

Quality Assurance Surveillance Plan (QASP) Pathology 36C26318R0477

Contract# _____

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: Shea Colby

Organization or Agency: VAMC Minneapolis, MN

- 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: Jessica Keehn

Organization or Agency: VACIHCS, Des Moines, IA

Quality Assurance Surveillance Plan

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: This method is used to ensure all samples submitted for pathologist examination are completed within the time frames outlined in the QASP. 100% of cases reporting a newly diagnosed malignancy will be reviewed for required documentation (called to ordering physician, reviewed by a second pathologist and appropriate cancer staging entered). The laboratory secretary and histology technicians conduct the surveillance and produce reports for the CORs review. This method is also used to ensure a pathologist is present Monday through Friday at the VA and arrives at 8 a.m. and that a pathology assistant is present Monday through Friday at the VA and arrives at 12:30 p.m. An attendance log with hours worked is kept in the VA Pathology office.

b. **PERIODIC INSPECTION.** Inspections scheduled and reported quarterly per COR delegation or as needed. Annual period inspection of all Pathologist and Pathology Assistant credentialing folders will be conducted to ensure licensing and certifications are current.

- c. VALIDATED USER/CUSTOMER COMPLAINTS. Customer complaint data is compiled quarterly and reviewed by the COR – any validated complaints against a Contractor that are not resolved within the required seven-day period will be further investigated.
- d. RANDOM SAMPLING. A 10% retrospective review of all cases signed off by an individual pathologist will be reviewed by a second pathologist within the group (second pathologist will not have the diagnosis rendered by the original pathologist, but rather will be interpreting/diagnosing the case independently). The results will be reviewed by the Pathology and Laboratory Medicine Service Chief or designee for discrepancy.
- e. Verification and/or documentation provided by Contractor. Monthly invoices provided by the contractor for per procedure off-site reference lab testing and off-site professional consultation will be reviewed by the histopathology technician against VA send-out logs. Discrepancies are reviewed by the COR for corrective action.

Measures	PWS Reference	Performance Requirement	Standard	Acceptable Quality Level	Surveillance Method	Met AQL/DID NOT MEET AQL – CPAR RATING/ADD COMENTS
1 - Qualifications of Key Personnel	4.4.4.2.	All contract Pathologists (s) shall have current board certifications in Clinical and Anatomic Pathology by the American Board of Pathology (ABP).	All (100%) contract Pathologists(s) are board certified in Anatomic and Clinical Pathology	100% No deviations accepted.	Random Inspection of qualification documents	
2 - Scope of Practice/Privileging	4.4.4.3.	Contract physician(s) perform within their individual scopes of practice/privileging	All (100%) contract physician (s) perform within their scope of practice/privileges 100% of the time.	All (100%) contract physician (s) perform within their scope of practice/privileges 100% of the time. No deviations accepted.	Random Inspection of records.	
3- Access	4.4.4.4.	Contract pathologist (s) and contract pathology assistant(s) shall be available and in location as needed to properly perform tasks as specified.	All (100%) contract physician (s) are on time and available to perform services.	Contract physician (s) are on-time and available to perform services 97% of the time. In the event of a delay in reporting of key personnel Contracted group must provide a backup pathologist & pathology assistant later that day 100% of the time	Direct Observation VA will call for a back-up pathologist if one does not report by 9 a.m. and for a backup pathology assistant if one does not report by 1 p.m.	

4 - Patient Safety—Corrected patient results.	4.4.4.5.	Patient safety incidents shall t be reported to the COR. This includes any correct patient results (diagnosis) that impact patient treatment & care. All incidents are to be reported immediately (within 24 hours of detection.)	All (100%) of patient safety incidents are reported to COR within 24 hours of incident.	All (100%) of patient safety incidents are reported to COR within 24 hours of incident. No acceptable deviation.	Direct Observation	
5-Maintains licensing, registration, and certification	4.4.4.6.	Updated Licensing, registration and certification shall be provided as they are renewed. Licensing and registration information kept current.	All (100%) licensing, registration(s) and certification(s) for contract physician (s) shall be provided as they are renewed. Licensing and registration information kept current.	All (100%) licensing, registration(s) and certification(s) for contract physician (s) shall be provided as they are renewed. Licensing and registration information kept current. No acceptable deviation.	Periodic Sampling	
6 - Mandatory Training	4.4.4.7.	Contractor shall complete all required training per VACIHCS policy	All (100%) of required training is complete on time by contract physician (s).	100% completions, no deviations.	Periodic Sampling	

7 - Privacy, Confidentiality and HIPAA	4.4.4.7.	Contractor 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%) contractor physician (s) comply with all laws, regulations, policies and procedures relating to Privacy, Confidentiality and HIPAA	100% compliance; no deviations.	Contractor shall provide evidence of annual training required by VACIHCS, reports violations per VA Directive 6500.6.	
8. Quality Assurance P&LMS	4.4.4.8	Contractor meets Quality goals for P&LMS as outlined in the annual P&LMS Quality Management Plan and in 5.2.2.2	All (100%) of Quality goals are meet	90% of goals are met, if goals are not met investigation and corrective action is required.	Quarterly Review of Quality data.	
9. Retrospective Case Review	4.4.4.9	retrospective review of cases for each pathologist for agreement with original diagnosis.	10% of cases reviewed	10% of cases reviewed	Periodic Sampling	
10. Consultation response time	4.4.4.10	Response time for emergent pathology consultations, including but not limited to unexpected frozen sections, and emergent back-up clinical pathology consultations, such as blood bank compatibility and blood bank transfusion reaction consultations	30-minute response time	30-minute response time	Periodic Sampling	

11. Receipt of frozen section to Physician notification of results.	4.4.4.11	Turn-around time from receipt of frozen section to Physician notification of results.	20-minute turn-around time.	20-minute turn-around time.	Periodic Sampling	
12. Second review of all malignancy diagnosis	4.4.4.12	Timeliness of second review of all new malignancy diagnosis, excluding skin, squamous and basal cell carcinoma	2 business days	2 business days	Periodic Sampling	
13. Notification of all new malignancies	4.4.4.13	Provider notification of all new malignancies	Within 24 hours of diagnosis	Within 24 hours of diagnosis	Periodic Sampling	
14. Correlation of frozen section results	4.4.4.14	Correlation of frozen section results and final diagnosis	95% correlation	95% correlation	Periodic Sampling	
15. Completion of routine surgical pathology cases	4.4.4.15	Completion of routine surgical pathology cases	90% within two working days of specimen receipt in VA lab	90% within two working days of specimen receipt in VA lab	Periodic Sampling	

16. Completion of urgent cytology cases	4.4.4.16	Completion of urgent cytology cases	90% within 3 working days of specimen receipt in VA lab	90% within 3 working days of specimen receipt in VA lab	Periodic Sampling	
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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.

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 must 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:

COR NAME/TITLE

DATE

SIGNED:

CONTRACTOR NAME/TITLE

DATE

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 CONTRACTOR:	BY	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:	
12. GOVERNMENT EVALUATION.				
13. GOVERNMENT ACTIONS				
14. CLOSE OUT				
	NAME	TITLE	SIGNATURE	DATE
CONTRACTOR NOTIFIED				
COR				

CONTRACTING OFFICER				
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