.8.1.1 A narrative of the methods of service delivery that will be initiated to fulfill all Department requirements.

2.8.1.2 Any activities that the Applicant is unable to provide.

2.8.2 Technical Requirements: Applicants should demonstrate the ability to meet the criteria for knowledge and expertise in Section 2.4, as applied to the specifications indicated in the Section 5.4 Task List section.

2.9 Description of Staffing and Organizational Capacity

2.9.1 The application must also include:

2.9.1.1 Documentation that Applicant has experience conducting on-site laboratory assessments to determine compliance with the 2003 and 2016 NELAC standards adopted by reference into the rules contained in Florida Administrative Code Chapter 64E-1.

2.9.1.2 Documentation that assessors employed or contracted by the Applicant, meet or exceed the requirements given in TNI Standard EL-V2M1-2009 and EL-V2M3-2009 and Chapter III, Sections 4.1 and 4.2 of the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition.

2.9.1.3 Documentation attesting as to whether or not that Applicant or Applicant's assessors have ever been investigated within the last seven years by the Department's or other's Inspector Generals and indicate whether the allegations were substantiated.

SECTION 3.0 SPECIAL INSTRUCTIONS

3.1 Instructions for Submitting Applications

3.1.1 Applications may be sent via U.S. Mail, Overnight delivery, Courier, or Hand-Delivered to the location identified in the Timeline. Electronic submission of applications will not be accepted for this solicitation.

3.1.2 Applications must be submitted in a sealed envelope or package with the solicitation number and the date and time of the bid opening clearly marked on the outside.

3.1.3 The Department is not responsible for any envelope that is not properly marked.

3.1.4 It is the responsibility of the Applicant to assure its application is submitted at the proper place and time indicated in the Timeline. The Department's clocks will provide the official time for bid receipt and opening.

3.1.5 Late applications will not be accepted.

3.2 Instructions for Formatting Applications

3.2.1 Applicants are required to complete, sign, and return the "Title Page" with their applications.

3.2.2 The application should be single-spaced and include:

a. Table of Contents
b. Index
c. Appendices
d. Experience
e. Other support materials

3.2.3 The pages should be numbered and one-inch margins should be used.

3.2.4 The font size and type is at the discretion of the Applicant but must be at least size 11 font.

3.2.5 One original application, three copies of the application, and one electronic copy of the application on CD. The electronic copy should contain the entire application as submitted, including all supporting and signed documents.

Materials submitted will become the property of the State of Florida. The state reserves the right to use any concepts or ideas contained in the response.

3.3 Public Records and Trade Secrets

Notwithstanding any provisions to the contrary, public records will be made available pursuant to the provisions of the Public Records Act. If the Applicant considers any portion of its response to this solicitation to be confidential, exempt, trade secret, or otherwise not subject to disclosure pursuant to Chapter 119, Florida Statutes, the Florida Constitution, or other authority, the Applicant must segregate and clearly mark the document(s) as **"CONFIDENTIAL."**

Simultaneously, the Applicant will provide the Department with a **separate redacted paper and electronic copy** of its response with the claimed protected information redacted and briefly describe in writing the grounds for claiming exemption from the public records law, including the specific statutory citation or other legal authority for such exemption. This redacted copy will contain the Solicitation name, number, and the name of the Applicant on the cover, and will be clearly titled **"REDACTED COPY."**

The Redacted Copy will be provided to the Department at the same time the Applicant submits

its response and must only exclude or redact those exact portions that are claimed confidential, proprietary, or trade secret. The Applicant will be responsible for defending its determination that the redacted portions of its response are confidential, trade secret, or otherwise not subject to disclosure. Further, the Applicant will protect, defend, and indemnify the Department for any and all claims arising from or relating to the determination that the redacted portions of its response are confidential, proprietary, trade secret, or otherwise not subject to disclosure. If the Applicant fails to submit a redacted copy with its response, all records submitted are public records and the Department will produce all documents, data, or records submitted by the Applicant in answer to a public records request.

3.4 Applicants Inquiries

Questions related to this RFA must be received, in writing (either via U.S. Mail, courier, e-mail, fax, or hand-delivery), by the contact person listed below, within the time indicated in the Timeline. Oral inquiries or those submitted after the period specified in the Timeline will not be addressed.

Answers to questions submitted in accordance with the RFA Timeline or during a pre-bid conference, if applicable will be posted on the Vendor Bid System web site: http://vbs.dms.state.fl.us/vbs/main_menu and on the DOH Grant Funding Opportunities page: Florida Department of Health Grant Funding Opportunities: http://www.floridahealth.gov/about- the-department-of-health/about-us/administrative-functions/purchasing/grant-funding- opportunities/index.html.

All inquiries must be submitted to:

Florida Department of Health
Environmental Laboratory Certification
Program Attention*: Vanessa Soto Contreras*
1217 Pearl Street
Jacksonville, Florida 32202
Email: Vanessa.sotocontreras@flhealth.gov

NOTE: FLORIDA LAW:

Applicants to this solicitation or persons acting on their behalf may not contact, between the release of the solicitation and the end of the 72-hour period following the agency posting the notice of intended award, excluding Saturdays, Sundays, and state holidays, any employee or officer of the executive or legislative branch concerning any aspect of this solicitation, except in writing to the procurement officer as provided in the solicitation documents. Violation of this provision may be grounds for rejecting a response. Section 287.057(23), Florida Statutes.

3.5 Special Accommodations

Any person who requires special accommodations at the Department's Purchasing location because of a disability should contact the Department's Purchasing Office at (850) 245-4199 at least five business days prior to any pre-application conference, application opening, or meeting. If you are hearing or speech impaired, please make contact through the Florida Relay Service at 1-800-955-8771 (TDD).

3.6 Minority and Service-Disabled Veteran Business – Participation

The Department encourages minority and women-owned business (MWBE) and service-disabled veteran business enterprise (SDVBE) participation in all its solicitations. Applicants are encouraged to contact the Office of Supplier Diversity at 850-487-0915 or visit its website

at http://osd.dms.state.fl.us for information on becoming a certified MWBE or SDVBE or for names of existing businesses that may be available for subcontracting or supplier opportunities.

3.7 Subcontractors

Provider may, only with prior written approval of the Department, enter into written subcontracts for performance of specific services under the contract resulting from this solicitation. Anticipated subcontract agreements known at the time of application submission must be identified in the application. If a subcontract has been identified at the time of application submission, a copy of

the proposed subcontract must be submitted to the Department. No subcontract that the Applicant enters into with respect to performance under the contract will in any way relieve the Applicant of any responsibility for performance of its contract responsibilities with the Department. The Department reserves the right to request and review information in conjunction with its determination regarding a subcontract request.

Provider will provide a monthly Subcontract Expenditure Report (Attachment VI) summarizing all subcontracting performed during the prospective contract period. This report will include the name and address, Federal Employment Identification number, and dollar amount expended for any subcontractor. A copy of this form will be submitted to the Department's Contract Manager. The Department encourages the use of MWBE and SDVBE vendors for subcontracting opportunities. For assistance locating a certified MWBE or a SDVBE, contact the Department' Minority Coordinator (850-245-4198) or the Office of Supplier Diversity (850-487-0915), as needed.

In accordance with Executive Order 11-116, "The provider agrees to utilize the U.S. Department of Homeland Security's E-Verify system, **https://e-verify.uscis.gov/emp,** to verify the employment eligibility of all new employees hired during the contract term by the Provider. Provider will also include a requirement in subcontracts that the subcontractor will utilize the E-Verify system to verify the employment eligibility of all new employees hired by the subcontractor during the contract term. Providers meeting the terms and conditions of the E-Verify System are deemed to be in compliance with this provision."

SECTION 4.0 SPECIAL CONDITIONS

4.1 Cost of Preparation

Neither the Department nor the state of Florida is liable for any costs incurred by an Applicant in responding to this solicitation.

4.2 Vendor Registration

Each vendor doing business with the state of Florida for the sale of commodities or contractual services as defined in Section 287.012, Florida Statutes, must register in the MyFloridaMarketPlace system, unless exempted under Florida Administrative Code Rule 60A- 1.030(3). State agencies will not enter into an agreement for the sale of commodities or contractual services as defined in Section 287.012, Florida Statutes, with any vendor not registered in the MyFloridaMarketplace system, unless exempted by rule. A vendor not currently registered in the MyFloridaMarketPlace system must do so within five days after posting of intent to award. Registration may be completed at: http://dms.myflorida.com/business_operations/state_purchasing/myflorida_marketplace/vendors

Those lacking internet access may request assistance from the MyFloridaMarketPlace Customer Service at 866-352-3776 or from State Purchasing, 4050 Esplanade Drive, Suite 300, Tallahassee, Florida 32399.

4.3 Identical Tie Applications

When evaluating vendor responses to solicitations where there is identical pricing or scoring from multiple Applicants, the Department will determine the order of award based on the Applicant providing the Best Value to the State.

4.4 Renewal

Contracts resulting from this solicitation may be renewed, in whole or in part, for a period not to exceed three years or the term of the original contracts, whichever is longer. Any renewal will be contingent upon satisfactory performance evaluations by the Department and subject to the availability of funds.

4.5 Verbal Instructions Procedure

Applicant may not initiate or execute any negotiation, decision, or action arising from any verbal discussion with any State employee. Only written communications from the Department's Purchasing Office may be considered as a duly authorized expression on behalf of the Department. Additionally, only written communications from Applicants are recognized as duly authorized expressions on behalf of the Applicant.

4.6 Addenda

If the Department finds it necessary to supplement, modify, or interpret any portion of the specifications or documents during the RFA period, a written addendum will be posted on the MyFlorida.com Vendor Bid System, http://vbs.dms.state.fl.us/vbs/main_menu. It is the responsibility of the Applicant to be aware of any addenda that might affect the submitted application.

4.7 Unauthorized Aliens

The employment of unauthorized aliens by any vendor is considered a violation of section 274A(a) of the Immigration and Nationality Act, 8 U.S.C. § 1324a (2006). A vendor who knowingly employs unauthorized aliens will be subject to a unilateral cancellation of the resulting contract.

4.8 Certificate of Authority

All corporations, limited liability companies, corporations not for profit, and partnerships seeking to do business with the state of Florida must be registered with the Florida Department of State in accordance with the provisions of Chapters 607, 608, 617, and 620, Florida Statutes, as applicable.

4.9 Standard Contract

Each Applicant will review and become familiar with the Department's Standard Contract and Direct Order, which contains administrative, financial, and non-programmatic terms and conditions mandated by federal or state statute and policy of the Department of Financial Services. Use of one of these documents is mandatory for Departmental contracts as they contain the basic clauses required by law. The terms and conditions contained in the Standard Contract are non-negotiable. The terms and conditions of the Standard Contract, Attachment V.

Acknowledge acceptance on Required Certifications, Attachment IV.

4.10 Licenses, Permits, and Taxes

Applicant will pay for all licenses, permits, and taxes required to operate in the state of Florida. Also, the Applicant will comply with all federal, state, and local codes, laws, ordinances, regulations and other requirements at no cost to the Department.

4.11 Conflict of Interest

Section 287.057(17)(c), Florida Statutes, provides "A person who receives a contract that has not been procured pursuant to subsections (1)-(3) to perform a feasibility study of the potential implementation of a subsequent contract, who participates in the drafting of a solicitation or who develops a program for future implementation, is not eligible to contract with the Department for any other contracts dealing with that specific subject matter, and any firm in which such person has any interest in not eligible to receive such contract. However, this prohibition does not prevent an Applicant who responds to a request for information form being eligible to contract with a department." The Department considers participation through decision, approval, disapproval, recommendation, preparation of any part of a purchase request, influencing the content of any specification or procurement standard, rendering of advice, investigation, or auditing or any other advisory capacity to constitute participation in drafting of the solicitation.

Acknowledge acceptance on Required Certifications, Attachment IV.

4.12 Termination

Termination will be in accordance with the Department's Standard Contract, Attachment V, Section III B.

4.13 Conflict of Law and Controlling Provisions

Any contract resulting from this RFA, plus any conflict of law issue, will be governed by the laws of the state of Florida.

4.14 E-Verify

In accordance with Executive Order 11-116, "Provider agrees to utilize the U.S. Department of Homeland Security's E-Verify system, **https://e-verify.uscis.gov/emp**, to verify the employment eligibility of all new employees hired during the contract term by Provider. Provider will also include a requirement in subcontracts that the subcontractor will utilize the E-Verify system to verify the employment eligibility of all new employees hired by the subcontractor during the contract term. Contractors meeting the terms and conditions of the E-Verify System are deemed to be in compliance with this provision."

4.15 Scrutinized Companies

In accordance with section 287.135, Florida Statutes, agencies, such as the Department, are prohibited from contracting with companies, for goods or services over $1,000,000, that are on either the Scrutinized Companies with Activities in Sudan List or the Scrutinized Companies with Activities in the Iran Petroleum Energy Sector List which have been combined to one PFIA List of Prohibited Companies which is updated quarterly. This list is created pursuant to section 215.473, Florida Statutes, which provides that false certification may subject company to civil penalties, attorney's fees, and costs.

Applicant must submit with its Application the "Applicant Certification Regarding Scrutinized Companies List (Attachment VII)"

4.16 Required Certifications

All Applicants must sign and return with its response the Required Certifications form, Attachment IV. **ANY VENDOR FAILING TO RETURN THE REQUIRED CERTIFICATIONS FORM WILL BE CONSIDERED NONRESPONSIVE.**

4.17 W9 Initiative

The State of Florida, Department of Financial Services requires vendors doing business with the state to submit a Substitute Form W-9 electronically. Vendors who do not have a verified Substitute Form W-9 on file will experience delays in processing contracts or payments from the state of Florida. For more information go to: https://flvendor.myfloridacfo.com/

SECTION 5.0 GENERAL CONTRACT CONDITIONS

5.1 Client General Description

The Department certified 350 environmental testing laboratories by Matrix-Method-Analyte (Matrix = Drinking Water, Non-Potable Water, Solid and Chemical Materials, Air and Emissions, or Biological Tissue) as of November 6, 2018. Except for those that are reciprocally certified, each of these laboratories must be reassessed at least once every two years.

1. **Breakdown by Laboratory Type**
   a. Commercial: 181
   b. Water and Wastewater: 129
   c. State: 13
   d. County Health Department: 7
   e. University: 5
   f. Federal: 5
   g. Other: 10
   h. Mobile labs (subset of the above types): 10

2. **Approximate Breakdown by Matrix**
   a. Drinking Water: 217
   b. Non-Potable Water: 281
   c. Solid and Chemical Materials: 157
   d. Biological Tissue: 18
   e. Air and Emissions: 27

3. **Approximate Breakdown by Scientific Discipline**
   a. Chemistry: 314
   b. Microbiology: 219
   c. Radiochemistry: 18
   d. Toxicity: 18 (11 are Toxicity only)
   e. Asbestos: 8
   f. Dioxin: 10
   g. Cryptosporidium / Giardia: 8
   h. Air and Emissions (only): 7

4. **Approximate breakdown by relative size (scope of accreditation)**
   a. Microbiology and/or 1 General Chemistry category: 122
   b. Intermediate (usually, Microbiology + Metals + General Chemistry): 131
   c. Full Service (4 or more categories of certification in any one matrix): 97

5. **In-State vs. Out-of-State**
   a. In-State: 225
   b. Out-of-State: 125

5.2 Client Eligibility

The Department will be solely responsible for determining laboratory eligibility for certification. Eligibility criteria and standards for certification are established by statutes and rules adopted pursuant thereto. Eligibility criteria may change but certification determinations are only the responsibility of the Department.

5.3 Contract Limits Provider

Numbers indicated in section 5.1, the Client General Description, are provided for planning purposes only. The Department reserves the right to alter the number of certification applicants by any amount.

5.4 Task List

5.4.1 Providers will perform the tasks listed below:

a. Complete and the NELAP assessor technologies table, Section 5.16, to the Department. Indicate the specific matrices and technologies for which each of Provider's assessors is qualified to conduct assessments on the Department's behalf. (Blank copies of Section 5.16 are available upon request from the Department.) Submit the completed assess technologies table for each assessor upon execution of the contract.

b. Submit all SOPs, and subsequent revisions, applicable to Provider's performance under this contract to the Department upon contract execution.

c. Create and sign a written attestation indicating that none of Provider's employed or contracted assessors who will work on this contract, are or have been investigated by a state or federal inspector general within the last seven years. Submit the signed attestation to the Department upon contract execution and by July 1 of each contract year.

d. Update the NELAP assessor technologies table, as necessary to include additional qualifications for its assessors or to include additional assessors. Submit all training course certifications that qualify the assessor for each additional technology submit with the Application and upon contract execution provide updates to the Assessor information. Ensure no assessor is assigned to conduct any assessment for an additional technology until the Department approves the assessor for the additional technology. Submit an outline of the training course that includes all the following training course material elements for the Department's review and comments during oversight assessments, or as requested by the Department:

1) Basic theoretical and operating principles of the analytical technology;

2) Instrumentation, apparatus, and software required;

3) Critical steps and processes of the analytical technology that must be executed to ensure quality data;

4) Relevant quality control indicators and expected acceptance criteria;

5) Major sources of error and how to control them;

6) Inappropriate procedures and practices for the analytical technology and ways to detect improper practices;

7) Key information required to document completely the reported results;

8) Essential elements for assessing data generated;

9) Summary of what the training involves and that the person has passed it and,

10) Certificate of satisfactory completion signed by the trainer or other responsible party.

e. Review applications assigned to Provider by the Department to include in the upcoming assessment of a client laboratory that selects Provider. Review the client laboratory's scope of certification provided by the Department, for accredited and pending analytes and test methods, in order to determine assessment needs in terms of the number of assessors needed and the time needed off-site and on-site at the client laboratory to conduct the assessment completely.

f. Evaluate and increase, if needed, the previously determined assessment needs appropriately if Provider intends to address applications assigned or submitted after the date of scheduling the assessment. Contact the Department to verify the eligibility of the application for inclusion in the assessment. Ensure that assessments for any additional certifications conducted by Provider of the client laboratory do not compromise the assessment team composition or the number of workdays required to assess the laboratory's existing certified Fields of Accreditation comprehensively.

g. Utilize an appropriate assessment team for the size of the client laboratory to be assessed. The team must include a qualified lead assessor and may include the following:

1) Additional qualified assessors;

2) Technical specialists; and,

3) Observers, if authorized by the client laboratory to ensure the assessment team has sufficient personnel, knowledge, skills, training, qualifications, personal attributes, and sufficient organizational authority and freedom to perform assigned duties.

h. Permit designated Department staff to participate in or observe any assessment performed.

i. Create and sign a written statement before conducting an assessment certifying that no conflict of interest exists between Provider and any of the assessors to be included in an assessment and the client laboratory. Provide any supporting information as required by the Department on any potential conflict of interest. Submit the written statement to the Department with the Assessor Table upon contract execution. Include the following in the written statement:

1) None of the assigned assessors have provided, provides, or will provide consultancy to the client laboratory before, during, or after the

assessment for any matter related to the assessment; and,

2) None of the assigned assessors is a staff or direct contracted employee of any laboratory certified by the Department through the Environmental Laboratory Certification Program (ELCP).

j. Notify the Department in writing or via email within one business day if any assessor or lead assessor under this contract has a change in his or her status at it pertains to a potential conflict of interest as stated herein. Immediately have that assessor stop performance under this contract until the Department provides written guidance on how to proceed.

k. Schedule an assessment with the client laboratory within 15 calendar days after receiving notification from the Department that Provider has been selected to perform the assessment for compliance with the requirements of the client laboratory's certification. Coordinate the assessment with the client laboratory to maintain compliance with the requirements of the certification issued by the Department and to conduct the assessment with reasonably minimal disruption of routine laboratory operations.

l. Notify the Department by email when an assessment is scheduled that the client laboratory is notified. Ensure that the assessment is scheduled and conducted with enough time to allow the assessors to plan and conduct a comprehensive and complete assessment Inform and explain to the Department when this is not possible and when the comprehensive assessment will be performed.

m. Create an assessment plan for conducting the on-site assessment of each client laboratory and submit it to the Department for review within seven days after requested by the Department.

n. Conduct assessments of client laboratories for the Fields of Accreditation on their scopes of certification and in the applications to determine compliance with the applicable provisions of Florida Administrative Code Chapter 64E-1. Notify the Department in writing if not all Fields of Accreditation, for which the laboratory is certified or seeking certification, were assessed during the on-site assessment. Ensure each assessment is conducted as follows:

1) Encompasses all Fields of Accreditation for which the client laboratory seeks initial certification, continued certification, or recertification; and,
2) Monitors and evaluates all elements of the NELAC and TNI Standards for each quality system matrix, test method, and analyte. Ensure this includes, but is not limited to, sample collection, preparation, equipment, analysis, reporting, quality control, and proficiency testing.

o. Prepare an on-site assessment report documenting any and all deficiencies discovered during the assessment and linking by reference each of these deficiencies directly to the NELAC and TNI Standards as incorporated into Florida Administrative Code Rule 64E-1. Cite deficiencies for the client laboratory's failure to follow certified test method specifications and link to the applicable NELAC and TNI Standard as well as to the applicable test method specifications. Use the form specified in Florida Administrative Code Rule 64E-1.104(5) for documenting the deficiencies in the assessment report. Ensure each deficiency in the assessment report pertains to the requirements given in NELAC and TNI Standards as incorporated into Florida Administrative Code Rule 64E-1. Include the applicable elements listed in Section 5.15 (below) in the assessment report.

Issue the on-site reports to the client laboratories and send electronic copies to the Department within 30 calendar days of the final day of the on-site assessment.

p. Submit, if applicable, completed copies of the EPA Method 1623 and 1623.1 checklists A, B, and C from Supplement 2 to the Fifth Edition of the US EPA "Manual for the Certification of Laboratories Analyzing Drinking Water" to the Department for laboratories testing for Cryptosporidium and Giardia, along with the assessment report.

q. Include in the assessment report, and notify the ELCP Program Administrator and the client laboratory in writing, if not all Fields of Accreditation for which the client laboratory is certified or seeking recertification were able to be assessed during an assessment.

r. Provide any and all materials gathered and used during an assessment to the Department, within seven business days of a request by the Department. Materials may include, but are not limited to, checklists, correspondence, quality manuals, laboratory data, conflict of interest forms, and confidential business information forms.

s. Instruct the client laboratory assessed to respond, using the form specified by Florida Administrative Code Rule 64E-1.104, within 30 calendar days of its receipt of the assessment report by submitting a proposed Plan of Correction and completion date, for each deficiency identified in the assessment report.

t. Review the client laboratory's proposed corrective actions and completion dates, and make written recommendations to the Department as to whether the Proposed Plan of Correction will correct each deficiency.

u. Prepare an itemized report of recommendations and submit it to the Department for approval along with final certification recommendations, within 30 calendar days of receipt of the laboratory's Plans of Correction, or within one business day of receiving payment from the client laboratory, whichever comes later. Accompany any recommendation to reject a laboratory's proposed Plan of Correction for a specific deficiency with the written rationale for the rejection.

v. Ensure that assessors are available, at no cost to the Department, whenever internal audits, external audits, legal matters, or resolutions of other disputes require their presence.

5.5 Staffing

Provider must maintain staff necessary to execute the duties specified in any resulting contract. It is Provider's responsibility to ensure staff members meet the minimum qualifications specified in this solicitation. The Department reserves the right to amend the minimum qualifications specified throughout this solicitation.

5.6 Professional Qualifications

Provider must ensure its employees and sub-contractors are competent and comply with the applicable provisions of state laws and rules as well as the terms of any contract awarded through this solicitation. Provider, including its employees and subcontractors, will avoid any conduct, regardless of whether in the context of business, financial, or social relationships, which might undermine the public trust, regardless of whether that conduct is unethical or merely has the appearance of unethical behavior.

5.7 Conflict of Interest

Provider will ensure its employees and sub-contractors have no conflict of interest which would compromise impartiality in the assessment process.

5.8 Reports

Where the resulting contract requires the delivery of reports to the Department, mere receipt by the Department will not be construed to mean or imply acceptance of those reports. It is specifically intended by the parties that acceptance of required reports will constitute a separate act. The Department reserves the right to reject reports as incomplete, inadequate, or unacceptable according to the parameters set forth in the resulting contract. The Department, at its option, may allow additional time where Provider may remedy the objections noted by the Department. The Department may, after having given Provider a reasonable opportunity to complete, make adequate or acceptable its response, and declare this agreement to be in default.

5.9 Records and Documentation

To the extent that information is utilized in the performance of the resulting contract or generated as a result of it, and to the extent that information meets the definition of "public record" as defined in subsection 119.011(1), Florida Statutes, said information is hereby declared to be and is hereby recognized by the parties to be a public record and absent a provision of law or administrative rule or regulation requiring otherwise, will be made available for inspection and copying by any person upon request as provided in Art. I, Sec. 24, Fla. Const. and Chapter 119, Florida Statutes. It is expressly understood that any state contractor's refusal to comply with these provisions of law will constitute an immediate breach of the contract resulting from this RFA entitling the Department to unilaterally terminate the contract. Provider will be required to notify the Department of any requests made for public records.

Unless state or federal law requires a greater retention period, all documents pertaining to the program contemplated by this RFA will be retained by Provider for a period of six (6) years after the termination of the resulting contract or longer as may be required by any renewal or extension of the contract. During this period, Provider will provide any documents requested by the Department in its standard word processing format (currently Microsoft Word 2016). If this standard should change, the successful vendor will adopt the new standard at no cost to the Department. Data files will be provided in a format directed by the Department.

Provider agrees to maintain the confidentiality of all records required by law or administrative rule to be protected from disclosure. Provider further agrees to hold the Department harmless from any claim or damage including reasonable attorney's fees and costs or from any fine or penalty imposed as a result of failure to comply with the public records law or an improper disclosure of confidential information and promises to defend the Department against the same at its expense.

5.10 Outcomes and Outputs (Performance Measures)

DEPARTMENT GOAL: The resulting contract services will allow the Department to ensure laboratories are inspected by qualified assessors according to statutory and regulatory requirements.

OBJECTIVE: Provide applicant and certified environmental testing laboratories with an on-site assessment process that meets statutory and regulatory requirements.

MEASURES: ***Provider is must meet a target of 100% completion for the below***

tasks (outlined in detail in Section 5.4):

a. Submit to the Department the assessment plan for conducting the on-site assessment of each client laboratory on the Department's behalf, and conduct the on-site assessment according to that plan.

b. Supply to the Department any and all materials gathered and used during a laboratory assessment within 7 days of a request from the Department.

c. Issue on-site assessment reports, including itemized deficiencies, to client laboratories and send electronic copies simultaneously to the Department.

d. Submit an itemized report of recommendations to approve or disapprove the proposed corrective actions and the laboratory's certification status, or else notify the Department in writing that the client laboratory has not paid Provider's on- site assessment expense fees.

e. Submit to the Department, for each assessor to be used, the completed assessor technologies table in Section 5.17.

f. Submit to the Department all Standard Operating Procedures, and subsequent revisions, applicable to Provider's performance under this contract.

g. Submit to the Department, initially and every July 1, written attestation that none of the Provider's assessors to be used under this contract have been investigated by a state or federal inspector general within the past seven years.

h. Submit to the Department all additions and changes to the assessor technologies tables, plus the training course materials used to justify the additions or changes.

i. Submit to the Department a written statement certifying that no conflicts of interest exist among Provider, Provider's assessors, and each laboratory to be assessed under this contract.

j. Notify the Department within one business day if any assigned assessor has a change in status such that a conflict of interest could exist with the laboratory to be assessed.

k. Notify the Department, at the same time as notifying the laboratory, the dates and the assessor(s) that Provider has scheduled for the laboratory's on-site assessment.

l. Notify the Department in writing if not all Fields of Accreditation, for which the laboratory is certified or seeking certification, were assessed during the on-site assessment.

2. Provider must meet a target of 95% completion for the below tasks (outlined in detail in Section 5.4):

a. On-site assessment reports contain all applicable content requirements in Section 5.16.

b. Issue on-site assessment reports, including itemized deficiencies, to client laboratories within 30 calendar days of the final day of the on-site assessment and send electronic copies simultaneously to the Department.

c. Submit an itemized report of recommendations to approve or disapprove the proposed corrective actions and the laboratory's certification status, or else notify the Department in writing that the client laboratory has not paid Provider's on- site assessment expenses, within 30 calendar days of receipt of the laboratory's Plans of Correction.

d. Notify the Department, at the same time as notifying the laboratory and at least 60 calendar days in advance of the assessment, the dates and the assessor(s) that Provider has scheduled for the laboratory's on-site assessment (NOTE: Provider may seek a waiver of the 60-day minimum requirement by submitting written notification to the Department).

OUTCOME: Timely TNI NELAP and EPA-compliant laboratory assessments conducted in a cost-effective manner, with the regulatory oversight required by law.

5.11 Provider Unique Activities

Provider is solely and uniquely responsible for the satisfactory performance of the tasks described in Section 5.4. By execution of the resulting contract, Provider recognizes its singular responsibility for the tasks, activities, and deliverables described therein and warrants that it has fully informed itself of all relevant factors affecting accomplishment of the tasks, activities, and deliverables, and agrees to be fully accountable for the performance thereof.

5.12 Department Obligations

The Department may provide technical support and assistance to Provider, within the resources of the Department, to assist in meeting the required tasks in Section 5.4. The support and assistance, or lack thereof, will not relieve Provider from full performance of contract requirements.

5.13 Department Determinations

The Department reserves the exclusive right to make certain determinations in these specifications. The absence of the Department setting forth a specific reservation of rights does not mean that all other areas of the resulting contract are subject to mutual agreement.

5.14 Financial Specifications

5.14.1 Funding Source: The fees for services, including travel when appropriate, will be paid by the laboratory being assessed. All travel costs must be in accordance with section 112.061, Florida Statutes, and Florida Administrative Code Rule 69I-42. No state funding is anticipated in this project.

5.14.2 Invoicing and Payment of Invoice: Provider's cost will be paid by the laboratory

seeking or maintaining primary certification from the Florida Department of Health. The laboratory will make payments directly to Provider. Provider will provide the laboratory with a cost estimate

before the assessment begins. Provider's costs may include travel expenses related to the on-site assessment.

5.15 On-Site Assessment Report Contents

5.15.1 Report Header - The laboratory name, physical and mailing addresses, Florida certification number, names of the assessment team, assessment dates, and categories assessed.

5.15.2 Introduction - A statement that the on-site assessment was performed to determine the laboratory's compliance with Florida Administrative Code Chapter 64E-1.

5.15.3 Deficiencies - Refers to the accompanying form referenced in Florida Administrative Code Rule 64E-1.104(5), currently DH 1137, if any deficiencies that require a Plan of Correction are noted during the on-site assessment. Each deficiency must contain an appropriate citation to the NELAC and/or TNI Standard that was violated.

5.15.4 Technical Directors/Managers - Lists the names and titles of the Laboratory Director, Technical Directors, QA Officer, supervisors, etc.

5.15.5 Comments - Includes in narrative format any of the following that are applicable:

a. Information that substantiates, supplements, or augments deficiencies noted on the form referenced in Florida Administrative Code Rule 64E-1.104(5), currently DH 1137.

b. The identifier and effective date of the laboratory Quality Manual reviewed (if applicable) during the assessment.

c. A list of all laboratory personnel interviewed or who participated in the assessment. Include if any Technical Director credentials were reviewed during the assessment, and if there were any changes in the laboratory's Technical Directors since the last assessment.

d. Fields of Accreditation that are recommended for certification with regard to any application addressed during the assessment. Include the application date(s) in which the laboratory requested certification of these Fields. Applications must be completed and closed at the time of the assessment unless otherwise approved by the Department.

e. Fields of Accreditation that require initial calibrations, IDOCs, MDLs, or other laboratory data not available during the on-site assessment, if any, that must be submitted in order to obtain or maintain certification. A reasonable time deadline for compliance should also be specified.

f. In the event the laboratory disagrees with the deficiencies of the assessors, and the Lead Assessor adheres to the original deficiencies; the deficiencies with which the laboratory takes exception will be documented and included in the report.

g. Other comments and technical recommendations that will improve laboratory performance and data quality within the constraints of allowed consultancy and respective of any conflict of interest.

h. Obsolete certifications for which the laboratory management may have requested relinquishment, including the effective date.

5.15.6 Conclusions – Includes recommendations regarding the laboratory's compliance with the provisions of Florida Administrative Code Chapter 64E-1.

5.16 Assessor's

Technologies Table

Assessor: _____

Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	BT	AE	Qualified Assessor(
Example	Example	X	X	X	X	X	Name or Initials*
AMP	Amperometric Titration (e.g., EPA 330.1, SM4500CL D, SM4500CLO2 E)						
AS	Alpha Spectrometry (e.g., EPA 907.0, NY-02)						
ASC	Alpha Scintillation Cell Counter (e.g., EPA 903.1)						
ASV	Anodic Stripping Voltammetry (e.g., Palintest 1001, EPA 7472)						
AUTO	Auto Analyzer (e.g., EPA 353.2, SM4500NO3- F)						
BETA	Beta Spectrometry (e.g., EPA 900.0)						
BGCS	Beta/Gamma Coincidence Scintillation Counter (e.g., EPA 902.0)						
CAL	Calorimetric or Thermometric (e.g, EPA 1010, SM2550B)						
CE-UV	Capillary Electrophoresis – UV (e.g., SM4140B)						
COND	Conductance (e.g., EPA 120.1, SM2510B)						
COUL	Coulometric Titration (e.g., EPA 9076, 9000)						
CVAAS	Atomic Absorption - Cold Vapor Spectrometry (e.g., EPA 245.1, SM3112B)						
CVAFS	Atomic Fluorescence - Cold Vapor Spectrometry (e.g., EPA 1631E)						
DCP-AES	Atomic Emission - Direct Current Plasma Spectrometry (e.g., ASTM D4190-94)						
DPP	Differential Pulse Polarography (e.g., EPA 7198)						
FAAS	Atomic Absorption - Flame Spectrometry (e.g., SM3111B)						
FAES	Atomic Emission - Flame Spectrometry (e.g., SM3500Na B)						
FLUOR	Ultraviolet or Visible Molecular Fluorescence Spectrometry (e.g., EPA 445.0, 908.1)						
GALV	Galvanic Probe (e.g., EPA 405.1, SM5210B, SM2710B)						
GC-AED	Gas Chromatography – Atomic Emission Detector						
GC-ECD	Gas Chromatography - Electron Capture Detection (e.g., EPA 608, 8081)						
GC- PID/FID	Gas Chromatography - Photoionization/Flame Ionization Detection (e.g., MA-VPH)						
GC-ELCD	Gas Chromatography - Electrolytic Conductivity Detection (e.g., EPA 601)						
GC- ELCD/PID	Gas Chromatography - Electrolytic Conductivity/Photoionization Detection (e.g., 8021)						
GC-FID	Gas Chromatography - Flame Ionization Detection (e.g., EPA 8015, 8100)						
GC-FPD	Gas Chromatography - Flame Photometric Detection (e.g., EPA 622, 8141)						

GC-FTIR	**Gas Chromatography - Fourier Transform Infrared Spectrometry (e.g., EPA 8410)**						
GC- HRMS	**Gas Chromatography - Mass Spectrometry - High Resolution (e.g., EPA 1613)**						
GC-MS	**Gas Chromatography - Mass Spectrometry (e.g., EPA 625, 8270)**						

Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	BT	AE	Qualified Assessor(s)
GC-MS-MS	Gas Chromatography - Tandem Mass Spectrometry						
GC-NPD	Gas Chromatography - Nitrogen/Phosphorus Detection (e.g., EPA 607, 8070)						
GC-PID	Gas Chromatography - Photoionization Detection (e.g., EPA 602)						
GFAAS	Atomic Absorption - Graphite Furnace Spectrometry (e.g., SM3113B, EPA 200.9)						
GRAV	Gravimetry (e.g., SM2540C, EPA 1664A)						
GS-HR	Gamma Spectrometry - High Resolution (e.g., EPA 901.1)						
GS-LR	Gamma Spectrometry - Low Resolution (e.g., EPA 901.0)						
HGAAS	Atomic Absorption - Hydride Generation Spectrometry (e.g., SM3114B)						
HPLC-ELEC	High Performance Liquid Chromatography - Electrochemical (e.g., EPA 605)						
HPLC-ELSC	High Performance Liquid Chromatogarphy – Evaporative Light Scattering Detector (e.g., Refractive Index)						
HPLC-FLUOR	High Performance Liquid Chromatography - Ultraviolet/Visible Molecular Fluorescence						
HPLC-IR	High Performance Liquid Chromatography - Infrared Molecular Absorption						
HPLC-PBMS	High Performance Liquid Chromatography - Mass Spectrometry-Particle Beam						
HPLC-ESMS	High Performance Liquid Chromatography – Mass Spectrometry-Electrospray						
HPLC-TSMS	High Performance Liquid Chromatography - Mass Spectrometry-Thermospray						
HPLC-MS-MS	High Performance Liquid Chromatography - Tandem Mass Spectrometry						
HPLC-UV	High Performance Liquid Chromatography - Ultraviolet/Visible Molecular Absorption						
HPLC-PDAUV	High Performance Liquid Chromatography – Photodiode Array UV/VIS						
IC-COND	Ion Chromatography - Electroconductivity (e.g., EPA 300.0, 314.0)						
IC-MS	Ion Chromatography - Mass Spectrometry (e.g., EPA 331.0)						
IC-MS-MS	Ion Chromatography - Tandem Mass Spectrometry						
IC-UV	Ion Chromatography - UV (e.g., EPA 7199, SM3500Cr C)						
ICP-AES	Atomic Emission - Inductively Coupled Plasma Spectrometry (e.g., EPA 200.7, 6010)						
ICP-MS	Mass Spectrometry - Inductively Coupled Plasma (e.g., EPA 200.8, 6020)						
ICP-MS-CRC	Inductively Coupled Plasma – Mass Spectrometry with Chemical Reaction Cell						
ISE	Ion Selective Electrode (e.g., SM4500H+ B, SM4500F- C)						
IMM	Immunoassay (e.g., EPA 4000-series methods)						
IR	Infrared Spectrometry (e.g., EPA 418.1, SM5520C)						
LSC	Liquid Scintillation Counter (e.g., EPA 906.0)						
LSP	Luminescence-based Sensor Procedure						
LP	LASER Phosphorimetry e.g., ASTM D5174-97)						
NAA	Neutron Activation Analysis (e.g., EPA 9022)						
PC	Proportional Counter (e.g., EPA 900.0, 903.0, 904.0)						

Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	BT	AE	Qualified Assessor(s)
PCM	Phase Contrast Microscopy (e.g., for Airborne Asbestos)						
PHYS	Miscellaneous Physical Properties (e.g., EPA 1030, 9095, SM2150B)						
PLM	Polarized Light Microscopy (e.g., for Bulk Asbestos)						
POL	Polarographic Probe						
PREP	Subsampling / Digestion / Distillation / Extraction						
SEM	Scanning Electron Microscopy						
TEM	Transmission Electron Microscopy (e.g., EPA 100.1, 100.2)						
TITR	Titrimetry - Visual Indicator (SM4500Cl- B, SM2340C)						
TOC-FID	Total Organic Carbon - Flame Ionization Detector (e.g., SM5310C)						
TOC-IR	Total Organic Carbon - Nondispersive Infrared Detector (e.g., SM5310B)						
TOC-UV	Total Organic Carbon – UV						
TURB	Turbidity (e.g., EPA 180.1, SM2130B)						
TOX	Total Organic Halide (also Coulometric Titration with EPA 1650, 9020?)						
UV-VIS	Ultraviolet or Visible Molecular Absorption Spectrometry (e.g., EPA 420.1)						
XRF	X-Ray Fluorescence Spectrometry (e.g., EPA 6200, 9075)						
XRT	X-Ray Transmission Spectrometry						
Other	Other (SPECIFY:)						
CF-QL	Chromofluorogenic - Qualitative (e.g., SM9223B/P-A)						
CF-QN	Chromofluorogenic - Quantitative (e.g., COLISURE/MPN)						
C-QN	Chromogenic/MPN - Quantitative (e.g., SM9223B/MPN Tot. Coliform)						
C-QT-QN	Chromogenic/Quantitray (e.g., SM9223B/QUANTITRAY Tot. Coliform)						
FB-LE-QL	Fermentation Broth - Qualitative (e.g., SM9221B)						
FB-PAE-QL	Fermentation Broth(PA) - Qualitative (e.g., SM9221D)						
FB-PAF-QL	Fermentation Broth(PA)+Fluorogenic – Qualitative						
FB-F-QN	Fermentation Broth+Fluorogenic - Quantitative (e.g., SM9221F)						
FB-QN	Fermentation Broth - Quantitative (e.g., SM9221E, SM9230B)						
FB-A1-QN	Fermentation Broth(A-1) - Quantitative (e.g., SM9221E)						
FFIFV (IMSFA)	Filtration/FA/IMS/FA/Viability (e.g., EPA 1623)						
F-HPC-QN	Fluorogenic(HPC) - Quantitative (e.g., SimPlate)						
F-QN	Fluorogenic/MPN - Quantitative (e.g., SM9223B/QUANTITRAY E. coli)						

Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	BT	AE	Qualified Assessor(s)
F-QT-QN	Fluorogenic/Quantitray (e.g., Enterolert)						
MF-QL	Membrane Filtration - Qualitative (e.g., SM9222B)						
MF-E-QL	Membrane Filtration+Fermentation Broth – Qualitative						
MF-QN	Membrane Filtration - Quantitative (e.g., SM9222D)						
MF-2S-QN	Membrane Filtration(2-Step) - Quantitative (e.g., SM9222C)						
MF-MEI-QN	Membrane Filtration(m-EI) - Quantitative (e.g., EPA 1600)						
MF-F-QL	Membrane Filtration+Fluorogenic - Qualitative (e.g., NA+MUG)						
MF-F-QN	Membrane Filtration+Fluorogenic - Quantitative (e.g., EPA 1604)						
MF-MTEC-QN	Membrane Filtration(m-TEC) - Quantitative (e.g., EPA 1603)						
PQ-2S-QN	Plaque Counts(2-Step) - Quantitative (e.g., EPA 1601)						
PQ-SL-QN	Plaque Counts(Single Layer) - Quantitative (e.g., EPA 1602)						
PP-QN	Pour Plate - Quantitative (e.g., SM9215B)						
SP-QN	Spread Plate - Quantitative (e.g, SM9215C)						
BioTox	Toxicity Testing (Acute and Chronic)						
MF-E-QN	Membrane Filtration+Fermentation Broth - Quantitative (e.g., SM9230C)						
FB-F-QL	Fermentation Broth+Fluorogenic - Qualitative (e.g., EC+MUG)						

***add initials key at bottom of table**

DW = Drinking Water matrix
NPW = Non-Potable Water matrix
SCM = Solids and Chemical Materials matrix
BT = Biological Tissues matrix
AE = Air and Emissions matrix

ORDER OF ATTACHMENTS:

Attachment I - Experience Form
Attachment II - Evaluation Criteria
Attachment III - Cost Application
Attachment IV - Required Certifications
Attachment V - Standard Contract
Attachment VI - Subcontract Expenditure Report
Attachment VII - Applicant Certification Regarding Scrutinized Companies List
Attachment VIII- HIPAA Business Associate Agreement

ATTACHMENT I
EXPERIENCE FORM
DOH RFA 18-006

Applicant's Name: _____

Applicants are required to submit with the application, contact information for three entities it has provided with services similar to those requested in this RFA. The Department reserves the right to contact any and all entities to verify information provided. The Department's fitness determination is not subject to review or challenge.

1.) Name of Company/Agency: _____

Contact Person: _____

Phone Number: _____

Address: _____

Email Address: _____

2.) Name of Company/Agency: _____

Contact Person: _____

Phone Number: _____

Address: _____

Email Address: _____

3.) Name of Company/Agency: _____

Contact Person: _____

Phone Number: _____

Address: _____

Email Address: _____

_____
Signature of Authorized Representative

ATTACHMENT II
Evaluation Criteria
DOH RFA 18-006

This evaluation sheet will be used by the Evaluation Team to assign scores to applications that are designated as responsive. Scores of the Evaluation Team members will be averaged and ranked, from highest averaged score to lowest averaged score. Both the presence and quality of the response will be evaluated when determining point value.

Point Value: Zero is the lowest possible score, and the number indicated in this column is the highest possible. **A minimum score of 75 will be required to be an approved Provider under this solicitation, but regardless of the minimum score, at least one of the Applicant's assessors must meet the qualifications criteria in Questions 9, 12, and 13.**

Points Awarded: The total number of points given by the Evaluation Team member.

RFA Question Number	Question	Point Value Zero is lowest possible, and the number indicated in this column is the highest possible	Points Awarded Total number of points given by the Evaluation Team member
1.	To what extent does the Applicant's Standard Operating Procedures (SOPs) for conducting on-site laboratory assessments address compliance with the Task List in Section 5.4, the rules contained in Florida Administrative Code Chapter 64E-1, and the 2003 and 2016 NELAC standards adopted by reference therein?	0-10	
2.	To what extent does the Applicant's application encompass the various Fields of Accreditation for which laboratories are Department-certified in accordance with Sections 5.4 and 5.17?	0-10	
3.	To what degree does the application describe the Applicant's experience in performing laboratory assessments in accordance with national or international standards for environmental laboratories?	0-5	
4.	How well does the Applicant's application address its capability to assemble an assessment team in accordance with Section 5.4?	0-5	

5.	How well does the documentation submitted by the Applicant show the ability to conduct the pre-assessment as specified in Section 5.4?	0-10	
6.	How well do the sample on-site assessment reports provided by the Applicant demonstrate compliance with the content requirements of Sections 5.4 and 5.17?	0-10	
7.	How well does the Applicant review, evaluate, and respond to laboratory Corrective Action Plans as evidenced by the documentation provided as specified in Sections 2.4. and 5.4?	0-5	
8.	How well does the application document the Applicant's conformance to TNI Standard EL-V2M1-2009 and EL-V2M3-2009, Chapter III, Sections 6.1 and 6.2 of the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition?	0-5	
9.	How well does the documentation provided by the Applicant demonstrate that the assessors' qualifications conform to TNI Standard EL-V2M1-2009 and EL-V2M3-2009 and/or Chapter III, Sections 4.1 and 4.2 of the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition?	0-10	
10.	How well does the documentation provided by the Applicant demonstrate that the assessors possess the attributes listed in 3.4?	0-5	
11.	How well do the assessors' training and experience credentials demonstrate the ability to technically evaluate test methods for the Fields of Accreditation for which laboratories are Department-certified? (2.4,5.4, and 5.16)	0-5	
12.	How well does the documentation submitted by the Applicant show that assessors investigated within the past 7 years by any state or federal Inspectors General or other investigatory authorities where not used and identify whether the allegations were substantiated as specified in Section 2.4 and 5.4?	0-10	

13.	How well does the documentation submitted by the Applicant show unequivocally that each assessor is not or has not, within the past 2 years, been employed by or under contract to any laboratory certified by the Department as specified in Sections 2.4 and 5.4?	0-10	

Total Score: _____

Evaluator Name:_____Applicant Name: _____

Total possible points = 100.

COMMENTS:

Attachment III
Cost Application
DOH RFA 18-006

Costs for services rendered under this RFA will be paid by the laboratory seeking certification Responders will provide pricing information per laboratory assessment and corrective action review according to the following breakdown:

"Small" Laboratories: Laboratories certified for or seeking certification for Microbiology and/or one General Chemistry category, or for Toxicity (only).

"Intermediate" Laboratories: Laboratories that are generally larger than the "small" description noted above but have certification in 3 categories or less in each matrix category group (see FL Administrative Code Rule 64E-1.007). Usually, these will be laboratories certified or seeking certification for Microbiology, Metals, and General Chemistry, or laboratories certified for few categories but with test methods that involve sophisticated measurement instrumentation (e.g., ICP, GC, Proportional Counters).

"Full Service" Laboratories: Laboratories that are certified for 4 or more categories in any one matrix category group.

Initial Term 1-3 years

Laboratory Size (number of Matrix-Method combinations)	**Assessment Cost per Laboratory**	**Corrective Action Review Cost per Laboratory**	**Total Cost per Laboratory**
"Small"			
"Intermediate"			
"Full Service"			

Sub total _____

Renewal period (may be years 4-6)

Laboratory Size (number of Matrix-Method combinations)	**Assessment Cost per Laboratory**	**Corrective Action Review Cost per Laboratory**	**Total Cost per Laboratory**
"Small"			
"Intermediate"			
"Full Service"			

Sub total _____

Initial Term + Renewal Period = Total Cost_____

ATTACHMENT IV
REQUIRED CERTIFICATIONS

ACCEPTANCE OF TERMS, CONDITIONS, PROVISIONS AND SPECIFICATIONS

BY AFFIXING MY SIGNATURE ON THIS APPLICATION, I HEREBY STATE THAT I HAVE READ THE ENTIRE *RFA* TERMS, CONDITIONS, PROVISIONS AND SPECIFICATIONS. I hereby certify that my company, its employees, and its principals agree to abide to all of the terms, conditions, provisions and specifications during the competitive solicitation and contracting process (if applicable) including those contained in the attached Standard Contract (Attachment V). *

Signature of Authorized Official Date

STATEMENT OF NO INVOLVEMENT
CONFLICT OF INTEREST STATEMENT (NON-COLLUSION)

I hereby certify that my company, its employees, and its principals, had no involvement in performing a feasibility study of the implementation of the subject contract, in the drafting of this solicitation document, or in developing the subject program. Further, my company, its employees, and principals, engaged in no collusion in the development of the instant application or offer. This application or offer is made in good faith and there has been no violation of the provisions of Chapter 287, Florida Statutes, the Administrative Code Rules promulgated pursuant thereto, or any procurement policy of the Department of Health. I certify I have full authority to legally bind the Applicant or Offeror to the provisions of this application or offer.

Signature of Authorized Official Date

Date

*An authorized official is an officer of the vendor's organization who has legal authority to bind the organization to the provisions of the applications. This usually is the President, Chairman of the Board, or owner of the entity. A document establishing delegated authority must be included with the application if signed by other than the President, Chairman or owner.

ATTACHMENT V

STANDARD CONTRACT
STATE OF FLORIDA
DEPARTMENT OF HEALTH

Contract may be obtained from the following web site: http://www.floridahealth.gov/about-the-department-of-health/about-us/administrative-functions/purchasing/index.html.
Document not inserted here due to formatting, allow for 6 or 7 pages

ATTACHMENT VI

DEPARTMENT OF HEALTH REPORTING OF SUBCONTRACTOR EXPENDITURES

PRIME CONTRACTORS WILL REPORT ALL SUBCONTRACTING EXPENDITURES REGARDLESS OF VENDOR DESIGNATION (SEE PAGE 2 FOR TYPES OF DESIGNATIONS)

PLEASE COMPLETE AND REMIT THIS REPORT TO YOUR DOH CONTRACT MANAGER.

COMPANY NAME: _____

DEPARTMENT OF HEALTH CONTRACT NUMBER: _____

REPORTING PERIOD-FROM:_____ **TO:** _____

SUBCONTRACTOR'S/VENDORNAME & ADDRESS	FEID NO.	EXPENDITURE AMOUNT

NOTE: YOU MAY USE A SEPARATE SHEET

DOH USE ONLY - REPORTING ENTITY (DIVISION, OFFICE, CHD, ETC.):
PLEASE SUBMIT ALL SUBCONTRACT FORMS TO: MBE COORDINATOR, BUREAU OF GENERAL SERVICES, 4052 BALD CYPRESS WAY, STE. 310, TALLAHASSEE, FL. 32399-1734

1. DESIGNATIONS:

MINORITY PERSON as defined by Section 288.703 FS; means a lawful, permanent resident of Florida who is, one of the following:

(A) **AN AFRICAN AMERICAN**, a person having origins in any of the racial groups of the African Diaspora.
(B) **A HISPANIC AMERICAN**, a person of Spanish or Portuguese cultures with origins in Spain, Portugal, Mexico, South America, Central America or the Caribbean regardless of race.
(C) **AN ASIAN AMERICAN**, a person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands, including the Hawaiian Islands prior to 1778.
(D) **A NATIVE AMERICAN**, a person who has origins in any of the Indian Tribes of North America prior to 1835, upon presentation of proper documentation thereof as established by rule of the Department of Management Services
(E) **AN AMERICAN WOMAN**.

CERTIFIED MINORITY BUSINESS ENTERPRISE as defined by Section 288.703 FS, means a small business which is at least 51 percent owned and operated by a minority person(s), which has been certified by the certifying organization or jurisdiction in accordance with Section 287.0943(1).

SERVICE-DISABLED VETERAN BUSINESS ENTERPRISE: As defined by Section 295.187, FS, means an Independently owned and operated business that employees 200 or fewer permanent full-time employees; Is organized to engage in commercial transactions; Is domiciled in Florida; Is at least 51% owned by one or more service-disabled veterans; and, who's management and daily business operations of which are controlled by one or more service-disabled veterans or, for a service-disabled veteran with a permanent and total disability, by the spouse or permanent caregiver of the veteran.

CERTIFIED SERVICE-DISABLED VETERAN BUSINESS ENTERPRISE as defined by Section 295.187, FS means a business that has been certified by the Department of Management Services to be a service-disabled veteran business enterprise

SMALL BUSINESS means an independently owned and operated business concern that employs 100 or fewer permanent full-time employees and has a net worth of not more than $3,000,000 and an average net income, after federal income taxes, of not more than $2,000,000.

NON-CERTIFIED MINORITY BUSINESS means a small business which is at least 51 percent owned and operated by a minority person(s).

MINORITY NON-PROFIT ORGANIZATION means a not-for-profit organization that has at least 51 percent minority board of directors, at least 51 percent minority officers, or at least 51 percent minority community served.

II. INSTRUCTIONS TO PRIME CONTRACTORS:

A) ENTER THE COMPANY NAME AS IT APPEARS ON YOUR DOH CONTRACT.

B) ENTER THE DOH CONTRACT NUMBER.

C) ENTER THE TIME PERIOD THAT YOUR CURRENT INVOICE COVERS.

D) ENTER THE CMBE SUBCONTRACTOR'S NAME and ADDRESS.

E) ENTER THE SUBCONTRACTOR'S FEDERAL EMPLOYMENT IDENTIFICATION NUMBER. THE SUBCONTRACTOR CAN PROVIDE YOU WITH THIS NUMBER

F) ENTER THE AMOUNT EXPENDED WITH THE SUBCONTRACTOR FOR THE TIME PERIOD COVERED BY THE INVOICE.

G) ENCLOSE THIS FORM AND SEND TO YOUR DOH CONTRACT MANAGER

ATTACHMENT VII
APPLICANT CERTIFICATION REGARDING SCRUTINIZED COMPANIES LIST

Applicant Name: _____

Applicant Mailing Address: _____

City-State-Zip: _____

Telephone Number: _____

Email Address: _____

Federal Employer Identification Number (FEID): _____

Section 287.135, Florida Statutes prohibits a company from bidding on, submitting a proposal for, or entering into or renewing a contract for goods or services of any amount if, at the time of contracting or renewal, the company is on the Scrutinized Companies that Boycott Israel List, created pursuant to section 215.4725, Florida Statutes, or is engaged in a boycott of Israel. Section 287.135, Florida Statutes, also prohibits a company from bidding on, submitting a proposal for, or entering into or renewing a contract for goods or services of $1,000,000 or more, that are on either the Scrutinized Companies with Activities in Sudan List or the Scrutinized Companies with Activities in the Iran Petroleum Energy Sector Lists which were created pursuant to section 215.473, Florida Statutes.

As the person authorized to sign on behalf of the Applicant, I hereby certify that the company identified above in the section entitled “Applicant Name” is not listed on either the Scrutinized Companies with Activities in Sudan List, the Scrutinized Companies with Activities in the Iran Petroleum Energy Sector List, or the Scrutinized Companies that Boycott Israel List. I further certify that the company is not engaged in a boycott of Israel. I understand that pursuant to section 287.135, Florida Statutes, the submission of a false certification may subject company to civil penalties, attorney’s fees, and/or costs.

Signature of Authorized Representative*: _____

Printed (Typed) Name and Title: _____

*An authorized representative is an officer of the Applicant’s organization who has legal authority to bind the organization to the provisions of the RFA. This usually is the President, Chairman of the Board, or owner of the entity. A document establishing delegated authority must be included with the Application if signed by other than the President, Chairman or owner.

ATTACHMENT VIII

HIPAA Business Associate Agreement

Combined HIPAA Privacy Business Associate Agreement and Confidentiality Agreement and HIPAA Security Rule Addendum and HI-TECH Act Compliance Agreement

This Agreement is entered into between the _____("Covered Entity"), and _____("Business Associate"). The parties have entered into this Agreement for the purpose of satisfying the Business Associate contract requirements in the regulations at 45 CFR 164.502(e) and 164.504(e), issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Security Rule, codified at 45 Code of Federal Regulations ("C.F.R.") Part 164, Subparts A and C; Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5 (Feb. 17, 2009) and related regulations.

1.0 Definitions

Terms used but not otherwise defined in this Agreement will have the same meaning as those terms in 45 CFR 160.103 and 164.501. Notwithstanding the above, "Covered Entity" will mean the State of Florida Department of Health. "Individual" will have the same meaning as the term "individual" in 45 CFR 164.501 and will include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g); "Secretary" will mean the Secretary of the U.S. Department of Health and Human Services or his designee; and "Privacy Rule" will mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

Part I: Privacy Provisions

2.0 Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or further disclose Protected Health Information ("PHI") other than as permitted or required by Sections 3.0 and 5.0 of this Agreement, or as required by Law.
(b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
(c) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
(d) Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.
(e) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
(f) Business Associate agrees to provide access, at the request of Covered Entity or an Individual, and in a prompt and reasonable manner consistent with the HIPAA regulations, to Protected Health Information in a designated record set, to the Covered

Entity or directly to an Individual in order to meet the requirements under 45 CFR 164.524.

(g) Business Associate agrees to make any Amendment(s) to Protected Health Information in a designated record set that the Covered Entity or an Individual directs or agrees to pursuant to 45 CFR 164.526, in a prompt and reasonable manner consistent with the HIPAA regulations.

(h) Business Associate agrees to make its internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity available to the Covered Entity, or at the request of the Covered Entity, to the Secretary in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

(i) Business Associate agrees to document disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(j) Business Associate agrees to provide to Covered Entity or an Individual an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528, in a prompt and reasonable manner consistent with the HIPAA regulations.

(k) Business Associate agrees to satisfy all applicable provisions of HIPAA standards for electronic transactions and code sets, also known as the Electronic Data Interchange (EDI) Standards, at 45 CFR Part 162 no later than October 16, 2003. Business Associate further agrees to ensure that any agent, including a subcontractor, that conducts standard transactions on its behalf, will comply with the EDI Standards.

(l) Business Associate agrees to determine the Minimum Necessary type and amount of PHI required to perform its services and will comply with 45 CFR 164.502(b) and 514(d).

3.0 Permitted or Required Uses and Disclosures by Business Associate General Use and Disclosure.

(a) Except as expressly permitted in writing by Department of Health, Business Associate may use Protected Health Information only to carry out the legal responsibilities of the Business Associate, but will not disclose information to any third party without the expressed written consent of the Covered Entity.

(b) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide data aggregation services to Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).

(c) Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j) (1).

4.0 Obligations of Covered Entity to Inform Business Associate of Covered Entity’s Privacy Practices, and any Authorization or Restrictions.

(a) Covered Entity will provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

(b) Covered Entity will provide Business Associate with any changes in, or revocation of, Authorization by Individual or his or her personal representative to use or disclose

Protected Health Information, if such changes affect Business Associate's uses or disclosures of Protected Health Information.

(c) Covered Entity will notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR 164.522, if such changes affect Business Associate's uses or disclosures of Protected Health Information.

5.0 Confidentiality under State Law.

(a) In addition to the HIPAA privacy requirements, Business Associate agrees to observe the confidentiality requirements of_____, Florida Statutes. (Program to supply applicable laws related to confidentiality)

(b) Receipt of a Subpoena. If Business Associate is served with subpoena requiring the production of Department of Health records or information, Business Associate will immediately contact the Department of Health, Office of the General Counsel, (850) 245-4005. A subpoena is an official summons issued by a court or an administrative tribunal, which requires the recipient to do one or more of the following:

1. Appear at a deposition to give sworn testimony, and may also require that certain records be brought to be examined as evidence.
2. Appear at a hearing or trial to give evidence as a witness, and may also require that certain records be brought to be examined as evidence.
3. Furnish certain records for examination, by mail or by hand-delivery.

(c) Employees and Agents. Business Associate acknowledges that the confidentiality requirements herein apply to all its employees, agents and representatives. Business Associate assumes responsibility and liability for any damages or claims, including state and federal administrative proceedings and sanctions, against Department of Health, including costs and attorneys' fees, resulting from the breach of the confidentiality requirements of this Agreement.

6.0 Permissible Requests by Covered Entity.

Covered Entity will not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

7.0 Term and Termination.

(a) Term.

The Term of this Agreement will be effective as of_____, and will terminate on_____. Prior to the termination of this Agreement, the Business Associate will destroy or return to the Covered Entity all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity. If it is infeasible or impossible to return or destroy Protected Health Information, the Business Associate will immediately inform the Covered Entity of that and the parties will cooperate in securing the destruction of Protected Health Information, or its return to the Covered Entity. Pending the destruction or return of the Protected Health Information to the Covered Entity, protections are extended to such information, in accordance with the termination provisions in this Section.

(b) Termination for Cause.

Without limiting any other termination rights the parties may have, upon Covered Entity's knowledge of a material breach by Business Associate of a provision under this Agreement, Covered Entity will provide an opportunity for Business Associate to cure the breach or end the violation. If the Agreement of Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, the Covered Entity will have the right to immediately terminate the Agreement. If neither termination nor cure is feasible, Covered Entity will report the violation to the Secretary.

(c) Effect of Termination.

1. Within sixty (60) days after termination of the Agreement for any reason, or within such other time period as mutually agreed upon in writing by the parties, Business Associate will return to Covered Entity or destroy all Protected Health Information maintained by Business Associate in any form and will retain no copies thereof. Business Associate also will recover, and will return or destroy with such time period, any Protected Health Information in the possession of its subcontractors or agents.
2. Within fifteen (15) days after termination of the Agreement for any reason, Business Associate will notify Covered Entity in writing as to whether Business Associate elects to return or destroy such Protected Health Information, or otherwise as set forth in this Section 4.4. If Business Associate elects to destroy such Protected Health Information, it will certify to Covered Entity in writing when and that such Protected Health Information has been destroyed. If any subcontractors or agents of the Business Associate elect to destroy the Protected Health Information, Business Associate will require such subcontractors or agents to certify to Business Associate and to Covered Entity in writing when such Protected Health Information has been destroyed. If it is not feasible for Business Associate to return or destroy any of said Protected Health Information, Business Associate will notify Covered Entity in writing that Business Associate has determined that it is not feasible to return or destroy the Protected Health Information and the specific reasons for such determination. Business
3. Associate further agrees to extend any and all protections, limitations, and restrictions set forth in this Agreement to Business Associate’s use or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses or disclosures to the purposes that make the return or destruction of the Protected Health Information not feasible.
4. If it is not feasible for Business Associate to obtain, from a subcontractor or agent, any Protected Health Information in the possession of the subcontractor or agent, Business Associate will provide a written explanation to Covered Entity and require the subcontractors and agents to agree to extend any and all protections, limitations, and restrictions set forth in this Agreement to the subcontractors’ or agents’ uses or disclosures of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses or disclosures to the purposes that make the return or destruction of the Protected Health Information not feasible.

Part II: Security Addendum

8.0 Security

WHEREAS, Business Associate and Department of Health agree to also address herein the applicable requirements of the Security Rule, codified at 45 Code of Federal Regulations ("C.F.R.") Part 164, Subparts A and C, issued pursuant to the Administrative Simplification provisions of Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA-AS"), so that the Covered Entity may meet compliance obligations under HIPAA-AS, the parties agree:

(a) Security of Electronic Protected Health Information.
Business Associate will develop, implement, maintain, and use administrative, technical, and physical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information (as defined in 45 C.F.R. § 160.103) that Business Associate creates, receives, maintains, or transmits on behalf of the Plans consistent with the Security Rule.

(b) Reporting Security Incidents.
1. Business Associate will report to Covered Entity within 24 hours of the discovery of any incident of which Business Associate becomes aware that is:
(a) a successful unauthorized access, use or disclosure of the Electronic Protected Health Information; or
(b) a successful major
(1) modification or destruction of the Electronic Protected Health Information or
(2) interference with system operations in an information system containing the Electronic Protected Health Information.

2. Upon the Department of Health's request, Business Associate will report any incident of which Business Associate becomes aware that is a successful minor
(a) modification or destruction of the Electronic Protected Health Information or
(b) interference with system operations in an information system containing the Electronic Protected Health Information.
(c) Compliance Date.
The parties to this Amendment will comply with Sections (a) through (c) of this Section 9 by the later of the (1) the last date set forth in the signature blocks below.
(d) Conflicts.
The provisions of this Section 9 will override and control any conflicting provision of this agreement.
(e) Corrective Action:
Business Associate agrees to take prompt corrective action and follow all provisions required in state and federal law to notify all individuals reasonably believed to be potentially affected by the breach.
(f) Cure:
Business Associate agrees to take prompt corrective action to cure any security deficiencies.

Part III

9.0 Miscellaneous

(a) Regulatory References. A reference in this Agreement to a section in the Privacy Rule or the Security Rule means the section as in effect or as amended, and for which compliance is required.

(b) Amendment. Upon the enactment of any law or regulation affecting the use or disclosure of Protected Health Information, Standard Transactions, the security of Health Information, or other aspects of HIPAA-AS applicable or the publication of any decision of a court of the United States or any state relating to any such law or the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, either party may, by written notice to the other party, amend this Agreement in such manner as such party determines necessary to comply with such law or regulation. If the other party disagrees with such Amendment, it will so notify the first party in writing within thirty (30) days of the notice. If the parties are unable to agree on an Amendment within thirty (30) days thereafter, then either of the parties may terminate the Agreement on thirty (30) days written notice to the other party.

(c) Survival. The respective rights and obligations of Business Associate under Section 7.0 of this Agreement will survive the termination of this Agreement.

(d) Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule and the confidentiality requirements of the State of Florida.

(e) No third party beneficiary. Nothing expressed or implied in this Agreement is intended to confer, nor will anything herein confer, upon any person other than the parties and the respective successors or assignees of the parties, any rights, remedies, obligations, or liabilities whatsoever.

(f) Governing Law. This Agreement will be governed by and construed in accordance with the laws of the state of Florida to the extent not preempted by the Privacy Rules or other applicable federal law.

(g) The laws of the State of Florida will apply to the interpretation of this Agreement or in case of any disagreement between the parties; the venue of any proceedings will be the appropriate federal or state court in Leon County, Florida.

(h) Indemnification and performance guarantees. Business Associate will indemnify, defend, and save harmless the State of Florida and Individuals covered for any financial loss as a result of claims brought by third parties and which are caused by the failure of Business Associate, its officers, directors or agents to comply with the terms of this Agreement.

(i) Assignment: Business Associate will not assign either its obligations or benefits under this Agreement without the expressed written consent of the Covered Entity, which will be at the sole discretion of the Covered Entity. Given the nature of this Agreement, neither subcontracting nor assignment by the Business Associate is anticipated and the use of those terms herein does not indicate that permission to assign or subcontract has been granted.

For: **DEPARTMENT OF HEALTH**

By: _____

Title: _____

Date: _____

_____

For: (Name of Business Associate)

By: _____

Title: _____

Date: _____

_____