

Attachment A: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval
For
Other Than Full and Open Competition**

1. Contracting Activity:

The contracting agency is the Department of Veterans Affairs (VA) Office for Research and Development, which is responsible for managing and monitoring VA research programs at more than 100 VA performance locations across the country. [REDACTED]

2. Nature and/or Description of the Action Being Processed:

The action under review is award of a new contract to the only animal research accrediting organization in the world, to provide accreditation services to VA's animal research programs. This organization is the non-profit Association for Assessment and Accreditation of Laboratory Animal Care, International, hereafter known as "AAALAC." The contract will be firm-fixed price, definite quantity.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

VA requires all services related to maintaining accreditation for its field animal research programs. There is only one source for this contract. VA Handbook 1200.7, Use of Animals in Research, 7(e), and Public Law 99-158, November 20 1985, Animals in Research (Public Health Service Policy on Humane Care and Use of Laboratory Animals IV, 2 (Category 1), both clearly state that AAALAC as a required accreditation agency.

a. **Services provided.** This contract would provide the following services, for each VA animal research program. The reports and correspondence written by AAALAC constitute the contract deliverables:

(1) Accreditation experts (site visit team) view a detailed written description of the VA facility's animal research program, then perform an on-site inspection. Applicable federal animal research laws promulgated by USDA and DHHS are used as the benchmarks for the review. The informal results of the inspection are provided to hospital managers at the end of the visit. Management then has an opportunity to provide additional information to the accreditation team.

(2) After evaluating any additional information provided by the station after the visit, the site visit team prepares a report of their findings. This report is then presented before the AAALAC Council, a peer group of animal research professionals chosen for their knowledge and experience in managing animal research programs. The AAALAC Council then approves written correspondence to go back to the station, listing any concerns and suggestions for improvement.

(3) Copies of the written Council findings are then sent to the station, ORD (contract requesting authority), and the VA Office of Research Oversight.

(4) The station then prepares a formal response, if needed, and sends it back to AAALAC for consideration. AAALAC Council subsequently reviews the response, and either accepts it or initiates further correspondence. In some cases, Council may insist on a repeat visit before making a final determination if a program deserves full accreditation.

(5) In the first and second years following the site visit, each station completes a follow-up annual report describing progress in addressing AAALAC concerns and any significant changes in personnel or policy. If AAALAC's review of the annual report results in concerns, these concerns are communicated in writing to the station, ORD, and ORO.

(6) At all times, stations must copy AAALAC to any written reports of deficiencies they are required to "self-report" to federal agencies. AAALAC then reviews these reports and initiates further correspondence as they deem necessary, again copying the station, ORD, and ORO.

(7) Quarterly, AAALAC sends a written report listing the accreditation status of all VA programs in the nation, including the date of the last visit by an accreditation team. This information is critically important to ORD for use in monitoring animal research, to maintain high quality in VA animal research programs.

b. **Estimated cost.** The estimated costs associated with these services are represented by three fees. The first is an annual accreditation maintenance fee, which is charged annually to all accredited institutions. The costs of the triennial site visit, AAALAC Council actions, and administrative tasks are covered by this fee (Fee Type "A" in the table below. If an institution does not fare well during the triennial visit, at its discretion, Council will require a mid-cycle visit before the next regularly scheduled triennial visit. This additional cost is Fee Type "B" in the table below. Finally, on occasion a new VA animal research program will develop, and a more detail initial site visit will be conducted (Fee Type "C" in the table below). [REDACTED]

c. **VA policy authority.** VHA Handbook 1200.07, "Use of Animals in research" (http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1268) mandates that all VA animal research

programs be accredited:

7e. **Accreditation.** All VA animal facilities and affiliates, or other animal facilities that house animals purchased with VA funds, or used for VA or VA research and education corporation projects must be accredited by AAALAC.

NOTE: There is one and only one accrediting organization recognized by VA policy (VHA Handbook 1200.7, "Use of Animals in Research"):

3e. **Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).** AAALAC is the accrediting body for animal research programs recognized by VA.

d. **Period of performance.** This new contract must be executed to prevent a lapse in accrediting services to replace the existing contract, which has been extended past the end of Option [REDACTED]

4. **Statutory Authority Permitting Other than Full and Open Competition:** Because there is only one vendor for these services, per 41 USC §253(c), as implemented by FAR 6.302, this contract can be appropriately awarded without full and open competition per 6.302-1 (2), which states the following:

6.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements.

(a) Authority.

(1) Citations: 10 U.S.C. 2304(c)(1) or 41 U.S.C. 253(c)(1).

(2) When the supplies or services required by the agency are available from only one responsible source, or, for DoD, NASA, and the Coast Guard, from only one or a limited number of responsible sources, and no other type of supplies or services will satisfy agency requirements, full and open competition need not be provided for.

Although the conditions set forth in subpar 6.302-1 (2) (ii)(A) and (B) may not apply to services of the type in this contract, this solicitation also meets the clause conditions because the cost of VA duplicating AAALAC's accreditation services would be far in excess of the estimated costs of this contract, and it would not be possible to implement such a program without causing unacceptable delays that would place our animal research programs and the agency at risk:

(ii) Supplies may be deemed to be available only from the original source in the case of a follow-on contract for the continued development or production of a major system or highly specialized equipment, including major components thereof, when it is likely that award to any other source would result in—

(A) Substantial duplication of cost to the Government that is not expected to be recovered through competition;

or

(B) Unacceptable delays in fulfilling the agency's requirements. (See 10 U.S.C. 2304(d)(1)(B) or 41 U.S.C. 253(d)(1)(B).)

Further details supporting solicitation under FAR 6.302-1 is provided in the next section.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

For appropriate use of FAR 6.302-1, documentation is provided that AAALAC is the only vendor providing animal research accreditation services, and that alternate approaches are not possible.

- a. The proposed COTR, [REDACTED] In his 25 years of experience in the animal research discipline, he has never heard of any other organization accrediting animal research, whether domestic or international. It is important to note that AAALAC has provided animal research accreditation services worldwide for a number of years, thus establishing them as world-wide experts in the area.
- b. Market research was conducted on April 8, 2011 using web searches for alternate animal research accrediting services (see Supplement 1). Worldwide, a review of over 200 ranked links using a Google search showed that all references to such services for American institutions link back to the AAALAC website. Aside from foreign national federal programs operant only in those countries, no evidence of any other vendors for this service could be found.
- c. Although it is not possible to duplicate such services because AAALAC accreditation is considered a community standard, for VA to offer similar services internally, at least 5 full time positions would have to be created (3 full-time veterinarians [\$125,000 ea], 1 high level technical staff member [\$60,000], and 1 administrative support position[\$45,000]). The estimated cost of these positions would total \$480,000 with a travel budget of \$25,000-\$30,000. Thus, the total cost would be at least \$500,000 per year, which is substantially higher than even the \$375,000 estimated cost for the last option year. It would easily take an entire year to set up such a program, which would leave a significant lapse in services to our programs. This would result in great vulnerability in our animal research programs and by the agency due to expected criticism by special interest groups concerned with animal welfare issues.
- d. From an ethical perspective, it is also not possible to have an "internal" accreditation program because by convention, a community accreditation process must be managed by neutral observers without bias.

Accordingly, AAALAC is the only vendor capable of providing the supplies and services described in Section III. Ethical issues aside, AAALAC is also the only vendor capable of providing the needed accreditation services to prevent the Veteran's Health Administration from experiencing substantial duplication of cost and experiencing unacceptable delays in fulfilling its requirements.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

As described in section 5 above, there are no other potential vendors for this solicitation. No evidence of any alternate vendor has been found, based upon the professional experiences of VA's senior subject matter expert, and an extensive web research. The web research involved checking hundreds of web links for evidence of another vendor. The only other animal research accrediting bodies found were internal, country-specific programs conducted by foreign national federal agencies.

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

Justification for pricing was provided by the vendor.

a. **Pricing for the annual accreditation maintenance fee.** The 2010/2011 standard cost pricing provided by the vendor for the annual fee is below. The base year fee of \$4075 per VA program is a little less than the Group III fee of \$4100.

Group # / (Square Feet)	(Square Meters)	Application Fee	Annual Fee
I (< 1,000)	(< 93)	\$3,600	\$2,475
II (1,000 - 9,999)	(94 - 929)	\$5,560	\$3,525
III (10,000 - 24,999)	(930 - 2,322)	\$6,070	\$4,100
IV (25,000 - 49,999)	(2,323 - 4,645)	\$6,900	\$5,375
V (50,000 - 99,999)	(4,646 - 9,290)	\$8,700	\$5,650
VI (100,000 - 199,999)	(9,291 - 18,580)	\$10,400	\$7,025
VII (200,000 - 499,999)	(18,581 - 45,451)	\$12,950	\$8,675
VIII (> 500,000)	(> 46,452)	Negotiated	Negotiated

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

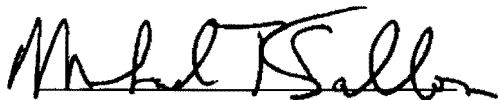
Although VA policy states that only AAALAC accreditation is recognized as compliant, market research was conducted on April 8, 2011 using web searches for alternate animal research accrediting services (see Supplement 1). Worldwide, a review of over 200 top-ranked links using a Google search showed that all references to such services for American institutions link back to the AAALAC website. Aside from foreign national federal programs operant only in those countries, no evidence of any other vendors for this service could be found.

As discussed in detail in Sections 5 and 6 in this document, no alternate means of acquiring independent accreditation services exist, and it is neither financially or ethically possible for VA to duplicate these services internally.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: None.
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: See Section 6 above.
11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

Unless another vendor enters the marketplace in the future, no other options for obtaining these services exist. The likelihood of another vendor arising is very low- AAALAC started in 1965 and has provided excellent stability and services since then, functioning as a non-profit organization.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

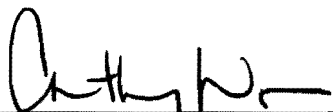


Name: Michael T. Fallon, DVM, PhD
Title: Chief Veterinary Medical Officer
Facility: Office of Research and Development, VHA

May 27, 2011
Date

13. Approvals in accordance with FAR 6.304

- a. Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



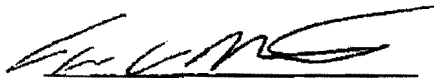
Name: Anthony Warner
Title: Contract Officer
Facility: SAO East

6/9/2011
Date

Service Area Office, East
Department of Veterans Affairs
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

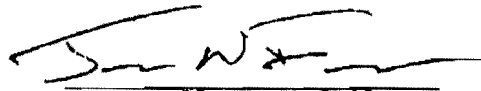
Memorandum 2011-003
March 16, 2011

- b. One Level above Contracting Officer: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name: Trevor Martin
Title: Supervisory Contract Specialist
Facility: SAO East

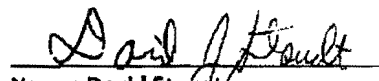
6/9/2011
Date

- c. Network Quality Assurance/Compliance Review: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name: Jeffrey W. F. Thayer
Title: Quality/Compliance Officer
Service Area Office, East

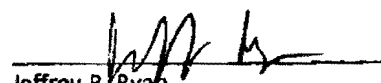
6/10/2011
Date

- d. Deputy Director, SAO East: I certify the justification meets requirements for other than full and open competition.


Name: David Staup
Service Area Office, East

6/20/2011
Date

- e. SAO East: I certify the justification meets requirements for other than full and open competition.


Jeffrey R. Ryan
Director
Service Area Office, East

7/6/11
Date

Service Area Office, East
Department of Veterans Affairs
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

Memorandum 2011-003
March 16, 2011

- f. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (over \$50 million), approve (up to \$ 50 million) for other than full and open competition.

Approved _____

Disapproved _____

Amount \$

163,289,300


Norbert S. Doyle

Acting Chief Procurement and Logistics Officer
VHA, Head of Contracting Activity

Date

3/16/11

- g. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary
Office of Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date