R1 - PERFORMANCE WORK STATEMENT (PWS)
CBER Annual Re-Verification of BSL-3 Suites
FDA OSIST IDIQ Contract No.: XXXX
Task Order 0001

1. GENERAL INFORMATION

1.1 Background

The Office of Occupational Safety and Health (OOSH) supports the FDA mission by providing services, policy, and oversight for laboratory science, laboratory security, environmental, and occupational safety and health programs.

The Center for Biologics Evaluation and Research (CBER) operates ten (10) active BSL-3 laboratories located in Building 52-72, 5th Floor, at the FDA White Oak Campus, Silver Spring, MD. These facilities require annual re-verification and vaporized hydrogen peroxide (VHP) decontamination in support of scheduled preventive maintenance and regulatory compliance.

1.2 Objective

The objective of this Task Order is to obtain professional biosafety, safety engineering, industrial hygiene, labor security, and Occupational Health and laboratory safety support services necessary to:

- Conduct annual re-verification of all BSL-3 suites.
- Perform VHP decontamination of BSL-3 laboratories and associated equipment.
- Evaluate and verify compliance with Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), United States Department of Agriculture / Animal and Plant Health Inspection Service (USDA/APHIS), and applicable federal biosafety requirements.
- Validate Heating, Ventilation, and Air Conditioning (HVAC) airflow, pressure differentials with certified test equipment, alarm systems, and failure scenarios.
- Meet Personal Protective Equipment (PPE) and entry requirements (PPE/Safety training provided to contractors by FDA staff)
- Issue required verification reports and certificates.

CBER requires contractor personnel with thorough familiarity with the BSL-3 facilities in Building 52-72, 5th floor, at the White Oak Campus of FDA to provide efficient services.

1.3 Scope

The Contractor shall provide all trained and cleared personnel, supervision, technical expertise, equipment, materials, and incidentals necessary to perform:

- BSL-3 consultation and compliance assessments
- VHP laboratory decontamination services
- HVAC airflow and pressure differential testing
- Failure scenario testing (HVAC and power)

- Review of biosafety documentation and maintenance programs
- Deficiency identification and corrective action review
- Final verification reporting and certification

Personnel requirements as specified in the IDIQ PWS are to be adequately trained, possess requisite experience, and be fully qualified to provide the high-level support required prior to being assigned to this individual order. Selection of individuals to work on this task is critical to the success of OC/OOSH.

Work shall be performed at FDA White Oak Campus and other NCR locations as required.

2. TECHNICAL REQUIREMENTS

2.1 BSL-3 Re-Verification Services

The Contractor shall:

1. Review certification testing of:

- Biosafety cabinets (BSCs)
- Primary barrier equipment
- High-Efficiency Particulate Air (HEPA) filter enclosures/housings
- Autoclaves
- Emergency power testing records
- Testing and Air Balance (TAB) reports

2. Evaluate secondary containment integrity.
3. Evaluate facility decontamination procedures.
4. Test HVAC systems for airflow compliance and space pressure differential relationships during HVAC failure scenarios.
5. Test room alarms.
6. Review policies, Standard Operating Procedures, operations and maintenance programs, and required compliance documentation.
7. Conduct exit briefing on inspection findings.
8. Provide up to four (4) engineer site visits, with two-week advance coordination.
9. Provide up to twenty (20) hours of consultation support annually.

2.2 VHP Decontamination Services

The Contractor shall:

- Provide sufficient VHP equipment and trained technical staff to complete decontamination over a short timeframe.
- Decontaminate rooms, laboratories, suites, corridors, and listed equipment.
- Deploy biological indicators (BI) and chemical indicators (CI).
- Provide a report of BI and CI results (kill verification data) to verify effectiveness of VHP.
- Provide diagram showing indicator placement.
- Support annual shutdown preventative maintenance schedule.

Decontamination applies to the ten (10) BSL-3 suites detailed in Attachment R2, (CBER BSL3 Areas for Decontamination).

2.3 Reporting Requirements

The Contractor shall provide Draft and Final Verification Reports including:

- Executive Summary
- Summary of Deficiencies and Corrective Actions
- HVAC testing data
- HVAC failure scenario data
- Power failure response evaluation
- Biosafety and maintenance manual review
- Calibration data for test instruments
- Overall summary

3. PERFORMANCE STANDARDS AND ACCEPTANCE CRITERIA

All re-verification testing shall comply with applicable CDC, NIH, USDA/APHIS, and industry standards. VHP decontamination shall demonstrate 100% biological indicator kill verification. Reports shall be submitted within required timelines and are subject to COR review and acceptance.

Performance Objective	**Standard**	**Acceptable Quality Level (AQL)**	**Surveillance Method**
Completion of Re-Verification Testing	All required testing completed per industry standards (CDC/NIH BMBL, NSF/ANSI 49, ASHRAE, etc.)	100% compliance	COR review
VHP Decontamination	BI shows successful microbial kill; CI confirms VHP presence	100% kill verification	Report validation
Draft Verification Report	Submitted within required timeframe	≤ 14 business days post-testing	COR review
Final Verification Report	Submitted within required timeframe	≤ 10 business days post-comment receipt	COR review
Site Visits	Up to 4 visits completed as scheduled	100% completed	COR validation

4. DELIVERABLES AND DELIVERY SCHEDULE

Deliverables:

1. Deficiency Report within 10 working days of completion and exit briefing (if applicable)
2. Draft Verification Report within 14 working days of FDA response to any deficiencies (if response applicable)
3. Final Verification Report within 10 days of FDA comment receipt to draft report

Draft and Final Verification Reports include the following:

a) Executive Summary

b) Deficiencies and Compliance Actions for the BSL-3 labs

c) Summary of Deficiencies

d) Facility HVAC Testing

e) Data for HVAC Failure Scenario Testing

f) Summary of HVAC failure scenario data

g) Response to Power Failure

h) Biosafety and Maintenance Manual Reviews

i) Overall Summary

J) Calibration of Test Instruments data

4. Verification of the FDA laboratories including Certificate of Verification (valid one year, reference Appendix A for area, number, and type of equipment)

5. Surveys of all BSL-3 Suites and related reviews and assessments
5. BI/CI Decontamination Results Report
6. BSL-3 Consultation Services (NTE 20 hours)

7. Exit meeting to provide an informal discussion of findings and if work can proceed.

Performance Delivery Timeline:

- Deficiency Report: Within 10 working days of testing completion.
- Draft Verification Report: Within 14 working days of FDA response to deficiencies.
- Final Verification Report: Within 10 working days of FDA comments.
- Decontamination: 2nd–3rd week of November (estimated).
- Recertification: 2nd week of December (estimated).

**Dates of completion of services may change due to events outside of FDAs control. Preparation to ensure work can be completed during these timeframes is expected in the months prior to decontamination and recertification.

5. PERIOD OF PERFORMANCE
Base: August 17, 2026 – February 28, 2027, with three (3) 12-month option years to be exercised at the Government's discretion.

6. PLACE OF PERFORMANCE
Primary location:
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

Work may also occur at other NCR FDA facilities as required.

Normal operating hours:
Monday–Friday, 7:30 AM – 4:00 PM, excluding Federal holidays.

7. PERSONNEL REQUIREMENTS
Contractor personnel must:

- Meet IDIQ labor category qualifications.
- Obtain Level V Public Trust clearance or higher.
- Maintain required medical clearance and vaccinations.
- Pass respirator fit testing and wear an N-95 and/or Powered Air Purifying Respirator (PAPR) as required by individual laboratories.
- Wear Personal Protection and Equipment (PPE) required.
- Provide documentation of up-to-date negative TB testing (PPD or IGRA), Polio vaccination/titer, and seasonal flu vaccination.
- Complete Laboratory Visitor Training including site orientation, PPE, entry and exit procedures (approx. 30 minutes) conducted by FDA staff or lab personnel.
- Sign 'No Contact with Avian Species' form for applicable labs (Suites 4&5) to ensure they won't have contact with avian species prior to or for 5 days after entering suites 4&5.

No Key Personnel are designated for this Task Order.

8. TRAVEL
Travel is not anticipated. If required, prior written approval from the CO, CS, and COR is mandatory and must comply with Federal Travel Regulation ceilings.

9. GOVERNMENT FURNISHED INFORMATION AND EQUIPMENT (GFI/GFE)
The Government may provide GFI and/or GFE as specified in the Task Order. All deliverables become property of the U.S. Government.

10. GOVERNANCE AND COMMUNICATION

Contractual matters shall be coordinated through the Contracting Officer (CO). Technical direction shall be provided by the COR and designated Government Task Lead (GTL). The Contractor shall coordinate scheduling and operational issues through the CO and COR.