Scope of Work

June 26, 2026

Project Title: Irvine Room 2309 Exhaust and Vacuum Pump Replacement
Location: U.S. Food and Drug Administration (FDA) Laboratory; 19701 Fairchild, Irvine, CA
Project Number: OC-2026-133488

1.0 Description of Work

1.1 **Background Information:**

The FDA Pacific Southwest Laboratory and District Office, an FDA owned facility located in Irvine, CA. Construction services shall include two portions.

- Replacement of end-of-life, obsolete vacuum pump systems at the FDA facility. Existing system is near 23 years old, does not have replacement parts available on the market for repair, representing a single-point failure risk to the facility's vacuum system, therefore requiring replacement.
- Irvine room 2309 has three isolators. These isolators use vaporized hydrogen peroxide (VHP) during their use. The room has VHP detection which have been alarming indicating that the levels have exceeded the safe levels for humans to be exposed to (>1ppm). A design has been completed to correct this issue and involves directly ducting the isolators to the outside and discharge via exhaust fan to the outside.

1.2 **Purpose and Scope of Work**

The purpose of this work is to provide construction services for the replacement of vacuum system (currently AES-Dekker Laboratory Vacuum System Model AES-VMX0153MA2-45-DS with capacity for each vacuum pump 23.3 SCFM @ 25 “HGVAC) at FDA Irvine and correct the exhaust in room 2309.

The Room 2309 Exhaust System is a fully designed construction component of this project and shall be constructed in accordance with the issued drawings and specifications dated August 15, 2025. The Scope of Work supplements the design documents by establishing administrative requirements, coordination requirements, commissioning requirements, BAS integration expectations, and clarification of project execution requirements.

The Vacuum System Replacement component is performance-based. Except where specifically identified otherwise, the Contractor shall provide all engineering, equipment selection, controls integration, startup, testing, commissioning, and incidental work necessary to furnish a complete and operational laboratory vacuum system meeting the requirements of this Scope of Work.

Where BAS integration requirements are not fully defined within the design documents or available existing documentation, the Contractor shall investigate existing conditions, coordinate with the FDA BAS service provider, and develop the required BAS integration documentation for Government review prior to implementation.

1.2.1 **Delivery Type:** The project is a firm fixed price Construction Services delivery type contract.

2.0 Period of Performance:

2.1 The work shall proceed promptly upon execution of this contract and only after the issuance of the Notice to Proceed (NTP) or contract award by the Government for the activities indicated.

2.2 The actual performance of the work and delivery of the required documents shall be in accordance with the project schedule and shall be completed within 222 calendar days of the NTP or on the negotiated date of completion at time of award otherwise agreed upon by the

3.0 Specific Requirements (SOW):

3.1 The Contractor shall perform all services described in this Scope of Services in accordance with applicable requirements and provisions set forth in this Scope of Work. The Contractor will be responsible for relocating any electrical, mechanical, commissioning, third party inspections, site walks, surveys, additional engineering, BAS integrations, or structural building system components necessary to perform this work.

The Contractor shall provide complete turnkey systems and all associated incidental work required for a fully operational installation, whether specifically identified or reasonably inferable from the contract documents, including but not limited to controls, supports, access provisions, electrical connections, startup, testing, balancing, commissioning, and restoration of affected finishes.

The Contractor shall provide all necessary labor, material, insurance, training, and equipment for the following.

3.1.1 Vacuum pump

- Contractor shall provide any necessary survey, study, engineering, or technical expert services to understand the existing conditions of the vacuum system at FDA Irvine.
- Contractor shall provide a complete replacement laboratory vacuum system with operating capacity equal to or greater than the existing AES-Dekker Laboratory Vacuum System and capable of maintaining required laboratory vacuum conditions during anticipated peak demand while maintaining N+1 redundancy capability.
- The replacement vacuum system shall include all pumps, receivers, controls, valves, piping modifications, isolation valves, disconnect means, vibration isolation, supports, alarms, BAS integration, electrical connections, startup, testing, and commissioning required for a complete and operational system.
- Contractor shall provide equipment cutsheet submittals and shop drawings to FDA for review and approval before procurement of materials.
- Contractor shall ensure N+1 redundancy integrated into new system for resilient facility operation. N+1 redundancy shall mean the system is capable of maintaining required operating vacuum with one vacuum pump out of service for maintenance or failure.
- Contractor shall assess and provide repairs or additions to any housekeeping pad intended to support new equipment, as needed.
- Contractor shall provide new control panel, field located in an accessible area near the vacuum system. Control panel shall be integrated with existing BAS and include alarms both to BAS and readout local to the panel. BAS integration shall include all programming, graphics, alarms, trending, point integration, and coordination necessary for full compatibility with the existing FDA BAS platform. The Contractor shall coordinate all BAS integration work with the existing FDA BAS service provider.
- Contractor shall utilize power feed to existing vacuum system. Existing electrical feeder capacity is assumed adequate for the replacement system unless deficiencies are identified during pre-award site investigation or field verification.

- Contractor shall provide independent isolations valves and disconnect means to permit service of each vacuum pump while maintaining the system's operation.
- Contractor shall keep equipment shutdowns to a minimum and schedule/coordinate all shutdowns with FDA while providing adequate notice. Contractor shall coordinate all shutdowns with FDA to minimize operational impacts. Temporary vacuum services shall be provided whenever shutdown duration or sequencing would otherwise interrupt required FDA laboratory operations. Any temporary vacuum system provided shall maintain equivalent operational capability necessary to support ongoing laboratory operations during the outage period.
- Contractor shall provide all inspection and testing, except where required by code, specification, or detailed elsewhere in the requirements of this document.
- Existing laboratory vacuum distribution piping is assumed suitable for reuse unless field conditions indicate otherwise. Concealed conditions materially differing from available design information shall be promptly reported to the Government prior to proceeding with corrective work.

3.1.2 Room 2309 Exhaust

- The Contractor shall utilize the design drawings and specifications dated August 15, 2025, in the performance of this scope of work. *All references to the General Services Administration (GSA) within the drawings, specifications, or related documents shall be interpreted as references to the Food and Drug Administration (FDA) for purposes of required approvals, submittals, and deliverables***.** The Contractor shall provide all work required for a complete and operational exhaust system including ductwork, roof penetrations, supports, structural attachments, flashing, controls, electrical work, BAS integration, startup, TAB, commissioning, and restoration of affected building finishes.
- BAS integration associated with the Room 2309 exhaust system shall include all programming, graphics, alarms, trending, and controls integration necessary for full system operation and monitoring through the existing FDA BAS platform.
- Roof penetrations and roofing modifications shall be performed in accordance with roofing manufacturer requirements and applicable roofing standards to maintain watertight integrity and preserve any existing roof warranty requirements.

3.2 The Contractor shall ensure compliance with NIH Design Requirements Manual (DRM). Section 12.4 is most applicable to this project. Variances from NIH DRM requirements shall require prior written approval from the FDA Contracting Officer.

***3.3* Execution**

***3.3* Project Goals & Objectives**

3.3.1 GOALS

a. Provide a safe working environment.
b. Maintain operations for the FDA through construction, with minimal interruption as possible.
c. Ensure a safe work environment during construction for workers and authorized visitors on the construction site.
d. Complete the project with no security violations or safety incidence.

3.3.2 OBJECTIVES

a. Build dynamic partnerships and a cohesive team with all contracted parties and FDA, aligning goals and vision to successfully deliver this project's scope on-time and on-budget.
b. Select systems and materials of high performance, comfortable, aesthetically pleasing, cost effective to operate and maintain, with durability and extended service life.
c. Provide best value to FDA's customer agencies and the American taxpayer.
d. Deliver the project efficiently and effectively – keeping the project on time and on budget.
e. Execute the scope of work of the building within the timeframe and budget limits established by the Government, minimizing cost and optimizing life-cycle cost to the facility.

3.3.3 Project Delivery Approach

FDA envisions a highly collaborative approach for this project, with the outcome that the Contractor must work closely with the FDA to deliver a final project that meets the needs and expectations as defined within the supporting documents.

The Contractor must perform commissioning-related tasks.

3.3.4 Contractor Team

STAFFING

The Contractor must provide experts in disciplines listed in the Facilities Standards for the Public Buildings Service (Core Building Standards), and as otherwise required in this section, with credentials as indicated, as they apply to this project. The Contractor must provide sufficient staff of project managers, superintendents, inspection and testing engineers, scheduling specialists, cost engineers, clerical and accounting personnel, etc. to perform the required work.

KEY PERSONNEL

The Government anticipates and expects that the Contractor will rely on and use key personnel listed, if any, in its proposal submitted to the Government as part of the underlying procurement process to perform the work required by the Contract. The Contractor may substitute any such personnel only with the advance written approval of the Contracting Officer within 30 days of departure. Any such substitution must be at no additional cost to the Government and the replacement must have equal or greater experience, expertise, and qualifications as the substituted personnel. The Contractor must provide any information as may be reasonably requested by the Contracting Officer such as a resume or curriculum vitae for review to determine acceptance.

OTHER PERSONNEL

In addition to the key team members identified within this document, the Contractor must provide administrative, clerical, and technical personnel as necessary to perform the services required under this contract.

EXPERTISE

At a minimum, the Contractor's team members should include the following experts to provide expertise (a single individual may be assigned more than ONE of the responsibilities / expertise listed below) as and when needed for efficient and effective operations:

Within 10 days after the Notice to Proceed (NTP) the Contractor must edit and the Communications Plan and complete the team entries.

a. Project Executive

b. Project Manager

c. Quality Control

d. Construction Superintendent

CONTRACTOR TEAM SUBSTITUTION

During the performance of the services required under this contract, the Contractor must obtain FDA written consent from the Contracting Officer before making any substitution for sub-contractors and outside associates or consultants specifically identified and agreed to in the request for qualifications, proposal, contract, and any contract modifications.

3.3.5 Project Stages, Phases and Work Sequence

This SOW is organized to identify the scope of services to be performed in a generally sequential manner. The Government anticipates this procurement as a fully designed construction project. Contractor sequencing may overlap procurement and construction activities; however, contractor-generated redesign is not anticipated except where required for delegated engineering, coordination, means and methods, or approved field conditions.

PRE-AWARD OFFEROR PROPOSAL PREPARATION STAGE
CONTRACT AWARD
PROCUREMENT PHASE OWNER COMMENTS
CONSTRUCTION STAGE
CLOSEOUT AND TURNOVER STAGE
FINANCIAL CLOSEOUT STAGE

3.3.6 COMMISSIONING PROVIDER (CX)

The Cx Scope of Services

a. For this contract, the Cx is a subconsultant to the Contractor.

b. The Cx is a contractor-hired commissioning provider.
c. The Cx is responsible for developing the commissioning requirements for incorporation into the SOW.
d. The Cx must develop the Cx plan, testing requirements and performance specifications, and propose/coordinate failure criteria.
e. The Cx manages and leads the Cx meetings.
f. The Cx advises FDA on issues involving the commissioning process, emphasizing the long-term performance and maintainability of the systems included in the commissioning scope of work.
g. The Cx must advise FDA of deficiencies involving the design, construction, testing, adjusting and balancing, or other deficiencies that would compromise the ability of the facility to meet the needs of FDA.
h. The Cx is authorized to recommend to FDA the acceptance, modification, or rejection of all materials, procedures, schedules, tests, reports, or other required commissioning submittals.
i. The Cx is not authorized to change the Contractor's Contract Documents, schedules, costs, or scope of work. The Cx recommendations shall be advisory only. Final authority for acceptance, rejection, modification, schedule impacts, and contract changes remains solely with the Contracting Officer.
j. Commissioning scope shall include vacuum system operation, exhaust system operation, BAS alarm functionality, TAB verification, startup procedures, functional performance testing, and integrated system operation necessary to demonstrate compliance with the contract requirements.

3.3.7 SCHEDULE MANAGEMENT

FDA effective scheduling practices to execute this project. These practices involve detailed project schedule combinations, development, and maintenance.

3.3.8 Change Management

Change Management is the procedure by which the CO and PM process all change orders. Change orders add or delete work from the SOW; serve as a written record of a technical change; modify the contract duration; and may authorize a change in cost of construction.

The PM does not have authority to approve change orders and obligate the government; they provide technical expertise to the CO. The CO has the authority to obligate the government to change orders.

1. The Contractor must submit all requests or recommendations for change(s) to the project scope to the CO for approval. Requests must include a rationale, cost and impact to the schedule.
2. In the event of a significant change in contract value as determined by the PM, the Contractor must update the Cost Allocation tabulation.

3.3.9 Shop Drawings Review

The Government will require copies of all submittals, and the FDA will approve a list of those submittals that require FDA review and feedback in advance of approval.

3.3.10 Closeout & Turnover Stage

1. PUNCH LIST

a. After the FDA certification that the work for each designated portion thereof is substantially complete, the Contractor must assist FDA in conducting a final inspection and in preparation of a Punch List documents the remaining work.
b. Contractor pre-punch to identify and correct items before the Government is requested to walk the project for the formal Punch List.
c. Government/Tenant Punch List to identify items requiring correction. The Government and occupying tenants will walk the project together and generate one Punch List.
d. Contractor activity to correct the Punch List.
e. Participate with FDA in conducting follow-up inspections to administer resolution of Punch List items acceptance.

2. ACCEPTANCE

Although the Punch List will occur by area, warranties for building systems will not begin until the final acceptance of the building by the Government. The project will not be accepted by the Government until the letter of Substantial Completion has been issued by the Contracting Officer.

3. SUBSTANTIAL COMPLETION

a. Prior to substantial completion, assist FDA in conducting a pre-final walk- through with the occupant agency.
b. The Contractor must provide time within their schedule for this inspection as well as time for any corrections to be made in order to receive the approval for Occupancy.

3.3.11 Travel, Reproduction, and Delivery

Unless otherwise indicated in this SOW, the Contractor is responsible for travel costs to support the requirements contained in this SOW, including all progress meetings, reviews, and site visits. The Contractor must assume all travel must be within the vicinity of the project site except as specifically indicated otherwise in the SOW.

Printing, reproduction and delivery costs necessary for execution of this contract must be included in the base contract price.

3.3.12 Security Clearance and Management

1. The Contractor shall comply with the HHS and FDA Security Clearances requirements. The Contractor shall comply with the policies outlined in the HHS and FDA Security

Standards and Requirements.

2. Application for HSPD-12 clearance includes an electronic application process, in-person fingerprinting at a federal facility, and in-person pickup of the badge. For any individual whose Initial Fitness Determination requires that the applicant wait for Final Fitness Determination, the Contractor shall promptly provide a qualified replacement.

3. No extensions for schedule will be given for failure to get personnel credentialed in a timely manner.

4. Building badges must be worn above the waist and below the neck in a visible fashion at all times by the Contractor while in the subject facility.

5. All Contractor personnel not authorized to be unescorted shall be escorted at all times in compliance with the HSPD-12 escorting requirements.

4.0 <u>General Requirements:</u>

4.1 The Contractor shall:

4.1.1 Adhere to Project Management responsibilities as defined herein.

4.1.2 Appoint a Project Manager who shall be the Government's primary point of contact and provide all necessary project representation for the successful accomplishment of the said work. The project manager shall be thoroughly familiar with all requirements and schedules. The project manager shall be identified in the firm's proposal prior to contract award.

4.1.3 Coordinate all project related activities including documentation through the Project Officer (PO) for approval unless otherwise denoted.

4.1.4 Bring any questions and/or industry specification additions to the attention of the PO for direction.

4.1.5 Perform all work in a skillful and workmanlike manner as deemed applicable to this project.

4.1.6 Provide appropriate communication and coordination efforts with the facility department and the PO to avoid disruption of facility operations while performing contract work such as meetings, proposed phasing plans, outage notifications, etc. (where applicable).

4.1.7 Obtain necessary badges per FDA policies and guidelines (if applicable). FDA binding process is to be anticipated of 1 month. All badging must be completed prior to start of on-site construction.

4.1.8 Provide (to the PO) a list of possible employees and sub-contractors who may require access to the FDA premises per the project being administered.

4.1.9 Provide utility outage notifications per facility department requirements (if applicable).

4.1.10 Perform all necessary measurements and sizing associated with the work assigned.

4.1.11 Confirm existing conditions of work assigned.

4.1.11.1 The Contractor shall field verify visible existing conditions prior to commencing work. Concealed conditions materially differing from the available drawings, specifications, or site observations shall be promptly reported to the Government before proceeding with corrective work.

4.1.12 Perform all associated project work in accordance with FDA and NIH Guidelines; Executive orders, EPACT, EISA, Sustainable design and Federal Regulations; Local City, County, and State building codes and regulations; NEC, ASME, NFPA, OSHA, UL, ANSI,

and IEEE rules and regulations and standards; and all other applicable industry standards.

4.1.12.1 The Government is not currently aware of hazardous materials requiring abatement within the identified work areas. Discovery of concealed hazardous materials shall be immediately reported to the Government and handled in accordance with applicable regulatory requirements and contract procedures.

4.1.13 Restore all affected areas back to pre-project conditions or better by the completion of the specified project including necessary patching, repairing and/or replacing.

4.1.13.1 All roofing penetrations and modifications shall be restored in a watertight condition consistent with applicable roofing manufacturer requirements and industry standards.

4.1.14 Provide all necessary drawings, documentation, and literature for all recommended items where applicable.

4.1.15 Provide all labor and equipment necessary to accomplish the above specified tasks.

4.1.16 Assume all risk and shall be liable for any damages to persons or property caused by the contractor.

4.1.17 Be solely responsible for the quality of his/her work. Deficiencies and omissions shall be corrected prior to Government acceptance of work.

4.1.18 Be responsible for removing construction and demolition debris daily from site. The contractor shall provide the dumpster for the debris.

5.0 <u>Government Furnished Material and Resources:</u>

5.1 The Government shall provide, but are not limited to, the following items:

- Site Utility Drawings (Upon request-PDF)
- Point(s) of contact at the FDA Site (at Kickoff Meeting)
- Photographs of work-site conditions and others as needed
- Irvine Lab specification report volume 2 (Section 15486) (Upon request-PDF)
- Existing BAS service provider contact information and coordination procedures (upon request after award)

SUBMITTAL REGISTER/DELIVERABLE MATRIX

Item	Submittal	Due Date / Timing	Frequency	Govt. Review Period	Required Format
1	Communication Plan	Within 10 calendar days of NTP	One-Time	10 Business Days	Electronic PDF
2	Project Kick-Off Meeting Agenda	Prior to Kick-Off Meeting	One-Time	5 Business Days	Electronic PDF
3	Project Schedule (Earned Value and Loaded Dollar Values)	Prior to start of work	Initial + Monthly Updates	10 Business Days	PDF and native scheduling file
4	Plan of Action (Project Team, PM, Contact Information)	Prior to start of work	One-Time; update as required	10 Business Days	PDF
5	Point of Contact / Project Manager Information	Prior to start of work	Update as required	N/A	PDF

Item	Submittal	Due Date / Timing	Frequency	Govt. Review Period	Required Format
6	Safety and Hazardous Material Plan	Prior to construction activities	One-Time; revise as required	10 Business Days	PDF
7	Site Logistics Plan	Prior to NTP	One-Time	10 Business Days	PDF
8	Accident Prevention Plan	Prior to NTP	One-Time	10 Business Days	PDF
9	Quality Control Plan	Prior to NTP	One-Time	10 Business Days	PDF
10	Construction Safety and Health Plan (CSHP)	Minimum 7 days prior to Pre-Construction Meeting	One-Time	10 Business Days	PDF
11	Hazard Communication Plan (HCP)	Submitted with CSHP	One-Time	10 Business Days	PDF including SDS inventory
12	IAQ Management Plan	Draft submitted 7 days prior to Pre-Construction Meeting	One-Time	10 Business Days	PDF
13	Waste Management Plan	Within 14 calendar days of NTP	One-Time	10 Business Days	PDF
14	TAB Plan	Minimum 14 calendar days prior to TAB activities	One-Time	10 Business Days	PDF
15	Work During Unoccupied Hours Schedule	Prior to commencement of affected work	Update as required	5 Business Days	PDF
16	Temporary Utilities Schedule	Prior to affected work	Update as required	5 Business Days	PDF
17	Selective Demolition Schedule	Prior to demolition activities	Update as required	10 Business Days	PDF
18	Qualification Data	Prior to applicable work activity	As Required	10 Business Days	PDF
19	Demolition Inventory	Prior to demolition	One-Time	10 Business Days	PDF
20	Existing Conditions Photographs/Videotape	Prior to start of work	One-Time	5 Business Days	JPG, PNG, MP4
21	Shop Drawings	Prior to fabrication and installation	As Required	14 Business Days	PDF and CAD
22	Equipment Cut Sheets	Prior to	As Required	14 Business	PDF

Item	Submittal	Due Date / Timing	Frequency	Govt. Review Period	Required Format
		procurement and installation		Days	
23	Product Data	Prior to procurement and installation	As Required	14 Business Days	PDF
24	Technical Data and Drawings	Prior to fabrication and installation	As Required	14 Business Days	PDF and CAD
25	BAS Integration Submittals (Points Lists, Graphics, Sequences, Narratives)	Prior to BAS programming and installation	As Required	21 Business Days	PDF and native controls format
26	Commissioning Plan	Prior to commissioning activities	One-Time	14 Business Days	PDF
27	Functional Testing Procedures	Prior to testing activities	As Required	14 Business Days	PDF
28	Startup Documentation	Following startup activities	As Required	10 Business Days	PDF
29	Roofing Manufacturer Coordination Documentation	Prior to roof penetration work	As Required	10 Business Days	PDF
30	Manufacturer Installation Instructions	Prior to installation	As Required	5 Business Days	PDF
31	Manufacturer Field Reports	Following field visits/startup	As Required	5 Business Days	PDF
32	Samples	Prior to installation	As Required	10 Business Days	Physical Samples and Supporting Documentation
33	Substitution Requests	Prior to procurement of substituted item	As Required	14 Business Days	Formal Request Package
34	Field Correction Requests	Upon discovery of discrepancy	As Required	5 Business Days	PDF
35	Test Reports	Following completion of testing	As Required	10 Business Days	PDF
36	Progress Meeting Minutes	Within 3 business days following each meeting	Monthly or as scheduled	5 Business Days	PDF
37	Equipment Submittal Package	Prior to procurement	As Required	14 Business Days	PDF

Item	Submittal	Due Date / Timing	Frequency	Govt. Review Period	Required Format
38	Demonstration and Training Plan	At least 30 days prior to training	One-Time	10 Business Days	PDF
39	Training Manuals	Prior to training sessions	Final Submission	10 Business Days	Four (4) hard copies and electronic PDF
40	Demonstration and Training Sessions	Prior to Final Acceptance	As Scheduled	N/A	In-Person and Recorded
41	Training Video Recordings	Within 5 business days after training	Final Submission	5 Business Days	MP4
42	O&M Manuals	Prior to Final Acceptance	Final Submission	14 Business Days	Two (2) hard-copy binders and electronic copy
43	Record As-Built Drawings	Prior to Final Acceptance	Final Submission	14 Business Days	Four (4) hard copies and PDF/CAD
44	Record Specifications	Prior to Final Acceptance	Final Submission	14 Business Days	Four (4) hard copies and PDF
45	Record Product Data	Prior to Final Acceptance	Final Submission	14 Business Days	Four (4) hard copies and PDF
46	Warranties and Guarantees	Prior to Final Acceptance	Final Submission	10 Business Days	Three (3) signed hard copies and electronic copy
47	Final TAB Report	Prior to Final Acceptance	Final Submission	14 Business Days	Four (4) hard copies and PDF
48	Final Commissioning Report	Prior to Final Acceptance	Final Submission	14 Business Days	Four (4) hard copies and PDF
49	Final Waste Diversion Report	Prior to Final Acceptance	Final Submission	10 Business Days	Four (4) hard copies and PDF
50	Final Electronic Deliverable Package (Reports, Drawings, Calculations, Photos, Videos, Models)	Prior to Final Acceptance	Final Submission	10 Business Days	Electronic Media and Network Submission

6.0 <u>Submittals:</u>

6.1 General: Under this contract, unless otherwise denoted, the Contractor shall provide all services necessary to perform the following activities as related to completing the FDA IRV Exhaust Lab and Vacuum Replacement mentioned above:

Submittal Register

6.2 **Deliverables:** Provide all deliverables in accordance with the project schedule and NIH Design Requirements Manual (DRM) Appendix E.

6.2.1 **Physical Deliverables (Format):** The documentation process shall be compiled and provided per the following per submission unless otherwise denoted:

Physical Deliverable Requirements

Deliverable	Quantity
O&M Manuals	Two (2) hard-copy binders and electronic copies
Warranties	Three (3) signed hard copies and electronic copies
Record Drawings	Four (4) hard copies and electronic PDF/CAD
Record Specifications	Four (4) hard copies and electronic copies
Record Product Data	Four (4) hard copies and electronic copies
Final Reports	Four (4) hard copies and electronic copies
Equipment Submission	One (1) complete equipment submission package
Training Videos	Electronic MP4 format
Photos/Videos	Electronic format
Calculations/Models	Electronic format

Binder Requirements

- Non-stick, locking slant D-ring, three-ring binders.
- 8½" x 11" format.
- Cover and spine shall include:
  - FDA Logo
  - Contract Number
  - Project Number
  - Submission Title
  - Submission Percentage (if applicable)
  - Date of Submission

Submittal Status Codes

- **A** – Approved
- **B** – Approved as Noted
- **C** – Revise and Resubmit
- **D** – Rejected

No work requiring Government approval shall proceed until the applicable submittal has received an "Approved" or "Approved as Noted" disposition from the Contracting Officer's Representative (COR) or designated Government reviewer.

6.2.2 **Electronic Deliverables (Format)**: Provide electronic deliverables in the following format using the latest version of software unless otherwise denoted or agreed upon:

Reports: MS Word **and** Adobe PDF
Presentation: MS PowerPoint

Spreadsheets:	MS Excel
Schedule:	MS Project (saved to PDF) with schedule of values
Drawings:	AutoCAD 2015 or later version **and** PDF
Catalog Cut Sheets:	PDF
Modeling:	PDF

6.3 **Project Schedule:** The IRV Exhaust Lab and Vacuum System Replacement Project shall be completed per the Period of Performance (or earlier) starting with the NTP or in accordance with the approved contractor project schedule incorporated at time of contract award, and per the following key milestones:

Submittal/Phase/Activity	Task Time Interval	Cumulative Duration
Kick-off Meeting	07 calendar days (from NTP)	07 days
Plan of Action (including schedule)	14 calendar days	21 days
Proposed Equipment – Submittal	30 calendar days	51 days
Proposed Equipment – FDA Review	14 calendar days	65 days
Comment Resolution/Approval	7 calendar days	72 days
Order material/lead times	30 calendar days	102 days
Construction (Demo and New Work)	60 calendar days	162 days
Inspection, Commissioning, Acceptance	30 calendar days	192 days
Close-Out (O&M Manuals, As-Builts)	30 calendar days	222 days

The Contractor shall incorporate shutdown coordination activities, temporary utility provisions, BAS integration activities, startup activities, TAB activities, and commissioning durations into the project schedule.

6.4 **Project Contacts:**
All technical questions shall be submitted to:

Darrel Wilmoth
Engineering Management Branch
Office of Facilities Engineering and Mission Support
U.S. Food and Drug Administration
301-529-2755
Darrel.Wilmoth@fda.hhs.gov

6.5 **Communication and Coordination:**

6.5.1 The Contractor shall prepare a detailed schedule for the project and provide to the Project Officer and Contracting Officer.

6.5.2 The Contractor shall appoint a Project Manager (PM), who shall be the Government's single point of contact, and provide all necessary project representation for the successful accomplishment of the work.

6.5.3 The Contractor shall hold weekly progress meetings unless otherwise denoted or agreed upon by the PO. Meetings shall be scheduled as required to satisfy the complete understanding and concurrence of stakeholders regarding the services to be rendered.

The progress meetings shall be held virtually (MS Teams, Zoom) or per conference call unless otherwise denoted or agreed upon. The contractor shall participate in additional meetings (such as on-board reviews) when prevailing issues require their input or resolution.

6.5.4 The progress meetings shall focus on the various task denoted in the contract; and shall cover project progress, timelines, existing and potential impediments, personnel, and delivery of services.

6.5.5 The Contractor shall take minutes of each meeting and distribute a narrative summary to each person in attendance within three (3) business days of any such meeting for review and comment prior to finalization. Meeting minutes shall be approved by the FDA PO prior to finalization or distribution.

6.5.6 Contractor shall notify the Government in writing no less than fifteen (15) business days prior to any planned utility shutdowns, disruptive work activities, or activities impacting laboratory operations. Where multiple notification periods are identified elsewhere in the contract documents, the longest notification period shall govern.

6.5.7 The Contractor shall issue submittal for signature, Catalog Cut Sheets, as-built marked-up drawings, and O&M manuals to the government for review and allow 10 business days for review (where applicable). The Contractor shall provide responses to FDA comments within five (5) business days of receipt.

6.6 **Liability:** The Contractor shall assume all risk and shall be liable for any damages to persons or property in connection with the above-mentioned project.

6.7 **Progress Payments:** The government shall only approve invoices for progress payments that reflect the percentage of the task completed (earned value) and submitted in accordance to contract requirements. The contractor shall be responsible for furnishing the government with the appropriate documentation to justify the invoice. The contractor shall provide a detailed cost breakdown per invoice. The cost breakdown shall only include cost incurred during the invoice period.

6.8 **Working Hours:** All field work shall generally be performed Monday through Friday from 6:00 A.M. to 5:00 P.M. unless otherwise approved by the Government. Noisy, vibration-producing, shutdown-related, odor-producing, or operationally disruptive activities shall be coordinated for after-hours or weekend execution as directed by FDA. No work shall be performed on Federal holidays or on days that the Government is closed unless otherwise approved.

6.9 **Contract Numbers:** The contract number assigned to this project shall be used on all reports, invoices, and any other related correspondence.

6.10 **Quality Control:** The Contractor shall be solely responsible for the quality of his work. Deficiencies and omissions shall be corrected prior to FDA's acceptance of work at no cost to the Government.

6.11 **Cost Proposal:** The cost proposal should be in the CSI format with detailed breakdown (labor, material, equipment per line item).

6.12 **Release of Information:** All documentation shall be the property of FDA. Documentation and information shall not be released to any other agency (government, private, or individual) without the prior approval of the Contracting Officer and PO.

6.13 **Attachments:** In the event of conflicts between contract documents, the following order of precedence shall apply:

1. Contract modifications and amendments
2. Contract clauses and solicitation provisions
3. This Scope of Work (SOW)
4. Specifications

5. Drawings
6. Manufacturer recommendations and industry standards

The Contractor shall promptly notify the Government of identified conflicts or ambiguities prior to proceeding with affected work.

The documents are to be utilized in the completion of the work.

- 251226 IRV Rm 2309 Drawings
- 251226 IRV Room 2309 Exhaust Spec

6.14 **Existing Equipment Disposition:** Existing equipment removed as part of this project shall become the property of the Contractor unless specifically identified by the Government for salvage or retention. The Contractor shall properly dispose of all removed equipment, oils, filters, and associated materials in accordance with applicable Federal, State, and local regulations.