

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

RESEARCH, TECHNICAL, AND SCIENTIFIC ADMINISTRATIVE SUPPORT SERVICES FOR THE MILITARY OPERATIONAL MEDICINE RESEARCH PROGRAM (MOMRP) RFQ W81XWH-11-R-0006

Contract Number: To Be Determined
Contractor's name: To Be Determined

1. PURPOSE:

This Quality Assurance Surveillance Plan (QASP) provides a systematic method to evaluate performance for the stated contract. This QASP explains the following:

- What will be monitored.
- How monitoring will take place.
- Who will conduct the monitoring.
- How monitoring efforts and results will be documented.

This QASP does not detail how the contractor accomplishes the work. Rather, the QASP is created with the premise that the contractor is responsible for management and quality control actions to meet the terms of the contract. It is the Government's responsibility to be objective, fair, and consistent in evaluating performance. In addition, the QASP should recognize that unforeseen and uncontrollable situations may occur.

This QASP is a "living document" and the Government may review and revise it on a regular basis. However, the Government shall coordinate changes with the contractor. Updates shall ensure that the QASP remains a valid, useful, and enforceable document. Copies of the original QASP and revisions shall be provided to the contractor and Government officials implementing surveillance activities.

a. QASP RELATION TO THE SOLICITATION:

QASPs shall be developed and appear in every solicitation, as well as the resultant service contract. MOMRP will retain the right to change the surveillance methods and Quality Assurance (QA) procedures, or to increase or decrease the degree of surveillance efforts at any time necessary to assure contract compliance. MOMRP may provide the contractor with an informational copy of the QASP to enable the contractor to enhance its Quality Control Program (QCP).

b. QASP RELATION TO THE QCP:

While the QCP represents the way in which the contractor will ensure its quality and timeliness of services, as defined in the PWS, the QASP represents the way in which MOMRP will evaluate the contractor's performance. The contractor's QCP and the QASP should be complementary programs that ensure successful contract performance.

c. REVISIONS TO THE QASP:

The QASP is a tool for use in Government administration of the Performance Work Statement (PWS) and remains subject to revision at any time by the Government throughout the contract performance period. Revisions to this surveillance plan are the responsibility of the Contracting Officer's Representative (COR). Changes to the QASP shall be made bilaterally and the Government must provide the contractor an opportunity to revise its Quality Control Plan accordingly.

The contractor will assume responsibility for all tasks and deliverables in the PWS under this award. All operational procedures and quality control measures will be tested and implemented. As the performance period progresses, the levels of surveillance may be altered for service areas in cases where performance is either consistently excellent or consistently unsatisfactory. If observations reveal consistently good performance, then the amount of surveillance may be reduced. If observations reveal consistent deficiencies, increased surveillance may be implemented.

2. GOVERNMENT ROLES AND RESPONSIBILITIES:

The following personnel shall oversee and coordinate surveillance activities.

a. Contracting Officer (KO) - The KO shall ensure performance of all necessary actions for effective contracting, ensure compliance with the contract terms, and shall safeguard the interests of the United States in the contractual relationship. The KO shall also assure that the contractor receives impartial, fair, and equitable treatment under this contract. The KO is ultimately responsible for the final determination of the adequacy of the contractor's performance.

Assigned KO: Jennifer Jackson
Organization or Agency: US Army Medical Research Acquisition Activity
Telephone: Phone: (301) 619-2054; Fax: (301) 619-3002
Email: Jennifer.Jackson1@us.army.mil

b. Contracting Officer's Representative (COR) – The COR will be located at Fort Detrick, Building #721, Military Operational Medicine Research Program (MOMRP) office. The COR will be responsible for technical administration of the contract, and shall assure proper Government surveillance of the contractor's performance. The COR shall keep a quality assurance file. At the conclusion of the contract or when requested by the KO, the COR shall provide documentation to the KO. A COR is not empowered to make any contractual commitments or to authorize any contractual changes on the Government's behalf. The contractor shall refer any changes they deem may affect contract price, terms, or conditions to the KO for action.

Assigned COR: To Be Determined

3. CONTRACTOR ROLES AND RESPONSIBILITIES:

The following employees of the contractor serve as the contractor's Program Manager and Task Manager for this contract.

a. **Program Division Manager:** To Be Determined
Telephone: Office: (301) xxx-xxxx or Mobile: (xxx) xxx-xxxx
Email: xxxx.xxxx@xxxxxx.com

b. **Project Manager:** To Be Determined
Telephone: (301) xxx-xxxx or Mobile: (xxx) xxx-xxxx
Email: xxxx.xxxx@xxxxxx.com

c. The contractor is responsible for delivering products or services in accordance with the Contract. The contractor is responsible for implementing a Quality Control Plan (QCP), which is included as part of its technical proposal. The QCP describes the contractor's methods for ensuring all products and services provided under this Contract meet established deliverables and performance standards. The contractor is responsible for producing, maintaining, and providing for audit, quality control records and reports and all records associated with the investigation. The contractor shall appoint a single off-site quality control point-of-contact to act as a central recipient of communication from the Government. Any additional reports required by the Government on the total contract-level will be on an 'ad-hoc' basis.

4. CONTRACT QUALITY REQUIREMENTS:

Contract quality requirements are the technical requirements in the contract relating to the quality of the product or service and those contract clauses prescribing inspection, and other quality controls incumbent on the contractor, to assure that the product or service conforms to the contractual requirements. Government contract quality assurance shall be performed at such times and places as may be necessary to determine that the supplies or services conform to the contract requirements. Failure to meet or exceed the contract quality requirements is defined as a “nonconformance” on the part of the contractor. The contractor shall be held responsible for any identified nonconformance, and MOMRP may require the work to be re-performed.

The Government’s contract quality assurance is defined as follows:

a. “Acceptance” means the act of an authorized representative of the Government by which the Government, for itself or as agent of another, assumes ownership of existing identified supplies tendered or approves specific services rendered as partial or complete performance of the contract.

b. “Conditional acceptance” means acceptance of supplies or services that do not conform to contract quality requirements, or are otherwise incomplete, that the contractor is required to correct or otherwise complete by a specified date.

c. “Minor nonconformance” means a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services.

d. “Major nonconformance” means a nonconformance, other than critical, that is likely to result in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose.

e. “Critical nonconformance” means a nonconformance that is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the supplies or services; or is likely to prevent performance of a vital agency mission.

f. Documentation:

Thorough documentation of unperformed or nonconformance is essential for tracking contractor performance throughout the period of performance. The COR will document deficient work by compiling facts describing the inspection methods and results. The COR will develop documentation to substantiate nonconformance with the Contract

a. REMEDIAL ACTION:

If nonconforming material or services are discovered after acceptance, the defect appears to be the fault of the contractor, any warranty has expired, and there are no other contractual remedies, the contracting officer:

(i) Shall notify the contractor in writing of the nonconforming material or service;

(ii) Shall request that the contractor repair or replace the material, or perform the service, at no cost to the Government; and

(iii) May accept consideration if offered. For guidance on solicitation of a refund, see Subpart 242.71. In accordance with *FAR 52.246-4: Inspection of Services-Fixed-Price*, the Government may require the contractor to re-perform any services that do not conform to contract requirements. If the defects cannot be corrected by re-performance, the KO may either require the contractor to take the necessary action to ensure that future performance conforms to the requirements, or the KO may reduce the Contract price to reflect the reduced value of the

services performed. At an extreme decision point, penalties may include a decision not to exercise contract options. The KO will determine the penalty for nonconformance based upon his or her judgment and the severity of the nonconformance.

5. METHODS OF QUALITY ASSURANCE SURVEILLANCE:

Various methods exist to monitor performance. The COR shall use the surveillance methods listed below in the administration of this QASP.

Regardless of the surveillance method, the COR shall always contact the contractor's Program Manager or off-site representative when a defect is identified and inform the manager of the specifics of the problem. The COR shall be responsible for monitoring the contractor's performance in meeting the contract's quality requirements.

- **DIRECT OBSERVATION:** (Can be performed periodically or through 100% surveillance.)
- **MANAGEMENT INFORMATION SYSTEMS:** (Evaluates outputs through the use of management information reports. Best used for general surveillance and may need to be supplemented by periodic inspections.)
- **PERIODIC INSPECTION:** Uses a comprehensive evaluation of selected outputs. Inspections may be scheduled as required.
 - Analysis of contractor's progress reports. (Evaluate cost, schedule, etc.)
 - Performance reporting.

Surveillance results may be used as the basis for actions (to include payment deductions) against the contractor. In such cases, the Inspection of Services clause in the Contract becomes the basis for the KO's actions.

6. FREQUENCY OF MEASUREMENT:

a. FREQUENCY OF MEASUREMENT:

During contract/order performance, the COR shall take periodic measurements, quarterly as specified in the AQL column of the Performance Standards Summary Matrix, and shall analyze whether the negotiated frequency of measurement is appropriate for the work being performed.

b. FREQUENCY OF PERFORMANCE ASSESSMENT MEETINGS:

The COR shall meet with the contractor quarterly to assess performance and shall provide a written assessment.

Task	Standard	AQL	Surveillance Method
Provide Technical Support	Research Process is implemented with high quality, within budget and meeting mission timelines	Services will be provided to the level of quality necessary to effectively implement the research mission, meeting mission timelines, and within the agreed budget.	COR reviews research outputs for compliance with mission and regulations. Services summarized in monthly invoices and reviewed by COR and Customer Feedback
Support Services	Provide support services in support of the design, implementation, analysis, and reporting of research protocols, conferences, workshops and reviews.	All support services will comply with the MOMRP standing operating procedures, regulatory requirements, and regulatory standards in support the medical research program. No variation is acceptable. Costs will be within the budget.	COR reviews research outputs for compliance with mission and regulations. Services summarized in monthly invoices and reviewed by COR and Customer Feedback
Arrange and Fund Travel for Contract Personnel	The Contractor shall arrange for travel of support personnel at the request of the COR when it is necessary to support basic & clinical research programs. Travel is to include within and outside the continental United States. The Contractor must provide for all necessary travel documents, immunizations, and safety plans that may be required for some destinations. Contractor must provide an invoice for all travel expenses, and if requested copies of receipts.	Travel will be arranged in accordance with requests and specifications of the COR. Travel arrangements will ensure that personnel are at the Conference, Workshop or Review location and be able to fully participate as needed to serve the research mission. Travel costs will not exceed previously agreed amounts.	COR review of invoices for travel costs to ensure that amounts are within budget.
Provide training to Contract Personnel	The Contractor shall ensure that support personnel receive appropriate training to maintain their skills and certifications necessary to provide the required services throughout MOMRP. Training courses for support personnel may be offered at the MOMRP's site with the approval of the COR.	When appropriate, accredited training programs providing certifications will be used. 95% of personnel attending accredited programs will achieve certification. Training must be coordinated in advance with the COR and then approved by the COR prior to the Contractor incurring the cost. Training costs must be within the budget. Professional employees must maintain valid licenses and certifications.	Review of training records by COR or designee. Review of licenses and professional certifications by COR or designee.
Provide Management Services	When requested by the COR to support specific studies or processes, provide personnel support and management services according to MOMRP's standing operating procedures or MRMC Command standards.	All data management practices will comply with all regulatory and electronic data submission requirements in support of MOMRP's submissions. No variation is acceptable. Costs will be within budget.	Internal and external review of all research program processes and Regulatory personnel. COR will review invoices to ensure that costs do not exceed budget.