

**JUSTIFICATION AND APPROVAL FOR OTHER THAN FULL AND OPEN
COMPETITION
(41 U.S.C. 3304(a)(1))**

J&A No.: FY26-0213

Pursuant to the requirements of the Competition in Contracting Act (CICA) as implemented by the Federal Acquisition Regulation (FAR) 6.103 (FAR Class Deviation 25-11¹) and in accordance with the requirements of RFO 6.104, the justification for the use of the statutory authority under RFO 6.103 is justified by the following facts and rationale required under RFO 6.104-1 as follows:

1. Agency and Contracting Activity.

The Department of Homeland Security (DHS), Office of Procurement Operations (OPO), Department Operations Division III (DOAD III), in support of the Office of Health Security (OHS), proposes to enter into a contract on a basis other than full and open competition.

2. Nature and/or Description of the Action being Approved

(a) Nature of action.

DHS/OPO/DOAD III intends to procure subject matter expertise on a sole source basis in support of the OHS-led Integrated Consortium of Laboratory Network (ICLN) to strengthen operational and technical linkages between the ICLN, the ICLN's constituent federal laboratory networks, and state/local public health, environmental, food, agricultural, and veterinary laboratories.

(b) Name and address of the contractor.

Association of Public Health Laboratories (APHL)
7700 Wisconsin Avenue, Suite 1000
Bethesda, MD 20814

(c) Contract type.

The contract type is Firm-Fixed Price (FFP).

(d) Estimated total value (including options). Provide breakdown as shown below:

¹ In this document, citations to RFO Parts 6, 10, 15, 25 are citations specifically to FAR Class Deviation 25-11 for FAR Part 6, FAR Class Deviation 25-06 for FAR Part 10, FAR Class Deviation 26-08 R1 for FAR Part 15, and FAR Class Deviation 25-09 R1 for FAR Part 25, which were issued as part of the Revolutionary FAR Overhaul (RFO), implemented in response to Executive Order 14275, *Restoring Common Sense to Federal Procurement*, signed April 15, 2025.

Under this anticipated contract, the contractor shall provide the following ICLN program support and integration activities:

Network Integration and Technical Coordination

- Coordinate between the ICLN (federal) and the state, local, territorial, and university public health laboratories.
- Facilitate integration of relevant public health laboratories into ICLN activities (exercises, planning, incident response).
- Assist ICLN in identifying and coordinating state/local lab participants in annual ICLN tabletop exercises and live sample exercises.
- Provide analysis, data, and recommendations to support the Government's plans for public health laboratory surge capacity during large-scale events.
- Provide recommendations on where further coordination among federal partners and State/Local/Tribal/Territorial (SLTT) partners is needed.

Subject Matter Expertise (SME) and Participation in ICLN Subgroups

- Participate regularly (3-4 meetings per month)
 - ICLN Methods Subgroup (lab methods, standardization, gaps).
 - ICLN Laboratory Logistics Subgroup (supply chain and logistics challenges).
 - ICLN Internetwork Comparison and Quality Assurance Subgroup (quality systems, inter-lab comparisons).
 - ICLN Radiological Laboratory Subgroup (radiological laboratory capability and coordination).
- Provide input on standardized laboratory protocols, quality assurance measures, and best practices to promote comparability among ICLN networks.
- Provide SME on data standardization needed for internetwork and interlaboratory data sharing in outbreaks and wide-scale CBRN events.

Information Sharing, Training, and Communication

- Provide information on relevant national public health training, workshops, and initiatives relevant to ICLN's mission.
- Collaborate with ICLN to develop and deliver joint workshops to enhance laboratory preparedness and technical proficiency across the consortium (approximately annually).
- Participate in ICLN capability assessments to convey public health laboratory gaps and opportunities for improvement (approximately annually).
- Meet monthly with ICLN leadership to identify and manage areas of collaboration.

The services described above are intended to ensure that ICLN's federal-level coordination is fully informed by, and integrated with, the capabilities, gaps, and needs of the national public health laboratory system.

4. Identification of Statutory Authority Permitting Other Than Full and Open Competition.

The statutory authority permitting other than full and open competition is 41 U.S.C.

3304(a)(1), implemented by RFO Subpart 6.103-1, entitled “Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.”

This authority is used because market research determined that APHL can provide necessary network integration and coordination and subject matter expertise required by the DHS OHS, and no other vendor can satisfy all agency requirements. Based on the initial market research, a formal Notice of Intent to Sole Source (NOI) with APHL was published on SAM.gov on June 26, 2026, with a response deadline of July 7, 2026. This notice invited any interested parties to submit capability statements. The Notice of Intent to Sole Source resulted in zero (0) responses from any interested parties, supporting the determination that APHL is the only source capable of fulfilling the ICLN's technical and operational requirements.

5. Identification of Exception to the Buy American Statute.

Not Applicable.

6. Demonstration that the proposed contractor’s unique qualifications or the nature of the acquisition requires use of the authority cited.

(a) Rationale for using the authority cited in section 3 of the J&A.

The authority for this procurement is 41 U.S.C. 3304(a)(1), implemented by RFO Subpart 6.103-1, entitled “Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.” This authority is appropriate because market research has demonstrated that only APHL is the only source possessing the unique qualifications and capabilities necessary to fulfill DHS’s requirement for ICLN programmatic and integration support. No commercial consulting firm or other professional organization can provide this specialized support. As the national professional association representing state, local, and territorial public health laboratories, APHL is uniquely positioned because its member laboratories conduct frontline testing for infectious diseases, chemical and radiological events, and other public health threats that form the operational underpinnings of the ICLN mission.

(b) Details covering what events lead to the situation requiring use of other than full and open competition procedures including whether any portion of the work can be segregated to allow for competition.

APHL is the only source capable of satisfying these requirements due to its status as the sole national association representing state, territorial, and local public health laboratories. The scope of work under this requirement is highly integrated and cannot be segregated to allow for partial competition. Achieving ICLN's objectives requires a seamless, unified approach to coordinating scientific subgroups (methods, data-sharing, and logistics) and translating those standards directly into national emergency tabletop exercises and operational plans. Additionally, APHL routinely acts as the interface

between federal agencies that also participate in the ICLN (e.g., CDC, FDA, USDA, EPA) and state public health labs for training, exercises, method implementation, and quality initiatives. Attempting to segment or parcel out these tasks to multiple commercial vendors is not technically feasible and would introduce severe operational risks. Specifically, dividing the coordination of state and local laboratories from the execution of the federal ICLN exercises and operational planning would sever the direct, operational-level representation that APhL uniquely provides, resulting in fragmented communication, inconsistent laboratory standards, and systemic operational mission failures during a national CBRN response.

(c) Summarize alternatives considered and why they will not work.

To identify potential alternative sources capable of performing this highly integrated coordination work, DHS conducted active market research by publishing a formal NOI on SAM.gov under NAICS 541690 (Other Scientific and Technical Consulting Services) on June 26, 2026, for a period of 10 days.

The results of this public notice support the determination that there are no viable commercial alternatives to satisfy the ICLN requirement:

1. Zero Industry Responses: The NOI yielded zero (0) responses from commercial providers, consulting firms, or other technical contractors. This complete lack of market response objectively demonstrates that no commercial vendors that possess the pre-existing, inter-governmental linkages, scientific trust, or national laboratory network required to execute the mission are known to be available.
2. Inability of Other Professional Associations to Fulfill the Scope: While other specialized scientific or medical associations exist, none possess APhL's comprehensive, cross-cutting reach across all required matrices (human, food, environmental, and veterinary) and threat domains (biological, chemical, and radiological). Consequently, there are no alternative organizations that can provide the necessary integrated operational perspective across the State, Local, Tribal, and Territorial (SLTT) public health laboratory network.

Therefore, utilizing APhL as a sole source is the only viable alternative. It ensures ICLN's programmatic execution and inter-network coordination reflect on-the-ground realities, preventing a total lapse in technical integration or operational mission failures.

(d) Impact to the mission that would result if the J&A is not approved and, consequently, the product or service not provided.

If this requirement is not awarded to APhL, the ICLN Program Office would continue to lack a formal, structured mechanism to obtain timely, coordinated input from the national public health laboratory system. Additionally, ICLN exercises, and response plans would risk being federal-centric, without systematic inclusion of state/local laboratory

perspectives and surge capacity considerations, which is critical to understanding the full scope of response plans and capabilities. Any attempts to gather equivalent input by separately contacting individual laboratories would be fragmented, duplicative, slow, and unlikely to yield the same level of coordinated consensus or participation. This would hinder integrated response planning for large-scale chemical, biological, or radiological incidents, potentially delaying detection, response, and recovery efforts. In summary, APHL's unique institutional role, relationships, and integrated SME coverage across the state public health laboratory system make it the only responsible source that can satisfy the ICLN support requirements.

- (e) Rationale for use of the nonavailability exception to the Buy American statute, including detailed information explaining why the particular articles, materials, or supplies of the class or kind to be acquired, either as end items or components, are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality.

Not Applicable.

7. Description of Efforts Made to Ensure that Offers are Solicited from as Many Potential Sources as is Practicable.

The Contracting Officer posted a notice of intent to award a sole source contract to APHL at [SAM.gov](https://sam.gov) on June 26, 2026, inviting other organizations that believe they can fully meet the requirements to submit capability statements by July 7, 2026. However, no responses were received. Any response received would have been reviewed to determine if they could demonstrably provide the same level of national public health laboratory integration, SME coverage, and operational relationships.

8. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable.

The contracting officer determines that the anticipated price(s) will be fair and reasonable based on the following: Analysis of APHL's proposed labor categories, rates, and associated costs as outlined in the Independent Government Cost Estimate (IGCE) prepared by the ICLN Program Office, with historical costs for similar SME and coordination support; APHL's cost structure for similar technical support activities for other federal agencies; and standing that APHL's unique position reduces duplication of effort and transaction costs that would be incurred if DHS attempted to replicate or patch together APHL's capabilities through multiple organizations or direct agreements with numerous state laboratories.

9. Description of Market Research.

- a) Describe the market research techniques utilized, the specific results of the market research, the date when the market research was conducted, and how the market research was used by the contracting officer to determine price reasonableness.

Market research included internet review of professional organizations and networks that support laboratory systems in human, animal, food, plant, and environmental domains, across chemical, biological, and radiological/nuclear threats including:

- Association of Public Health Laboratories (APHL)
- American Society for Microbiology (ASM)
- American Association of Veterinary Laboratory Diagnosticians (AAVLD)
- International Association for Food Protection (IAFP)
- AOAC INTERNATIONAL
- American Phytopathological Society (APS)
- American Water Works Association (AWWA) and Water Environment Federation (WEF)

Market research also involved consultation with ICLN network representatives and other federal SMEs to identify organizations with significant relationships to state public health laboratories. The ICLN Program Office evaluated organizational missions, membership structures, and existing contractual or cooperative roles relevant to laboratory coordination and SME support.

- b) Describe the market research results that support the determination that the items are non-available.

APHL was identified as the only national association whose institutional membership consists of state, local, and territorial public health laboratories, with a mission explicitly focused on their operations, capacity, quality, and readiness.

Other identified organizations have important but narrower or different roles. As a few examples:

- American Society for Microbiology (ASM) is a professional society focused largely on individual microbiologists (academia, clinical, research). It does not serve as a primary institutional association for state public health laboratories, nor does it coordinate laboratory operations or surge capacity across states.
- AAVLD: veterinary diagnostic labs; relevant for animal health but not for the broader human public health laboratory system.
- IAFP, AOAC INTERNATIONAL, APS, WEF: domain-specific focus (food, analytical methods, plant health, water/wastewater) but not overarching coordination of state public health labs across all threat matrices.
- Council of State and Territorial Epidemiologists (CSTE) focuses on epidemiologists and surveillance; it does not represent laboratory directors or manage laboratory operations.
- National Association of County and City Health Officials (NACCHO) represent local health departments broadly; its focus is not the specialized management of public health laboratory technical operations.

No other organization combines national institutional membership of public health labs, cross cutting chem/bio/rad/nuc focus, ongoing operational coordination with federal agencies, and capacity/SME to support the specific recurring engagements required by the ICLN. The market research supports the conclusion that APHL is the only responsible source that can meet the ICLN Program Office's requirements for integrated public health laboratory SME support and coordination.

- c) If market research was not conducted, a reason for its absence must be cited here.

Not Applicable.

- d) If patents, copyrights, and/or intellectual property are applicable to the acquisition, describe the circumstances for acquiring a patented or copyrighted product on the representation of the intellectual property holder that has not been licensed for resale.

Not Applicable.

10. Any Other Facts Supporting the Use of Other Than Full and Open Competition.

- a) An explanation why technical data packages, specifications, statement of work, or purchase descriptions are not suitable for full and open competition.

The technical data packages, specifications, and statement of work for this requirement are tailored to DHS's unique operational needs. From a practical standpoint for the ICLN, this means that APHL can rapidly identify and coordinate appropriate public health laboratories for participation in ICLN exercises or incident support, because these labs are already members and engaged in APHL activities. Likewise, APHL's joint work with the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and other agencies on public health laboratory preparedness directly overlaps with ICLN's mission to integrate federal and SLTT laboratory networks. Other organizations may have academic or advisory relationships with labs, but they do not have the operational role APHL has in managing and coordinating the national public health laboratory system. These requirements are highly specialized and reflect mission-critical functions that cannot be met by generic or broadly available commercial products, as no other vendor possesses the necessary content, data integration, or operational capabilities.

- b) Discuss why your requirement cannot be modified to enhance competition.

The requirement cannot be modified to enhance competition without compromising essential features and operational effectiveness. Any attempt to relax or alter the specifications would result in a loss of critical functionality, introduce unacceptable risks, and undermine DHS's ability to maintain workforce health readiness and mission continuity. APHL has extensive institutional knowledge based on years of laboratory coordination, which cannot reasonably be replaced. Additionally, since this requirement is tied to specific state and local public health labs as a system, not individual SMEs,

splitting across multiple vendors would undermine the required integrated approach and increase administrative burdens.

- c) For a proposed contract subject to the restrictions of RFO 6.103-1 for follow-on acquisitions as described in 6.103-1(c)(2)(i), ***all Components*** must provide an estimate of the cost to the Government that would be duplicated and detailed information on how the estimate was derived.

Not applicable.

- d) For a proposed contract subject to the restrictions of RFO 6.103-2(c) or HSAR 3006.103-2(c)(70) (HSAR Class Deviation 25-01) and where RFO 6.103-2 is cited as the authority, describe the exceptional circumstances allowing for an award for a period of performance in excess of the one-year limitation (applicable to all federal agencies) or the DHS-specific statutory 150-day limitation.

Not Applicable.

11. A Listing of the Sources, if Any That Expressed, in Writing, an Interest in the Acquisition.

None

12. A Statement of the Actions, if Any, the Agency May Take to Remove or Overcome Any Barriers to Competition Before Any Subsequent Acquisition for Supplies or Services Required.

The ICLN Program Office will periodically assess the market to determine whether other entities have emerged to provide comparable national coordination capabilities. Currently, competition is limited based on APHL's unique role, as described above. This sole source action would meet ICLN mission-critical needs, while keeping open the possibility of more competitive approaches should the marketplace grow and evolve. This justification is not being issued for the purpose of acquiring services without a competitive procurement, but rather because extensive market research suggests that only one source is capable of providing these highly unique and specialized services that OHS requires. The marketplace will be monitored to determine if a more competitive approach is viable and warranted in the future.

- a) Will the Government revise overly technical specifications, acquire data rights, etc.?

Currently, no other organization combines institutional membership of public health laboratories with a mission explicitly centered on supporting those labs' technical operations, quality systems, and readiness that the OHS requires for the ICLN program. APHL has longstanding, operational relationships with state and local public health laboratories across all 50 states and territories, including existing communications channels, governance processes, and mutual workplans. APHL also has established roles in coordinating public

health laboratory responses to outbreaks and emergencies, including participation in federal-cooperative programs (e.g., those with CDC and other agencies). If in the future the requirements change, and specifications/expertise are able to be adapted for future competitive acquisitions among more industry partners, then OHS will support the evolving mission requirements and associated strategy.

b) When a J&A is issued for the purposes of acquiring goods or services while a competitive procurement is being conducted, the justification should include a detailed timeline for completion of the competitive procurement. The period of performance for the sole source action should fairly balance the time needed to complete the competitive procurement. The focus should be on minimizing the need for additional sole source awards.

Not Applicable.

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- 13. Contracting Officer's Certification.** I certify that the data supporting the recommended use of other than full and open competition is accurate and complete to the best of my knowledge and belief.

[Redacted Signature]

Contracting Officer

Date

- 14. Technical/Requirements Personnel Certification.** I certify this requirement meets the Government's minimum need and that the supporting data, which forms a basis for this justification, is complete and accurate.

[Redacted Signature]

Technical Representative

Date

APPROVAL:

[Redacted Signature]

Date

[Redacted Signature]