C1 - INDEFINITE-DELIVERY/INDEFINITE-QUANTITY (IDIQ)

PERFORMANCE WORK STATEMENT (PWS)

Occupational Safety, Policy, and Laboratory Quality Support; Primary Barrier Maintenance and Support; Industrial Hygiene; Information and Data Management Support; and Training Development and Management (OSIST)

1.0 GENERAL INFORMATION

1.1 Background

The Food and Drug Administration (FDA), a component of the U.S. Department of Health and Human Services (HHS), protects and promotes public health by ensuring the safety, efficacy, and security of regulated products. To fulfill that mission, FDA facilities, laboratories, and workplaces must operate in a manner that ensures product integrity, employee and visitor health, workplace safety, and environmental stewardship.

The Office of Occupational Safety and Health (OOSH), under the Office of the Chief Scientist, oversees the Agency's Environmental, Occupational Safety, and Health (EOSH) program. OOSH's vision is for FDA to serve as a model of excellence for robust and integrated laboratory science, laboratory security, environmental, and occupational safety and health programs. Its mission includes protecting employees, surrounding communities, and the environment; providing occupational health services in a timely manner; supporting high-quality laboratory results; and promoting a culture of shared responsibility and safety.

Industrial hygiene services are embedded within laboratory, inspection, and field operations to ensure chemical, biological, radiological, noise, and other physical hazards are anticipated, recognized, evaluated, and controlled.

1.2 Objective

The objective of this IDIQ is to obtain enterprise-level technical and programmatic support services for:

- Occupational Safety, Policy, and Laboratory Quality Support
- Primary Barrier Equipment Maintenance and Certification
- Industrial Hygiene Support Services
- Information and Data Systems Program Support
- Training Development and Management.

This contract supports the development and execution of a robust Occupational Safety and Health Program across all FDA facilities.

1.3 Scope

The Contractor shall provide comprehensive technical, engineering, program management, and professional services across FDA headquarters and nationwide facilities.

The enterprise laboratory footprint includes approximately one million square feet across 2600 laboratories (Attachment C2 – OSIST Facility Inventory).

Scope includes:

1. IDIQ-level Program Management
2. Order-level Project Management
3. Transition-in and Transition-out services
4. Occupational Safety and Laboratory Quality Support
5. Primary Barrier Equipment Maintenance and Lifecycle Management
6. Enterprise Industrial Hygiene Program Architecture
7. Information & Data Systems Program Support
8. EOSH Training Development and Management.

Services shall support headquarters (White Oak Federal Research Center) and field laboratories nationwide.

1.4 Period of Performance

Five (5) year IDIQ ordering period. Task Orders may be Firm-Fixed-Price (FFP), Labor Hour (LH), Time-and-Materials (T&M), or hybrid, as specified.

1.5 Place of Performance

Performance shall occur at FDA facilities nationwide, including but not limited to:

- White Oak Federal Research Center (Silver Spring, MD)
- National Capital Region (NCR) facilities
- Jefferson, AR (National Center for Toxicological Research (NCTR))
- Field laboratories across multiple states.

Specific locations are identified in Attachment C2 and may change based on mission needs.

1.6 Applicable Standards and Regulations

The Contractor shall comply with:

- Occupational Safety and Health Act of 1970

- Title 29, Code of Federal Regulations, Part 1910.134 – Respiratory Protection
- National Institutes of Health (NIH) Design Requirements Manual
- Centers for Disease Control and Prevention (CDC) Biosafety Specifications
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Federal Select Agent Program (FSAP)
- National Sanitation Foundation / American National Standards Institute Standard 49 (NSF/ANSI 49) – Biosafety Cabinetry: Design, Construction, Performance, and Field Certification
- American National Standards Institute (ANSI) Z10 – Occupational Health and Safety Management Systems
  (Note: The current designation is ANSI/ASSP Z10, issued jointly with the American Society of Safety Professionals.)
- International Organization for Standardization (ISO) 9001 – Quality Management Systems
  International Organization for Standardization (ISO) 14001 – Environmental Management Systems
- American Industrial Hygiene Association (AIHA) Guidance Documents
- U.S. Food and Drug Administration (FDA), Office of Laboratory Science and Safety (OLSS) Policies.

2.0 PERFORMANCE REQUIREMENTS

Task Area 1 – Program and Order Management

The Contractor shall provide IDIQ-level Program Management and Task Order-level Project Management.

Program Management Plan (PMP)

The PMP shall include:

- Management approach and staffing plan
- Organizational chart with roles and responsibilities
- Personnel recruitment, retention, and replacement strategy
- Process to oversee and manage work activities at IDIQ level
- Communication diagram showing Government/Contractor lines of communication.

Meetings

The Contractor shall:

- Coordinate monthly program meetings
- Prepare agendas and distribute materials

- Document meeting minutes (including decisions, attendees, action items)
- Track issues and action items.

Task Area 2 – Transition Services

Transition-In

The Contractor shall:

- Develop Transition-In Plan
- Coordinate onboarding and badging
- Review existing processes
- Participate in joint transition meetings
- Certify personnel have reviewed FDA/OSIST policies.

Transition-Out

The Contractor shall:

- Develop Transition-Out Plan and Schedule
- Deliver all SOPs and Manuals of Operations
- Reconcile Government-Furnished Equipment (GFE) and Government-Furnished Information (GFI)
- Support follow-on contractor shadowing
- Ensure no degradation of service during turnover.

Task Area 3 – Occupational Safety, Policy, and Laboratory Quality Support

The Contractor shall:

- Assist with ISO 17025 laboratory quality implementation
- Support development and implement of a culture-of-safety
- Provide administrative and technical support to the IBC (Institutional Biosafety Committee (IBC)), Radiation Safety Committee, and similar chartered groups.
- Develop and revise manuals, guides, plans, templates, forms, and documents
- Revise risk assessment guides and resources (chemical, biological, radiological, physical)
- Assist with laboratory audits and inspections (Chemical. Biological,

  machine-produced radiation)

- Design and execute strategic communication strategies to promote occupational safety and health initiatives at the FDA, including development of digital display advertisements and leadership presentations to communicate OOSH programs and objectives to internal and external audiences
- Support National Safety Month and National Biosafety Month
- Assist in revising OOSH Strategic Plan, Operating Plan, and Implementation Plan.

Task Area 4 – Primary Barrier Equipment Maintenance

The Contractor shall:

- Assess and inventory all primary barrier equipment
- Perform needs analysis
- Conduct testing, repair, certification
- Perform decontamination services
- Maintain centralized repository of certification status
- Proactively monitor expiration dates.

Equipment includes but is not limited to:

- Class I, II (A/B), III BSCs
- Air exhaust/supply plenums
- Automated dampers and controls
- Autoclave HEPA vent systems
- Vacuum/CO_2 HEPA filters
- Magnehelic HEPA equivalent filters
- HEPA filtered exhaust units
- Ventilation hoods and alarm calibration
- Downdraft tables and slot hoods
- Laminar flow clean benches
- HEPA filtered animal care modules.

Task Area 5 – Industrial Hygiene Support Services

The Contractor shall serve as architect of FDA's enterprise IH program and shall:

- Draft procedures, forms, protocols

- Align with AIHA and ANSI Z10 frameworks
- Conduct local and enterprise-wide programs and plan assessments (e.g. respiratory protection, chemical hygiene, hazard communication)
- Conduct exposure monitoring and job hazard analysis
- Provide field IH support
- Deliver leadership presentations
- Conduct quality assurance review of IH reports.

Task Area 6 – Information & Data Systems Program Support

The Contractor shall:

- Coordinate with FDA IT governance
- Develop and maintain project plans and schedules,
- Document user requirements for databases, inventories, and tracking tools that support OSH programs.
- Validate inventory data (equipment, chemicals, biological materials, radiological materials, lasers)
- Develop document repository solutions
- Support interagency/enterprise database transfers
- Develop dashboards and presentations to inform strategic decisions, document compliance, assess effectiveness.

Task Area 7 – Training Development and Management

The Contractor shall support the FDA EOSH Training Program.

- Ensure adherence to established quality standards, deliverable requirements, and established timelines.
- Develop training evaluation and feedback mechanisms to assess training effectiveness, participant satisfaction, and knowledge transfer outcomes.
- Ensure all personnel meet required training standards and regulatory compliance requirements, document training completion rates, certification status, renewal schedules, and regulatory adherence for management review and audit purposes.

- Create comprehensive training support materials such as PDF resource guides, job aids, post-course examination questions, assessment tools, and other resources, as needed, (e.g., graphics and/or videos).

Instructor-Led Training

Includes:

- Hazardous Waste Operations and Emergency Response (29 CFR 1910.120) (HAZWOPER)
- Powered Industrial Truck Operations
- Hoisting/Rigging/Crane Operations
- Marine Safety
- Resource Conservation and Recovery Act (RCRA) Compliance
- U.S. Department of Transportation (DOT) Hazardous Materials Regulations
- Shipping Infectious Substances and Related Materials.

The Contractor shall manage logistics, instructor procurement, venue coordination, registration, attendance tracking, and Section 508 reviews. Training delivery shall be flexible to accommodate in-person, virtual, or hybrid formats as needed to meet participant requirements and operational constraints.

eLearning

- Develop and revise modules following FDA EOSH Training Program development processes using industry-standard platforms such as Articulate, Lectora, or other approved eLearning authoring software tools
- Conduct 508 compliance review for all eLearning modules, training materials, and digital resources to ensure full accessibility
- Emergency Response and Incident-Specific Training, and
- Develop or coordinate/host specialized training programs tailored to specific FDA facility risks, including but not limited to chemical spills, equipment failures, medical emergencies, and facility evacuations. Create incident-specific training modules based on lessons learned from actual events, near-misses, and industry incidents to enhance preparedness and prevent recurrence.

Design scenario-based training exercises including tabletop exercises, drills, and simulations to test emergency response capabilities and identify areas for improvement.

3.0 DELIVERABLES

3.1 Monthly Status Report (MSR)

The MSR shall include:

- Previous month activities
- Deviations from planned progress
- Current month planned activities
- Current risks and mitigations
- Status of unfilled positions
- Performance & Cost Report including recurring/non-recurring costs, cumulative costs, labor hours by task area
- Status of action items from meetings.

Submitted by third business day of each month.

3.2 PERFORMANCE DELIVERABLE SUMMARY TABLE (PDST)

Deliverable	Description	Task Area	Frequency	Due Date	Acceptance Authority	Acceptance Criteria
Program Management Plan (PMP)	IDIQ-level management plan including staffing, communication diagram, recruitment/retention strategy	1	Once at IDIQ award; updated as required	30 calendar days after award (unless otherwise directed)	COR	Complete; aligns with PWS; communication structure defined
Order Management Plan (OMP)	Task Order-specific project management approach	1	Per Task Order	As specified in TO	COR	Meets TO requirements
Monthly Project Meeting Minutes	Documented agendas, attendees, decisions, action items	1	Monthly	Within 5 business days after meeting	COR	Accurate, complete documentation

Deliverable	Description	Task Area	Frequency	Due Date	Acceptance Authority	Acceptance Criteria
Monthly Status Report (MSR)	Monthly progress report including P&CR and staffing status	All	Monthly	3rd business day of month	COR	Includes all required elements per SOW
Performance & Cost Report (P&CR)	Recurring/non-recurring costs, cumulative costs, labor hours by task area	1	Monthly	With MSR	COR	Accurate financial and labor reporting
Transition-In Plan	Plan for assuming operational responsibility	2	Per TO	As specified in TO	COR	Ensures uninterrupted operations
Transition-Out Plan	Closeout and turnover strategy	2	Per TO	As specified in TO	COR	Includes GFE/GFI reconciliation
SOP Repository & Manual of Operations	Current versions of SOPs and operating documents	2,3,4,5, 6,7	Updated as required	Delivered during transition-out and as updated	COR	Complete, current, organized
Primary Barrier Equipment Assessment Report	Inventory and needs analysis of equipment	4	As tasked	Per TO	COR	Includes certification status and recommendations
Primary Barrier Certification Report	certification documentation	4	As performed	Within 5 business days of certification	COR	Meets applicable certification standards
Decontamination Certificate	Documentation of decontamination activities	4	As performed	Within 5 business days	COR	Method documented and compliant
Equipment Certification Repository	Centralized database of	4,6	Monthly update	With MSR or as directed	COR	100% current and accurate

Deliverable	Description	Task Area	Frequency	Due Date	Acceptance Authority	Acceptance Criteria
	equipment status and expiration					
Industrial Hygiene Assessment Report	exposure assessment findings	5	As performed	Within 10 business days of site visit	COR	Technically accurate; includes recommendations
Enterprise IH Program Framework	Enterprise-level IH program documentation aligned with AIHA and ANSI Z10	5	Initial + updates	Per TO	COR	Strategically aligned; complete documentation
Information Systems Project Plan	Data system planning and governance documentation	6	As tasked	Per TO	COR	Aligned with FDA IT governance
Inventory Validation Report	Data comparison and discrepancy analysis	6	Quarterly or as directed	Per TO	COR	Discrepancies identified and resolved
Compliance Dashboard	Equipment, certification, and training compliance metrics	6,7	Monthly or quarterly	Per TO	COR	Accurate metrics
Training Needs Assessment Report	Gap analysis of EOSH training program	7	As tasked	Per TO	COR	Complete and documented
Instructor-Led Training Delivery Report	Documentation of delivered training and attendance	7	As conducted	Within 5 business days after course	COR	Attendance verified; content delivered
eLearning Module (New or Updated)	508-compliant module using approved authoring tools	7	As tasked	Per TO	COR	Technically accurate; 508 compliant

Deliverable	Description	Task Area	Frequency	Due Date	Acceptance Authority	Acceptance Criteria
Training Evaluation Summary	Assessment of effectiveness and feedback	7	Quarterly or as directed	Per TO	COR	Includes analysis and recommendations
Emergency Exercise Report	After-action report for drills/tabletop exercises	7	As conducted	Within 10 business days	COR	Lessons learned documented
Annual Enterprise Summary Report	Summary of program performance, trends, and recommendations					

PDST Notes:

1. Task Orders may refine deliverables or timelines.
2. Acceptance is governed by Section 8.0 Inspection and Acceptance.
3. Failure to meet deliverable timelines requires notification within 10 business days and submission of corrective action plan.
4. Final Task Order acceptance requires completion of transition activities and reconciliation of GFE/GFI.

4.0 INSPECTION AND ACCEPTANCE

4.1 General

Inspection and acceptance of all deliverables under this IDIQ shall be performed by the Contracting Officer's Representative (COR) or designated Government Technical Lead (GTL), unless otherwise specified in the individual Task Order.

Acceptance shall be based on compliance with:

- Requirements defined in this PWS and applicable Task Order
- Applicable regulatory and technical standards (OSHA, ANSI Z-10, NSF/ANSI 49, ISO, AIHA, etc.)
- Deliverable quality, completeness, and timeliness
- Technical accuracy and professional standards.

Acceptance under this IDIQ is formal and documented. Informal review or feedback does not constitute acceptance.

4.2 Acceptance Timeframes

Unless otherwise specified in the individual Task Order:

Deliverable Type	Government Review Period	Acceptance Method
Plans (PMP, OMP, Transition Plans)	10 business days	Written approval via email
Monthly Status Report (MSR)	5 business days	Written acceptance or request for revision
Technical Reports (IH assessments, certification reports, gap analyses)	10 business days	Written acceptance
Training Materials / eLearning Modules	10 business days	Written approval following 508 validation
Data Dashboards / Inventory Reports	5 business days	Written acceptance
Risk Registry Updates	Ongoing; formal review monthly	Acceptance via MSR review

If no written response is provided within the review period, acceptance shall not be assumed unless expressly stated in the Task Order.

4.3 Acceptance Criteria

A deliverable will be accepted when it meets all the following:

1. **Technical Compliance**
    - Meets all PWS and Task Order requirements
    - Aligns with referenced standards and regulations.
2. **Quality and Accuracy**
    - Accurate data and analysis
    - Professional formatting
    - Logical organization
    - Free from material errors.
3. **Completeness**
    - All required components included

    - Required attachments provided
    - Supporting documentation included.

4. **Regulatory Alignment**
    - OSHA compliance where applicable
    - NSF/ANSI 49 compliance for BSC certifications
    - ANSI Z-10 alignment for management systems
    - Section 508 compliance for training materials.
5. **Timeliness**
    - Submitted in accordance with required deadlines.

4.4 Rejection and Revisions

If a deliverable is determined to be unacceptable:

- The Government shall provide written notice identifying deficiencies.
- The Contractor shall correct and resubmit within:
    - 5 business days for reports or dashboards
    - 10 business days for plans or complex technical products
    - As specified in the Task Order for specialized deliverables.

Re-submittals shall clearly identify revisions and corrective actions taken.

Failure to correct deficiencies may result in:

- Withholding payment (as applicable to the Task Order type)
- Performance documentation
- Corrective Action Plan requirement within 10 business days.

4.5 Acceptance of Services (Non-Document Deliverables)

For performance-based services such as:

- Primary barrier equipment certification
- Industrial hygiene exposure monitoring
- Training delivery
- Committee support.

Acceptance shall be based on:

- Completion of required services
- Submission of required documentation
- Compliance with technical standards (e.g., NSF/ANSI 49 for BSCs)
- Absence of substantiated performance deficiencies.

The Government reserves the right to:

- Witness testing or certification activities
- Perform independent validation
- Audit documentation or certification records.

4.6 Conditional Acceptance

The Government may grant conditional acceptance if:

- Minor administrative corrections are required
- Technical content is substantively acceptable
- Corrections do not impact safety, compliance, or performance.

Conditional acceptance shall be documented in writing.

4.7 Final Acceptance (Task Order Closeout)

Final acceptance of a Task Order shall require:

- All deliverables accepted
- All reports submitted
- Transition-out activities completed (if applicable)
- GFE/GFI reconciled
- Outstanding risks closed or transferred.

5.0 LABOR CATEGORIES, MINIMUM QUALIFICATIONS, AND SUBSTITUTION PROVISIONS

5.1 General Requirements

The Contractor shall provide personnel who meet or exceed the minimum education, certification, licensure, and experience requirements specified herein. All personnel shall possess demonstrated experience directly relevant to the duties to be performed under the applicable Task Order.

All academic degrees shall be obtained from institutions accredited by an accrediting body recognized by the U.S. Department of Education. Required certifications and licenses shall be current, active, and maintained throughout performance of the contract.

The Government reserves the right to review and verify personnel qualifications at any time and may require replacement of personnel who fail to meet the minimum qualification requirements.

Minimum qualifications represent baseline requirements and do not guarantee acceptance of proposed personnel. Task Orders may specify additional or more stringent qualification requirements based on mission need.

5.2 Education and Experience Substitution Policy

Unless otherwise restricted by required licensure or certification, the following substitution provisions apply:

1. Experience in Lieu of Education
    - Four (4) years of additional directly relevant professional experience may be substituted for a Bachelor's Degree.
    - Six (6) years of additional directly relevant professional experience may be substituted for a Master's Degree.
2. Education in Lieu of Experience
    - A Master's Degree in a directly related field may substitute for up to two (2) years of required experience.
    - A Doctorate in a directly related field may substitute for up to three (3) years of required experience.
3. Certification and Licensure Requirements
    - Where a Professional Engineer (PE), Certified Industrial Hygienist (CIH), Certified Safety Professional (CSP), American Board of Health Physics (ABHP) certification, or similar credential is expressly required, substitution is not permitted unless otherwise authorized in writing by the Contracting Officer.
4. Highly Desirable Certifications
    - Certifications identified as "highly desirable" may not substitute for required education or licensure but may be considered evidence of advanced competency.

5.3 Labor Category Minimum Qualifications

Program Manager

The Program Manager shall possess a minimum of eight (8) years of directly relevant professional experience in program or project management of comparable scope and complexity. The individual shall hold a Master's Degree in business, public administration, legal studies, or a related field and shall maintain a current Project Management Professional (PMP) certification. Substitution for the Master's Degree may be made in accordance with Section 5.2; however, PMP certification is mandatory.

Project Manager

The Project Manager shall possess a minimum of five (5) years of directly relevant professional experience. The individual shall hold a Bachelor's Degree in business, public administration, legal studies, or a related field and shall maintain current PMP certification. Substitution for education may be made consistent with Section 5.2. PMP certification is mandatory.

Senior Professional Engineer

The Senior Professional Engineer shall possess a minimum of eight (8) years of directly relevant engineering experience. The individual shall hold a four-year degree in engineering from an accredited engineering program and shall maintain a current Professional Engineer (PE) license. PE licensure is mandatory and not subject to substitution. Certifications such as Certified Industrial Hygienist (CIH), Certified Safety Professional (CSP), or Certified Biological Safety Professional (CBSP) are highly desirable.

Professional Engineer

The Professional Engineer shall possess a minimum of five (5) years of directly relevant engineering experience. The individual shall hold a four-year engineering degree from an accredited engineering program and shall maintain current PE licensure. PE licensure is mandatory and not subject to substitution. CIH, CSP, or CBSP certifications are highly desirable.

Biosafety Consultant

The Biosafety Consultant shall possess a minimum of four (4) years of directly relevant biosafety or laboratory safety experience. The individual shall hold a Bachelor's Degree in microbiology, occupational health and safety, or a related scientific field. Substitution provisions apply per Section 5.2. Certifications such as Registered Biosafety Professional (RBP) or Certified Biological Safety Professional (CBSP) are highly desirable.

Safety Engineer I

The Safety Engineer I shall possess a minimum of one (1) year of directly relevant professional experience. The individual shall hold a Bachelor's Degree or equivalent in engineering, science, or a related field. Substitution provisions apply per Section 5.2.

Safety Engineer II

The Safety Engineer II shall possess a minimum of five (5) years of directly relevant professional experience. The individual shall hold a Master's Degree in a scientific or engineering discipline. Substitution provisions apply per Section 5.2.

Industrial Hygiene Management Consultant

The Industrial Hygiene Management Consultant shall possess a minimum of eight (8) years of directly relevant industrial hygiene experience, including program management responsibilities. The individual shall hold a Master's Degree or equivalent in engineering, science, or a related field and shall maintain certification as a Certified Industrial Hygienist (CIH) or Certified Safety Professional (CSP). CIH or CSP certification is mandatory and not subject to substitution.

Certified Industrial Hygienist

The Certified Industrial Hygienist shall possess a minimum of five (5) years of directly relevant professional experience. The individual shall hold a Bachelor's Degree in a scientific or engineering discipline and shall maintain active CIH certification. CIH certification is mandatory and not subject to substitution.

Industrial Hygienist

The Industrial Hygienist shall possess a minimum of two (2) years of directly relevant professional experience. The individual shall hold a Bachelor's Degree in a scientific or engineering discipline. Substitution provisions apply per Section 5.2.

Analyst I

The Analyst I shall possess a minimum of two (2) years of directly relevant professional experience and shall hold a Bachelor's Degree from an accredited academic institution. Substitution provisions apply per Section 5.2.

Analyst II

The Analyst II shall possess a minimum of six (6) years of directly relevant professional experience and shall hold a Bachelor's Degree from an accredited academic institution. Substitution provisions apply per Section 5.2.

Communications Specialist I

The Communications Specialist I shall possess a minimum of two (2) years of directly relevant professional experience and shall hold a Bachelor's Degree from an accredited academic institution. Substitution provisions apply per Section 5.2.

Training Specialist

The Training Specialist shall possess a minimum of two (2) years of directly relevant experience in instructional design or training development. The individual shall hold a Bachelor's Degree in

Education or Instructional Design and Technology; or a Bachelor's Degree and certification in Instructional Design and Technology, Online Learning Professional, or equivalent credential. Substitution provisions apply for education; however, documented instructional design competency is required.

Senior Health Physicist

The Senior Health Physicist shall possess a minimum of ten (10) years of directly relevant professional experience in radiation safety or health physics. The individual shall hold a Bachelor's Degree in a scientific or engineering discipline and shall maintain certification by the American Board of Health Physics (ABHP). ABHP certification is mandatory and not subject to substitution.

Health Physicist

The Health Physicist shall possess a minimum of three (3) years of directly relevant professional experience and shall hold a Bachelor's Degree or equivalent in engineering, science, or a related field. Substitution provisions apply per Section 5.2.

5.4 Personnel Replacement

If personnel replacement or substitution is required, the Contractor shall notify the Contracting Officer and COR at least 30 calendar days advance notice for planned changes; 24 hours for emergency changes. The Contractor shall propose qualified replacement personnel within fifteen (15) calendar days. Replacement personnel shall meet or exceed the minimum qualification requirements stated herein.

6.0 SECURITY & ACCESS

Badging, facility access, and compliance with FDA security requirements shall be specified per Task Order and remain in compliance with the overall IDIQ.

7.0 QUALITY CONTROL PLAN (QCP)

7.1 General Requirement

The Contractor shall develop, implement, and maintain a written Quality Control Plan (QCP) that ensures all services and deliverables performed under this IDIQ and resulting Task Orders comply with the requirements of this PWS, applicable Task Orders, and all referenced regulatory and technical standards.

The QCP shall describe the Contractor's internal management system for planning, monitoring, evaluating, and correcting work to ensure consistent, compliant, and high-quality performance across all Task Areas.

The Contractor is solely responsible for the quality of all work performed under this contract.

7.2 Submission Requirements

The Contractor shall submit a draft Quality Control Plan to the Contracting Officer's Representative (COR) within thirty (30) calendar days after IDIQ award, unless otherwise specified.

The QCP shall be:

- Reviewed and approved by the COR prior to implementation
- Updated as necessary to reflect process improvements or regulatory changes
- Resubmitted for approval within fifteen (15) calendar days of any substantive revision

Task Orders may require order-specific QCP supplements.

7.3 Minimum Content Requirements

At a minimum, the Quality Control Plan shall include:

7.3.1 Quality Management Approach

- Description of the Contractor's quality philosophy and governance structure
- Roles and responsibilities for quality oversight
- Organizational reporting structure for quality issues

7.3.2 Performance Monitoring Procedures

- Internal review procedures for each Task Area
- Inspection and verification processes for technical services (e.g., equipment certification, exposure monitoring, training development)
- Documentation control procedures
- Data validation and verification processes

7.3.3 Deliverable Review Process

- Pre-submission technical review procedures
- Compliance verification checklist aligned to PWS requirements
- Formatting and documentation standards
- Final approval authority within the Contractor organization

7.3.4 Regulatory Compliance Controls

- Process to ensure compliance with OSHA, NSF/ANSI 49, ANSI Z10, ISO standards (if applicable), and other referenced standards
- Certification validation procedures (e.g., PE, CIH, ABHP, PMP)

- Control of required licenses and credentials

7.3.5 Risk Management Integration

- Integration of Quality Control with the Risk Registry
- Procedures for identifying, documenting, and mitigating quality-related risks
- Escalation procedures for safety-critical deficiencies

7.3.6 Corrective and Preventive Action (CAPA)

- Procedures for identifying performance deficiencies
- Root cause analysis methodology
- Corrective action implementation timelines
- Preventive action procedures
- Documentation and tracking of corrective actions

7.3.7 Continuous Improvement

- Performance metric tracking
- Lessons-learned documentation
- Process improvement initiatives
- Periodic internal audits

7.3.8 Records Management

- Quality records retention policy
- Version control procedures for SOPs and reports
- Secure storage of sensitive documentation

7.4 Quality Control Inspections and Reviews

The Contractor shall conduct internal quality reviews at a frequency sufficient to ensure compliance with contract requirements. At a minimum, the Contractor shall:

- Review monthly performance data prior to MSR submission
- Conduct quarterly internal quality reviews
- Validate primary barrier equipment certification documentation before submission
- Validate industrial hygiene assessment reports prior to delivery
- Verify Section 508 compliance of all training materials

Results of internal quality reviews shall be documented and made available to the Government upon request.

7.5 Quality Control Metrics

The QCP shall define measurable performance indicators, which may include but are not limited to:

- On-time deliverable rate
- Documentation accuracy rate
- Certification compliance rate
- Training completion compliance rate
- Error or rework rate
- Risk resolution timeliness

These internal metrics shall support Government Quality Assurance Surveillance activities.

7.6 Deficiency Notification

If the Contractor identifies a deficiency that may affect safety, regulatory compliance, or mission continuity, the Contractor shall:

1. Notify the COR within two (2) business days for safety-critical issues;
2. Notify the COR within five (5) business days for non-critical performance issues;
3. Submit a written corrective action plan within ten (10) business days, unless otherwise directed.

7.7 Government Oversight

The Government retains the right to:

- Review and approve the QCP
- Conduct surveillance and audits
- Witness testing or certification activities
- Request documentation supporting quality control processes

Approval of the QCP does not relieve the Contractor of responsibility for quality performance.

7.8 Relationship to Quality Assurance Surveillance Plan (QASP)

The Contractor's QCP is distinct from the Government's Quality Assurance Surveillance Plan (QASP). The QCP describes how the Contractor manages internal quality control, while the QASP describes how the Government monitors performance.

8.0 QUALITY ASSURANCE SURVEILLANCE

8.1 General

The Government will monitor Contractor performance to ensure compliance with this PWS and all applicable Task Orders. Quality Assurance Surveillance (QAS) will be conducted by the Contracting Officer's Representative (COR), Government Technical Leads (GTLs), or other designated Government officials.

Surveillance will focus on ensuring that services are delivered in a timely, technically accurate, compliant, and professional manner consistent with applicable regulatory standards and mission requirements.

Government surveillance does not relieve the Contractor of responsibility for quality control.

8.2 Performance Standards

Performance under this contract shall be assessed based on the following core standards:

1. Timeliness
   Deliverables and services are completed within required deadlines.
2. Technical Accuracy
   Work products are technically sound, factually correct, and professionally prepared.
3. Regulatory Compliance
   Services comply with applicable OSHA standards, NSF/ANSI 49 requirements, ANSI/ASSP Z10, BMBL, NIH design standards, and other referenced regulations.
4. Responsiveness
   Contractor responds promptly to Government inquiries, emerging issues, and corrective actions.
5. Documentation Completeness
   Reports, certifications, inventories, and training records are complete, properly formatted, and traceable.
6. Stakeholder Satisfaction
   Services are delivered in a professional manner that supports FDA operational and safety objectives.

8.3 Surveillance Methods

The Government may employ one or more of the following surveillance methods:

- 100% review of critical deliverables (e.g., certification reports, transition plans)
- Periodic sampling of reports and data entries
- Observation or witnessing of equipment certification and testing

- Review of Monthly Status Reports (MSR)
- Validation of inventory and certification databases
- Inspection of training materials and Section 508 compliance
- On-site inspections and facility walkthroughs
- Stakeholder feedback
- Audit of quality control documentation

Surveillance may be scheduled or unscheduled.

8.4 Performance Metrics and Acceptable Quality Levels (AQLs)

The following measurable performance standards apply unless otherwise specified in a Task Order:

8.4.1 Timeliness

- 95% of deliverables submitted on or before required due date
- 100% of safety-critical deficiencies reported within required timeframe

Failure Threshold: More than 5% late submissions within a reporting period.

8.4.2 Technical Accuracy

- 98% documentation accuracy rate
- No material technical errors affecting safety, regulatory compliance, or certification validity

Failure Threshold: Any recurring or safety-critical technical deficiency.

8.4.3 Responsiveness

- Government inquiries acknowledged within 2 business days
- Corrective action plans submitted within 10 business days when required

Failure Threshold: Failure to acknowledge or respond within required timeframe.

8.4.4 Documentation Completeness

- 100% of required report elements included
- 100% required risk registry data fields populated

Failure Threshold: Missing required documentation elements.

8.4.5 Stakeholder Satisfaction

Measured through:

- Feedback from laboratory leadership
- Feedback from safety committees
- Training evaluations

Target: 90% satisfactory or higher feedback ratings.

8.5 Deficiency Classification

Performance deficiencies may be classified as:

- Critical Deficiency: Impacts safety, containment, regulatory compliance, or mission continuity.
- Major Deficiency: Impacts deliverable quality or operational effectiveness but not immediate safety.
- Minor Deficiency: Administrative or formatting issue not affecting technical validity.

Critical deficiencies may trigger immediate corrective action and potential escalation to the Contracting Officer.

8.6 Corrective Action Requirements

If performance deficiencies are identified:

1. The Government will issue written notification describing the deficiency.
2. The Contractor shall submit a written Corrective Action Plan (CAP) within ten (10) business days.
3. The CAP shall include:
    - Root cause analysis
    - Immediate corrective steps
    - Preventive measures
    - Timeline for resolution
4. The Contractor shall implement corrective actions within agreed timelines.

Repeated deficiencies may result in:

- Increased surveillance
- Withholding of payment (as applicable to Task Order type)
- Contractor Performance Assessment Reporting System (CPARS) documentation

- Other remedies available under the contract

8.7 Surveillance Reporting

Surveillance results may be documented through:

- MSR review comments
- Independent Government review memoranda
- Meeting minutes
- Formal performance notices
- CPARS evaluations

8.8 Integration with Contractor Quality Control Plan

The Contractor's Quality Control Plan (QCP) shall align with this QAS section. The Contractor's internal controls must demonstrate the ability to meet or exceed the performance standards defined herein.

Government surveillance activities are not a substitute for the Contractor's internal quality control responsibilities.