

**United States Small Business Administration  
Office of Hearings and Appeals**

NAICS APPEAL OF:

LJR Solutions, LLC,

Appellant,

Solicitation No. 16-223-SOL-00036

U.S. Food & Drug Administration

Jefferson, Arkansas

SBA No. NAICS-5791

Decided: November 17, 2016

APPEARANCE

Christopher R. Shiplett, Esq., Randolph Law, PLLC, Falls Church, Virginia, for  
Appellant

DECISION

I. Introduction and Jurisdiction

On October 18, 2016, the Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR) at the Jefferson Laboratories in Jefferson, Arkansas, issued Solicitation 16-223-SOL-00036, a Request for Proposals (RFP) for On-Site Animal Care, Technical Procedures, Formulation and Veterinary Care Services at NCTR. The Contracting Officer (CO) set the procurement aside entirely for Small Business and designated North American Industry Classification System (NAICS) code 541711, Research and Development in Biotechnology, with a corresponding 1,000 employee size standard, as the appropriate code. Offers were due November 18, 2016, later extended by Amendment 2 to December 7, 2016.

On October 28, 2016, LJR Solutions, LLC (Appellant) filed the instant appeal. Appellant argues the appropriate NAICS code for this procurement is 561210, Facilities Support Services, with a corresponding \$38.5 million annual receipts size standard. For reasons discussed *infra*, the appeal is denied.

The SBA Office of Hearings and Appeals (OHA) decides NAICS code appeals under the Small Business Act of 1958, 15 U.S.C. § 631 *et seq.*, and 13 C.F.R. parts 121 and 134. Appellant filed the instant appeal timely. Federal Acquisition Regulation (FAR) 19.303(c)(1); 13 C.F.R. §§ 121.1103(b)(1), 134.304(b), 134.202(d). Accordingly, this matter is properly before OHA for decision.

## II. Background

### A. The Performance Work Statement

The objective of this procurement is:

to provide support services to NCTR's animal research program, specifically the provision of quality care to all research animals, sanitation of all animal care and diet preparation/formulation facilities, provision of protocol-specified technical procedures, provision of veterinary care to the Nonhuman Primate (NHP) colony, and provision of formulation services (receipt, storage, formulation, packaging, and distribution of animal diets and test articles). Ancillary tasks necessary to accomplish these services are included (e.g., quality control, occupational safety and health, inventory control, equipment maintenance, development and maintenance of standard operating procedures, as well as maintaining a comprehensive employee training program). The need for these services is paramount as the preponderance of NCTR's research mission can only be accomplished through animal research.

(Performance Work Statement (PWS) at 3.)

Services shall include collaboration with NCTR Principal Investigators (PIs) and other NCTR Contractors during planning and development of research protocols, provision of Animal Care, Technical Procedures, Formulation and Veterinary Care support services to conduct Institutional Animal Care and Use Committee (IACUC)-approved research protocols, and provision of data for preparation of scientific manuscripts. As requested by the COR and approved by the CO, the Contractor shall serve on committees (e.g., IACUC, Safety, etc.) and participate in seminars, workshops, and training programs on topics appropriate to fulfill NCTR's goals.

The primary services requested by this PWS are for the Contractor to:

- 1) provide animal husbandry services including, but not limited to feeding, watering, maintaining a clean environment, operating cage processing areas, making and recording observations, and breeding laboratory animals;
- 2) provide extensive technical research support procedures in support of animal research protocols including, but not limited to, dosing by gavage, intravenous (IV), intraperitoneal (IP), and topical routes;
- 3) conduct blood collection from all species on-site as defined in research protocols;
- 4) provide support for research on behavioral testing of rodents and NHP;
- 5) provide veterinary medical services and psychological well-being programs for the NHP colony primarily, and for other species secondarily;
- 6) provide diet preparation/formulation services including, but not limited to receiving, storing, processing, and distributing a) produce for NHP enrichment programs, b) animal diets, and c) diets, water, gavage solutions, topical mixtures and other formulations containing specific amounts of test articles. Other important aspects of this Contract requiring Contractor resources

include Quality Assurance, Quality Control, Occupational Safety and Health, Employee Training, Inventory Control, Equipment Management, and Data Management. In addition, the Contractor shall provide management and administrative support to ensure effective and efficient utilization of staff, participate in NCTR's time keeping system (NEAT), provide for planning and scheduling of work, ensure the highest quality of work, and effectively carry out the business aspects of this contract.

(PWS at 6-7.)

The contractor shall provide Internal Quality Assurance (IQA) for the portion of each protocol performed by the Contractor. This IQA shall ensure that the processes followed for Good Laboratory Practice (GLP) studies are performed correctly and documented properly. (*Id.* at 9.) The contractor's IQA will be independent of the personnel engaged in the conduct of the regulated study, and will monitor each regulated study to assure equipment, personnel, and methods are in conformance with applicable regulations. The IQA will maintain a master schedule of all non-clinical laboratory studies conducted by the testing facility that require animal care, technical procedures or formulation support, containing detailed information on studies. The IQA will maintain copies of all protocols pertaining to regulated non-clinical laboratory studies, and inspect each such study at intervals to assure its integrity. (*Id.*) The IQA will provide results of its inspections to the study director, and contractor management. The IQA will ensure there are no deviations from protocols. (*Id.* at 10.)

The RFP requires animal husbandry services, and all services required to maintain various species of animals under laboratory conditions will be performed in accordance with Standard Operating Procedures. The current version of the *Guide for the Care and Use of Laboratory Animals* shall serve as a guide for minimum acceptable standards for operation within the animal facility. Laboratory animal husbandry services shall include but may not be limited to feeding and watering animals, cleaning primary enclosures, cage change-outs, daily observation of animals, cleaning and sanitation of animal facilities, cage processing operations, quarantine support for animals arriving from outside the facility, animal transport, health and environmental monitoring activities, provision of environmental enrichment for laboratory animals, recordkeeping and documentation, and maintaining work areas in a clean and orderly condition. Provision of animal husbandry shall be performed per SOP. (PWS at 21.)

The contractor will be responsible for all housekeeping duties in all animal facilities and other areas used by contractor personnel during performance. (*Id.* at 22.) The contractor will feed the animals according to approved protocols, check water bottles daily, clean water racks, and change bedding and litter pans. (*Id.* at 23.) The contractor will remove animal wastes and carcasses, and make daily observations for abnormal conditions. (*Id.* at 24.) The contractor will provide support for environmental and health monitoring programs. This will include providing nestlets and nylabones for rodents, and toys, puzzle feeders, and behavioral testing units for primates. (*Id.*) The contractor must make accurate and current records of all operations. (*Id.*)

The contractor will be responsible for rodent breeding. (*Id.* at 25.) The contractor will also be responsible for diet preparation and formulation. (*Id.* at 26.) The contractor must provide veterinary care for the animals. (*Id.* at 27.)

The Contractor shall provide the necessary professional, technical, and administrative personnel with the required qualifications needed to provide the NCTR with high-quality animal care, technical procedures, formulations, and veterinary care support services. (*Id.* at 10.) The Government places a high priority on the technical workforce (foremen, technicians, assistant technicians, and production aides) being American Association for Laboratory Animal Science (AALAS) certified at the Assistant Laboratory Animal Technician level or higher. “At least 85% of the technical workforce is required to be AALAS certified at all times.” (*Id.*)

Contractor personnel will include an onsite Project Director who is a Veterinarian, a Clinical Veterinarian, a Project Manager certified as a Laboratory Animal Technologist (LATG); Supervisors who are at least LATG certified, a Behaviorist and a Training Coordinator for the Non-Human Primates, an LATG-certified Technical Specialist to oversee and coordinate the planning and execution of specific animal experiments or tasks, Certified Animal Care Technician, Assistant Animal Care Technicians, Certified Formulations Supervisor and Formulation Technician, an Internal Quality Assurance with Registered Quality Assurance Professionals in Good Laboratory Practice Certification, Production Aide, and Equipment Support Specialist. (PWS at 11-13.)

The evaluation factors for award are Technical Proposal, Past Performance and Price. In evaluating the Technical Proposal, the FDA will consider Technical Approach and Management Approach and Personnel Qualifications. In evaluating Technical Approach, FDA will evaluate proposals to determine the extent the offeror's technical strategy/approach will ensure the scope, schedule, performance and offeror's resources are controlled and consistent with the contract and present minimal risk to the Government. As to Management Approach and Personnel Qualifications, proposals will be evaluated to determine whether the offeror's proposed methodology for organizing, staffing and managing the project will result in successfully providing Animal Care, Technical Procedures, Formulation and Veterinary Care Services as described in the PWS. (RFP at 23.)

## B. The Appeal

On October 28, 2016, Appellant filed the instant appeal. Appellant argues the appropriate NAICS code for this procurement is 561210, Facilities Support Services, with a corresponding \$38.5 million annual receipts size standard.

Appellant notes that the RFP calls for animal care, technical procedures, formulation, and veterinary care services at the FDA's facility. These services include providing quality care to research animals, including feeding, sanitation, and technical procedures support. (Appeal at 2-4.) Appellant asserts that FDA has released solicitations under NAICS code 541711. Appellant points to four other FDA solicitations, portions of which Appellant attaches to its appeal as Exhibits 4-7. These solicitations call for hip simulator tests; production of monoclonal antibodies from mice using influenza antigens; a study of factors that control the safety and biodistribution

of Adenovirus vectors; and MircoRNA sequencing in conjunction with a study of translational Biomarkers for Drug-Induced Liver Injury. (*Id.* at 5-6.)

Appellant argues that based upon the *NAICS Manual* description of NAICS code 541711 and the other solicitations which have used it, the code applies to scientific research services directly involved in experimentation related to biological processes. The services required in the four sample solicitations are examples of the conduct of biotechnological research and the development of biotechnological experiments. (*Id.* at 7.) By contrast, the instant RFP seeks services to maintain the research animals and research facilities and equipment. The solicitation seeks “quality care to all research animals, sanitation of all animal care and formulation facilities and provision of protocol-specified technical procedures support.” The contractor here will not engage in research or develop experiments. (Appeal at 7, citing RFP at 4.) This RFP does not call for biotechnological research, which NAICS code 541711 covers, but seeks a combination of veterinary care, animal husbandry, facility maintenance and cleaning, and HR services. (Appeal at 7.)

Appellant argues NAICS code 561210 best describes the services sought in this RFP. This code describes establishments who provide operating staff to perform a combination of services within a client's facility and the company is not involved with or responsible for the core business or activities of the client. (*Id.* at 8.) The RFP calls for operating staff from a number of different disciplines. (*Id.*) It requires animal husbandry services, technical research support procedures, veterinary medical services, and diet preparation services. (*Id.* at 8-9, citing PWS at 3.) The PWS calls for staff from a number of different service areas. The PWS requires a Clinical Veterinarian, a service position falling within NAICS code 541940, Veterinary Services. It also requires an Animal Care Technician, to perform routine husbandry and facility sanitation procedures, covered by either NAICS code 812910, Pet Care (except Veterinary) Services, or 115210, Support Activities for Animal Production. There is a further requirement for an Equipment Support Specialist required to maintain and perform minor repairs on equipment, whose work falls within NAICS code 811310, Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance. There is also a Human Resources Administrator providing human resources services under NAICS code 541612, Human Resources Consulting Services. (*Id.* at 9, citing PWS at 4, 11, 12, 13, & 40.)

The contractor is not required to perform any of the FDA's core business of biotechnological research. Because the RFP calls for the contractor to provide operating staff to perform a combination of services within the FDA's facility, and no one service dominates, NAICS code 561210 best describes the services sought here, and is the appropriate NAICS code for this solicitation.

The FDA did not respond to this appeal.

C. NAICS Manual<sup>1</sup> Descriptions

The NAICS code designated by the CO, 541711, Research and Development in Biotechnology, comprises:

[E]stablishments primarily engaged in conducting biotechnology research and experimental development. Biotechnology research and experimental development involves the study of the use of microorganisms and cellular and biomolecular processes to develop or alter living or non-living materials. This research and development in biotechnology may result in development of new biotechnology processes or in prototypes of new or genetically-altered products that may be reproduced, utilized, or implemented by various industries.

Illustrative Examples:

Recombinant DNA research and experimental development laboratories  
 DNA technologies (e.g., microarrays) research and experimental development laboratories  
 Cloning research and experimental development laboratories  
 Protein engineering research and experimental development laboratories  
 Nucleic acid chemistry research and experimental development laboratories  
 Nanobiotechnologies research and experimental development laboratories

*NAICS Manual*, at 762-63. NAICS code 541711 is one of two industries that are part of industry group 5417, Scientific Research and Development Services, which is described as follows:

This industry group comprises establishments engaged in conducting original investigation undertaken on a systematic basis to gain new knowledge (research) and/or the application of research findings or other scientific knowledge for the creation of new or significantly improved products or processes (experimental development). The industries within this industry group are defined on the basis of the domain of research; that is, on the scientific expertise of the establishment.

*NAICS Manual*, at 761. The other industry included in industry group 5417 is NAICS code 541712, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology).

NAICS code 541711 is further described in SBA's size regulations.

(a) "Research and Development" means laboratory or other physical research and development. It does not include economic, educational, engineering, operations, systems, or other nonphysical research; or computer programming, data processing, commercial and/or medical laboratory testing. . . .

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<sup>1</sup> Executive Office of the President, Office of Management and Budget, North American Industry Classification System-United States (2012), *available* at <http://www.census.gov>.

13 C.F.R. § 121.201, fn. 11.

The NAICS code advanced by Appellant, 561210, Facilities Support Services, comprises:

[E]stablishments primarily engaged in providing operating staff to perform a combination of support services within a client's facilities. Establishments in this industry typically provide a combination of services, such as janitorial, maintenance, trash disposal, guard and security, mail routing, reception, laundry, and related services to support operations within facilities. These establishments provide operating staff to carry out these support activities; but are not involved with or responsible for the core business or activities of the client. Establishments providing facilities (except computer and/or data processing) operation support services and establishments providing private jail services or operating correctional facilities (i.e., jails) on a contract or fee basis are included in this industry.

*NAICS Manual*, at 782.

This NAICS code is also described in SBA's size regulations:

(a) If one or more activities of Facilities Support Services as defined in paragraph (b) (below in this footnote) can be identified with a specific industry and that industry accounts for 50% or more of the value of an entire procurement, then the proper classification of the procurement is that of the specific industry, not Facilities Support Services.

(b) "Facilities Support Services" requires the performance of three or more separate activities in the areas of services or specialty trade contractors industries. If services are performed, these service activities must each be in a separate NAICS industry. If the procurement requires the use of specialty trade contractors (plumbing, painting, plastering, carpentry, etc.), all such specialty trade contractors activities are considered a single activity and classified as "Building and Property Specialty Trade Services." Since "Building and Property Specialty Trade Services" is only one activity, two additional activities of separate NAICS industries are required for a procurement to be classified as "Facilities Support Services."

13 C.F.R. § 121.201, fn. 12.

### III. Discussion

#### A. Standard of Review

Appellant has the burden of proving, by a preponderance of the evidence, all elements of its appeal. Specifically, Appellant must show that the CO's NAICS code designation is based upon a clear error of fact or law. 13 C.F.R. § 134.314; *NAICS Appeal of Durodyne, Inc.*, SBA

No. NAICS-4536, at 4 (2003). SBA regulations do not require the CO to select the perfect NAICS code. *NAICS Appeal of Evanhoe & Assocs., LLC*, SBA No. NAICS-5505, at 14 (2013). Rather, the CO must assign the NAICS code that best describes the principal purpose of the product or service being acquired in light of the industry descriptions in the *NAICS Manual*, the description in the solicitation, the relative value and importance of the components of the procurement making up the end item being procured, and the function of the goods or services being acquired. FAR 19.303(a)(2); 13 C.F.R. § 121.402(b). OHA will not reverse a NAICS code designation “merely because OHA would have selected a different code.” *NAICS Appeal of Eagle Home Med. Corp.*, SBA No. NAICS-5099, at 3 (2009).

### B. Analysis

This procurement seeks a contractor to care for the animals used in the NCTR's research. The contractor will be in charge of the animals' diet. This will involve more than merely feeding them and providing them with clean drinking water, although these tasks are required. The contractor will have to formulate and prepare the animals' diet. The contractor must also clean the animals' environments and ensure they are sanitary. The contractor is to provide technical assistance in support of the animal studies. The contractor will administer injections and IV doses and collect blood. The contractor will collect physiological data on the animals. The contractor will perform routine husbandry procedures and provide veterinary services. The contractor's IQA will maintain a master schedule of all studies conducted by the facility which require animal care, maintain copies of all protocols pertaining to the studies, and inspect each study. The IQA will provide the results to the study director.

All of these activities are part of the research process. The contractor here will be caring for the animals, which are vital for the continuing research. Further, the contractor will be involved in the research process itself, administering injections, collecting data, and observing and recording behavior. The IQA will be inspecting the studies and reporting to the study director. Thus the contractor will be deeply involved in the research process.

While OHA has not considered NAICS appeals of code 541711, OHA has ruled in NAICS appeals on the other industry that is part of industry group 5417, Scientific Research and Development Services. That NAICS code is 541712, Research and Development in the Physical, Engineering and Life Sciences (except Biotechnology). The industry group description states that both industries in this group “are defined on the basis of the domain of research; that is, on the scientific expertise”. *NAICS Manual*, at 761. Thus, both codes describe scientific research and development, and one may draw analogies based on those concepts from one industry to the other.

In its decisions regarding NAICS code 541712, OHA considered what type of activity is properly included under a research NAICS code. Work which is an integral part of an agency's research, and essential for the conduct of the research, is properly classified under a research NAICS code. *NAICS Appeal of Information Ventures, Inc.*, SBA No. NAICS-4882 (2008). Even if the contractor will not perform any research itself, nor provide advice and assistance, but it will perform work which is a vital part of the research process, the contract is properly classified under a research NAICS code. *NAICS Appeal of Information Ventures, Inc.*, SBA No. NAICS-

4945 (2008). Researchers do not work in a vacuum, and when they require the support of technically experienced personnel to assist their efforts, it cannot be said that a contracting officer is incorrect to assign a research NAICS code to support competencies required for the success of the research effort. *NAICS Appeal of Inklings Media Company*, SBA No. NAICS-5054 (2009).

Here, the contractor's work will be an integral part of NCTR's research effort. The care of the subject animals is a vital part of the research effort. The requirement that “[a]t least 85% of the technical workforce is required to be AALAS certified at all times” is very persuasive that the core purpose of this RFP is to care for laboratory animals that are the subject of scientific research. These animals are neither pets nor livestock, so Appellant's attempt to classify this care under NAICS codes 812910 (pet care) or 115210 (agricultural animal production) are meritless. Further, contractor personnel will be taking active part in the research, by administering injections, collecting samples, and overseeing the studies to be sure the proper protocols are followed. The contractor's work is vital for the animal research to succeed. I therefore conclude the CO's designation of NAICS code 541712 for this RFP is correct.

Because Appellant has not established that NAICS code 541711 is not appropriate for this RFP, OHA need not consider any alternate code or size standard. It is settled law that OHA will not assign a different NAICS code to a procurement unless the contracting officer's choice of NAICS code is shown to be clearly erroneous. *NAICS Appeal of DCS Corporation*, SBA No. NAICS-5703 (2016).

Nevertheless, I find Appellant's argument that NAICS code 561210 is appropriate to be unpersuasive. NAICS code 561210 covers establishments which provide a combination of support services, but are not involved with the client's core business. *NAICS Appeal of CWU, Inc.*, SBA No. NAICS-5226 (2011). Contracts covered by the code are usually for an agency's ancillary support services, such as maintenance, janitorial and clerical services. *NAICS Appeal of Alon, Inc.*, SBA No. NAICS-5148 (2010). Services which are central to the procuring agency's mission cannot be classified under NAICS code 561210. *NAICS Appeal of JBS International, Inc.*, SBA No. NAICS-5021 (2008). Here, the services required are vital to the animal experiments which are central to FDA's mission. Accordingly, NAICS code 561210 is not an appropriate code for this procurement.

Further, Appellant's reference to other solicitations whose NAICS codes OHA has not decided is unavailing here. These are other procurements, with different statements of work. Each NAICS code appeal must be decided based upon the solicitation at issue, and other solicitations are not of great probative value. *NAICS Appeal of Ferris Optical*, SBA No. NAICS-5285 (2011).

I therefore conclude Appellant has failed to establish clear error in the CO's NAICS code designation. NAICS code 541711, Research and Development in Biotechnology, with a corresponding 1,000 employee size standard, is the appropriate code for this procurement

Accordingly, I conclude that Appellant has failed to meet its burden of establishing clear error in the CO's NAICS code designation, and I must deny this appeal.

IV. Conclusion

For the above reasons, the appeal is DENIED. The CO reasonably selected NAICS code 541711, Research and Development in Biotechnology, with a corresponding 1,000 employee size standard.

This is the final decision of the Small Business Administration. 13 C.F.R. § 134.316(d).

CHRISTOPHER HOLLEMAN  
Administrative Judge