

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

Cardiovascular Perfusion Services

The contractor will be evaluated in accordance with the following:

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 through contract modification. 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: Christopher Lankford
Organization or Agency: NCO 15

b. Contracting Officer's 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: April Kirkley
Organization or Agency: VA St. Louis Healthcare System

Alternate COR: Amanda Westlund
Organization or Agency: VA St. Louis Healthcare System

3. CONTRACTOR REPRESENTATIVES

The following employee(s) of the contractor serve as the contractor's program manager(s) for this contract.

Primary: _____

Alternate: _____

The contractor is responsible for performance of ALL terms and conditions of the contract. CORs will provide contract progress reports quarterly to the CO reflecting performance on this plan and all other aspects of the resultant contract. The performance standards outlined in this QASP shall be used to determine the level of contractor performance in the elements defined.

Performance standards define desired services. The Government performs surveillance to determine the level of Contractor performance to these standards.

The Performance Requirements are listed below in Section 6. The Government shall use these standards to determine contractor performance and shall compare contractor performance to the standard and assign a rating. At the end of the performance period, these ratings will be used, in part, to establish the past performance of the contractor on the contract.

5. INCENTIVES/DEDUCTS

The Government shall use past performance as incentives. Incentives shall be based on ratings received on the 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. 100% surveillance: The Cardiac Surgeon will observe the contract Perfusionist during each case and provide feedback to the COR.
- b. PERIODIC INSPECTION. Inspections scheduled and reported quarterly per COR delegation or as needed. COR will ask the contract Perfusionist for licensure, certification, registration, and maintenance of certification as a perfusionist information updates each month.
- c. VALIDATED USER/CUSTOMER COMPLAINTS. COR will pull monthly training requirements to ensure that the training is completed timely.

PERFORMANCE MEASURES

Measure	PWS Reference	Performance Requirement	Standard	Acceptable Quality Level	Surveillance Method	Incentive	Disincentive
Duties and Responsibilities	1.2.3.	Shall be able to set-up and operate: intra-aortic balloon pumps, heart and lung machine, cell saver, and other extracorporeal circulatory machines.	100%	100%	Direct Observation	Favorable contractor performance evaluations.	Unfavorable contractor performance evaluation
Duties and Responsibilities	1.2.6.	Generate perfusion related records and documentation for each case.	100%	100%	Contractor Employee shall provide documentation within 3 hours of case completion	Favorable contractor performance evaluations.	Unfavorable contractor performance evaluation
Qualifications of Key Personnel and maintaining licensing, registration and certifications	1.2.9.	All contractor Perfusionist (s) shall have current certification in accordance with ABCP Standards for cardiovascular Perfusion, and maintain licensing, registrations and certifications.	All (100%) contract Perfusionist (s) are certified.	100% No deviations accepted.	Random Inspection of qualification documents	Favorable contractor performance evaluation.	Unfavorable contractor performance evaluation. Removal from contract until such time the contract physician (s) meet qualification standard.
Patient Safety	3.6.1.	Patient safety incidents (near misses and actual events), including medical events involving radioactive material and misadministration must be reported.	All incidents reported promptly (within 24 hours of discovery.)	100%	Direct Observation	Favorable contractor performance evaluation.	Unfavorable contractor performance evaluation
Mandatory Training	3.16.	Contractor completes all mandatory required training	Contractor will complete all required training per VAMC policy	100%	Contractor to provide documented evidence	Favorable contractor performance evaluation.	Suspension or termination of all physical and/or electronic access privileges and removal from contract until such time as the training is complete

7. RATINGS

Metrics and methods are designed to determine rating for a given standard and acceptable quality level. The following ratings shall be used:

<p>EXCEPTIONAL:</p>	<p>Performance meets contractual requirements (AQL) and exceeds many to the Government’s benefit. The contractual performance of the element or sub-element being assessed was accomplished with few minor problems for which corrective actions taken by the contractor were highly effective.</p> <p>Note: To justify an Exceptional rating, you should identify <u>multiple</u> significant events in each category and state how it was a benefit to the GOVERNMENT. However a singular event could be of such magnitude that it alone constitutes an Exceptional rating. Also there should have been NO significant weaknesses identified.</p>
<p>VERY GOOD:</p>	<p>Performance meets contractual requirements (AQL) and exceeds some to the Government’s benefit. The contractual performance of the element or sub-element being assessed was accomplished with some minor problems for which corrective actions taken by the contractor were effective.</p> <p>Note: To justify a Very Good rating, you should identify a significant event in each category and state how it was a benefit to the GOVERNMENT. Also there should have been NO significant weaknesses identified.</p>
<p>SATISFACTORY: (Acceptable Quality Level)</p>	<p>Performance meets contractual requirements. The contractual performance of the element or sub-element contains some minor problems for which corrective actions taken by the contractor appear or were satisfactory.</p> <p>Note: To justify a Satisfactory rating, there should have been only minor problems, or major problems the contractor recovered from without impact to the contract. Also there should have been NO significant weaknesses identified.</p>
<p>MARGINAL:</p>	<p>Performance does not meet some contractual requirements. The contractual performance of the element or sub-element being assessed reflects a serious problem for which the contractor has not yet identified corrective actions. The contractor’s proposed actions appear only marginally effective or were not fully implemented.</p> <p>Note: To justify Marginal performance, you should identify a significant event in each category that the contractor had trouble overcoming and state how it impacted the GOVERNMENT. A Marginal rating should be supported by referencing the management tool that notified the contractor of the contractual deficiency (e.g. Management, Quality, Safety or Environmental Deficiency Report or letter).</p>
<p>UNSATISFACTORY:</p>	<p>Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element or sub-element being assessed contains serious problem(s) for which the contractor’s corrective actions appear or were ineffective.</p> <p>Note: To justify an Unsatisfactory rating, you should identify multiple significant events in each category that the contractor had trouble overcoming and state how it impacted the GOVERNMENT. However, a singular problem could be of such serious magnitude that it alone constitutes an unsatisfactory rating. An Unsatisfactory rating should be supported by referencing the management tools used to notify the contractor of the contractual deficiencies (e.g. Management, Quality, Safety or Environmental Deficiency Reports, or letters).</p>

8. DOCUMENTING PERFORMANCE

a. The Government shall document positive and/or negative performance. Any report may become a part of the supporting documentation for any contractual action and preparing annual past performance using CONTRACTOR PERFORMANCE ASSESSMENT REPORT (CPAR).

b. If contractor performance does not meet the Acceptable Quality level, the CO shall inform the contractor. This will normally be in writing unless circumstances necessitate verbal communication. In any case the CO shall document the discussion and place it in the contract file. When the COR and the CO determines formal written communication is required, the COR shall prepare a Contract Discrepancy Report (CDR), and present it to CO. The CO will in turn review and will present to the contractor's program manager for corrective action.

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 CO. The Government shall review the contractor's corrective action plan to determine acceptability. The CO shall also assure that the contractor receives impartial, fair, and equitable treatment. The CO is ultimately responsible for the final determination of the adequacy of the contractor's performance and the acceptability of the Contractor's corrective action plan.

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

9. FREQUENCY OF MEASUREMENT

a. Frequency of Measurement - The frequency of measurement is defined in the contract or otherwise in this document. The government (COR or CO) will periodically analyze whether the negotiated frequency of surveillance is appropriate for the work being performed.

b. Frequency of Performance Reporting - The COR shall communicate with the Contractor and will provide written reports to the Contracting Officer quarterly (or as outlined in the contract or COR delegation) to review Contractor performance.

10. COR AND CONTRACTOR ACKNOWLEDGEMENT OF QASP

SIGNED:

April Kirkley
Administrative Officer

DATE

SIGNED:

Contractor Name
Title

DATE