FICTION STATE OF FLORIDA	
Division of Disease Control and Health Protection	
Bureau of Public Health Laboratories	
REQUEST FOR APPLICATION	
RFA # 24-002	
Environmental Laboratory Assessments	
Environmental Laboratory Certification Program Florida Department of Health <u>1217 Pearl Street</u> 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	

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.

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

TIMELINE		3
SECTION 1.0	GENERAL INSTRUCTIONS TO APPLICANTS (PUR1001), AS AMENDED.	4
SECTION 2.0	INTRODUCTORY MATERIALS	4
SECTION 3.0	TECHNICAL SPECIFICATIONS	6
SECTION 4.0	SPECIAL INSTRUCTIONS	8
SECTION 5.0	SPECIAL CONDITIONS1	1
SECTION 6.0	GENERAL CONTRACT CONDITIONS (PUR 1000), AS AMENDED1	5
ATTACHMENT	I EXPERIENCE FORM2	<u>29</u>
ATTACHMENT	II EVALUATION CRITERIA	30
ATTACHMENT	III COST APPLICATION	33
ATTACHMENT	IV REQUIRED CERTIFICATIONS	34
ATTACHMENT	V STANDARD CONTRACT	35
	VI DEPARTMENT OF HEALTH REPORTING OF SUBCONTRACTOR S4	10
ATTACHMENT	VII DIRECT ORDER TERMS AND CONDITIONS4	12
ATTACHMENT	VIII HIPAA BUSINESS ASSOCIATE AGREEMENT4	5

TIMELINE DOH RFA 24-002

EVENT	DUE DATE	LOCATION
RFA Advertised – Released	January 17, 2025	DOH Grant Opportunities: <u>https://www.floridahealth.gov/about/administrative-</u> <u>functions/purchasing/grant-funding-opportunities/index.html</u> Vendor Information Portal: <u>https://vendor.myfloridamarketplace.com</u>
Questions submitted in writing.	Prior to <u>5:00 PM EST</u> February 7, 2025	Submit to: Florida Department of Health Attention: <i>ELCP Program Administrator (vacant) and</i> <i>Susanne Crowe</i> DrPH, MHA, HCLD(ABB) Assistant Bureau Chief & Jacksonville Laboratory Director 1217 Pearl Street Jacksonville, FL 32202 Email: Susanne.crowe@flhealth.gov
Answers to Questions	February 14, 2025	Posted electronically via the following Internet sites: <u>https://www.floridahealth.gov/about/administrative-</u> <u>functions/purchasing/grant-funding-opportunities/index.html</u> <u>https://vendor.myfloridamarketplace.com</u>
Sealed Applications/ Replies Due and Opened	Must be received PRIOR to: 3:00 PM EST February 28, 2025	Submit to: Florida Department of Health Attention: <i>ELCP Program Administrator (vacant) and</i> <i>Susanne Crowe,</i> DrPH, MHA, HCLD(ABB) Assistant Bureau Chief & Jacksonville Laboratory Director 1217 Pearl Street Jacksonville, FL 32202
Anticipated Evaluation of Applications	Beginning March 3, 2025	Individual Evaluation of applications
Anticipated Posting of Intent to Award	March 28, 2025	DOH Grant Opportunities: <u>https://www.floridahealth.gov/about/administrative-</u> <u>functions/purchasing/grant-funding-opportunities/index.html</u> Vendor Information Portal: <u>https://vendor.myfloridamarketplace.com</u>

SECTION 1.0 GENERAL INSTRUCTIONS TO APPLICANTS (PUR 1001), as amended.

The General Instructions to Applicants are outlined in PUR 1001 which is a downloadable document incorporated in this Request for Applications (RFA) by reference. There is no need to return the PUR document with the RFA response. http://dms.myflorida.com/content/download/2934/11780

SECTION 2.0 INTRODUCTORY MATERIALS

2.1 Statement of Purpose

The purpose of this RFA is to solicit applications from parties with the ability to provide 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.

2.2 Term

The term of any contract resulting from this solicitation will be for three years, beginning on July 1, 2025 and ending on June 30, 2028.

2.3 Definitions

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.

Accreditation Body: Authoritative body that performs accreditation or certification of environmental testing laboratories. In the context of this RFA, the accreditation body is ELCP.

Accreditation Systems: A set of rules and processes related to an environmental testing laboratory conveying formal demonstration of its competence to carry out specific tasks associated with the conduct of the testing, to which the same requirements apply.

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: A 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 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 or held.

Assessment: A complete and detailed inspection that is conducted at the laboratory's premises where environmental testing takes place, pursuant to Florida Administrative Code Rule 64E-1.104.

Assessor Technologies Table: A tabular listing of matrices and technologies that an assessor is deemed qualified to conduct assessments for laboratory certification.

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

Application: An Applicant's entire submittal to this RFA, unless otherwise specified

Laboratory Application: Form DH 1762, "Application for Certification of Environmental Testing Laboratories," December 2016 adopted by reference in Rule 64E-1.102(1), Florida Administrative Code. Application form and Rule Chapter 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.

Client Laboratory: An environmental laboratory that is seeking certification for environmental testing analysis or is already certified for environmental testing analysis by the Department. These laboratories may be located in Florida and other states.

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

Environmental Laboratory Certification Program (ELCP): The office unit within the Department's Division of Disease Control and Health Protection, Bureau of Public health Laboratories that is responsible for environmental testing laboratory certification as authorized by the Florida Statutes.

ELCP Standard Operating Procedures: Task specific quality documents that describes ELCP procedures. The SOPs are provided by the Department.

Fields of Accreditation: Areas for which the Department offers certification and by which laboratories are certified.

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-(TCLP) 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 another device.

NELAC: National Environmental Laboratory Accreditation Conference – The organization that developed standards for the evaluation and accreditation of environmental testing laboratories prior to its reorganization as The NELAC Institute (TNI).

NELAP: National Environmental Laboratory Accreditation Program – A national program created by NELAC, and subsequently TNI, for the accreditation of environmental laboratories.

Oversight Assessment: An on-site assessment conducted by ELCP at Provider's workplace to review documentation and verify assessor activities throughout the contract term. The assessment also includes ELCP observations at client laboratories to verify assessors' performance during assessments.

Preliminary Preparations Procedures: Steps to be completed prior to an assessment, as specified in ELCP's SOP QA-006.

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

Program Administrator: A Department staff member within ELCP responsible for supervising laboratory certifications.

Scope of Accreditation: The specific list of sample matrices, test methods, and analytes that the laboratory is certified through ELCP, which is issued to the laboratory from ELCP concurrently with the "Environmental Testing Laboratory Certificate" referenced in Florida Administrative Code Rule 64E-1.105.

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.

Technologies: Specific laboratory analysis determinative procedures listed on Section 6.17 of this RFA.

The NELAC Institute (TNI) Standards: The consensus standards developed and established by The NELAC Institute for the evaluation and accreditation of environmental testing laboratories.

SECTION 3.0 TECHNICAL SPECIFICATIONS

3.1 Scope of Service

Providers will conduct periodic 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 a laboratory's application for initial or additional certification on Form DH1762, 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 assessment for that application, or to perform the laboratory's biannual assessment that is required by Florida law. When Provider notifies the Department of a pending inspection, the Department will forward the

laboratory's application information and the scope of certification to Provider for review and use in its assessment of the laboratory.

3.2 **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

3.3 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 assessing laboratory facilities, management, personnel, quality systems, and analytical activities at competitive rates that will be used by the laboratory facilities seeking certification.

3.4 Applicants will provide to the Department:

a. 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:

- 1. Be familiar with the relevant regulations, certification procedures, and certification requirements;
- 2. Have a thorough knowledge of the relevant assessment methods and assessment documents;
- 3. Be thoroughly familiar with the various forms of records (hardcopy and electronic) used by environmental laboratories;
- 4. Be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;
- 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;
- 6. Be able to communicate effectively, both orally and in writing;
- 7. Exhibit sound judgment and appropriate conduct when performing duties associated with any contract awarded through this solicitation; and
- 8. Sign a statement before conducting an assessment certifying that no conflict of interest exists and provide any supporting information as required by the Department. Failure to provide this information makes the proposed assessor ineligible to participate in the assessment.
- b. A proposed staffing plan for technical, administrative, and clerical support. The names, titles, roles, and responsibilities for all proposed Provider support personnel and assessors must be included with this application.

- c. 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.
- d. Copies of documentation of Provider'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.
- e. 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.

3.5 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.

3.6 **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:

- 1. Title Page
- 2. Attachment I Experience Form
- 3. Attachment III Required Certifications
- 4. Attachment IV- Cost Application

3.7 Evaluation of Application

Each application will be evaluated based on the criteria outlined in Attachment II. Applicants that have been awarded contracts from prior Requests for Application RFA 13-009, RFA 14-008, RFA 17-008, or RFA 18-006 will be evaluated based on the contract oversight reports that the Department has issued under programmatic monitoring, and the subsequent corrective actions that have been submitted to the Department. Evaluation sheets will be used for new Applicants that have not been awarded contracts under these prior RFAs, and they will be completed 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 on the evaluation sheet (average score from among all evaluators on the Evaluation Team) will be required for a new Applicant to be an approved provider under this RFA.

3.8 Description of Approach to Performing Task

a. 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 6.4. Applicants' technical approach will demonstrate a thorough understanding and insight into this project. At a minimum, this section should address:

- 1. A narrative of the methods of service delivery that will be initiated to fulfill all Department requirements.
- 2. Any activities that the Applicant is unable to provide.
- b. <u>Technical Requirements:</u> Applicants should demonstrate the ability to meet the criteria for knowledge and expertise in Section 3.9, as applied to the specifications indicated in the Section 6.4 Task List section.

3.9 Description of Staffing and Organizational Capacity

- a. The Respondent's application must also include:
 - 1. Documentation that Applicant has experience conducting laboratory assessments to determine compliance with the 2003 NELAC Standards and 2016 TNI NELAC standards adopted by reference into the rules contained in Florida Administrative Code Chapter 64E-1.
 - 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.
 - 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.

4.0 SPECIAL INSTRUCTIONS TO APPLICANTS

The following Special Instructions will take precedence over Section 1.0 General Instructions to Applicants PUR1001 unless a statutorily required provision in the PUR 1001 supersedes.

4.1 Instructions for Submitting Applications

- a. 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. *This Special Instruction takes precedence over General Instruction #3 in PUR1001.*
- b. 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.
- c. The Department is not responsible for any envelope that is not properly marked.
- d. 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.
- e. Late applications will not be accepted.

4.2 Instructions for Formatting Applications

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

- b. The application should be single-spaced and include:
 - 1. Table of Contents
 - 2. Index
 - 3. Appendices
 - 4. Experience
 - 5. Other support materials
- c. The pages should be numbered, and one-inch margins should be used.
- d. The font size and type are at the discretion of the Applicant but must be at least size 11 font.
- e. 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.

4.3 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.

4.4 Applicants' Inquiries

These instructions take precedence over General Instruction #5 in PUR1001.

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 will be posted on the DOH Grant Opportunities website:

https://www.floridahealth.gov/about/administrative-functions/purchasing/grant-funding-opportunities/index.html

and the Vendor Information Portal web site: <u>https://vendor.myfloridamarketplace.com</u>

All inquiries must be submitted to:

Florida Department of Health Environmental Laboratory Certification Program Attention: *ELCP Program Administrator (vacant) and Susanne Crowe DrPH, MHA, HCLD(ABB) Assistant Bureau Chief & Jacksonville Laboratory Director* 1217 Pearl Street Jacksonville, Florida 32202 Email: Susanne.crowe@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.

4.5 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).

4.6 Minority and Service-Disabled Veteran Business – Participation

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

https://www.dms.myflorida.com/business_operations/state_purchasing/office_of_supplier_divers_ ity_osd

for information on becoming a certified MWBE or SDVBE or for names of existing businesses that may be available for subcontracting or supplier opportunities.

4.7 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 VII) 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 Office of Supplier Development (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, <u>https://e-verify.uscis.gov/emp</u>, 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 5.0 SPECIAL CONDITIONS

The following Special Conditions will take precedence over Section 2.0 General Contract Conditions PUR 1000 unless a statutorily required provision in the PUR 1000 supersedes:

5.1 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.

5.2 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/mfmp v endors

Those lacking internet access may request assistance from the MyFloridaMarketPlace Customer Service at 866-352-3776 or from State Purchasing, 4050 Esplanade Way, Suite 360, Tallahassee, Florida 32399.

5.3 <Reserved>

5.4 Renewal

This Special Condition takes precedence over General Conditions #26 in PUR1000.

Contracts resulting from this solicitation may be renewed one time, 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.

5.5 Verbal Instructions Procedure

Applicant may not initiate or execute any negotiation, decision, or action arising from any verbal discussion with any State employee with regards to this RFA. 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 Respondent.

5.6 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 Information Portal, <u>https://vendor.myfloridamarketplace.com</u>. It is the responsibility of the Applicant to be aware of any addenda that might affect the submitted application.

5.7 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.

5.8 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.

5.9 Standard Contract and Purchase Order

Each Applicant will review and become familiar with the Department's Standard Contract, Memorandum of Agreement, 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 Memorandum of Agreement, Standard Contract or Purchase Order are non-negotiable. The terms and conditions of the Standard Contract (including Memorandum of Agreement) and Direct Order are Attachments V and VII.

Acknowledge acceptance on Required Certifications, Attachment IV.

5.10 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.

5.11 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 a Respondent 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.

5.12 Termination

This Invitation to Bid Special Condition takes precedence over General Condition #22 and #23 in PUR1000.

Termination will be in accordance with the Department's Standard Contract or Memorandum of Agreement, Attachment V, or the Department's Direct Order, Attachment VII.

5.13 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.

5.14 E-Verify

In accordance with Executive Order 11-116, "Provider agrees to utilize the U.S. Department of Homeland Security's E-Verify system, <u>https://e-verify.uscis.gov/emp</u>, 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."

5.15 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 <u>PFIA List of Prohibited Companies</u> 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.

5.16 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.

5.17 Preference to Florida Businesses

Section 287.084, Florida Statutes, is applicable to this RFA:

(1)(a) When an agency, university, college, school district, or other political subdivision of the state is required to make purchases of personal property through competitive solicitation and

the lowest responsible and responsive bid, application, or reply is by a vendor whose principal place of business is in a state or political subdivision thereof which grants a preference for the purchase of such personal property to a person whose principal place of business is in such state, then the agency, university, college, school district, or other political subdivision of this state will award a preference to the lowest responsible and responsive vendor having a principal place of business within this state, which preference is equal to the preference granted by the state or political subdivision thereof in which the lowest responsible and responsive vendor has its principal place of business. In a competitive solicitation in which the lowest bid is submitted by a vendor whose principal place of business is located outside the state and that state does not grant a preference in competitive solicitation to vendors having a principal place of business in that state, the preference to the lowest responsible and responsive vendor having a principal place of business in this state will be 5 percent.

- (b) Paragraph (a) does not apply to transportation projects for which federal aid funds are available.
- (c) As used in this section, the term "other political subdivision of this state" does not include counties or municipalities.
- (2) A vendor whose principal place of business is outside this state must accompany any written bid, application, or reply documents with a written opinion of an attorney at law licensed to practice law in that foreign state, as to the preferences, if any or none, granted by the law of that state to its own business entities whose principal places of business are in that foreign state in the letting of any or all public contracts.

(3)(a) A vendor whose principal place of business is in this state may not be precluded from being an authorized reseller of information technology commodities of a state contractor as long as the vendor demonstrates that it employs an internationally recognized quality management system, such as ISO 9001 or its equivalent, and provides a warranty on the information technology commodities which is, at a minimum, of equal scope and length as that of the contract.

(b) This subsection applies to any renewal of any state contract executed on or after July 1, 2012.

5.18 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: <u>https://flvendor.myfloridacfo.com/</u>

SECTION 6.0 GENERAL CONTRACT CONDITIONS (PUR 1000), as amended. http://dms.myflorida.com/content/download/2933/11777

6.1 Client General Description

The Department certifies 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 May 31, 2024. 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: 175

- b. Water and Wastewater: 125
- c. State: 11
- d. County Health Department: 6
- e. University: 7
- f. Federal: 6
- g. Other: 12
- h. Mobile labs (subset of the above types): 2

2. Approximate Breakdown by Matrix

- a. Drinking Water: 236
- b. Non-Potable Water: 279
- c. Solid and Chemical Materials: 140
- d. Biological Tissue: 21
- e. Air and Emissions: 26

3. Approximate Breakdown by Scientific Discipline

- a. Chemistry: 265
- b. Microbiology: 216
- c. Radiochemistry: 22
- d. Toxicity: 14
- e. Asbestos: 9
- f. Dioxin: 12
- g. Cryptosporidium / Giardia: 7
- h. Air and Emissions (only): 8

4. Approximate breakdown by relative size (scope of accreditation)

- a. Small (usually, Microbiology and/or 1 General Chemistry category): 142
- b. Intermediate (usually, Microbiology + Metals + General Chemistry): 120
- c. Full Service (4 or more categories of certification in any one matrix): 81

5. In-State vs. Out-of-State

- a. In-State: 210
- b. Out-of-State: 143

6.2 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.

6.3 Contract Limits Provider

Numbers indicated in section 6.1, the Client General Description, are provided for planning purposes only. The Department reserves the right to alter the number of laboratory certification applicants by any amount.

6.4 Task List

- 1. Providers will perform the tasks listed below:
 - a. Complete the NELAP assessor technologies table (Section 6.17 of this RFA) for each assessor, to indicate the specific matrices and technologies for which each assessor is qualified to conduct assessments on the Department's behalf.

Submit the completed assessor technologies table(s) to the Program Administrator upon contract execution.

b. Prepare all Standard Operating Procedures (SOP) and subsequent revisions, applicable to Provider's performance under this contract, and submit them to the Department's Environmental Laboratory Certification Program (ELCP) Program Administrator upon contract execution and upon any subsequent SOP revisions.

Perform all laboratory assessment activities under this contract in accordance with the SOP and its subsequent revisions.

Ensure that the SOP contents include, at a minimum, the following:

- (1) The applicable minimum content given in ELCP's SOP QA-006 "Conducting On-Site Laboratory Assessments", in the Preliminary Preparations, Procedures, and Results and Reports sections.
- (2) The requirements in ELCP's SOP QA-034 when Cryptosporidium and Giardia laboratories are assessed.
- c. Create and sign a written attestation indicating that none of Provider's employed or contracted assessors, who will perform services under 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 ELCP Program Administrator upon contract execution and by July 1 of each contract year.

d. Update the NELAP assessor technologies table(s) as necessary to include additional qualifications for its assessor(s) or to include additional assessors.

Collect all training course certifications that qualify the assessor for each additional technology and submit them to the ELCP Program Administrator prior to those assessors conducting an assessment.

Ensure no assessor is assigned to conduct any assessment for an additional technology until the Department approves the assessor for the additional technology.

Prepare an outline of the training course that includes all the following training course material elements and submit it to the Department for review and comment during oversight assessments by ELCP, 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 laboratory applications assigned to Provider by the Department to include in the upcoming assessment of a client laboratory.

Review the client laboratory's scope of accreditation provided by the Department for accredited and pending analytes and test methods, plus any previous assessment reports conducted by the Provider or provided by the Department, in order to determine the number of assessors needed and the time needed off-site and on-site at the client laboratory to conduct the assessment completely, to cover all pending and certified Fields of Accreditation.

Document the determination of assessment needs and make the documentation available to the Department as requested.

f. Evaluate and revise the previously determined assessment needs appropriately for any client laboratory applications assigned or submitted after the assessments have been scheduled.

Contact the ELCP Program Administrator to verify the eligibility of the laboratory's application for inclusion in the assessment.

Ensure that assessments for any additional certifications or accreditation systems conducted by Provider of a client laboratory do not compromise the assessment team composition or the number of workdays required to assess **all** of the laboratory's existing ELCP 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, at a minimum, 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. Notify the ELCP Program Administrator in writing or via email of the name and credentials or contact information of the lead assessor and assessment team, **at the same time the client laboratory is notified**.

i. Permit designated Department staff to observe any assessments performed and, if requested by the assessor(s) or by the client laboratory being observed, participate in the assessment.

The TNI NELAC Standards require the Department to monitor and observe each assessor on-site periodically, normally every 3 years, to determine that the assessor is performing competently or requires additional training. The Department reserves the right to not approve an assessor for any laboratory assessment until such monitoring has been performed and competency has been confirmed.

Ensure all observations and participation requests are conducted in a professional manner and do not disrupt laboratory activities.

If there are questions or concerns about oversight assessments, contact the ELCP Program Administrator or Susanne Crowe, DrPH, MHA, HCLD(ABB), Assistant Bureau Chief & Jacksonville Laboratory Director, to discuss further.

j. 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 the assessment and the client laboratory.

Provide any supporting information as required by the Department on any potential conflict of interest to the ELCP Program Administrator upon request.

Include all of Provider's current assessors and all client laboratories currently certified by ELCP, then submit the written statement to the Department with the Assessor Technology Table(s) upon contract execution.

Include the following conditions 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:
- (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; and,
- (3) Provider and its assessors agree to follow the rules of the ELCP in conducting assessments under this contract.
- Notify the ELCP Program Administrator 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 as 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.
- I. Schedule and coordinate an assessment with the client laboratory within 15 calendar days after receiving notification from the client laboratory that Provider has been selected to perform the assessment for compliance with the requirements of the client laboratory's certification.
- m. Notify the ELCP Program Administrator by email when an assessment is scheduled **at the same time that the client laboratory is notified**.

Notify the ELCP Program Administrator of any subsequent changes in the schedules and include a reason for the change.

Ensure that the assessment is scheduled and conducted with enough time to allow the assessor(s) to plan and conduct a comprehensive and complete assessment and enough time for ELCP to review any pending application(s). Provide a written explanation to the ELCP Program Administrator when the assessment is not possible in the time allotted and when the rescheduled assessment will be performed.

n. Submit an assessment plan for Department review for each upcoming assessment that delineates the assessment team including the team leader, and the assessment activities and timeframes (dates and person-days) to be performed off-site and on-site at the client laboratory's premises. Submit each plan to the Department after the assessment is scheduled but before the assessment takes place.

Submit for Department review any needed revisions to the assessment plan, such as when dates and assessors need to be changed or when new laboratory applications are to be included.

Maintain each assessment plan on file throughout the contract term.

The Department reserves the right not to accept any assessments for which the Department was not simultaneously notified of the assessment and which were not performed according to the Department-submitted assessment plan.

- o. In accordance with the assessment plan that was submitted to the Department, conduct assessments of client laboratories for the Fields of Accreditation on their scopes of certification and in their applications to determine compliance with the applicable provisions of Florida Administrative Code, Chapter 64E-1. Ensure each assessment is conducted, at a minimum, as follows:
 - (1) Assess all Fields of Accreditation for which the client laboratory seeks initial certification, continued certification, or recertification.
 - (2) Monitor and evaluate all elements of the test methods, the NELAC and The 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.
- p. Prepare an assessment report of each client laboratory as follows:
 - (1) Document all deficiencies discovered during the assessment and link by reference each of these deficiencies directly to the NELAC and TNI Standards as incorporated into Florida Administrative Code Rule 64E-1.
 - (2) Cite deficiencies for the client laboratory's failure to follow certified test method specifications and link the deficiency to the applicable NELAC and TNI Standard as well as to the applicable test method specifications.
 - (3) Use the form specified in Florida Administrative Code Rule 64E-1.104(5) for documenting the deficiencies in the assessment report.

- (4) 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.
- (5) Include all applicable elements listed in Section 6.16 of this RFA (Assessment Report Contents) in the assessment report.
- (6) Document and list in the report all Fields of Accreditation for which the client laboratory is certified or seeking certification and were not assessed during the assessment. Assessment reports for clients that are seeking certification must list (separately) Fields of Accreditation that were and were not assessed.
- (7) Issue the assessment reports to the client laboratories and simultaneously send electronic copies to the Department within 30 calendar days of the first day of the on-site portion of the assessment. Revise and re-issue assessment reports to the client and send simultaneous electronic copies to the Department, if assessment reports need revisions.
- q. Complete, if applicable, the Environmental Protection Agency (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." Submit a completed copy of the checklist to the Department for client laboratories testing for Cryptosporidium and Giardia, along with the assessment report.
- r. Submit to the Department all checklists and assessment notes gathered and completed during and after the assessment, within 30 calendar days after the issuance of the assessment report.

Provide any additional 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, attendance forms, correspondence, quality manuals, laboratory data, conflict of interest forms, and confidential business information forms.

- s. Instruct the client laboratory assessed to respond to Provider, 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. The assessor(s) that conducted the laboratory assessment must be included in the reviews of the corrective actions and final recommendations on laboratory certification status to the Department.

Prepare an itemized report of the recommendations (including recommendations for additional certification) 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 a written rationale for the rejection.

- u. Ensure Provider's assessors meet or exceed the requirements in TNI Standard EL-V2M1-2009 and EL- V2M3-2009 and, if assessing client laboratories certified in the Drinking Water matrix, Chapter III, Sections 4.1 and 4.2 of the US Environmental Protection Agency (EPA) Manual for Certification of Laboratories Analyzing Drinking Water, Fifth Edition, available at: http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two
- 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.
- Maintain records for each assessment sufficient to show that all items in task (o) above were covered during the assessment. Examples of records to be maintained by the Provider should include the following:

- Completed checklists based on TNI's Standards for proficiency testing, quality management systems, and the technical modules.

- Documentation that demonstrates laboratory competence for each pending and certified Field of Accreditation within the past year, as delineated by one or more of the following:

* Acceptable proficiency testing results for the analyte at a non-zero Assigned Value.

- * Evaluation or verification of the Limit of Detection for the analyte.
- * Evaluation or verification of the Limit of Quantitation for the analyte.
- * Initial or continuing Demonstration of Capability for the analyte.

* Acceptable quality control results for the analyte in control standards, sample matrix spikes, and/or matrix duplicates.

x. Within 6 months of the expiration date, notify each client laboratory of the Provider's upcoming contract expiration date, and not schedule any client laboratories for assessment after that date until this contract has been renewed or until a new contract has been executed in response to a future Request for Application (RFA).

6.5 Documentation: Provider will submit the following to the Department:

- 1. Submit to the Department the assessment plan for conducting the assessment of each client laboratory on the Department's behalf (and any subsequent changes needed), and conduct the assessment according to that plan.
- 2. Supply to the Department the checklists and assessment notes gathered and used during each laboratory assessment, within 30 calendar days after the assessment report has been issued, and supply to the Department any other materials gathered and used during the assessment within 7 business days of a request from the Department.
- 3. Submit an itemized report of recommendations to approve or disapprove the proposed corrective actions to the Department within 30 calendar days of receipt of the laboratory's Plans of Correction.
- 4. Issue assessment reports, including itemized deficiencies, to client laboratories within 30 calendar days of the first day of the on-site portion of the assessment, and send electronic copies simultaneously to the Department. Include all content specified in Section 6.16 in each report.

- 5. Submit to the Department, for each assessor to be used, the completed assessor technologies table in Section 6.17.
- 6. Submit to the Department all Standard Operating Procedures, Subcontractor agreements, and subsequent revisions to each, as applicable to the Provider's performance under this contract.
- 7. 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.
- 8. Submit to the Department all additions or changes to the assessor technologies tables, plus the training course materials used to justify the additions or changes.
- 9. Submit to the Department a written statement certifying that no conflicts of interest exist among the Provider, the Provider's assessors, and each laboratory to be assessed under this contract.
- 10. 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.
- 11. Notify the Department, at the same time as notifying the laboratory, the dates and the assessor(s) that the Provider has scheduled for the laboratory's on-site portion and any offsite portions of the assessment, inclusive of any changes in this scheduling or of any revisions needed to the assessment plan, prior to the on-site portion of the assessment taking place.
- 12. Notify the Department in writing and list all Fields of Accreditation, for which the laboratory is certified or seeking certification, that were not assessed during the assessment and whether the Provider has intentions of completing the assessment.

6.6 Staffing

Provider must maintain and identify the 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 staff must meet the same qualifications as assessors if they perform any portion of the laboratory assessment activities in on-site or off-site venues. The Department reserves the right to amend the minimum qualifications specified throughout this solicitation.

6.7 **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.

6.8 Conflict of Interest

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

6.9 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 and make adequate or acceptable its response, declare this agreement to be in default.

6.10 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.

6.11 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 assessment process that meets statutory and regulatory requirements.

MEASURES: a. Provider is expected to meet a target of 100% completion for the below tasks (outlined in detail in Section 6.5):

a. Submit to the Department the assessment plan for conducting the assessment of each client laboratory on the Department's behalf, before the assessment commences, and conduct the assessment according to that plan. Submit to the Department any changes needed to the assessment plan, prior to conducting the on-site portion of the assessment.

- 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 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 assessment expense fees.
- e. Submit to the Department, for each assessor to be used, the completed assessor technologies table in Section 6.17.
- f. Submit to the Department all contract agreements with subcontractors (if any), 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 and off-site portions of the assessment, inclusive of any changes in dates and assessor(s) used and the reason(s) for the change.
- I. Notify the Department in writing and list all Fields of Accreditation, for which the laboratory is certified or seeking certification, that were not assessed during the assessment.

1. Provider is expected to meet a target of 95% completion for the below tasks (outlined in detail in Section 6.5):

a. Assessment reports contain all applicable content requirements in Section 6.16.

- b. Issue assessment reports, including itemized deficiencies, to client laboratories within 30 calendar days of the first day of the on-site portion of the 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 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, the dates and the assessor(s) that Provider has scheduled for the laboratory's on-site portion and any off-site portions of the assessment. Similarly, notify the Department of any changes in this scheduling including the reason for the change.
- e. Supply to the Department all checklists and assessment notes gathered and used during each laboratory assessment.
- **OUTCOME:** Timely TNI NELAP and EPA-compliant laboratory assessments conducted in a cost-effective manner, with the regulatory oversight required by law.

6.12 **Provider Unique Activities**

Provider is solely and uniquely responsible for the satisfactory performance of the tasks described in Sections 6.4, 6.5, and 6.11. 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.

6.13 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 6.5. The support and assistance, or lack thereof, will not relieve Provider from full performance of contract requirements.

6.14 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.

6.15 Financial Specifications

1. <u>Funding Source:</u> 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.

 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 portion of the assessment.

6.16 Assessment Report Contents

- 1. Report Header The laboratory name, physical and mailing addresses, Florida certification number, names of the assessment team, assessment dates for the on-site portion of the assessment, and categories assessed.
- 2. Introduction A statement that the assessment was performed to determine the laboratory's compliance with Florida Administrative Code Chapter 64E-1.
- 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 assessment. Each deficiency must contain an appropriate citation to the NELAC and/or TNI Standard that was violated.
- 4. Technical Directors/Managers Lists the names and titles of the Laboratory Director, Technical Directors, QA Officer, supervisors, etc.
- 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 laboratory application addressed during the assessment. Include the application date(s) in which the laboratory requested certification of these Fields on Form DH1762. Laboratory 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 portion of the 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 shall 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.
- 6. Conclusions Includes recommendations regarding the laboratory's compliance with the provisions of Florida Administrative Code Chapter 64E-1.

6.17 Assessor's Technologies Table

Assessor: _____

Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	вт	AE	Qualified Assessor(s)
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 608.3, 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 625.1, 8270)						

Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	вт	AE	Qualified Assessor(s)
GC-MS-	reciniology Description (with test methods as examples)	Dvv	NPVV	SCIVI	Ы	AE	A5565501(5)
MS	Gas Chromatography - Tandem Mass Spectrometry						
	Gas Chromatography - Nitrogen/Phosphorus Detection						
GC-NPD	(e.g., EPA 607, 8070)						
	Gas Chromatography - Photoionization Detection (e.g.,						
GC-PID	EPA 602)						
	Atomic Absorption - Graphite Furnace Spectrometry (e.g.,						
GFAAS	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)						
	Atomic Absorption - Hydride Generation Spectrometry						
HGAAS	(e.g., SM3114B)					_	
HPLC- ELEC	High Performance Liquid Chromatography - Electrochemical (e.g., EPA 605)						
HPLC-	High Performance Liquid Chromatogarphy – Evaporative						
ELSC	Light Scattering Detector (e.g., Refractive Index)						
HPLC-	High Performance Liquid Chromatography -						
FLUOR	Ultraviolet/Visible Molecular Fluorescence						
	High Performance Liquid Chromatography - Infrared						
HPLC-IR	Molecular Absorption						
HPLC-	High Performance Liquid Chromatography - Mass						
PBMS HPLC-	Spectrometry-Particle Beam						
ESMS	High Performance Liquid Chromatography – Mass Spectrometry-Electrospray						
HPLC-	High Performance Liquid Chromatography - Mass						
TSMS	Spectrometry-Thermospray						
HPLC-	High Performance Liquid Chromatography - Tandem						
MS-MS	Mass Spectrometry						
	High Performance Liquid Chromatography -						
HPLC-UV	Ultraviolet/Visible Molecular Absorption						
HPLC-	High Performance Liquid Chromatography – Photodiode						
PDAUV	Array UV/VIS Ion Chromatography - Electroconductivity (e.g., EPA						
IC-COND	300.0, 314.0)						
	Ion Chromatography - Mass Spectrometry (e.g., EPA						
IC-MS	331.0)						
IC-MS-MS	Ion Chromatography - Tandem Mass Spectrometry						
IC-UV	Ion Chromatography - UV (e.g., EPA 7199, SM3500Cr C)						
	Atomic Emission - Inductively Coupled Plasma						
ICP-AES	Spectrometry (e.g., EPA 200.7, 6010)						
	Mass Spectrometry - Inductively Coupled Plasma (e.g.,	Í					
ICP-MS	EPA 200.8, 6020)						
ICP-MS-	Inductively Coupled Plasma – Mass Spectrometry with						
CRC	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)	1	1	l			

Task Kasa							Qualified
Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	BT	AE	Assessor(s)
PCM	Phase Contrast Microscopy (e.g., for Airborne Asbestos) Miscellaneous Physical Properties (e.g., EPA 1030, 9095,						
PHYS	SM2150B)						
PLM	Polarized Light Microscopy (e.g., for Bulk Asbestos)						
POL	Polarographic Probe						
PREP	Subsampling / Digestion / Distillation / Extraction						
SEM	Scanning Electron Microscopy						
ТЕМ	Transmission Electron Microscopy (e.g., EPA 100.1, 100.2)						
TITR	Titrimetry - Visual Indicator (SM4500CI- 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)						
тох	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)						
CALC	Calculations						
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) Fluorogenic/MPN - Quantitative (e.g.,						
F-QN	SM9223B/QUANTITRAY E. coli)						

							Qualified
Tech. Key	Technology Description (with test methods as examples)	DW	NPW	SCM	BT	AE	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-El) - 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)						

Certifications not offered for fields in Gray

*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 –	Direct Order Terms and Conditions
Attachment VIII-	HIPAA Business Associate Agreement

ATTACHMENT I EXPERIENCE FORM DOH RFA 24-002

Applicant's Name:

Applicants are required to submit with the application, contact information for three (3) 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 24-002

This evaluation sheet will be used by the Evaluation Team to assign scores to applications from Providers that have not previously been issued contracts under RFA 13-009, RFA 14-008, RFA 17-008, or RFA 18-006. 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.

Numbers in parentheses refer to the Section numbers in this RFA.

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 laboratory assessments address compliance with the Task List in Section 6.4, the rules contained in Florida Administrative Code Chapter 64E-1, and the 2003 and 2016 NELAC standards adopted by reference therein? (3.8, 6.4)	0-10	
2.	To what extent does the Applicant's application encompass the various Fields of Accreditation for which laboratories are Department-certified? (6.4, 6.17)	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? (3.4.1, 3.5, 3.8)	0-5	
4.	How well does the Applicant's application address its capability to assemble an assessment team consisting of a Lead Assessor and additional assessors in sufficient numbers for the size and scope of the laboratory to be assessed comprehensively and within a reasonable number of contiguous workdays? (6.4)	0-5	

5.	How well does the documentation submitted by the Applicant show that appropriate pre- assessment planning takes place, inclusive of reviewing laboratory certification applications provided by the Department, developing assessment plans, and allotting adequate numbers of person-days off-site and on-site at the client laboratory's premises to ensure comprehensive assessment for the entire scope of accreditation? (6.4)	0-10	
6.	How well do the sample assessment reports provided by the Applicant demonstrate compliance with the content requirements of Section 6.16 and issuance within 30 calendar days of the first date of the on-site portion of the assessment? (3.4.2, 6.4, 6.16)	0-10	
7.	How well does the Applicant review, evaluate, and respond to laboratory Corrective Action Plans as evidenced by the documentation provided? (3.4.3, 6.4)	0-5	
8.	How well does the application document the Applicant's conformance to TNI Standard EL- V2M1-2009 and EL-V2M3-2009 and/or Chapter III, Sections 6.1 and 6.2 of the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition? (3.4.1, 3.5, 3.9.2)	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? (3.4.1, 3.9.1, 3.9.2)	0-10	
10.	How well does the documentation provided by the Applicant demonstrate that the assessors possess the attributes listed in 3.4.1.a-h?	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? (3.9.1, 3.9.2, 6.4)	0-5	
12.	How well does the documentation submitted by the Applicant show unequivocally that assessors were not used when those assessors had been investigated within the past 7 years by any state or federal Inspectors General or other investi- gatory authorities and indicated whether the allegations were substantiated? (3.4.4, 6.4)	0-10	

the Applicant assessor is no	s the documentation submitted by show unequivocally that each of or has not been employed by or t to any laboratory certified by the (3.4.5, 6.4)	0-10	
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Sub Total:_____

14.	If the Applicant's place of business is not within the state of Florida, does the application include a written opinion of an attorney at law licensed	0 if the opinion is provided;	
	to practice law in the Applicant's state, as to the preferences, if any or none, granted by the law of that state to its own business entities whose principal places of business are in that foreign state in the letting of any or all public contracts? (5.17)	-10 if not included (points subtracted from the Sub Total)	

Total Score: _____

Evaluator Name: ______Applicant Name: _____

Total possible points = 100.

COMMENTS:

Attachment III Cost Application DOH RFA 24-002

Costs for services rendered under this RFA will be paid by the laboratory seeking certification. Applicants will provide estimated 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.

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"			

Initial Term 1-3 years

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 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 INCLUDING PUR 1000 AND PUR 1001. 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 (or Memorandum of Agreement) / Direct order. (Attachment V and Attachment VII). **

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.

** The terms and conditions contained in the Standard Contract or Direct order are nonnegotiable. If a vendor fails to certify their agreement with these terms and conditions and or abide by, their response will be deemed non-responsive

ATTACHMENT V

STANDARD CONTRACT STATE OF FLORIDA DEPARTMENT OF HEALTH

If the Standard Contract language is used as a result of this RFA, the Contract may be obtained from the Contracts Administration web site. Document not inserted here due to formatting, allow for 13 pages <u>http://floridahealth.gov/about/Administrative-functions/purchasing/Standard_Contract.pdf</u>

Because any contracts to be issued based on this RFA will be no-cost contracts (no cost to the State of Florida), a Memorandum of Agreement may be executed instead of the Standard Contract format. The Memorandum of Agreement will be similar to the text shown below:

MEMORANDUM OF AGREEMENT Between the Florida Department of Health and

This Memorandum of Agreement (agreement) is entered into between the ____ (Provider) and the Florida Department of Health (the Department), Division of Disease Control and Health Protection, located at 1217 N. Pearl Street, Jacksonville, FL 32202, jointly referred to as the "parties."

Whereas, the Department seeks to allow choice and availability for assessments of environmental testing laboratories to determine the laboratories' compliance with applicable laws and regulations, and

Whereas, Provider has been awarded a contract by the Department in accordance with and application submitted in response to RFA 24-002 Environmental Laboratory Assessments.

Therefore, in consideration of the mutual promises contained herein, the parties agree as follows:

- A. <u>Scope of the Agreement:</u> Provider will complete and update the National Environmental Laboratory Accreditation Program (NELAP) assessor technologies table for each assessor, manage assessor eligibility to provide services under this contract, and conduct laboratory assessments throughout the contract term. Provider will also provide assessment reports and schedules to the Department and the review and evaluation of laboratory corrective action plans for non-conformances identified and reported during the assessments.
- B. <u>Definition of Terms</u>:

<Definitions consistent with Section 3 of this RFA>

C. <u>Legal Authority</u>: Sections 403.0625, 403.863, and 403.8635, Florida Statutes; Florida Administrative Code Chapter 64E-1; and Title 40 Code of Federal Regulations Parts 141 and 142.

- D. <u>Term of Agreement</u>: This agreement is effective upon execution by both parties and will remain in full force and effect for a period of three years or until terminated in writing by either party, in accordance with Section G. The parties may mutually agree to renew the term of this Agreement once for up to three years.
- E. <u>Responsibilities of the Parties</u>:
 - 1. <u>Provider's Responsibilities</u>: Provider will perform the following:
 - a. Complete the NELAP assessor technologies table (Appendix B) for each assessor, to indicate the specific matrices and technologies for which each assessor is qualified to conduct assessments on the Department's behalf.

Submit the completed assessor technologies table(s) to the Program Administrator upon contract execution.

b. Prepare all Standard Operating Procedures (SOP) and subsequent revisions, applicable to Provider's performance under this contract, and submit them to the Department's Environmental Laboratory Certification Program (ELCP) Program Administrator upon contract execution and upon any subsequent SOP revisions.

Perform all laboratory assessment activities under this contract in accordance with the SOP and its subsequent revisions.

Ensure that the SOP contents include, at a minimum, the following:

- (1) The applicable minimum content given in ELCP's SOP QA-006 "Conducting On-Site Laboratory Assessments", in the Preliminary Preparations, Procedures, and Results and Reports sections.
- (2) The requirements in ELCP's SOP QA-034 when Cryptosporidium and Giardia laboratories are assessed.
- c. Create and sign a written attestation indicating that none of Provider's employed or contracted assessors, who will perform services under 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 ELCP Program Administrator upon contract execution and by July 1 of each contract year.

d. Update the NELAP assessor technologies table(s) as necessary to include additional qualifications for its assessor(s) or to include additional assessors.

Collect all training course certifications that qualify the assessor for each additional technology and submit them to the ELCP Program Administrator prior to those assessors conducting an assessment. Ensure no assessor is assigned to conduct any assessment for an additional technology until the Department approves the assessor for the additional technology.

Prepare an outline of the training course that includes all the following training course material elements and submit it to the Department for review and comment during oversight assessments by ELCP, 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 laboratory applications assigned to Provider by the Department to include in the upcoming assessment of a client laboratory.

Review the client laboratory's scope of accreditation provided by the Department for accredited and pending analytes and test methods, plus any previous assessment reports conducted by the Provider or provided by the Department, in order to determine the number of assessors needed and the time needed off-site and onsite at the client laboratory to conduct the assessment completely, to cover all pending and certified Fields of Accreditation.

Document the determination of assessment needs and make the documentation available to the Department as requested.

f. Evaluate and revise the previously determined assessment needs appropriately for any client laboratory applications assigned or submitted after the assessments have been scheduled.

Contact the ELCP Program Administrator to verify the eligibility of the laboratory's application for inclusion in the assessment.

Ensure that assessments for any additional certifications or accreditation systems conducted by Provider of a client laboratory do not compromise the assessment team composition or the number of workdays required to assess the laboratory's existing ELCP 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, at a minimum, 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. Notify the ELCP Program Administrator in writing or via email of the name and credentials or contact information of the lead assessor and assessment team **at the same time the client laboratory is notified**.
- i. Permit designated Department staff to observe any assessments performed and, if requested by the assessor(s) or by the client laboratory being observed, participate in the assessment.

The TNI NELAC Standards require the Department to monitor and observe each assessor on-site periodically, normally every 3 years, to determine that the assessor is performing competently or requires additional training. The Department reserves the right to not approve an assessor for any laboratory assessment until such monitoring has been performed and competency has been confirmed.

Ensure all observations and participation requests are conducted in a professional manner and do not disrupt laboratory activities.

If there are questions or concerns about oversight assessments, contact the ELCP Program Administrator or Susanne Crowe, DrPH, MHA, HCLD(ABB), Assistant Bureau Chief & Jacksonville Laboratory Director, to discuss further.

j. 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 the assessment and the client laboratory.

Provide any supporting information as required by the Department on any potential conflict of interest to the ELCP Program Administrator upon request.

Include all of Provider's current assessors and all client laboratories currently certified by ELCP, then submit the written statement to the Department with the Assessor Technology Table(s) upon contract execution.

Include the following conditions in the written statement:

- 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;
- (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; and,
- (3) Provider and its assessors agree to follow the rules of the ELCP in conducting assessments under this contract.
- k. Notify the ELCP Program Administrator 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 as 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.
- I. Schedule and coordinate an assessment with the client laboratory within 15 calendar days after receiving notification from the client laboratory that Provider has been selected to perform the assessment for compliance with the requirements of the client laboratory's certification.
- m. Notify the ELCP Program Administrator by email when an assessment is scheduled at the same time that the client laboratory is notified.

Notify the ELCP Program Administrator of any subsequent changes in the schedules and include a reason for the change.

Ensure that the assessment is scheduled and conducted with enough time to allow the assessor(s) to plan and conduct a comprehensive and complete assessment and enough time for ELCP to review any pending laboratory application(s). Provide a written explanation to the ELCP Program Administrator when the assessment is not possible in the time allotted and when the rescheduled assessment will be performed.

n. Submit an assessment plan for Department review for each upcoming assessment that delineates the assessment team including the team leader, and the assessment activities and timeframes (dates and person-days) to be performed off-site and

on-site at the client laboratory's premises. Submit each plan to the Department after the assessment is scheduled but before the on-site portion of the assessment takes place.

Submit for Department review any needed revisions to the assessment plan, such as when dates and assessors need to be changed or when new laboratory applications are to be included.

Maintain each assessment plan on file throughout the contract term.

The Department reserves the right not to accept any assessments for which the Department was not simultaneously notified of the assessment and which were not performed according to the Department-submitted assessment plan.

- o. In accordance with the assessment plan that was submitted to the Department, conduct assessments of client laboratories for the Fields of Accreditation on their scopes of certification and in their applications to determine compliance with the applicable provisions of Florida Administrative Code, Chapter 64E-1. Ensure each assessment is conducted, at a minimum, as follows:
 - (1) Assess all Fields of Accreditation for which the client laboratory seeks initial certification, continued certification, or recertification.
 - (2) Monitor and evaluate all elements of the test methods, the NELAC and The 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.
- p. Prepare an assessment report of each client laboratory as follows:
 - (1) Document all deficiencies discovered during the assessment and link by reference each of these deficiencies directly to the NELAC and TNI Standards as incorporated into Florida Administrative Code Rule 64E-1.
 - (2) Cite deficiencies for the client laboratory's failure to follow certified test method specifications, and link the deficiency to the applicable NELAC and TNI Standard as well as to the applicable test method specifications.
 - (3) Use the form specified in Florida Administrative Code Rule 64E-1.104(5) for documenting the deficiencies in the assessment report.
 - (4) 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.
 - (5) Include all applicable elements listed in Appendix A (Assessment Report Contents) in the assessment report.

- (6) Document and list in the report all Fields of Accreditation for which the client laboratory is certified or seeking certification and were not assessed during the assessment. Assessment reports for clients that are seeking certification must list (separately) Fields of Accreditation that were and were not assessed.
- (7) Issue the assessment reports to the client laboratories and simultaneously send electronic copies to the Department within 30 calendar days of the first day of the on-site portion of the assessment. Revise and re-issue assessment reports to the client and send simultaneous electronic copies to the Department, if assessment reports need revisions.
- q. Complete, if applicable, the Environmental Protection Agency (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." Submit a completed copy of the checklist to the Department for client laboratories testing for Cryptosporidium and Giardia, along with the assessment report.
- r. Submit to the Department all checklists and assessment notes gathered and completed during and after the assessment, within 30 calendar days after the issuance of the assessment report.

Provide any additional 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, attendance forms, correspondence, quality manuals, laboratory data, conflict of interest forms, and confidential business information forms.

- s. Instruct the client laboratory assessed to respond to Provider, 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. The assessor(s) that conducted the laboratory assessment must be included in the reviews of the corrective actions and final recommendations on laboratory certification status to the Department.

Prepare an itemized report of the recommendations (including recommendations for additional certification) 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 a written rationale for the rejection.

- u. Ensure Provider's assessors meet or exceed the requirements in TNI Standard EL-V2M1-2009 and EL- V2M3-2009 and, if assessing client laboratories certified in the Drinking Water matrix, Chapter III, Sections 4.1 and 4.2 of the US Environmental Protection Agency (EPA) Manual for Certification of Laboratories Analyzing Drinking Water, Fifth Edition, available at: http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two
- 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.
- Maintain records for each assessment sufficient to show that all items in task (o) above were covered during the assessment. Examples of records to be maintained by the Provider should include the following:

- Completed checklists based on TNI's Standards for proficiency testing, quality management systems, and the technical modules.

- Documentation that demonstrates laboratory competence for each pending and certified Field of Accreditation within the past year, as delineated by one or more of the following:

* Acceptable proficiency testing results for the analyte at a non-zero Assigned Value.

* Evaluation or verification of the Limit of Detection for the analyte.

* Evaluation or verification of the Limit of Quantitation for the analyte.

- * Initial or continuing Demonstration of Capability for the analyte.
- * Acceptable quality control results for the analyte in control standards, sample matrix spikes, and/or matrix duplicates.
- x. Within 6 months of the expiration date, notify each client laboratory of the Provider's upcoming contract expiration date, and not schedule any client laboratories for assessment after that date until this contract has been renewed or until a new contract has been executed in response to a future Request for Application (RFA).
- 2. <u>Department's Responsibilities</u>: The Department will perform the following:
 - a. Provide ELCP SOP QA 006 "Conducting On-Site Laboratory Assessments" and SOP QA-034 "Conducting On-Site Assessments for Laboratories Certified or Seeking Certification for Cryptosporidium and Giardia in Water by Filtration/IMS/FA Utilizing EPA Methods 1623 or 1623.1 in Support of LT2 Monitoring" to Providers via email.
 - b. Email laboratory applications, key personnel information, and Scopes of Accreditation to Providers when applicable.
 - c. Determine and notify Provider of application eligibility.

- d. Provide Proficiency Test results for Fields of Testing included in a client laboratory's application.
- e. Review and approve Provider's assessment plans for each client laboratory, so that Provider's assessors may conduct the assessment according to that plan. Timely notify the Provider, nominally within 7 calendar days of submittal, if the proposed assessment plan will not be approved by the Department. Provide any amendments to the Provider's proposed or previously approved assessment plans if necessary.
- f. Notify Provider if the client laboratory is being scheduled passed the biennial assessment due date (two years after the first day that the previous biennial assessment was performed).
- g. During observation of assessments, if requested by the assessor(s) or by the client laboratory being observed, participate in the assessment. Following Provider's submission of assessment reports and after receiving applicable fees, update and issue Scopes of Accreditation and Certificates to client laboratories seeking additional certification.
- Conduct contract oversight activities of Provider to verify compliance with contract terms, including observation of Provider's assessors' on-site assessments at client laboratories and site visits at Provider's place of business.
- 3. <u>Both Parties' Responsibilities</u>:
 - a. Both parties must comply with all applicable administrative rules, and all applicable state and federal laws in the carrying out of their responsibilities under this agreement.
 - b. Communicate any known or suspected laboratory situation that might affect the public health and safety.
 - c. Ensure all observations and participation requests are conducted in a professional manner and do not disrupt laboratory activities.
- F. <u>Financial Obligations</u>:
 - 1. Both parties are responsible for their own costs associated with performing their respective responsibilities under the agreement.
 - 2. Provider will be compensated for assessment services by the client laboratories.
- G. <u>Special Provisions</u>:
 - 1. <u>Compliance with Applicable Laws</u>: If any provision of this agreement is held to be invalid under any applicable statute or rule of law, such provision, or portion thereof, is to that extent deemed to be omitted and the remaining provisions of this agreement will remain in full force and effect.

2. <u>Notice</u>: Any notices given by either party to the other party under this agreement will be in writing and sent either: by overnight courier, with a verified receipt; or by registered or certified United States Mail, postage prepaid. Notice will be deemed sufficiently given upon receipt at the following addresses:

If to Provider:

If to Department: The Florida Department of Health Environmental Laboratory Certification Program 1217 N. Pearl Street Jacksonville, Florida 32202

3. <u>Subcontractors</u>: Provider may enter into written subcontracts for performance of certain functions under this agreement, such as the client laboratory assessments, with prior written approval from the Department. Nothing contained herein or by virtue of delivery of services by the assessors on Provider's behalf shall create a relationship, contractual or otherwise, between the Department and the assessor.

4. <u>Records and Documentation</u>:

Public Records: Keep and maintain public records, as defined by a. Chapter 119, Florida Statutes that are required by the Department to perform the services required by the agreement. Upon request from the Department's custodian of public records, provide the Department with a copy of the requested public records or allow the records to be inspected or copied within a reasonable time at a cost that does not exceed that provided in Chapter 119, Florida Statutes, or as otherwise provided by law. Ensure that public records that are exempt or that are confidential and exempt from public record disclosure are not disclosed, except as authorized by law for the duration of the contract term and following completion of the agreement if Provider does not transfer the public records to the Department. Upon completion of the contract, transfer to the Department at no cost, all public records in possession of Provider or keep and maintain public records required by the Department to perform the contract services. If Provider transfers all public records to the Department upon completion of the agreement, Provider will destroy any duplicate public records that are exempt or confidential and exempt. If Provider keeps and maintains public records upon completion of the agreement, Provider will meet all applicable requirements for retaining public records and maintain those records for at least six (6) years after the completion, termination, or expiration of this agreement. All records stored electronically must be provided to the Department, upon request of the Department's custodian of public records, in a format that is compatible with the information technology systems of the Department. The Department may unilaterally terminate this agreement if Provider refuses to allow access to all public records made or maintained by Provider in conjunction with this agreement, unless the records are exempt

from section 24(a) of Article I of the State Constitution and section 119.07(1), Florida Statutes.

If the Provider has questions regarding the application of Chapter 119, Florida Statutes, to the Provider's duty to provide public records relating to this contract, contact the custodian of public records at (850)245-4005, PublicRecordsRequest@flhealth.gov or 4052 Bald Cypress Way, Bin A02, Tallahassee, FL 32399.

- b. <u>Information Security</u>: Maintain confidentiality of all data, files, and records including client records related to the services provided pursuant to this agreement and will comply with state and federal laws, including, but not limited to, sections 381.004, 384.29, 392.65, and 456.057, Florida Statutes.
- 5. <u>Disputes</u>: Florida law governs all matters arising out of or related to this agreement. In the event of a dispute, venue will lie in a state court of competent jurisdiction in Leon County, Florida.
- 6. <u>Termination at Will</u>: Any party may terminate this agreement at any time by giving the other party written notice at least 30 days prior to the intended termination date.
- 7. <u>Compliance with Applicable Laws</u>: If any provision of this agreement is held to be invalid under any applicable statute or rule of law, such provision, or portions thereof, are to that extent deemed to be omitted and the remaining provisions of this agreement will remain in full force and effect.
- 8. <u>Periodic Review</u>: To the extent applicable, the Parties will cooperate with the inspector general in any investigation, audit, inspection, review, or hearing pursuant to section 20.055(5), Florida Statutes.
- 9. <u>Waiver</u>: The failure of either party, in any respect, to exercise, or delay in exercising any right, power, or privilege provided for hereunder will not be deemed a waiver thereof; nor will any single or partial exercise of any such right, power or privilege preclude any other, or further exercise thereof, or the exercise of any other right, power, or privilege under this agreement. No party will be deemed to have waived a right, power, or privilege provided for hereunder, unless such waiver is made in writing, and signed by the party against whom such waiver is sought.
- 10. <u>Independent Contractors</u>: The parties hereto are independent contractors with respect to each other, and nothing contained herein will be construed to create the relationship of an employer-employee, joint venture, partnership, or association between the parties.
- 11. <u>Modification</u>: Neither this agreement, nor any provision hereof, may be amended or otherwise modified, except by a written instrument signed by all parties hereto.

- 12. <u>Renewal</u>: This Agreement may be renewed <u>once</u> for a period that may not exceed three years or the term of the original Agreement, whichever period is longer. Renewals must be in writing and subject to the same terms and conditions set forth in the initial Agreement.
- 13. <u>Confidentiality</u>: Where applicable, Provider will comply with the Health Insurance Portability Accountability Act as well as all regulations promulgated there under (45 CFR Parts 160 and 164).
- 14. <u>Entire Agreement</u>: This agreement, Provider's response to RFA 24-002, and RFA 24-002 Environmental Laboratory Assessments, embodies the entire agreement and understanding between the parties, on the subject hereof. In the event of any conflict among these documents, the order of precedence will be this agreement, Provider's response, and then the RFA 24-002.

In Witness hereof, the parties have caused this agreement to be executed by the following duly authorized officials:

Provider:	State of Florida, Department of Health
Ву:	Ву:
Date:	Date:
FEID:	

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:

<u>MINORITY PERSON</u> as defined by <u>Section 288.703</u> 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) <u>A HISPANIC AMERICAN</u>, a person of Spanish or Portuguese cultures with origins in Spain, Portugal, Mexico, South America, Central America or the Caribbean regardless of race.
- (C) <u>AN ASIAN AMERICAN</u>, 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) <u>A NATIVE AMERICAN</u>, 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.

<u>CERTIFIED MINORITY BUSINESS ENTERPRISE</u> as defined by <u>Section 288.703</u> 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 <u>Section 295.187</u>, 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.

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

<u>SMALL BUSINESS</u> means an independently owned and operated business concern that employs 100 or fewer permanent fulltime 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.

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

<u>MINORITY NON-PROFIT ORGANIZATION</u> 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

DIRECT ORDER TERMS AND CONDITIONS STATE OF FLORIDA, DEPARTMENT OF HEALTH (the "Department")

For good and valuable consideration, received and acknowledged sufficient, the parties agree to the following in addition to terms and conditions expressed in the MyFloridaMarketPlace (MFMP) direct order:

- 1. Provider is an independent contractor for all purposes hereof.
- 2. The laws of the State of Florida will govern this direct order and the venue for any legal actions arising herefrom is Leon County, Florida, unless issuer is a county health department, in which case, venue for any legal actions will be the issuing county.
- 3. Provider agrees to maintain appropriate insurance as required by law and the terms hereof.
- 4. Provider will comply, as required, with the Health Insurance Portability and Accountability Act (42 USC & 210, et seq.) and regulations promulgated thereunder (45 CFR Parts 160, 162 and 164).
- 5. Provider will maintain confidentiality of all data, files, and records related to the services/commodities provided pursuant to this direct order and will comply with all state and federal laws, including, but not limited to Sections 381.004, 384.29, 392.65 and 456.057, F.S. Provider's confidentiality procedures will be consistent with the most recent edition of the Department of Health Information Security Policies, Protocols, and Procedures. A copy of this policy will be made available upon request. Provider will also comply with any applicable professional standards of practice with respect to confidentiality of information.
- 6. Excluding Universities, Provider agrees to indemnify, defend, and hold the State of Florida, its officers, employees and agents harmless, to the full extent allowed by law, from all fines, claims, assessments, suits, judgments, or damages, consequential or otherwise, including court costs and attorneys' fees, arising out of any acts, actions, breaches, neglect or omissions of Provider, its employees and agents, related to this direct order, as well as for any determination arising out of or related to this direct order, that Provider or Provider's employees, agents, subcontractors, assignees or delegates are not independent contractors in relation to the Department. This direct order does not constitute a waiver of sovereign immunity or consent by the Department or the State of Florida or its subdivisions to suit by third parties in any matter arising herefrom.
- 7. Excluding Universities, all patents, copyrights, and trademarks arising, developed or created in the course or as a result hereof are Department property and nothing resulting from Provider's services or provided by the Department to Provider may be reproduced, distributed, licensed, sold or otherwise transferred without prior written permission of the Department. This paragraph does not apply to Department purchase of a license for Provider's intellectual property.

- 8. If this direct order is for personal services by Provider, at the discretion of the Department, Provider and its employees, or agents, as applicable, agree to provide fingerprints and be subject to a background screen conducted by the Florida Department of Law Enforcement and / or the Federal Bureau of Investigation. The cost of the background screen(s) will be borne by Provider. The Department, solely at its discretion, reserves the right to terminate this agreement if the background screen(s) reveal arrests or criminal convictions. Provider, its employees, or agents will have no right to challenge the Department's determination pursuant to this paragraph.
- 9. Unless otherwise prohibited by law, the Department, at its sole discretion, may require Provider to furnish, without additional cost to the Department, a performance bond or negotiable irrevocable letter of credit or other form of security for the satisfactory performance of work hereunder. The type of security and amount is solely within the discretion of the Department. Should the Department determine that a performance bond is needed to secure the agreement, it will notify potential Providers at the time of solicitation.
- 10. Section 287.57(17)(c), F.S., 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 agency for any other contracts dealing with that specific subject matter, and any firm in which such person has any interest is not eligible to receive such contract. However, this prohibition does not prevent a Provider who responds to a request for information from being eligible to contract with an agency."

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.

11. TERMINATION: This direct order agreement may be terminated by either party upon no less than thirty (30) calendar days notice, without cause, unless a lesser time is mutually agreed upon by both parties. Said notice will be delivered by certified mail, return receipt requested, or in person with proof of delivery.

In the event funds to finance this direct order agreement become unavailable, the Department may terminate the agreement upon no less than twenty-four hours' notice in writing to the provider. Said notice will be delivered by certified mail, return receipt requested, or in person with proof of delivery. The Department will be the final authority as to the availability of funds. Unless Provider's breach is waived by the Department in writing, the Department may, by written notice to Provider, terminate this direct order agreement upon no less than twenty-four hours' notice. Said notice will be delivered by certified mail, return receipt requested, or in person with proof of delivery. If applicable, the Department may employ the default provisions in Florida Administrative Code Chapter 60A-1.006(4). Waiver of breach of any provisions of this contract will not be deemed to be a waiver of any other breach and will not be constructed to be a modification of

the terms of this agreement. The provisions herein do not limit the Department's right to remedies at law or to damages.

- 12. The terms of this direct order will supersede the terms of any and all prior or subsequent agreements you may have with the Department with respect to this purchase. Accordingly, in the event of any conflict, the terms of this direct order will govern.
- 13. In accordance with Executive Order 11-116, "The Provider agrees to utilize the U.S. Department of Homeland Security's E-Verify system, <u>https://e-verify.uscis.gov/emp</u>, to verify the employment eligibility of all <u>new employees</u> hired during the contract term by the Provider. The Provider will also include a requirement in subcontracts that the subcontractor will utilize the E-Verify system to verify the employment eligibility of all <u>new employees</u> 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."

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.
- 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 <u>Permitted or Required Uses and Disclosures by Business Associate General Use</u> <u>and Disclosure.</u>

- (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 Cwill 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 <u>Obligations of Covered Entity to Inform Business Associate of Covered Entity's</u> <u>Privacy Practices, and any Authorization or Restrictions.</u>

- (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 <u>Confidentiality under State Law</u>.

- (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 <u>Term and Termination.</u>

(a) <u>Term</u>.

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.
 - 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 Information, Business Associate Protected Health 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 <u>Security</u>

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) <u>Reporting Security Incidents</u>.
 - 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) <u>Conflicts</u>.

The provisions of this Section 9 will override and control any conflicting provision of this agreement.

(e) <u>Corrective Action</u>:

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) <u>Cure</u>:

Business Associate agrees to take prompt corrective action to cure any security deficiencies.

<u>Part III</u>

9.0 Miscellaneous

- (a) <u>Regulatory References</u>. 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) <u>Amendment</u>. 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) <u>Survival</u>. The respective rights and obligations of Business Associate under Section 7.0 of this Agreement will survive the termination of this Agreement.
- (d) <u>Interpretation</u>. 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) <u>No third party beneficiary</u>. 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) <u>Governing Law</u>. 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) <u>Indemnification and performance guarantees</u>. 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) <u>Assignment</u>: 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

Ву: _____

Title: _____

Date: _____

For: (Name of Business Associate)

By: _____

Title: _____

Date: _____

Approved as to form and legality:

_____ Office of the General Counsel

Date: _____