

Quality Assurance Surveillance Plan (QASP)

for

**EPIDEMIOLOGY ANALYTIC SUPPORT FOR
U.S. ARMY MEDICAL SURVEILLANCE ACTIVITY / ARMED FORCES
HEALTH SURVEILLANCE CENTER**

Contract Number: _____

Task Order Number: _____

Date of Award: _____

Contractor's Name and Address: _____

Installation: _____

Contracting Officer's Representatives (COR): LTC STEVEN TOBLER

Contracting Officer: GILBERT HOVERMALE

APPROVED:

DATE: _____

Contractor Manager Name and Title

1. INTRODUCTION: This Quality Assurance Surveillance Plan (QASP) has been developed to ensure the performance of critical contract elements. The QASP serves as the plan for surveillance of performance and identifies the performance indicators, standards, inspections methods and procedures to be used in monitoring performance. It details thresholds for acceptable and unacceptable performance for specific tasks within the SOW/PWS.

1.1 Overview. This QASP outlines the procedures for surveillance of the contract order. Included are procedures for evaluating the contractor's performance and how key services will be inspected.

1.2 Purpose and Objectives. The objective of this surveillance plan is to provide a systematic method to evaluate the services the Contractor is required to furnish by the contract. The primary interest is in the final product/service that the Contractor is providing and not in the details of how the contractor is accomplishing the task. The COR may evaluate work at any time during the Contractor's work performance. This plan documents the methods to be used for measuring each contract requirement, the scheduling of inspections, and the results of the surveillance program.

2. RESPONSIBILITIES: The Contractor is responsible for management and quality control actions necessary to meet the terms of the contract. The role of the government is quality assurance to ensure contract services are achieved.

2.1 The contractor, not the Government, is responsible for the management and quality control actions necessary to meet the terms of the contract. It is understood that on rare exceptions unforeseen and uncontrollable problems do occur. This has been recognized and incorporated into thresholds for acceptable and unacceptable performance. Good management and use of an adequate quality control plan will allow the contractor to operate within specified performance requirements. The contractor is responsible for providing all information to the government that is necessary to accurately evaluate performance.

2.2 The government desires to maintain a quality standard for completion of all tasks specified in the SOW/Contract and is responsible for developing measurable standards to evaluate performance against. This contract requires services in the field of public health which directly impacts the security of the U.S. and which requires access to protected health information. Due to the sensitivity and the nature of this contract and the adverse events that will occur if inadequate performance is allowed, the level of surveillance and performance standards will be higher than for many governmental contracts. COs / CORs are to be objective, fair and consistent in evaluating contractor performance against the standards.

2.3. Each document provided for analysis by the contractor will be maintained by the contractor for inspection for the period of the contract. Each evaluation made by the

CO/COR will also be documented and filed for further reference, audit, and proof of inspection by the CO/COR.

3. PROCEDURES/METHODS OF ASSESSMENT:

3.1 Contracting Officer Representative Surveillance Schedule. The COR will develop a routine monthly, weekly, and daily surveillance schedule based on the surveillance plan's requirements. The monthly schedule shall be completed not later than the last workday of the preceding month. Copies of the schedule shall be sent to the Contracting Officer. The schedule shall be marked "FOR OFFICIAL USE ONLY" and shall not be shown to the Contractor. In addition, periodic unscheduled surveillance will also be conducted.

3.2 Inspection Methods. This plan may use a combination of surveillance methods which adequately assures the Government of the Contractor's performance.

3.2.1 Periodic Inspection: Periodic inspection is a QA method based on a predetermined plan to evaluate part of the contract outputs using subjective judgment and analysis of agency resources to decide what work to inspect and how frequently to inspect it (daily, weekly, monthly, quarterly, etc.) as determined by the COR.

3.2.2 100% inspection: 100% inspection is a QA method designed to evaluate all outputs of the contract requirement. This method requires a total inspection of Contractor's performance.

3.2.3 Validated Customer Complaints: Validated customer complaints is a QA method whereby deficiencies in the outputs of the contract requirement are identified by a person other than the COR/QAE. These persons (customers) are made aware of contract requirements and monitor the services provided by the Contractor. Where there is a case of poor performance or nonperformance, the COR is notified. Then, the COR/QAE investigates the report, and, if found to be valid, documents it. Each complaint should be validated to ensure the service was required, and that the requirement was not fulfilled.

3.3 Inspection Method Selection. The depth and detail of observations of work shall be based on the relative importance of the items of work under evaluation. The principal method of surveillance shall be periodic inspection with 100% inspection of key requirements; however, any surveillance method can be used at the Government's discretion. Certain tasks may be so important that nonperformance or poor performance may significantly impact the mission and warrant 100% inspection. Joint inspections may be made by the COR/QAE and the Contractor. These are beneficial when routinely performed. They are vital when any disagreement or misunderstanding occurs.

3.4 Performing Surveillance. Surveillance results must be able to support action taken by the COR/Contracting Officer when nonperformance or unacceptable performance occurs.

3.4.1 Inspection Checklists. An essential part of any QASP is the Inspection Checklist for the service that will be evaluated. A standard Inspection Checklist form ensures documented, uniform appraisal of each service occurrence, and that equal weight is given to each evaluation. The checklist shall contain such information as type of service, QAE, inspection results, date, time, and other remarks relevant to the inspection. These checklists form the basis for all QA evaluations and constitute the documentation which will be used to substantiate determination of unsatisfactory performance should that occur.

Required Service	Paragraph Number	Performance Standards	Maximum allowable deviation from requirement (AQL)	Method of Surveillance and Procedures
Evaluation of Present analytic processes management approach	Task 1/ Para 3.1	<ul style="list-style-type: none"> •Contractor begins evaluation within 15 days of contract award • Contractor completes evaluation within 30 days of contract award 	0%	<ul style="list-style-type: none"> •Contractor provides oral outbrief to COR at evaluation completion date • Contractor provides written evaluation/ synopsis within 7 days of the oral outbrief date
Provide Analytic Staff Support to AMSA/AFHSC	Task 2/ Para 3.2	<ul style="list-style-type: none"> • Hire personnel within 30 days upon request to fill vacancies • Personnel demonstrate adequate skills and knowledge to function within work environment 	<10% of work days will be unfilled with qualified candidates	<ul style="list-style-type: none"> •Periodic Review •Review of Monthly reports by CORs and PM
Provide Consultative Support	Task 3/ Para 3.3	<ul style="list-style-type: none"> •At least one PhD level Epidemiologist and one PhD Biostatistician with the level of expertise in study methods and design necessary to provide consultative support will be employed. 	<10% of work days will be unfilled with qualified candidates	<ul style="list-style-type: none"> • Periodic Reviews and customer (including governmental personnel) complaints
Continued Enhanced Data Analysis, Interpretation, and Reporting Capabilities in Support of AI/PI Missions-Ad Hoc Request Timeliness	Task 3/ Para 3.3	<ul style="list-style-type: none"> •Contract staff completes all rapid turnaround requests within four hours of receipt • Contract staff completes all ASAP turnaround requests within two days of receipt • Contract staff completes all other turnaround requests within timeline 	<5% of reports not completed within timeline	<ul style="list-style-type: none"> •Rapid turnaround ad hoc requests-Hourly or more frequent monitoring by PM and COR/designee • Others: There will be a daily status assessment to monitor progress and completion. The DMSS Management Tool, a customized application used for DMSS, will be used as applicable to track progress.

		developed by governmental staff and customers		
Continued Enhanced Data Analysis, Interpretation, and Reporting- Special Studies and Report Timeliness	Task 3&4/ Para 3.3 and #.4	<ul style="list-style-type: none"> • Contract staff completes all special study and MSMR requests within timeline developed by governmental staff, customers and MSMR editor and publishes them in the specified format within specified intervals. 	<5% of reports not completed within timeline	<ul style="list-style-type: none"> • There will be a weekly meeting to monitor progress and completion. The DMSS Management Tool will be used to monitor compliance. As necessary contract staff will meet with MSMR editorial staff. •The DMSS Management Tool and Excel file of report due dates which lists report due dates will be used to monitor requirements compliance.
Continued Enhanced Data Analysis, Interpretation, and Reporting -Quality	Task 2, 3, 4 / Para 3.2, 3.3, 3.3	<ul style="list-style-type: none"> •Contract staff completes all analysis and reports without error and meeting the requirements specified in the project proposal. •Contract staff (analysis PM) will always (100%) contact the governmental staff if instructions or methods are unclear prior to beginning work •Contract staff (analysis PM) will always (100%) contact the governmental staff prior to deviating from project proposal 	<5% of reports with errors	<ul style="list-style-type: none"> • After review by senior contract analyst/ epidemiologist there will be a 100% review by governmental staff. Immediate correction if incorrect. Governmental staff will document if standards not met.
ALL TASKS-Data release	Task 1-5/ Para 3.1-3.5	<ul style="list-style-type: none"> •No information will be released without clearance from governmental staff and the Director, AFHSC •No data will be copied on personal media or electronically transferred without written clearance from the Director, AFHSC •No breach of 	0% (large amounts of protected and sensitive health information is stored and used that fall under HIPPA; personnel that violate this are removed and the government stops paying for the position immediately. There is no remediation possible in this case.)	<ul style="list-style-type: none"> • Periodic Reviews / customer complaints-If any instance of this occurs, whoever discovers it will immediately notify the Director, AFHSC and the PM will immediately be notified. Contract staff involved will immediately be escorted from the building and suspended from employment. An emergency meeting with senior contract staff will be scheduled.

		protected health information laws will occur		
Monthly reports on expenditures and status of funds	Task 1-5/ Para 3.1-3.5	•A status of funds will be provided in excel spreadsheet format to the CORs at least once per 30 day period. The spreadsheet shall list each charge per CLN	0%	•PM shall maintain a by CLIN, by month list of billed items. This will be provided to the CORs on a routine monthly basis. •Excel file shall be provided within 3 days if requested by COR.

3.4.2 Other Surveillance Records. The COR/QAE at times will need to make other types of records such as MFRs, or Memoranda of Telephone Conversation.

4. SUCCESSFUL PERFORMANCE AND REMEDIES:

4.1 Unacceptable Performance. If performance is judged unacceptable, the COR will initiate a Contract Discrepancy Report (CDR) and obtain the contractor’s representative’s initials on the record of the observation and submit the CDR, along with the Inspection Checklist recording the unacceptable performance, to the Contracting Officer. The seriousness of the situation should govern whether the COR should provide the CDR to the Contracting Officer as soon as unacceptable performance is indicated or wait until not later than the third workday of the month following the surveillance.

4.2 Inform Contract Manager. The COR must always contact the Contractor’s manager or on-site representative and inform them of the unacceptable performance, and have the manager initial the entry on the Inspection Checklist. The COR must note on the back of the checklist where the defect was found, the time and method of notification, and the COR’s initials.

5. EXAMPLE CDR:

Contract Discrepancy Report (CDR)

1. CONTRACTOR	2. CONTRACT NUMBER	3. Reference	
4. INCIDENT		5. DATE OCCURENCE	6. CONTROL NUMBER
7. MAJOR <input type="checkbox"/> MINOR <input type="checkbox"/>			
FINDING:			
FINDING IMPACT:			

--	--

8. COR

TYPED NAME AND GRADE

SIGNATURE AND DATE



9. CONTRACTOR CORRECTIVE ACTIONS AND ACTIONS TAKEN TO PREVENT RECURRENCE

--	--

10. Contractor's Representative/On-site manager

TYPED NAME AND POSITION

SIGNATURE AND DATE



11. COR Evaluation of Contractor Response

ACCEPTED REJECTED

12. CLOSE DATE

13. COR/Government Program Manager

TYPED NAME AND GRADE

SIGNATURE AND DATE

6. **REVISIONS TO QASP:** revisions to the surveillance plan are the joint responsibility of the COR and the Contracting Officer.