

QUALITY ASSURANCE SURVEILLANCE PLAN

For: Reference Laboratory Services

Contract Number: < Upon award, Government will enter contract number >

Contract Description: Reference Laboratory Services

Contractor's name: <Upon Award, Government will enter company name.>
(hereafter referred to as the contractor).

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.

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. Copies of the original QASP and revisions shall be provided to the contractor and Government officials implementing surveillance activities.

2. GOVERNMENT ROLES AND RESPONSIBILITIES

The following personnel shall oversee and coordinate surveillance activities.

a. Contracting Officer (CO) - The CO 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 CO shall also assure that the contractor receives impartial, fair, and equitable treatment under this contract. The CO is ultimately responsible for the final determination of the adequacy of the contractor's performance.

Assigned CO: <Upon award, Government will enter CO name.>

Organization or Agency: Department of Veterans Affairs,
Network Contracting Office 17

b. Contracting Officer's Technical Representative (COR) - The COR is 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. The COR is not empowered to make any contractual commitments or to authorize any contractual changes on the Government's behalf.

Assigned COR: <Upon award, Government will enter COR Name>

c. Other Key Government Personnel - <Upon award, Government will enter name, if applicable. This may include Performance Monitors, Clinical Quality experts, etc. who act on behalf of the COR to monitor performance.>

3. CONTRACTOR REPRESENTATIVES

The following employees of the contractor serve as the contractor's program manager for this contract.

a. Program Manager - <Enter name.>

b. Other Contractor Personnel - <Enter name(s) or delete these lines if not applicable>

Title: <Enter title(s) or delete these lines if not applicable.>

4. PERFORMANCE STANDARDS

Performance standards define desired services. The Government performs surveillance to determine if the contractor exceeds, meets or does not meet these standards.

The Performance Requirements Summary Matrix, Technical Exhibit 1 in the Performance Work Statement (PWS), includes the performance standards. The Government shall use these standards to determine contractor performance and shall compare contractor performance to the Acceptable Quality Level (AQL).

Task	Standard ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
Specimen Integrity	1	Specimens rejected due to loss of specimen integrity during transportation from facility	No loss or destruction of specimens once they have been picked up by the courier.	100%	<ul style="list-style-type: none"> Exception report. Contractor reporting. Government Inquiry 	Exercise of Option Period and past performance
Turn-around Time (TAT)	2	Results are not reported by the TAT specified by the contractors test manual	Results are reported within the TAT listed in the contractor's laboratory reference test manual	90%	<ul style="list-style-type: none"> Contractor provided monthly TAT report. TAT inspection on 6 randomly selected tests per quarter. 	Exercise of Option Period and past performance
Communication Specimen Rejection	3	Missing results due to specimen's rejection.	Incidents where a specimen must be rejected are communicated within 24 hours of specimen shipment.	95%	<ul style="list-style-type: none"> Exception report. Contractor reporting. Random audit of orders against results on 6 test requests per quarter 	Exercise of Option Period and past performance

Task	Standard ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
Communication Testing Issues	4	Tests cancelled due to problems with testing at test site	Any issues affecting testing or result reporting must be communicated within 24 hours of specimen shipment.	95%	<ul style="list-style-type: none"> • Exception report. • Contractor reporting. • Random audit of orders against results on 6 test requests per quarter 	Exercise of Option Period and past performance
Result Reporting: Critical Results	5	Critical results are not called upon verification of critical test result	Critical results as defined by contractor's laboratory reference test manual are to be called upon verification of critical test result	100%	Documentation on result report showing the time the test result was verified and the time the critical result was called, who made the call and who received the result.	Exercise of Option Period and past performance
Result Reporting: Electronic Interface	6	Results are not received via electronic interface	Final test results are to be electronically delivered via computer interface upon finalization. Results that cannot be electronically submitted must be delivered via fax or courier within 24 hours of completion.	90%	Observation and random inspection (auditing)	Exercise of Option Period and past performance

Task	Standard ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
Courier Service	7	Couriers do not arrive or do not arrive at scheduled time.	Courier services shall occur once per day from each Government Site stated in PWS within designated timeframe.	90%	<ul style="list-style-type: none"> Courier Specimen pick up log Direct Observation 	Exercise of Option Period and past performance
Billing accuracy	8	<ul style="list-style-type: none"> Overcharging for tests per contract/FSS schedule prices Charging for tests not performed 	<ul style="list-style-type: none"> Invoices shall accurately reflect the correct pricing Tests that are not performed shall not be billed 	100%	Verification of invoice against patient reports	Exercise of Option Period and past performance

¹ AQL's of 100% are based on the fact that all circumstances outside of the contractor's control have been accounted for in the performance work statement. For instance, loss or destruction of specimens and missed routes are "justified" in the case of *force majeure* events and therefore are not included in determining the contractor's acceptable quality level of performance

- If the contractor believes there are excusable circumstances, the contractor shall inform the Contracting Officer and the COR. Excusable circumstances may result in adjustment of the disincentives established in the Performance Matrix based upon the Contracting Officer's Determination and Findings.

5. INCENTIVES

The Government shall use Exercise of an Option Period and past performance and/or any other incentive that was proposed in your solution as incentives. Incentives shall be based on exceeding, meeting, or not meeting performance standards.

6. METHODS OF QA SURVEILLANCE

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

- a. DIRECT OBSERVATION. (Can be performed periodically or through 100% surveillance.)
6 & 7

b. USER SURVEY. (Combines elements of validated user complaints and random sampling. Random survey is conducted to solicit user satisfaction. May also generate inspections and sampling.)

1, 2

c. VALIDATED USER/CUSTOMER COMPLAINTS. (Relies on the patient to identify deficiencies. Complaints are then investigated and validated.)

5

d. 100% INSPECTION. (Evaluates all outcomes.)

8

e. PERIODIC SAMPLING. (Variation of random sampling. However, sample is only taken when a problem/deficiency is suspected. Sample results are applicable only for the specific work inspected. Since sample is not entirely random, it cannot be applied to total activity performance.)

3, 4, 5

f. RANDOM SAMPLING. (Designed to evaluate performance by randomly selecting and inspecting a sample of cases.)

2, 6

g. Analysis of contractor's progress reports. (Evaluate cost, schedule, etc.)

1, 2, 3, 4

8. RATINGS

Metrics and methods are designed to determine if performance exceeds, meets, or does not meet a given standard and acceptable quality level. A rating scale shall be used to determine a positive, neutral, or negative outcome. The following ratings shall be used:

EXCEPTIONAL:	Performance meets contractual requirements and exceeds many to the Government's benefit.
VERY GOOD:	Performance meets contractual requirements and exceeds some to the Government's benefit.
SATISFACTORY:	Performance meets contractual requirements.
MARGINAL:	Performance does not meet some contractual requirements.
UNSATISFACTORY:	Performance does not meet most contractual requirements.

9. DOCUMENTING PERFORMANCE

a. ACCEPTABLE PERFORMANCE

The Government shall document positive performance. Any report may become a part of the supporting documentation for any contractual action.

b. UNACCEPTABLE PERFORMANCE

When unacceptable performance occurs, the COR shall inform the contractor. This will normally be in writing unless circumstances necessitate verbal communication. In any case, the COR shall document the discussion and place it in the COR file.

When the COR determines formal written communication is required, the COR shall prepare a Contract Discrepancy Report (CDR) and present it to the contractor's program manager.

The contractor shall acknowledge receipt of the CDR in writing. The CDR will specify if the contractor is required to prepare a corrective action plan to document how the contractor shall correct the unacceptable performance and avoid a recurrence. The CDR will also state how long after receipt the contractor has to present this corrective action plan to the COR. The Government shall review the contractor's corrective action plan to determine acceptability.

Any CDRs may become a part of the supporting documentation for any contractual action deemed necessary by the CO.

10. FREQUENCY OF MEASUREMENT

a. Frequency of Measurement.

During contract performance, the COR will periodically analyze whether the negotiated frequency of surveillance is appropriate for the work being performed.

b. Frequency of Performance Assessment Meetings.

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

<After award, both the contractor's Program Manager and the COR shall sign this document.>

Signature:

<Contractor Name> _____ Date:
Contractor Program Manager