Template for Justification and Approval for Other Than Full and Open Competition

Completion Instructions: The Department of Health and Human Services (HHS) has established a standard template for the preparation of a J&A for Other Than Full and Open Competition. If this is an 8(a) set-aside, please note this form is not required unless the acquisition is valued (including all options) at greater than $22 million. This template is NOT applicable for actions using simplified acquisition procedures (FAR Subpart 13.5), Federal Supply Schedule orders (FAR 8.4), or task or delivery orders subject to fair opportunity (FAR 16.505).

Tailor all aspects of this template to the individual acquisition. Consult FAR Subpart 6.3 for guidance.

Delete the blue italic portions of this document prior to signature. Do not include these instructions in the final document or contract file.

JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

Acquisition Title:	Biorad Quality Control Material and Unity access for RLSU and CLSU
Agency:	IHS
Acquisition Year:	2026
Author:	Christine Woidyla

2. Description of Action:

Nature:	☒ New Requirement	☐ Follow-on Requirement	
	☐ Modification to Existing Purchase Order/Contract Number:		
Pricing:	☒ Firm-Fixed Price	☐ Time & Materials	☐ Cost
	☐ Other:		
Funds:	☐ OMA	☐ Other Funds:	

Name of Proposed Contractor(s):	Biorad Laboratories
Street Address:	5500 EAST SECOND STREET
City, State, Zip:	BENICIA, CA 94510

3. Description of Services or Supplies:

Basis for Approval (FAR 6.303-1(d)):	☐ Individual Basis	☐ Class Basis

The total estimated value of the proposed action, including all options is $ 193,795.33

As applicable, briefly describe the services or supplies required to meet the agency's needs, including make & model number where appropriate. Include quantities of supplies or period of performance for services. Provide information for any options included. If the action is a modification to an existing contract, distinguish clearly between the work covered by the basic order and the work to be obtained by the proposed modification.

The RLSU and CLSU has identified a need for suppliers of quality control material, as well as a quality control data manager. Allow the Red Lake Hospital and Cass Lake IHS Laboratories to accomplish a number of requirements including:

- Receive necessary standardized quality control material, matching testing menus at the RLSU and CLSU, to perform patient care and comply with CLIA and The Joint Commission
- Receive said supplies within a timely manner as not to disrupt patient care
- Ability to compare results of Quality Control to other laboratories worldwide, using the same equipment

• Ability to run fluidly, not having to compare an old lot of material to a new lot more often than once annually.

4. Authority and Rationale: Identify the statutory authority, FAR title and FAR citation permitting other than full and open competition. It may be one of the following most commonly used citations by the operating divisions of the Department of Health and Human Services (HHS), but other exceptions may apply per **FAR Subpart 6.3.**

Actions other than simplified acquisition procedures (select only one and provide an explanation):

☒ FAR 6.302-1: Only one responsible source and no other supplies or services will satisfy agency requirements, 41 U.S.C. 3304(a)(1)

Explain why the intended contractor is the only responsible source who can provide the required supplies or services. Discuss the unique capabilities, expertise, etc. that support the lack of competition/why no other type of supplies or services will satisfy agency requirements. Explain factors/unique qualifications such as proprietary data or exclusive licensing rights, if applicable. If brand name, explain why an adequate purchase description or other information suitable to solicit by full and open competition has not been developed or are not available. If in connection with a follow-on contract for continued development or production of highly specialized equipment, detail the substantial duplication of cost or unacceptable delays.

BioRad Laboratories is a manufacturer of Quality Control material that is acceptable to be run on the laboratory's chemistry anayzler. BioRad also provides technical support and an online tool to compare against peer data. The laboratory has been using BioRad materials since 2009. The performance of this QC material on the laboratory's chemistry analyzer has been very consistent and reliable. It also allows for use of the Unity web and Web Connect 2.0

☐ FAR 6.302-2: Unusual and compelling urgency, 41 U.S.C. 3304(a)(2)

If unusual and compelling urgency is the basis for the justification, explain the chronological events leading up to the requirement and explain why time constraints cannot permit even a limited competition. Establish that the action will cover only the minimum quantity or period of performance necessary; in most cases options are unacceptable when citing urgency. Describe impact of required delivery/performance date. Describe the detrimental effects/serious injury to the mission of the requiring activity or to the government, financial or otherwise, that will result if this justification is not approved and the product or service cannot be provided by the intended sole source contractor. Failure to plan for expiring funds is not a valid reason for citing this exception.

☐ FAR 6.302-5: Authorized or Required by Statute, 41 U.S.C. 3304(a)(5)

Provide a citation to the statutory authorization and a brief description of its content, or identify the specified source or other agency.

☐ Other (See FAR Subpart 6.3 for additional authority):

Provide a citation to the applicable section of FAR 6.3 and a full explanation to justify use of the exception.

5. Bridge Contracts:

For contract extensions or bridge contracts when a competitive follow-on is in the process of being developed, summarize history of current contract and explain the reasons for any delays in the acquisition. Include discussion of the milestones for the follow-on action; the milestones should be as efficient as possible. Discuss why it would be neither cost effective nor realistic to expect another contractor to perform during the brief interim period; include issues such as start-up costs, phase-in, transfer of GFP, recruitment and staffing, etc. If the action is because of a protest, provide a brief discussion of the protest including the date the protest was filed and the basis of the protest. Explain that the action will provide the minimum quantity or performance period.

6. Actions to Increase Competition:

Describe efforts made to compete the action, including whether a notice was or will be publicized as required by FAR Subpart 5.2 or which exception under FAR 5.202 applies. If a notice was publicized, discuss the number of written responses to the synopsis and the results of the assessment of the written responses. List sources, if any, that expressed, in writing, an interest in the acquisition. Provide rationale if interested sources were rejected. If applicable, state that no other sources have expressed interest, but all offers received shall be considered. Describe what actions will be taken to increase competition before subsequent acquisition of the supplies or services is required. You may state that an action is a one-time requirement, but if a similar requirement arises, every effort will be made to compete it to the maximum extent possible. If action is sole source because of proprietary data or licensing rights and there will be a continuing need for the requirement, there must be evidence that advanced planning has been initiated to overcome the barriers to competition, or there should be documentation to support an analysis that replacement costs/licensing purchase costs outweigh the benefits of competition. If the action is a contract extension or bridge, explain actions to compete the follow-on. If action is an urgent new requirement and a competitive follow-on is anticipated, explain that efforts are underway to facilitate a full and open competition.

7. Market Research:

Describe the extent of the market research conducted to identify all qualified sources and the results thereof. "Market Research" is defined as those attempts you made to ascertain whether other qualified sources exist, and can include contact with knowledgeable experts regarding similar or duplicate requirements, contact with industry, results of a sources sought synopsis, or draft solicitations. Research of the marketplace may consist of written, electronic (i.e. email) telephonic, or world wide web inquiries. Lack of advanced planning is not an acceptable reason for the lack of market research, but true urgency may necessitate abbreviated market research that is limited to readily available historical and commercial information. If action is a contract extension or bridge contract, describe the market research efforts underway or completed for the follow-on.

Market research was conducted in accordance with FAR Part 10 to identify capable sources, including a review of GSA Schedule holders, manufacturer catalogs, and publicly available vendor information for laboratory quality control (QC) materials and data management systems. Schedule contractors and major industry vendors were evaluated to determine their ability to provide independent, multi-analyte QC materials with an integrated peer comparison data management platform comparable to the required system. Vendors reviewed included large diagnostic manufacturers and third-party QC providers; however, most offer instrument-specific controls or lack a comprehensive, real-time peer comparison database equivalent to the required capability. While some schedule holders can distribute QC materials, they do not manufacture products that meet the Government's requirement for a fully integrated QC and analytics solution.The market research determined that the required features—specifically third-party QC materials compatible across multiple platforms and access to a robust, established peer comparison database—are not available from other sources in a form that meets the agency's needs, nor can existing alternatives be reasonably modified without significant cost, time, or risk to clinical operations. Therefore, the use of brand name specifications is justified, as the identified brand name product is essential to meeting the Government's minimum requirements, and other companies' products either do not meet or cannot be modified to meet those requirements.

8. Procurement History:

Purchase order or contract number: 75H70521P00043

Was action competed?	☐ Yes	☒ No

If action was not competed, state the cited authority, summarize rationale, and describe the actions that were supposed to be taken to increase competition and the results thereof:

At this time, no specific actions have been taken to remove or overcome the barriers that resulted in restricted consideration, as the limitations are primarily driven by the specialized and proprietary nature of the required laboratory quality control (QC) materials and the integrated peer comparison data management system. The current requirement depends on compatibility with existing laboratory instrumentation, established workflows, and access to a proprietary peer database, which is not readily replicable by other manufacturers.

9. Additional Information to support the justification

If applicable, explain why technical packages or specifications to facilitate competition were not developed or available; describe actions taken to remedy the situation.

10. Technical / Requirements Certification: ***By my signature below,*** I certify that the supporting data under my review which is included in this J&A is accurate and complete.

Program Manager	
Name:	Christine Woidyla
Position Title:	(a) Laboratory Supervisor
Email address:	christine.woidyla@ihs.gov
Phone:	218-679-0235
Program Manager Supervisor (or one level above Program Manager)	
Name:	Toni Lafriniere
Position Title:	(a) Ancillary Services Director
Email address:	toni.lafriniere@ihs.gov
Signature	TONI L. LAFRINIERE -S Digitally signed by TONI L. LAFRINIERE -S Date: 2026.06.23 14:17:47 -05'00'
Date:	Jun 23, 2026

11. Fair and Reasonable Price Determination: As Contracting Officer, by my signature below, I hereby determine that the anticipated cost to the Government for this contract action will be fair and reasonable.

Provide the basis for this determination, e.g., describe techniques to be used to determine fair and reasonable price (FAR Subpart 15.402), such as price analysis, cost analysis, cost realism. Per FAR Subpart 15.403-4(a)(1), the threshold for obtaining cost or pricing data is $750,000.

12. Contracting Officer's Approval (Required for proposed contract not to exceed $700,000 (value calculated including all options)): I hereby certify that this justification is accurate and complete to the best of my knowledge. I approve this sole source justification subject to availability of funds, and provided that the services and supplies herein described have otherwise been authorized for acquisition.

Name:	JENNIFER RICHARDSON	Phone:	
Signature:	Jennifer L. Richardson -S Digitally signed by Jennifer L. Richardson -S Date: 2026.06.24 08:17:32 -05'00'	Date:	

13. Legal Review:

All J&As equal to or greater than $68 million must have a legal review from the General Law Division of the Office of the General Counsel prior to sending it to the Department.

14. OPDIV Competition Advocate Approval (Required for proposed contract over $700,000 but not exceeding $13.5 million value calculated including all options):

I have reviewed this justification and find that it adequately supports other than full and open competition.

Name:		Phone:	
Signature:		Date:	

15. Office of Small and Disadvantaged Business Utilization

I have reviewed this justification and find that it adequately supports other than full and open competition.

Name:		Phone:	
Signature:		Date:	

16. OPDIV HCA Approval (Required for proposed contract over $13.5 million but not exceeding $68 million value calculated including all options):

Name:		Phone:	
Signature:		Date:	

(The below approval paragraph is required if the cumulative contract value, including all options, equals or exceeds $68 million.)

HHS Senior Procurement Executive (SPE) Approval

Based on the foregoing justification, I hereby approve the procurement of (state supplies/services being procured) on an other than full and open competition basis pursuant to the authority of (state the full statutory authority and FAR cite and title, consistent with paragraph 4, e.g. 41 U.S.C. 3304), as implemented by FAR 6.301), subject to the availability of funds, and provided that the services herein described have otherwise been authorized for acquisition.

Name:		Phone:	
Signature:		Date:	