

Quality Assurance Surveillance Plan

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:

Organization or Agency:

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:

Quality Assurance Surveillance Plan

Organization or Agency:

3. CONTRACTOR REPRESENTATIVES

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

Primary:

Alternate:

4. PERFORMANCE STANDARDS

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. 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: (Performed by the Cardiac Surgeon once per quarter.)
- b. PERIODIC INSPECTION. Inspections scheduled and reported quarterly per COR delegation or as needed. (Contractors Employees Training and Certification records will be reviewed per inspection period. All inspections and reports will be conducted in compliance with VA Privacy and Information security standards.)
- c. VALIDATED USER/CUSTOMER COMPLAINTS. NA
- d. RANDOM SAMPLING. NA
- e. Verification and/or documentation provided by Contractor. NA

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Measures	PWS Reference	Performance Requirement	Standard	Acceptable Quality Level	Surveillance Method	Met AQL/DID NOT MEET AQL- CPAR RATING/ADD COMMENTS
1 – Provider Quality Performance	4.6.4.1	All contract provider (s) shall perform in accordance with clinical standards	Ongoing Provider Performance Evaluation (OPPE) documentation for all (100%) staff providing services under the contract	90%	Direct Observation	
2 - Qualifications of Key Personnel	4.6.4.2	All contract Perfusionists shall have current certification in accordance with American Board of Cardiovascular Perfusion and maintain license, registration and/or certification.	All Perfusionists shall be certified and compliant with all certifications	100%	Periodic Inspection of qualification documents	
3 – Scope of Practice/Privileging	4.6.4.3	Contract personnel (s) perform within their individual scopes of practice/privileging	All (100%) contract personnel (s) perform within their scope of practice/privileges 100% of the time		Periodic inspection of records	
4 – Patient Access (A)	4.6.4.4	Patient must receive treatment in a timely manner	Perfusionists shall be onsite and available during all scheduled OR hours and within 30 minutes of the facility		Direct Observation	
5- Patient Access (B)	4.6.4.5	Perfusionists/Autotransfusionist shall be available and be in location as needed to properly perform tasks as specified	<i>Perfusionists shall be onsite and available during all scheduled OR hours and within 30 minutes of the facility</i>		Periodic inspection of time and attendance sheets	

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6. Patient Safety	4.6.4.6	Patient safety incidents shall be reported using Patient Safety Report. All incidents reported immediately (within 24 hours.)	All (100%) of patient safety incidents are reported using Patient Safety Report within 24 hours of incident.	90%of patient safety incidents are reported using Patient Safety Report within 24 hours of incident.	Direct Observation	
7. Maintains licensing, registration, and certification	4.6.4.7	Updated certification shall be provided as they are renewed. Licensing and registration information kept current.	All (100%) Certification(s) for Contractor's employee(s) shall be provided as they are renewed. Licensing and registration information kept current.	100% Certification(s) for Contractor's employee(s) shall be provided as they are renewed. Licensing and registration information kept current. No acceptable deviation.	Periodic Inspection of licenses, registrations, and certifications	Maintains Certification
8. Mandatory Training, Privacy, Confidentiality and HIPAA	4.6.4.8	Contractor shall complete all required training on time per VAMC policy. Contractor personnel (s) is aware of all laws, regulations, policies and procedures relating to Privacy, Confidentiality, and HIPAA and complies with all standards Zero breaches of privacy or confidentiality.	All (100%) of required training is complete on time by Contractor personnel (s). Contractor personnel (s) shall comply with all laws, regulations, policies and procedures relating to Privacy, Confidentiality and HIPAA.	100% completions,	Periodic Inspection	
9 – Clinical Information Return	4.6.4.9	Perfusionists shall be responsible to check and compute all calculations of perfusion, autotransfusion and cell saver treatments.	All cases		Direct observation and periodic inspection	

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10 – Documentation /Timesheet	4.6.4.1 0.	Time sheet documentation to be completed weekly and turned in to Section Chief for concurrence	Weekly		Periodic inspection	
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7. RATINGS

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

OUTSTANDING: Performance meets contractual requirements 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.

***Note:** To justify an **Exceptional** rating, you should identify multiple 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.*

VERY GOOD: Performance meets contractual requirements 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.

***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.*

SATISFACTORY: 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.

***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.*

MARGINAL: 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.

***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).*

UNSATISFACTORY: 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.

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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).

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. See Sample CDR below.

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 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:

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CONTRACT REPORT		
1. CONTRACT NUMBER		2. REPORT NUMBER FOR THIS DISCREPANCY
3. TO: <i>(Contracting Officer)</i>		4. FROM: <i>(Name of COR)</i>
5. DATES		
a. CR PREPARED	b. RETURNED BY CONTRACTOR:	c. ACTION COMPLETE
6. Issue Identified <i>(Describe in detail. Include reference to PWS Directive; attach continuation sheet if necessary.)</i>		
7. SIGNATURE OF COR		Date:
8. SIGNATURE OF CONTRACTING OFFICER		Date:
9a. TO <i>(Contracting Officer)</i>	9a. FROM <i>(Contractor)</i>	
10. CONTRACTOR RESPONSE AS TO CAUSE AND ACTIONS TO PREVENT RECURRENCE. <i>(Cite applicable quality control program procedures or new procedures. Attach continuation sheet(s) if necessary.)</i>		
11. SIGNATURE OF CONTRACTOR REPRESENTATIVE		Date:

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12. GOVERNMENT EVALUATION.

13. GOVERNMENT ACTIONS

14. CLOSE OUT

	NAME	TITLE	SIGNATURE	DATE
CONTRACTOR NOTIFIED				
COR				
CONTRACTING OFFICER				