

**Quality Assurance Surveillance Plan (QASP)
For
Animal Care and Other Research Support Services
United States Army Medical Research Institute of Infectious Diseases (USAMRIID)**

- 1. Purpose:** The purpose of this Quality Assurance Surveillance Plan (QASP) is to provide the quality standards and procedures for evaluating the quality-level of services provided by the Contractor under this contract. The QASP addresses the following: 1) the Government's and Contractor's quality control responsibilities; 2) surveillance procedures; and 3) performance standards.
- 2. Responsibilities:**
 - 2.1. The Government is responsible for inspecting the services received and ensuring that the services meet the contract terms. The Government's Contracting Officer Representative (COR) will perform and document quality surveillance activities described in the QASP. Surveillance documentation will be provided to the Contract Specialist no less than quarterly.
 - 2.2. The Contractor is responsible for ensuring quality control actions are taken to meet the terms of the contract. The Contractor will create a Quality Control Plan to assist in managing this process. The Contractor will cooperate fully with the COR when quality surveillance actions are taken and will provide all information necessary to allow the COR to accurately evaluate performance.
 - 2.3. This QASP is a "living document" and the Government may review and revise it on a regular basis. However, revisions will be coordinated with the Contractor. The Contractor is encouraged to suggest QASP improvements to the COR.
- 3. Surveillance Procedures:**
 - 3.1. Performance of the contracted services will be evaluated by the COR to determine whether or not services meet the performance requirements of the contract. Quality surveillance will be documented and signed by the both the COR and the Contractor's on-site representative. Surveillance documentation will include the following: contract number, date and time of surveillance, location of surveillance, performance requirement, acceptable quality level, method of surveillance, observed quality level, observation notes, and surveillance results.
 - 3.1.1. When the performance requirement is met, the COR will file the signed surveillance report in the COR contract file.
 - 3.1.2. When the performance requirement is not met, or a customer complaint is found to be valid, the COR will prepare a Contract Discrepancy Report (CDR) and will notify the Contractor's on-site representative of the unacceptable performance. The COR will provide the surveillance documentation and CDR to the Contracting Officer who will forward copies of the documents to the Contractor for completion. The Contractor shall respond to the CDR by completing the form and returning it to the KO within 15 calendar days of receipt. A Contract Discrepancy Report template is included on the last page of the QASP.
 - 3.2. The QASP prescribes the use of three surveillance methods: 1) Periodic Inspection; 2) 100% Inspection; and 3) Customer Complaints.
 - 3.2.1. Periodic Inspection – this method evaluates parts of the Contractor's performance, processes, or output items using subjective judgment to decide what work to inspect and how frequently to inspect it.

3.2.2. 100% inspection – this method evaluates all parts of the Contractor’s performance, processes, or output items. The COR will determine the frequency of inspections.

3.2.3. Customer Complaints – this method evaluates performance which has been identified by a person (customer), other than the COR, to be unacceptable. Upon receiving a customer complaint, the COR will conduct an investigation to validate the complaint to confirm whether the Contractor’s reported performance constitutes a discrepancy.

3.3. Surveillance results will be recorded using the following ratings: 1) Exceeds standards; 2) Meets standards; and 3) Does not meet standards.

3.3.1. Exceeds standards – performance exceeds the acceptable quality level.

3.3.2. Meets standards – performance meets the acceptable quality level.

3.3.3. Does not meet standards – performance does not meet the acceptable quality level.

4. Performance Standards:

4.1. The Performance Requirement Summary Table (PRST) defines the following: 1) performance requirement; 2) contract reference; 3) acceptable quality level; and 4) surveillance method. The absence of any contract requirement from the PRST shall not detract from its enforceability nor limit the rights or remedies of the Government under any other provision of this contract. The government has the right to inspect all services required in the contract.

4.2. Performance Requirement Summary Table:

<u>Performance Requirement</u>	<u>Paragraph Numbers</u>	<u>Acceptable Quality Level</u>	<u>Surveillance Method</u>
Animal Care. Establish and maintain a world class animal care program. Follow all animal care SOPs and mandatory regulations.	All	No loss of animals due to contractor negligence 99% of the time.	Periodic Inspection and Customer Complaints
Receipt of Animals. Follow AC-04 and AC-06 series SOPs and Guide for the Care and Use of Laboratory Animals.	1 .3.B	No deviations to caging requirements. Same day reporting of discrepancies to COR so there is no loss to the Government for discrepancies not reported on time.	Periodic Inspection and Customer Complaints
Feeding and Watering of Animals. All animals shall be fed and watered by end of shift. Follow AC-08 series SOPs.	1.3.C	100% compliance with food and water directions.	Periodic Inspection and Customer Complaints
Handling and Restraint of Animals. Cause no injury when handling or restraining animals due to	1.3.D	No loss of animals due to contractor negligence 99% of the time.	Periodic Inspection and Customer Complaints

negligence.			
Sterilization, Sanitation and Cleaning of Animal Caging, Equipment and Facilities. Follow AC-02, EQ-01 and FC-01 series SOPs. Run no washer or autoclave below required temperature or conduct 100% rewash/re-sterilize.	1.3.E	Note equipment failure and respond accordingly 100% of the time. Comply with cage and room sanitation SOPs 99% of the time.	Periodic Inspection and Customer Complaints
Animal Health Surveillance/Environmental Monitoring. Observe all animals twice daily. Monitor and record environmental conditions.	1.3.F	Observe animals twice daily 99% of the time. Monitor and record on a daily basis environmental conditions 98% of the time. Report problems immediately.	Periodic Inspection and Customer Complaints
General Animal Equipment Maintenance. Perform operator/user maintenance as required by operators manual or SOPs.	1.3.G	Repair or remove from service inoperable equipment within 1 day 99% of the time.	Periodic Inspection
Veterinary Technician Services 1.3.H Optional Services. Perform animal monitoring, treatment and research support; environmental enrichment; and animal and sanitation quality control; as directed by COR and as per SOPs.	1.3.H.1	No repeat customer complaints concerning any technical services; Veterinarian in charge satisfaction with support – no repeat complaints. No repeat customer complaints concerning any technical services; no failures of providing service under the EEP; no positive animals allowed to enter the facility; all failed equipment QC tests are reported promptly to management.	Customer Complaints; at least 95% of all recurring suspenses for sentinel program testing are met; zero animals with positive tests allowed into facility without veterinarian approval.
Glassware Services. Clean, sterilize as required, and store glassware for investigator use.	1.3.I	Maintain stock of clean and sterile glassware 97% of the time. No repeat customer complaints.	Periodic Inspection and Customer Complaints

Emergency Services. Respond to emergency calls from COR.	1.3.J	100% response to emergency calls from COR during and after core working hours.	100% Inspection
Full Time Services. Provide cagewash and glassware services M-F. Provide caretaker services 7 days a week. Provide other services M-F and as requested for overtime.	1.3.K	No loss of performance quality due to personnel absences.	Periodic Inspection
Providing Administrative Information. Provide requested information in less than 1 week.	1.3.L	80% of the time. In two weeks, 98% of the time.	Periodic Inspection
Training of Personnel. Perform and document all required employee training.	1.3.M	80% of the time. Document training through QC plan. Follow the plan 100% of the time.	Periodic Inspection
Medical Requirements. Provide pre-employment physicals. Ensure required vaccinations are current. Perform PPD testing semiannually.	1.3.N, 4.11	100% of the time.	100% Inspection
Personnel Background Investigation. Obtain background checks on all personnel.	1.3.O, 4.9	NCIC and credit check initiated prior to work, NAC/NACLC initiated not later than first day of work 100% of the time.	100% Inspection
Security. Have a USAMRIID photo ID badge prior to work in all cases. Never open a secure area for others.	1.3 P, 4.9.2	Comply with security directives 100% of the time. No security violations.	Periodic Inspection and Customer Complaints
Repairs and Preventive Maintenance of Large Mechanical Equipment. Provide operator/user maintenance as required by equipment manuals or EQ-01 and FC-01 series SOPs. Clean screens and jets in cagewash equipment.	1.3.Q	No plugged drains or equipment malfunction due to contractor failure 95% of the time. No equipment misuse.	Periodic Inspection and Customer Complaints

<p>Vehicle Operation. All drivers appropriately trained and licensed. Report vehicle problems immediately.</p>	1.3.R	100% of the time.	100% Inspection
<p>Contractor Management, Control and Supervision. Fully qualified key personnel supervisor on duty when employees are working.</p>	1.3.S, 4.1.2.1	100% of the time.	100% Inspection
<p>Contractor Quality Control. Quality Control Plan and metrics completed and current for all PRST items. Corrective actions on time and sufficient.</p>	1.3.T	QC plan and metrics complete and current 100% of the time. Corrective actions on time and sufficient 90% of the time.	Periodic Inspection and Customer Complaints
<p>Safety Programs and Safety Training. Safety plan developed and implemented prior to performance start.</p>	1.3.U, 4.10	100% of the time.	100% Inspection
<p>Accident/Injury Incident Reports. Immediate reporting of accidents and injuries.</p>	1.3.V, 4.10	100% of the time.	100% Inspection
<p>Occupational Health and Safety. Ensure no employees on the job without full medical requirement compliance. Provide occupational health program for all employees. Ensure biocontainment employees comply with Special Immunization Program requirements.</p>	1.3.W, 4.10	100% of the time.	100% Inspection
<p>Logistical Support. Order all requirements so as not to have an out of stock or overstock</p>			

condition. Rotate feed and items with a shelf life to use oldest, non-expired stock first. Comply with feed age and storage requirements.	1.3.X	95 % compliance for all items except direct-care items; 100% of the time for feed and other direct-animal care item (i.e., feed, water, bedding, enrichment).	Periodic Inspection and Customer Complaints
Provide Qualified Personnel. Contractor shall propose for work under this contract only qualified personnel. All replacements shall be fully trained to the required contract level within two weeks of reporting to work.	1.3Y, 4.1	100% of the time.	100% Inspection
Maintain AAALACi accreditation. Follow all applicable SOPs, policy directives and regulations. Project Manager shall assist in reviewing SOPs and assist with AAALAC and IACUC site visits.	1.3Z	100% of time. No major deficiencies in any Contractor-controlled areas. Not more than 3 minor deficiencies in any one Contractor controlled program area.	Triennial Inspection and Semiannual USAMRIID Inspection.
Following, Implementing, reviewing SOPs. Reviewing as requested by VMB management, implementing new SOPs as required.	1.3.Z.1	100% of the time. No repeat SOP violations; available for all SOP reviews.	Periodic inspection.

CONTRACT DISCREPANCY REPORT (CDR)

1. Contract Number: _____
2. To: _____
3. From: _____
4. Date/Time of Observed Discrepancy: _____
5. Description of Discrepancy:

6. Corrective Action Plan:

A written corrective action plan () is, () is not required.

COR Signature

Date

Contractor Representative's Name and Signature

Date