



State of New Hampshire
Department of Health and Human Services

REQUEST FOR APPLICATIONS

FOR

State of New Hampshire Clinical Laboratory Improvement
Amendments (CLIA) Laboratory Director

RFA-2024-DPHS-01-STATE

RELEASE DATE: March 8, 2023

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1. PURPOSE AND OVERVIEW

1.1. Introduction

The New Hampshire Department of Health and Human Services, Division of Public Health Services, Bureau of Laboratory Services (“Department”) is seeking responses to this Request for Applications (“solicitation” or “RFA”) from qualified Vendors to act as the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratory Director to provide management and direction for the clinical testing performed at the Department’s Public Health Laboratories.

Qualified Vendors must meet qualification requirements as a laboratory director as defined in the Federal Register 42 CFR Part 493.1443, satisfying at least one of the following:

- Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine, and licensed in New Hampshire; and be certified in clinical pathology or possess qualifications that are equivalent to those required for such certification; or
- Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and certified by a board approved by the Department of Health and Human Services.

The Department anticipates awarding one (1) contract for the services in this solicitation.

1.2. Key Information

The information in the table below is as anticipated by the Department. All information is subject to change, the availability of funds, and/or approval by the Governor and Executive Council.

Contract Effective Date	July 1, 2023	
Contract End Date	June 30, 2025	
Renewal Options	The Department may extend contracted services for up to four (4) additional years.	
Funding for the resulting contract is anticipated to be approximately:	\$70,000	
Funding Source	The Department anticipates using General funds for resulting contract	
	Assistance Listing #	N/A
	Award Name	N/A
Match Requirements	N/A	
Point of Contact	Christy Adamson, Contract Specialist Christy.d.adamson@dhhs.nh.gov 603-271-9540	
From the date of release of this solicitation until an award is made and announced regarding the selection of a Vendor, all communication with personnel employed by or under contract with the Department regarding this solicitation is prohibited unless first approved by the Point of Contact listed above. Department employees have been directed not to hold conferences and/or discussions concerning this solicitation with any potential contractor during the selection process,		

unless otherwise authorized by the Point of Contact. Vendors may be disqualified for violating this restriction on communications.

1.3. Procurement Timetable

All times are according to Eastern Time. The Department reserves the right to modify these dates and times at its sole discretion.		
Item	Action	Date
1.	Solicitation Released	3/8/2023
2.	Letter of Intent Submission Deadline (Optional)	3/14/2023
3.	Questions Submission Deadline	3/21/2023 12:00PM
4.	Department Response to Questions Published	3/28/2023
5.	Vendor Solicitation Response Due Date	4/4/2023 12:00PM

1.4. Background

1.4.1. New Hampshire Department of Health and Human Services, Division of Public Health Services, Bureau of Laboratory Services

The Public Health Laboratories (PHL) mission is to protect the public's health in New Hampshire through responsive, unbiased, quality laboratory testing; to actively participate in national and international surveillance networks; and to improve the quality of health and laboratory services in both the public and private sector. As such, the PHL performs high complexity testing on human specimens to detect and characterize biological agents and chemicals for diagnosis, surveillance, prevention and control of infectious diseases. The Centers for Medicare & Medicaid Services' (CMS) federal regulatory standard, title 42 CFR Part 493, Clinical Laboratory Improvement Amendments (CLIA) of 1988, applies to all U.S. facilities or sites that test clinical laboratory testing performed on human specimens for health assessment or to diagnose, prevent, or treat diseases. The PHL must have a CLIA laboratory director who meets the qualification requirements for high complexity clinical testing in accordance with § 493.1443, and provides management and direction for the clinical testing performed at the PHL.

1.4.2. Objective

The PHL is soliciting applications for a CLIA laboratory director in order to maintain compliance with the Centers for Medicare & Medicaid Services' federal regulatory standard, Federal Register 42 CFR Part 493, Clinical Laboratory Amendments of 1988 (CLIA), which applies to all clinical laboratory testing performed on humans in the United States. Even though the CLIA laboratory director has the option to delegate some of their responsibilities, they remain ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is the CLIA laboratory director's responsibility to ensure that the PHL develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.

2. STATEMENT OF WORK

2.1. Scope of Services

2.1.1. Scope of Work

- 2.1.1.1. The selected Vendor must oversee the overall operation and administration of the clinical Public Health Laboratories (PHL) testing related to CLIA regulations, § 493. The Vendor must:
 - 2.1.1.1.1. Ensure all contract duties are properly performed in accordance with CLIA regulations.
 - 2.1.1.1.2. Ensure the PHL develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.
 - 2.1.1.1.3. Ensure testing systems developed and used for each of the tests performed in the laboratory are of acceptable quality for all aspects of test performance, which includes, but is not limited to:
 - 2.1.1.1.3.1. The pre-analytic phase of testing;
 - 2.1.1.1.3.2. The analytic phase of testing; and
 - 2.1.1.1.3.3. The post-analytic phase of testing.
 - 2.1.1.1.4. Ensure that the physical plant and environmental conditions of the laboratory:
 - 2.1.1.1.4.1. Are appropriate for the testing performed; and
 - 2.1.1.1.4.2. Provide a safe environment in which employees are protected from physical, chemical, biological, and radiological hazards.
 - 2.1.1.1.5. Maintain the clinical consultant responsibilities for PHL as defined in § 493.1457 to ensure consultation services are available to PHL clients on matters relating to:
 - 2.1.1.1.5.1. The quality of the test results reported; and
 - 2.1.1.1.5.2. PHL client interpretation concerning specific patient condition.
- 2.1.1.2. The selected Vendor must ensure selected test methodologies are capable of providing quality results required for patient care. The Vendor must:

- 2.1.1.2.1. Ensure verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
 - 2.1.1.2.2. Ensure laboratory personnel perform the test methods required for accurate and reliable results;
 - 2.1.1.2.3. Ensure the PHL is enrolled in a US Department of Health and Human Services (HHS) approved proficiency-testing program for all testing performed;
 - 2.1.1.2.4. Ensure quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
 - 2.1.1.2.5. Ensure acceptable levels of analytical performance for each test system are established and maintained;
 - 2.1.1.2.6. Ensure necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; and
 - 2.1.1.2.7. Ensure test results reported include pertinent information required for interpretation of results.
- 2.1.1.3. The selected Vendor must ensure a sufficient number of laboratory personnel with the appropriate education and either experience or training are available to provide appropriate consultation as well as proper supervision to accurately perform tests and report test results, in accordance with the personnel responsibilities described in the CLIA regulations. The selected Vendor must:
- 2.1.1.3.1. Ensure personnel testing patients' specimens:
 - 2.1.1.3.1.1. Have the appropriate education and experience to perform the testing;
 - 2.1.1.3.1.2. Receive the appropriate training for the type and complexity of the services offered; and
 - 2.1.1.3.1.3. Have demonstrated the ability to perform all testing operations reliably to provide and report accurate results.
 - 2.1.1.3.2. Ensure policies and procedures are established for monitoring individuals who conduct pre-analytical,

analytical, and post-analytical phases of testing to ensure that they have and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

2.1.1.3.3. Ensure an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

2.1.1.3.4. Perform routine periodic PHL site visits to address requirements in the resulting contract. The selected Vendor must:

2.1.1.3.4.1. Attend a minimum of two meetings per year with the PHL Management Team;

2.1.1.3.4.2. Attend a minimum of one meeting per year with the PHL Staff;

2.1.1.3.4.3. Meet with the PHL Quality Manager on a monthly basis, with at least six meetings on site; and

2.1.1.3.4.4. Provide onsite, telephone or electronic consultation, as needed, or delegate qualified personnel specific responsibilities, as allowable in state and federal regulations.

2.1.1.3.5. Be available for consultation within 24 hours of notification of need.

2.1.1.3.6. Conduct CMS CLIA surveys every other year.

2.1.1.4. The selected Vendor must review and sign their acceptance of documents related to activities defined in subsection 2.1.1., within one month of the event occurring.

2.1.2. **Reporting**

2.1.2.1. The selected Vendor must submit quarterly reports to the PHL Quality Manager, which include, but are not limited to:

2.1.2.1.1. A summary of PHL's performance meeting CLIA regulations for clinical testing services, including activities defined in subsection 2.1.1.2.; and

2.1.2.1.2. A summary of the Vendor's participation in the meetings defined in subsection 2.1.1.3.4.

2.1.2.2. The selected Vendor may be required to provide other data and metrics to the Department in a format specified by the Department.

2.2. Mandatory Questions

2.2.1. In response to this solicitation, Vendor(s) must respond to the Mandatory Questions below in Appendix E, Technical Responses to Questions.

2.2.1.1. **Q1** – What is your ability to perform the entire scope of work in this solicitation, including any specialized trainings completed? Provide your licenses and certificates that satisfy § 493.1443 for laboratory director of high complexity testing.

2.2.1.2. **Q2** – What is your experience as a CLIA laboratory director?

2.2.1.3. **Q3** – What is your knowledge of the responsibilities involved in the overall operation and administration of high complexity clinical testing in a public health laboratory setting?

2.2.1.4. **Q4** – What is your experience with CLIA surveys? Describe how you administer surveys and how you approach responding to identified deficiencies.

2.3. Compensation & Contract Value

2.3.1. The Department anticipates utilizing General Funds for the resulting contract. The Department may choose to modify the source of funding contingent upon the availability of funds at the time of award.

2.3.2. Funding is anticipated to be available for the resulting contract as follows:

State Fiscal Year	Funding Amount
2024	\$35,000
2025	\$35,000
TOTAL	\$70,000

2.3.3. Funds are anticipated to be available in the State Fiscal Years identified above with the ability to adjust encumbrances between state fiscal years, if needed and justified.

2.3.4. Payment for services will be made on a quarterly basis based on the approved budgets, which will be included in the resulting contract.

2.3.5. The selected Vendor must submit quarterly invoices using a form satisfactory to the Department, which identifies and requests reimbursement for authorized expenses incurred. The selected Vendor must ensure invoices are completed, dated and submitted to the Department to initiate payment.

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3. SOLICITATION RESPONSE EVALUATION

3.1. The Department will evaluate responses from Vendors based upon the criteria and standards contained in this solicitation and by applying the points set forth below.

TECHNICAL RESPONSE	POSSIBLE SCORE
Ability to Direct Public Health Laboratories (Q1)	40 Points
CLIA Laboratory Director Experience (Q2)	40 Points
Knowledge of Clinical Testing in a Public Health Laboratory (Q3)	10 Points
Experience with CLIA surveys and deficiencies response (Q4)	10 Points
Technical Response – Total Possible Score	100 Points

MAXIMUM POSSIBLE SCORE	100 Points
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4. SOLICITATION RESPONSE PROCESS

4.1. Letter of Intent

- 4.1.1. A Letter of Intent to submit a Response to this solicitation is optional.
- 4.1.2. Receipt of the Letter of Intent by Department will be required to receive electronic notification of any solicitation amendments, in the event such are produced; any further materials on this project, including electronic files containing tables required for response to this solicitation; any addenda, corrections, or schedule modifications; notifications regarding any informational meetings for Vendors; or responses to comments or questions.
- 4.1.3. The Letter of Intent must be transmitted by email to the Contract Specialist identified in Subsection 1.2 and include the name, telephone number, mailing address and email address of the Vendor’s designated contact. **Notwithstanding the Letter of Intent, Vendors remain responsible for reviewing the most updated information related to this solicitation before submitting a response.**

4.2. Questions and Answers

4.2.1. Vendors’ Questions

- 4.2.1.1. All questions about this Solicitation including, but not limited to, requests for clarification, additional information or any changes to the Solicitation must be made in writing, by email only, citing the Solicitation page number and part or subpart, and submitted to the Contract Specialist identified in Subsection 1.2.
- 4.2.1.2. The Department may consolidate or paraphrase questions for efficiency and clarity. Questions that are not understood will not be answered. Statements that are not questions will not receive a response.

4.2.1.3. The questions must be submitted by email; however, the Department assumes no liability for ensuring accurate and complete email transmissions.

4.2.1.4. Questions must be received by the Department by the deadline given in Subsection 1.3, Procurement Timetable.

4.2.2. **Department Responses**

4.2.2.1. The Department intends to issue responses to properly submitted questions by the deadline specified in Subsection 1.3, Procurement Timetable. All oral answers given are non-binding. Written answers to questions received will be posted on the Department's website at (<https://www.dhhs.nh.gov/doing-business-dhhs/contracts-procurement-opportunities>). This date may be subject to change at the Department's discretion.

4.2.3. **Exceptions**

4.2.3.1. The Department will require the successful Vendor to execute a contract using the Form P-37, General Provisions and Standard Exhibits, which are attached as Appendix A. To the extent that a Vendor believes that exceptions to Appendix A will be necessary for the Vendor to enter into a Contract, the Vendor must note those issues during the Question Period in Subsection 1.3. Vendors may not request exceptions to the Scope of Services or any other sections of this Solicitation.

4.2.3.2. The Department will review requested exceptions and accept, reject or note that it is open to negotiation of the proposed exception at its sole discretion in its response to Vendor questions.

4.2.3.3. Any exceptions to the standard form contract and exhibits that are not raised by a Vendor during the Question Period may not be considered. In no event is a Vendor to submit its own standard contract terms and conditions as a replacement for the Department's terms in response to this Solicitation.

4.3. **Solicitation Amendment**

4.3.1. The Department reserves the right to amend this Solicitation by publishing any addenda, as it deems appropriate, prior to the Submission Deadline on its own initiative or in response to issues raised through Vendor questions. In the event that an addendum is published, the Department, at its sole discretion, may extend the Submission Deadline.

5. **SOLICITATION RESPONSE SUBMISSION INSTRUCTIONS**

5.1. Responses to this Solicitation must be submitted electronically via email to rfx@dhhs.nh.gov **AND** to the Contract Specialist at the email address specified in Subsection 1.2.

5.1.1. The subject line must include the following information:

RFA-2024-DPHS-01-STATE (email xx of xx).

- 5.2. The maximum size of file attachments per email is 10 MB. Submissions with file attachments exceeding 10 MB must be sent via multiple emails.
- 5.3. The Department must receive submissions by the time and date specified in the Procurement Timetable in Section 1.3 and in the manner specified or it may be rejected as non-compliant, unless waived by the Department as a non-material deviation.
- 5.4. The Department will conduct an initial screening step to verify Vendor compliance with the requirements of this Solicitation. The Department may waive or offer a limited opportunity for a Vendor to cure immaterial deviations from the Solicitation requirements if it is deemed to be in the best interest of the Department.
- 5.5. Late submissions that are not accepted will remain unopened. Disqualified submissions will be discarded. Submission of solicitation responses shall be at the Vendor's expense.

6. SOLICITATION RESPONSE REQUIREMENTS

- 6.1. Acceptable solicitation responses must offer all services identified in Section 2 - Statement of Work, unless an allowance for partial scope is specifically described in Section 2.

6.2. Technical Response Contents

Each Technical Response must contain the following, in the order described in this section:

- 6.2.1. **Appendix D – Transmittal Letter and Vendor Information**, including:

- 6.2.1.1. **Vendor Code Number** - Prior to executing any resulting contract(s), the selected Vendor(s) will be required to provide a vendor code number issued by the State of New Hampshire Department of Administrative Services upon registering as an authorized vendor with the State. Vendors are strongly encourage to provide a vendor code number in the Appendix D if available. More information can be found at: <https://das.nh.gov/purchasing/vendorresources.aspx>

- 6.2.2. **Appendix E – Vendor Technical Response to Mandatory Questions**

- 6.2.3. **Resumes** – Vendors must provide resumes for those key personnel who would be primarily responsible for meeting the terms and conditions of any agreement resulting from this Solicitation. Vendors must redact all personal information from resumes.

- 6.2.4. **Three (3) references for the Applicant** –The Applicant must submit three (3) written references from individuals or organizations who have knowledge of the Applicant's ability to deliver services applicable to this solicitation. A current Department employee will not be considered a valid reference. The Department may contact reference(s) at their discretion.

7. ADDITIONAL TERMS AND REQUIREMENTS

7.1. Non-Collusion

The Vendor's required signature on the Appendix D – Transmittal Letter and Vendor Information submitted in response to this Solicitation guarantees that the prices, terms and conditions, and services quoted have been established without collusion with other Vendors

and without effort to preclude the Department from obtaining the best possible competitive solicitation response.

7.2. Collaborative Solicitation Responses

Solicitation responses must be submitted by one organization. Any collaborating organization must be designated as a subcontractor subject to the terms of Appendix A, P-37 General Provisions and Standard Exhibits.

7.3. Validity of Solicitation Responses

Solicitation responses must be valid for one hundred and eighty (180) days following the deadline for submission in the Procurement Timetable above in Subsection 1.3, or until the Effective Date of any resulting contract, whichever is later.

7.4. Debarment

Vendors who are ineligible to bid on proposals, bids or quotes issued by the Department of Administrative Services, Division of Procurement and Support Services pursuant to the provisions of RSA 21-I:11-c shall not be considered eligible for an award under this solicitation.

7.5. Property of Department

Any material property submitted and received in response to this solicitation will become the property of the Department and will not be returned to the Vendor. The Department reserves the right to use any information presented in any solicitation response provided that its use does not violate any copyrights or other provisions of law.

7.6. Solicitation Response Withdrawal

Prior to the Response Submission Deadline specified in Subsection 1.3, Procurement Timetable, a submitted Letter of Intent or solicitation responses may be withdrawn by submitting a written request for its withdrawal to the Contract Specialist specified in Subsection 1.2.

7.7. Confidentiality

- 7.7.1. Pursuant to RSA 21-G:37, the content of responses to this solicitation must remain confidential until the Governor and Executive Council have awarded a contract. The Vendor's disclosure or distribution of the contents of its solicitation response, other than to the Department, will be grounds for disqualification at the Department's sole discretion.

7.8. Public Disclosure

- 7.8.1. The information submitted in response to this solicitation (including all materials submitted in connection with it, such as attachments, exhibits, addenda, and presentations), any resulting contract, and information provided during the contractual relationship may be subject to public disclosure under Right-to-Know laws, including RSA 91-A. In addition, in accordance with RSA 9-F:1, any contract entered into as a result of this solicitation will be made accessible to the public online via the New Hampshire Secretary of State website (<https://sos.nh.gov/>).
- 7.8.2. Confidential, commercial or financial information may be exempt from public disclosure under RSA 91-A:5, IV. If a Vendor believes any information submitted in response to this solicitation should be kept confidential, the Vendor

must specifically identify that information where it appears in the submission in a manner that draws attention to the designation and must mark/stamp each page of the materials that the Vendor claims must be exempt from disclosure as "CONFIDENTIAL." Vendors must also provide a letter to the person listed as the point of contact for this solicitation, identifying the specific page number and section of the information considered to be confidential, commercial or financial and providing the rationale for each designation. Marking or designating an entire submission, attachment or section as confidential shall neither be accepted nor honored by the Department. Vendors must also provide a separate copy of the full and complete document, fully redacting those portions and shall note on the applicable page or pages that the redacted portion or portions are "confidential."

- 7.8.3. Submissions which do not conform to these instructions by failing to include a redacted copy (if necessary), by failing to include a letter specifying the rationale for each redaction, by failing to designate the redactions in the manner required by these instructions, or by including redactions which are contrary to these instructions or operative law may be rejected by the Department as not conforming to the requirements of the solicitation.
- 7.8.4. Pricing, which includes but is not limited to, the administrative costs and other performance guarantees in responses or any subsequently awarded contract shall be subject to public disclosure regardless of whether it is marked as confidential.
- 7.8.5. Notwithstanding a Vendor's designations, the Department is obligated under the Right-to-Know law to conduct an independent analysis of the confidentiality of the information submitted in response to the solicitation. If a request is made to the Department to view or receive copies of any portion of the response that is marked confidential, the Department shall first assess what information it is obligated to release. The Department will then notify the Vendor that a request has been made, indicate what, if any, information the Department has assessed is confidential and will not be released, and specify the planned release date of the remaining portions of the response. To halt the release of information by the Department, a Vendor must initiate and provide to the Department, prior to the date specified in the notice, a court action in the Superior Court of the State of New Hampshire, at its sole expense, seeking to enjoin the release of the requested information.
- 7.8.6. By submitting a response to this solicitation, Vendors acknowledge and agree that:
- 7.8.7. The Department may disclose any and all portions of the response or related materials which are not marked as confidential and/or which have not been specifically explained in the letter to the person identified as the point of contact for this solicitation;
- 7.8.8. The Department is not obligated to comply with a Vendor's designations regarding confidentiality and must conduct an independent analysis to assess the confidentiality of the information submitted; and

- 7.8.9. The Department may, unless otherwise prohibited by court order, release the information on the date specified in the notice described above without any liability to a Vendor.

7.9. Electronic Posting of RFA Results and Resulting Contract

- 7.9.1. At the time of receipt of responses, the Department will post the number of responses received with no further information. No later than five (5) business days prior to submission of a contract to the Department of Administrative Services pursuant to this solicitation, the Department will post the name, rank or score of each responding Vendor. In the event that the resulting contract does not require Governor and Executive Council approval, the Agency will disclose the rank or score at least five (5) business days before final approval of the contract.
- 7.9.2. Pursuant to RSA 91-A and RSA 9-F:1, the Secretary of State will post to the public any document submitted to G&C for approval, including contracts resulting from this solicitation, and posts those documents on its website (<https://sos.nh.gov/administration/miscellaneous/governor-executive-council/>). By submitting a response to this solicitation, vendors acknowledge and agree that, in accordance with the above mentioned statutes and policies, (and regardless of whether any specific request is made to view any document relating to this solicitation), any contract resulting from this solicitation that is submitted to G&C for approval will be made accessible to the public online.

7.10. Non-Commitment

Notwithstanding any other provision of this solicitation, this solicitation does not commit the Department to award a contract. The Department reserves the right to reject any and all responses to this solicitation or any portions thereof, at any time and to cancel this solicitation and to solicit new solicitation responses under a new procurement process.

7.11. Liability

By submitting a response to this solicitation, the Vendor agrees that in no event shall the Department be either responsible for or held liable for any costs incurred by a Vendor in the preparation or submittal of or otherwise in connection with a solicitation response, or for work performed prior to the Effective Date of a resulting contract.

7.12. Request for Additional Information or Materials

The Department may request any Vendor to provide additional information or materials needed to clarify information presented in the solicitation response. Such a request will be issued in writing and will not provide a Vendor with an opportunity to change, extend, or otherwise amend its solicitation response in intent or substance.

7.13. Oral Presentations and Discussions

The Department reserves the right to require some or all Vendors to make oral presentations of their solicitation response. The purpose of the oral presentation is to clarify and expound upon information provided in the written solicitation response. Vendors are prohibited from altering the original substance of their solicitation response during the oral presentations. The Department will use the information gained from oral presentations to refine the technical

review scores. Any and all costs associated with an oral presentation shall be borne entirely by the Vendor.

7.14. Successful Vendor Notice and Contract Negotiations

If a Vendor is selected, the Department will send written notification of their selection and the Department's desire to enter into contract negotiations. Until the Department successfully completes negotiations with the selected Vendor, all submitted solicitation responses remain eligible for selection by the Department. In the event contract negotiations are unsuccessful with the selected Vendor, the evaluation team may recommend another Vendor. The Department will not contact Vendor(s) that are not initially selected to enter into contract negotiations.

7.15. Scope of Award and Contract Award Notice

- 7.15.1. The Department reserves the right to award a service, part of a service, group of services, or total solicitation response and to reject any and all solicitation responses in whole or in part. A contract award is contingent on approval by the Governor and Executive Council.
- 7.15.2. If a contract is awarded, the selected Vendor must obtain written consent from the State before any public announcement or news release is issued pertaining to any contract award.

7.16. Site Visits

The Department may, at its sole discretion, at any time prior to contract award, conduct a site visit at the Vendor's location or at any other location deemed appropriate by the Department, to determine the Vendor's capacity to satisfy the terms of this solicitation. The Department may also require the Vendor to produce additional documents, records, or materials relevant to determining the Vendor's capacity to satisfy the terms of this solicitation. Any and all costs associated with any site visit or requests for documents shall be borne entirely by the Vendor.

7.17. Protest of Intended Award

Any challenge of an award made or otherwise related to this solicitation shall be governed by RSA 21-G:37, and the procedures and terms of this solicitation. The procedure set forth in RSA 21-G:37, IV, shall be the sole remedy available to challenge any award resulting from this solicitation. In the event that any legal action is brought challenging this solicitation and selection process, outside of the review process identified in RSA 21-G:37, IV, and in the event that the State of New Hampshire prevails, the challenger agrees to pay all expenses of such action, including attorney's fees and costs at all stages of litigation.

7.18. Contingency

Aspects of the award may be contingent upon changes to state or federal laws and regulations.

7.19. Ethical Requirements

From the time this solicitation is published until a contract is awarded, no Vendor shall offer or give, directly or indirectly, any gift, expense reimbursement, or honorarium, as defined by RSA 15-B, to any elected official, public official, public employee, constitutional official, or family member of any such official or employee who will or has selected, evaluated, or awarded a solicitation, or similar submission. Any Vendor that violates RSA 21-G:38 shall be subject to prosecution for an offense under RSA 640:2. Any Vendor who has been convicted

of an offense based on conduct in violation of this section, which has not been annulled, or who is subject to a pending criminal charge for such an offense, shall be disqualified from submitting a response to this solicitation, or similar request for submission and every such Vendor shall be disqualified from submitting any solicitation response or similar request for submission issued by any state agency. A Vendor that was disqualified under this section because of a pending criminal charge which is subsequently dismissed, results in an acquittal, or is annulled, may notify the Department of Administrative Services, which shall note that information on the list maintained on the state's internal intranet system, except in the case of annulment, the information, shall be deleted from the list.

7.20. Liquidated Damages

The selected Vendor agrees that liquidated damages may be determined by the Department as part of the contract specifications, as failure to achieve required performance levels will more than likely substantially delay and disrupt the Department's operations.

8. COMPLIANCE

8.1. The selected Vendor must be in compliance with applicable federal and state laws, rules and regulations, and applicable policies and procedures adopted by the Department currently in effect, and as they may be adopted or amended during the contract period.

8.2. The selected Vendor may be required to participate in monitoring activities for the resulting contract(s), at the sole discretion of the Department, including, but not limited to:

- 8.2.1. Site visits.
- 8.2.2. File reviews.
- 8.2.3. Staff training.

8.3. Records

8.3.1. The selected Vendor must maintain the following records during the resulting contract term where appropriate and as prescribed by the Department:

- 8.3.1.1. Books, records, documents and other electronic or physical data evidencing and reflecting all costs and other expenses incurred by the selected Vendor(s) in the performance of the resulting contract(s), and all income received or collected by the selected Vendor(s).
- 8.3.1.2. All records must be maintained in accordance with accounting procedures and practices, which sufficiently and properly reflect all such costs and expenses, and which are acceptable to the Department, and to include, without limitation, all ledgers, books, records, and original evidence of costs such as purchase requisitions and orders, vouchers, requisitions for materials, inventories, valuations of in-kind contributions, labor time cards, payrolls, and other records requested or required by the Department.
- 8.3.1.3. Statistical, enrollment, attendance or visit records for each recipient of services, which shall include all records of application and eligibility (including all forms required to determine eligibility for each such recipient), records regarding the provision of services and all invoices submitted to the Department to obtain payment for such services.

- 8.3.2. During the term of the resulting contract(s) and the period for retention hereunder, the Department, the United States Department of Health and Human Services, and any of their designated representatives shall have access to all reports and records maintained pursuant to the resulting contract(s) for purposes of audit, examination, excerpts and transcripts. If, upon review of the Final Expenditure Report, the Department must disallow any expenses claimed by the selected Vendor(s) as costs hereunder, the Department shall retain the right, at its discretion, to deduct the amount of such expenses as are disallowed or to recover such sums from the selected Vendor(s).

8.4. Credits and Copyright Ownership

- 8.4.1. All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services of the resulting Contract(s) must include the following statement, "The preparation of this (report, document etc.) was financed under a Contract with the State of New Hampshire, Department of Health and Human Services, with funds provided in part by the State of New Hampshire and/or such other funding sources as were available or required, e.g., the United States Department of Health and Human Services."
- 8.4.2. All written, video and audio materials produced or purchased under the contract must have prior approval from the Department before printing, production, distribution or use.
- 8.4.3. The Department will retain copyright ownership for any and all original materials produced, including, but not limited to:
- 8.4.3.1. Brochures.
 - 8.4.3.2. Resource directories.
 - 8.4.3.3. Protocols.
 - 8.4.3.4. Guidelines.
 - 8.4.3.5. Posters.
 - 8.4.3.6. Reports.
- 8.4.4. The selected Vendor(s) must not reproduce any materials produced under the contract without prior written approval from the Department.

8.5. Confidential Data

- 8.5.1. The selected Vendor must meet all information security and privacy requirements as set by the Department and in accordance with the Department's Exhibit K, DHHS Information Security Requirements

8.6. State Owned Devices, Systems and Network Usage

- 8.6.1. If the selected Vendor's workforce is authorized by the Department's Information Security Office to use a Department issued device (e.g. computer, tablet, mobile telephone) or access the State network in the fulfilment of this Agreement, the selected Vendor must:

New Hampshire Department of Health and Human Services

State of New Hampshire Clinical Laboratory Improvement Amendments (CLIA)

Laboratory Director

- 8.6.1.1. Sign and abide by applicable Department and NH Department of Information Technology (DOIT) use agreements, policies, standards, procedures and/or guidelines;
- 8.6.1.2. Use the information solely for conducting official Department business;
- 8.6.1.3. Not access or attempt to access information in a manner inconsistent with the approved policies, procedures, and/or agreement relating to system entry/access;
- 8.6.1.4. Not copy, share, distribute, sub-license, modify, reverse engineer, rent, or sell software licensed, developed, or being evaluated by the state. At all times the selected Vendor(s) must use utmost care to protect and keep such software strictly confidential in accordance with the license or any other agreement executed by the state. Only equipment or software owned, licensed, or being evaluated by the State can be used by the selected Vendor. Non-standard software must not be installed on any equipment unless authorized by the Department's Information Security Office:
- 8.6.1.5. Agree that email and other electronic communication messages created, sent, and received on a state-issued email system are the property of the State of New Hampshire and to be used for business purposes only. Email is defined as "internal email systems" or "state-funded email systems." The selected Vendor(s) must understand and agree that use of email must follow Department and DOIT standard policies. When utilizing the Department's email system, the selected Vendor must:
 - 8.6.1.5.1. Include in the signature lines information identifying the contractor as a non-state employee; and
 - 8.6.1.5.2. Contain the following embedded confidentiality notice:

CONFIDENTIALITY NOTICE: "This message may contain information that is privileged and confidential and is intended only for the use of the individual(s) to whom it is addressed. If you receive this message in error, please notify the sender immediately and delete this electronic message and any attachments from your system. Thank you for your cooperation."
- 8.6.2. The State internet/Intranet is to be used for access to and distribution of information in direct support of the business of the State of New Hampshire according to policy. At no time should the State's internet be used for personal use or used by the selected Vendor(s) without written approval by the Department's Information Security Office.
- 8.6.3. All workforce members of the selected Vendor(s) or its subcontractors with a workspace in a Department building and/or facility must sign the Department's Business Use and Confidentiality Agreement upon execution of the agreement and annually until contract end.

8.7. Audit Requirements

- 8.7.1. The selected Vendor must email an annual audit to dhhs.act@dhhs.nh.gov if any of the following conditions exist:
 - 8.7.1.1. Condition A - The selected Vendor expended \$750,000 or more in federal funds received as a subrecipient pursuant to 2 CFR Part 200, during the most recently completed fiscal year.
 - 8.7.1.2. Condition B - The selected Vendor is subject to audit pursuant to the requirements of NH RSA 7:28, III-b, pertaining to charitable organizations receiving support of \$1,000,000 or more.
 - 8.7.1.3. Condition C - The selected Vendor is a public company and required by Security and Exchange Commission (SEC) regulations to submit an annual financial audit.
- 8.7.2. If Condition A exists, the selected Vendor(s) must submit an annual single audit performed by an independent Certified Public Accountant (CPA) to the Department within 120 days after the close of the Vendor's fiscal year, conducted in accordance with the requirements of 2 CFR Part 200, Subpart F of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal awards.
- 8.7.3. If Condition B or Condition C exists, the selected Vendor(s) must submit an annual financial audit performed by an independent CPA within 120 days after the close of the selected Vendor's fiscal year.
- 8.7.4. Any selected Vendor that receives an amount equal to or greater than \$250,000 from the Department during a single fiscal year, regardless of the funding source, may be required, at a minimum, to submit annual financial audits performed by an independent CPA if the Department's risk assessment determination indicates the Vendor is high-risk.
- 8.7.5. In addition to, and not in any way in limitation of obligations of the resulting Contract(s), it is understood and agreed by the selected Vendor(s) that the selected Vendor(s) shall be held liable for any state or federal audit exceptions and shall return to the Department all payments made under the resulting Contract(s) to which exception has been taken, or which have been disallowed because of such an exception.

9. APPENDICES TO THIS SOLICITATION

- 9.1. Appendix A – Form P-37 General Provisions and Standard Exhibits**
- 9.2. Appendix B – Not Used**
- 9.3. Appendix C – Not Used**
- 9.4. Appendix D – Transmittal Letter and Vendor Information**
- 9.5. Appendix E – Technical Response to Questions**