United States Department of Agriculture
Agricultural Research Service

Performance Work Statement

PROJECT: Autoclave Temperature Mapping, Cycle Development, and Cycle Validation

National Bio and Agro-Defense Facility (NBAF) USDA-ARS, Manhattan, KS

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Performance Work Statement

Autoclave Temperature Mapping, Cycle Development, and Cycle Validation

PART 1
GENERAL INFORMATION

GENERAL INFORMATION: Performance Work Statement for the validation of the Getinge manufactured Autoclaves at the National Bio and Agro-Defense Facility (NBAF).

1.1 Background and Purpose

The National Bio and Agro-Defense Facility (NBAF) located at 1980 Denison Avenue, Manhattan, Kansas, is a state-of-the-art biocontainment facility that is designed to support research and diagnostic activities for the purpose of protecting our nation from emerging and foreign animal disease threats. NBAF is looking for a contractor to heat map 30 autoclaves and perform autoclave cycle development and cycle validation for various cycle profiles associated with the 30 autoclaves.

1.2 Definitions

ARS: Agricultural Research Services
BSL-4: Biosafety Level 4
BI: Biological Indicator
CI: Chemical Integrator
CLIN: Contract Line-Item Numbers
CO: Contracting Officer
COR: Contracting Officer's Representative
CUI: Controlled Unclassified Information
NBAF: National Bio and Agro-Defense Facility is a USDA owned facility.
QCP: Quality Control Program
SOP: Standard Operating Procedure
USDA: United States Department of Agriculture

1.3 Period of Performance

The period of performance shall be for a period of 210 days.

1.4 Qualifications

The contractor shall provide written documentation showing the specialist performing work under this contract has demonstrated experience or certification and operate under a quality system such as ISO 9000, ISO 14000, ISO 17665-1:2006, ANSI/AAMI ST67:200, ANSI/AAMI/ISO 11137: 2006, or similar industry standards for developing validations for autoclaving biohazardous waste, and other equivalent standards that provide sterility assurance level for steam sterilization. The contractor shall have organizational experience in validating decontamination cycles of biological hazards in a high containment facility operating under the Federal Select Agent Program (FSAP). This documentation shall be submitted to the contracting officer's representative (COR) for approval prior to the individual coming on-site. The contractor shall have adequate staffing to complete the scope of work in a timely manner. The contractor must have demonstrated experience with operating Getinge brand of autoclaves.

1.5 Security Requirements

Personnel employed by the Contractor or any representative of, or agent of the Contractor, entering this facility shall conform to the facility security regulations. The Contractor shall provide all information required for security background checks to meet facility access requirements as performed by the facility security office. Contractor personnel shall comply with all personal identity verification requirements as directed by USDA-ARS Security office. Each person accessing the site will be required to provide personal details, (full name, DOB, SSN, DL#) and will undergo a routine background check, such as a National Agency Check with additional inquiries, which may include a criminal and credit check. Details required for the check should be submitted the security office NLT 5 days prior to the visit. Results of this check may return earlier; however, it should not be planned to have results earlier than 5 days. If, while on site the contractor/vendor will have access to sensitive information, they must complete a Non-Disclosure Agreement (NDA), along with the required training. The NDA training will most likely be completed by reviewing a series of slides covering the topics of the definition of controlled unclassified information (CUI), access, handling, distribution, storage, and destruction of CUI. Each person will acknowledge receiving and understanding the training on the NDA. The process should not exceed two hours. Acknowledgement and completion of the NDA will be turned in with the form required for the background check. Results will be returned through the Contracting Officer or Contracting Officer Representative.

1.6 Physical Security

The certifying engineer/technician performing work under this contract shall safeguard all USDA-ARS equipment, information and property provided for Contractor use. At the close of each work period, USDA-ARS facilities, equipment, and materials shall be secured.

1.7 General Work Performance Location & Hours

The work shall be scheduled during normal business hours of the NBAF between 7:00 am and 5:00 pm local time; Monday – Friday. Work completed after hours or on weekends and/or holidays will be proposed at least a week in advance of the requested work time and may coordinated and reviewed in conjunction with by the NBAF Chief Facility Engineer/Contracting Officer's Representative.

1.8 Federal Observed Holidays

New Year's Day
Martin Luther King Jr.'s Birthday
President's Day
Memorial Day
Independence Day
Juneteenth
Labor Day
Native American Day
Veteran's Day
Thanksgiving Day
Christmas Day

1.9 Quality Control Program (QCP)

The Contractor shall develop, implement, and maintainan effective QCP to ensure services are performed in accordance with industry standards and this Performance Work Statement (PWS). The QCP, including changes, shall be forwarded to, and accepted by the Contracting Officer (CO). The Contractor shall develop and implement procedures to identify, remedy, and prevent future deficiencies and submit to the Contracting Officer's Representative (COR) for approval. The contractor shall review the plan with his onsite personnel to ensure complete understanding. The Contractor's Quality Control Program is the means by which the Contractor assures that the work complies with the requirement of the contract. The QCP must be provided within 30 days of the notice to proceed and shall be kept current, reflecting the pertinent contract modifications, and building changes or conditions, with updates being submitted within five (5) days of changes being made.

1.10 Contractor Performance Assessments

The Contractor will evaluate his contract services, correcting any deficiencies, which deviate from the commercially acceptable standard for the work under this contract. The Contractor shall furnish a copy of the evaluation/inspection reports to the designated COR for this contract as requested.

1.10.1 The name of the Project Manager
1.10.2 A communication plan that shall describe methods of direct and indirect communication with USDA-ARS regarding performance of the contract.
1.10.3 The Contractor shall give immediate written notice to the CO or COR of any condition which is discovered that may present a hazard to either the operational mission or staff.
1.10.4 The method(s) for identifying and preventing defects in the quality of service performed before the level of performance becomes unacceptable.
1.10.5 On site records of all inspections conducted by the Contractor and necessary corrective action taken. This documentation shall be made available to the CO and/or COR during the term of the contract.

1.11 USDA-ARS Performance Assessments

USDA-ARS performance assessments will be assigned to and authorized by the COR. The COR will evaluate the contractor's performance under this contract IAW the Quality Assurance Surveillance Plan (QASP). This plan is primarily focused on what USDA-ARS must do to ensure that the contractor has performed IAW the performance standards. It defines how the performance standards will be applied, the frequency of surveillance, and the minimum acceptable defect rate(s). Although USDA-ARS may develop a Quality Assurance Surveillance Plan, USDA-ARS surveillance of Contractor performance is not limited to the QASP or the performance objectives, incentives/remedies, etc. USDA-ARS has the right to inspect and test all services called for by the contract and commitments made by the Contractor during the solicitation process, to the extent practicable at all places and times during the term of the contract. USDA-ARS will perform inspections and tests in a manner that will not unduly delay the work. If any of the services performed do not conform to contract requirements, USDA-ARS may require the Contractor to perform the services again in conformity with contract requirements, at no increase in contract amount. When the defects in services cannot be corrected by re-performance, USDA-ARS may: (1) require the Contractor to take necessary action to ensure that future performance conforms to contract requirements, and (2) reduce the contract price to reflect the reduced value of the services performed. If the Contractor fails to promptly perform the services again or take the action necessary to ensure future performance in conformity with contract requirements, USDA-ARS may: (1) by contract or otherwise, perform the services and charge to the Contractor any cost incurred by USDA-ARS that is directly related to the performance of such service, or (2) terminate the contract for default. "Services", as used in this clause, includes services performed, workmanship, and material furnished or used in performing services.

1.11.1 On site records of all inspections conducted by the Contractor and necessary correctiveaction taken. This documentation shall be made available to the CO and/or COR during the term of the contract.

1.11.2 USDA-ARS personnel will accompany Contractor personnel during regular maintenance, service calls, or other work visits to observe and or ask for explanation of work performed. The intent is to inspect the work and not to delay the Contractor in any way.

1.11.3 Performing quality assurance in accordance with the PWS does not preclude USDA-ARS from conducting inspections as defined in Federal Acquisition Regulation (FAR) 52.212-4 Contract Terms and Conditions for Commercial Items for Inspection/Acceptance.

1.11.3.1 If performance or quality measures are not being met by the Contractor, USDA-ARS will revisit the QCP and may request revisions. Upon review of the plan and related documents, USDA-ARS will take appropriate action to ensure that all quality and performance measures are met as specified in this contract.

1.11.3.2 Type of Contract: USDA-ARS will award a performance-based commercial services contract. This means that USDA-ARS has described WHAT is to be accomplished, not HOW to accomplish it, and states a basis for determining whether finished work meets USDA-ARS quality requirements. It does not state detailed procedures for accomplishing the

requirement unless there are safety, security, or communication requirements. It is the intent of USDA-ARS to provide the Contractor the maximum amount of flexibility to propose an innovative approach, and to find the most efficient and cost-effective method for meeting the stated objectives and requirements.

1.11.3.3 Post Award Conference / Performance Evaluation Meetings: The Contractor agrees to attend any post award conference convened by the contracting activity or contract administration office in accordance with FAR Subpart 42.5. The CO and COR shall have performance evaluation meetings with the Contractor to review the Contractor's performance as needed. At these meetings the CO will apprise the Contractor of how the Government views the Contractor's performance and the Contractor will apprise USDA-ARS of problems, if any, being experienced. Appropriate action shall be taken to resolve outstanding issues. Meetings may be held at any time thereafter as determined beneficial by USDA-ARS and Contractor.

1.11.3.4 Contracting Officer's Representative (COR): The COR monitors all technical aspects of the contract and assists in contract administration. The COR is authorized to perform the following functions: Assure that the Contractor performs the technical requirements of the contract; perform inspections necessary in connection with contract performance; maintain written and oral communications with the Contractor concerning technical aspects of the contract; issue written interpretations of technical requirements, including Government drawings, designs, and specifications; monitor Contractor's performance and notifies both the CO and Contractor of any deficiencies; coordinate availability of government furnished property, and provide site entry of Contractor personnel. The COR is not authorized to change any of the terms and conditions of the resulting order.

1.12 Personnel

1.12.1 Contractor Key Personnel: The Contractor shall provide a contract manager who shall be responsible for the performance of the work and shall be the central point of contact with the Government. The name of this person and an alternate who shall act for the contractor when the manager is absent shall be designated in writing to the CO. The contract manager or alternate shall have full authority to act for the Contractor on all contract matters relating to daily operation of this contract. The contract manager or alternate shall be available from 8:00 a.m. to 4:00 p.m., Monday through Friday except Federal holidays or when the USDA-ARS facility is closed for administrative reasons.

1.12.2 Identification of Contractor Employees: All contract personnel attending meetings, answering Government telephones, and working in other situations where their contractor status is not obvious to third parties are required to identify themselves as such to avoid creating an impression in the minds of members of the public that they are USDA/Government officials. They must also ensure that all documents or reports produced by Contractors are suitably marked as Contractor products or that Contractor participation is appropriately disclosed.

1.12.3 Rosters: For NBAF Facility security purposes, the Contractor shall provide the CO a list of all employees who will perform work under this contract. The list shall include name and work assignment of each employee. The Contractor shall maintain revisions and updates to this list and submit them to the COR monthly.

1.12.4 Employee Badges: The Contractor shall furnish each employee a contract identification badge that shall be conspicuously displayed when working. The ID badge shall include the full name of the employee, company name, a badge serial number.

1.12.5 Contractor Personnel Conduct: The CO may require the contractor to remove any employee(s) from the contract and worksite for nonperformance, misconduct, or failure to abide by all laws and regulations. The contractor shall immediately comply with these requests. The following is a not an all-inclusive list of specific conduct NOT be condoned:

1.12.5.1 There shall be no fraternization or interference with the work of employees at the NBAF.

1.12.5.2 There shall be no violation of the GSA Publication; Rules and Regulations Governing Conduct on Federal Property (Federal Management Regulation Title 41, Code of Federal Regulations, Part 102-74, Sub-Part C, November 2005) found at the following internet link: https://www.ecfr.gov/current/title-41/subtitle-C/chapter-102/subchapter-C/part-102-74

1.12.5.3 Contractor personnel's conduct shall not reflect discredit upon USDA-ARS.

1.12.5.4 The Contractor shall ensure that personnel present a professional appearance.

1.12.5.5 The Contractor's employees shall observe and comply with all NBAF and local policies and procedures concerning fire, safety, environmental protection, sanitation, security, and possession of firearms or other lethal or illegal weapons or substance. The Contractor is responsible for ensuring that any contractor employees or subcontractor providing services under this contract conduct themselves and perform services in a professional, safe, and responsible manner.

1.12.5.6 The Contractor shall remove from the job site any employee or subcontractor for reasons of misconduct or security.

1.12.5.6.1 Neglect of Duties - includes sleeping on duty, failure to be attentive to assigned duties, failure to carry out assigned tasks, conducting personal business during duty hours.

1.12.5.6.2 Disorderly Conduct - e.g., the use of abusive or offensive language, quarreling, intimidation by words, actions, fighting, or participation in disruptive activities which interfere with normal and efficient operations of the NBAF or any organization or function on the NBAF Campus.

1.12.5.6.3 Criminal Actions - e.g., falsification or unlawful concealment, removal, mutilation, or destruction of any official documents, reports, or records, unauthorized use of Government property, theft, vandalism, immoral conduct, organizing or participating in

gambling of any form, unethical, improper, or fraudulent use of official authority or identification, the unauthorized, improper, or fraudulent use of communications equipment.

1.12.5.6.4 Release of Information - all contractor employees shall be prohibited from releasing any information pertaining to duty assignments, manpower, personnel, or other information to any outside organization or person(s), without the explicit, written consent of the CO or COR.

1.12.5.6.5 Violations of Security Procedures or Regulations - includes violations of established security procedures, policies, regulations, or guidelines, as well as failure to report to appropriate security officials any unauthorized security activity, observed or otherwise known to have occurred, or which is about to occur, on or which could affect USDA, APHIS, ARS, any specific organization or mission within USDA, or the security posture of the NBAF.

1.12.5.7 Particular attention should be paid to acceptance of gifts/ gratuities, and on non-disclosure of sensitive or classified information.

1.12.5.8 The Contractor shall ensure employee or subcontractor conduct complies with 41 USC 423 relative to release of acquisition related information, or actions or discussions which may prejudice future competitions.

1.12.5.9 The Contractor shall ensure no contractor employees conduct political related activities or events on the Installation.

PART 2
CONTRACTOR FURNISHED ITEMS AND SERVICES

2.1 Contractor Furnished Items and Responsibilities

The contractor shall furnish all personnel, equipment, materials, supplies, services required to achieve the quality performance standards of the work in this contract, unless otherwise specified herein. The contractor shall provide wireless temperature probes that have current NIST certifications, are rated to operate at temperatures up to 140°C, and the software to read the probes.

PART 3
GOVERNMENT FURNISHED ITEMS

3.1 Government Furnished Items

3.1.1 The government shall provide access to the needed Autoclaves units.

3.1.2 The government shall provide documentation to confirm that areas and Autoclaves and load configured profiles have not been exposed to biological hazards and do not pose human exposure risk.

3.1.3 The government shall supply the water, steam, and electricity to operate the units.

3.1.4 The government shall provide the 3M 1292-S biological indicators and associated 3M Auto-reader 390 incubators, along with the 3M comply SteriGage 1243, spore ampoules, chemical integrator as identified by the government to meet the requirements of this PWS.

3.1.5 The government shall provide the needed pre-packaged load configured profile materials and autoclave pans, racks, carts, etc. for loading autoclaves.

3.1.6 The government shall provide assurance that all the material that is being handled are free of exposure hazards.

3.1.7 The government shall provide up to 24 MadgeTech HiTemp 140 temperature probes, if desired for use by the Contractor.

PART 4
SPECIFIC TASKS

4.1 General Project Requirements

4.1.1 All services must meet all Local, State and Federal codes.

4.1.2 The Contractor shall furnish a detailed technical proposal and detailed cost proposal, including all prime and sub pricing showing labor cost, material cost, and estimated service time including crew size per independent Task listed herein.

4.1.3 The project is located at the National Bio and Agro-Defense Facility (NBAF) in Manhattan, KS.

4.1.4 The contract involves 30 Getinge autoclaves. The breakdown of the autoclaves by model is listed below.

- **4.1.4.1** 8 units of Getinge model GE 122222 ARB-2
- **4.1.4.2** 3 units of Getinge model GE 6610 AR-1
- **4.1.4.3** 1 unit of Getinge model GE 6610 ARB-2
- **4.1.4.4** 10 units of Getinge model GEB 6913 ARB-2
- **4.1.4.5** 4 units of Getinge model GEB 6915 ARB-2
- **4.1.4.6** 1 unit of Getinge model GEQ 6610 ARC-1
- **4.1.4.7** 3 units of Getinge model GEQ 6610 ARC-2

4.1.5 The contractor will propose a plan and perform heat mapping on all 30 autoclaves.

4.1.6 The contractor will propose a plan and perform the necessary activities to develop the appropriate cycle parameters to autoclave specific profile configurations assigned to each autoclave. There are up to 9 profiles that will be required to be developed. The number of profiles configurations will vary between autoclaves based on the determined use of the autoclave (refer to Plan Implementation for more detail). Cycle development data may be substituted across identical profiles and autoclave model numbers.

4.1.7 The contractor will propose a plan and perform the necessary activities to validate the profiles for the applicable autoclaves. Cycle validation will require 5 successful cycles for each profile for each autoclave (total of at least 540 successful cycles).

4.1.8 The 9 profiles are listed below.

- **4.1.8.1** Profile 1: Personal protective equipment waste, laboratory waste, and sharp waste. 25 autoclaves require this profile to be validated.
- **4.1.8.2** Profile 2: Special waste. 2 autoclaves require this profile to be validated.
- **4.1.8.3** Profile 3: Laundry. 19 autoclaves require this to be validated.
- **4.1.8.4** Profile 4: Glassware and tools. 20 autoclaves require this to be validated.
- **4.1.8.5** Profile 5: Special glassware and tools. 4 autoclaves require this to be validated.
- **4.1.8.6** Profile 6: Liquid: 16 autoclaves require this to be validated.
- **4.1.8.7** Profile 7: Animal bedding and feed. 10 autoclaves require this to be validated.
- **4.1.8.8** Profile 8: Rodent caging. 6 autoclaves require this to be validated.
- **4.1.8.9** Profile 9: Carts and bins. 6 autoclaves require this to be validated.

4.1.9 The contractor shall provide a formal report for the heat mapping, cycle development, and cycle validation activities. The report will include results, discussion, and all calibration information. The report shall include calculations and temperature trend graphs of each autoclave successful run characteristics for each load configured profile and standard deviations (with upper and lower limits) from

the average reading for each configured profile.

4.1.9.1 Results shall be provided in both hard and digital format. The final report will be provided in PDF format. The raw data and analytical charts will be provided in Excel format. Government will provide means for digital transfer.

4.1.10 The Contractor shall work with USDA personnel to ensure project is accomplished in a timely manner.

4.1.11 The Contractor's work shall adhere to the criteria stated within these project requirements and specifications.

4.1.12 At a minimum, an autoclave run to be considered successful, the run shall produce a 100% pass rate of biological indicators (BIs) and chemical integrators (CIs - CIs must fully max out at the acceptance range agreed upon by the Technical POC), and temperature trends must maintain readings as specified in the plan implementation.

4.1.13 Payment bid or other bonds may be required per the Contracting Officer's bid package. Obtaining and the cost of these bonds is the responsibility of the Contractor. Proof of Insurance will also be required.

4.1.14 The Contractor is responsible for visiting the site prior to submitting a bid to observe existing conditions. No compensation will be provided for conditions that would be visible during an on-site visit for persons experienced performing this type of work.

4.2 Bid Schedule

4.2.1 All bids shall be broken out by individual tasks for potential execution dependent on cost, time, and estimated impacts. All bids must be in whole dollars, no cents, otherwise, bids will be rounded to the nearest dollar.

4.3 Plan

4.3.1 The contractor shall provide a plan for the completion of the work outlined in this PWS and submit to the COR at a minimum of seven days (7) prior the start of work.

4.4 Plan Implementation

4.4.1 The contractor shall perform work in accordance with NBAF's safety standards to accomplish the Autoclave validation effort. USDA may request certain autoclaves be validated sooner or later than the contractors schedule depending on need and use of listed equipment. The contractor shall coordinate with the Technical POC/or designee on plan implementation of all the CLIN components. The cycle development results must be approved by the Technical POC/or designee prior to proceeding to the cycle validation stage of the CLIN. Daily reports with preliminary data for both the BI/CI and temperature trends must be provided to the Technical POC/or designee at the beginning of the day to identify any course correction with the cycle parameters or packaging configuration. This preliminary data must be provided and approved by the Technical POC/or designee before initiates for the day. If a cycle parameter or waste configuration is required to be altered the contractor will need to repeat the validations with the new requirements on units sharing the same model or waste configuration. Any stop work or corrective action plans must approved by CO/COR.

4.4.2 CLIN 1: The contractor shall provide Performance Qualifications (PQ) for Getinge model GE 122222 ARB-2Serial Number 0011126502-090-01.

4.4.2.1 Temperature Mapping

4.4.2.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment (wireless).

4.4.2.1.2 Temperature mapping will include 3M Attest Challenge Pack at 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.2.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.2.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.2.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.2.2 Cycle Development

4.4.2.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.2.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) laundry, and (1) animal bedding and feed configuration. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.2.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.2.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥126°C continuously for at least 35 minutes. The cycle development report will include measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile above the 35 minutes. The results of the final parameter will be provided to the Technical POC for approval prior to proceeding with the cycle validation.

4.4.2.2.5 The contractor shall provide a Standard Operating Procedure (SOP) and formal report for cycle development.

4.4.2.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.2.3 Cycle Validation Five (5) Successful Runs

4.4.2.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete **5 consecutive successful** runs for each cycle and configuration described in 4.4.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.2.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.2.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.2.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.2.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.3 CLIN 2: The contractor shall provide PQ validation for Getinge model GE 122222 ARB-2 Serial Number 0011126502-110-01.

4.4.3.1 Temperature Mapping

4.4.3.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.3.1.2 Temperature mapping will include 3M Attest Challenge Pack at 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.3.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.3.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.3.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.3.2 Cycle Development

4.4.3.2.1 CLIN 2 and CLIN models are identical. Provided CLIN 1 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 1 can be used for CLIN 2. If cycle development from CLIN 1 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 1 must be performed for CLIN 2.

4.4.3.3 Cycle Validation Five (5) Successful Runs

4.4.3.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.2.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.3.3.2 Cycle verification will include running the developed cycle using

CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.3.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.3.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.3.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.4 CLIN 3: The contractor shall provide PQ validation for Getinge model GEB 6915 ARB-2 Serial Number 0011126504-050-01.

4.4.4.1 Temperature Mapping

4.4.4.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.4.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.4.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.4.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.4.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.4.2 Cycle Development

4.4.4.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.4.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) laundry, and (1) animal bedding and feed configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.4.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.4.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥126°C continuously for at least 35 minutes. The results of the final parameter will be provided to the Technical POC for approval prior to proceeding with the cycle validation.

4.4.4.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.4.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.4.3 Cycle Validation Five (5) Successful Runs

4.4.4.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.2.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.4.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.4.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.4.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.4.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.5 CLIN 4: The contractor shall provide PQ validation for Getinge model GE6610 ARC-2 Serial Number 0011126507-020-01.

4.4.5.1 Temperature Mapping

4.4.5.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.5.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.5.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.5.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.5.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.5.2 Cycle Development

4.4.5.2.1 CLIN 4 and CLIN 3 models are identical. Provided CLIN 3 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 3 can be used for CLIN 4. If cycle development from CLIN 3 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 3 must be performed for CLIN 4.

4.4.5.3 Cycle Validation Five (5) Successful Runs

4.4.5.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.2.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.5.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.5.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.5.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.5.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.6 CLIN 5: The contractor shall provide PQ validation for Getinge model GE 6610 AR-1 Serial Number 0011176970-020-01.

4.4.6.1 Temperature Mapping

4.4.6.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.6.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.6.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.6.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.6.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.6.2 Cycle Development

4.4.6.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.6.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) glassware and tools, and (1) liquid configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.6.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.6.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time

when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.6.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.6.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.6.3 Cycle Validation Five (5) Successful Runs

4.4.6.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.6.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.6.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.6.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.6.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.6.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.7 CLIN 6: The contractor shall provide PQ validation for Getinge model GE 6610 AR-1 Serial Number 0011176970-010-01.

4.4.7.1 Temperature Mapping

4.4.7.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.7.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.7.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.7.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.7.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.7.2 Cycle Development

4.4.7.2.1 CLIN 6 and CLIN 5 models are identical. Provided CLIN 5 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 5 can be used for CLIN 6. If cycle development from CLIN 5 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 5 must be performed for CLIN 6.

4.4.7.3 Cycle Validation Five (5) Successful Runs

4.4.7.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.6.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.7.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.7.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.7.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.7.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.8 CLIN 7: The contractor shall provide PQ validation for Getinge model GEB 6915 ARB-2 Serial Number 0011126504-010-01.

4.4.8.1 Temperature Mapping

4.4.8.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.8.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.8.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.8.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.8.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.8.2 Cycle Development

4.4.8.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.8.2.2 The contractor shall complete cycle development of (1) glassware

and tools. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.8.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.8.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.8.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.8.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.8.3 Cycle Validation Five (5) Successful Runs

4.4.8.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.8.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.8.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.8.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.8.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.8.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.9 CLIN 8: The contractor shall provide PQ validation for Getinge model GEB 6915 ARB-2 Serial Number 0011126504-030-01.

4.4.9.1 Temperature Mapping

4.4.9.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.9.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.9.1.3 The run parameters will be as recommended by the 3M Attest

Challenge Pack.

4.4.9.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.9.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.9.2 Cycle Development

4.4.9.2.1 CLIN 8 and CLIN 7 models are identical. Provided CLIN 7 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 7 can be used for CLIN 8. If cycle development from CLIN 7 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 7 must be performed for CLIN 8.

4.4.9.3 Cycle Validation Five (5) Successful Runs

4.4.9.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.8.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.9.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.9.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.9.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.9.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.10 CLIN 9: The contractor shall provide PQ validation for Getinge model GE 6610 AR-1 Serial Number 0011176970-030-01.

4.4.10.1 Temperature Mapping

4.4.10.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.10.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.10.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.10.1.4 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.11 CLIN 10: The contractor shall provide PQ validation for Getinge model GEB 6913 ARB Serial Number 0011126505-170-01.

4.4.11.1 Temperature Mapping

4.4.11.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.11.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.11.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.11.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.11.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.11.2 Cycle Development

4.4.11.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.11.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) glassware and tools, and (1) liquid configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.11.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.11.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.11.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.11.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.11.3 Cycle Validation Five (5) Successful Runs

4.4.11.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. This task shall

include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.11.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.11.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.11.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.11.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.12 CLIN 11: The contractor shall provide PQ validation for Getinge model GEB 6913 ARB Serial Number 0011126505-050-01.

4.4.12.1 Temperature Mapping

4.4.12.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.12.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.12.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.12.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.12.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.12.2 Cycle Development

4.4.12.2.1 CLIN 11 and CLIN 10 models are identical. Provided CLIN 10 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 can be used for CLIN 11. If cycle development from CLIN 10 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 must be performed for CLIN 11.

4.4.12.3 Cycle Validation Five (5) Successful Runs

4.4.12.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.12.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.12.3.3 The contractor shall recover all BIs and CIs and process and interpret

results.

4.4.12.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.12.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.13 CLIN 12: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-090-01.

4.4.13.1 Temperature Mapping

4.4.13.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.13.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.13.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.13.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.13.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.13.2 Cycle Development

4.4.13.2.1 CLIN 12 and CLIN 10 models are identical. Provided CLIN 10 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 can be used for CLIN 12. If cycle development from CLIN 10 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 must be performed for CLIN 12.

4.4.13.3 Cycle Validation Five (5) Successful Runs

4.4.13.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.13.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.13.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.13.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.13.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend

data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.14 CLIN 13: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-070-01.

4.4.14.1 Temperature Mapping

4.4.14.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.14.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.14.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.14.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.14.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.14.2 Cycle Development

4.4.14.2.1 CLIN 13 and CLIN 10 models are identical. Provided CLIN 10 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 can be used for CLIN 13. If cycle development from CLIN 10 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 must be performed for CLIN 13.

4.4.14.3 Cycle Validation Five (5) Successful Runs

4.4.14.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.14.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.14.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.14.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.14.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.15 CLIN 14: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-010-01.

4.4.15.1 Temperature Mapping

4.4.15.1.1 The contractor shall complete empty chamber temperature mapping.

The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.15.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.15.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.15.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.15.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.15.2 Cycle Development

4.4.15.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.15.2.2 CLIN 14 and CLIN 10 models are identical except that CLIN 14 has an additional (1) laundry configuration. Provided CLIN 10 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 can be used for CLIN 14. If cycle development from CLIN 10 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 must be performed for CLIN 14.

4.4.15.2.3 The contractor shall complete cycle development for (1) laundry configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.15.2.4 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.15.2.5 The cycle development shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. The development will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for the configured profile.

4.4.15.2.6 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.15.3 Cycle Validation Five (5) Successful Runs

4.4.15.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. and 4.4.15.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.15.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.15.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.15.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.15.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.16 CLIN 15: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-130-01.

4.4.16.1 Temperature Mapping

4.4.16.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.16.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.16.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.16.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.16.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.16.2 Cycle Development

4.4.16.2.1 CLIN 15 model is identical both CLIN 10 and CLIN 14. CLIN 15 cycle configuration comprise the requirements of both CLIN 10 and 14. Provided both CLIN 10 and CLIN 14 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 and CLIN 14 can be used for CLIN 15. If cycle development from CLIN 10 and CLIN 14 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 and CLIN 14 must be performed for CLIN 15.

4.4.16.3 Cycle Validation Five (5) Successful Runs

4.4.16.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. and 4.4.15.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.16.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.16.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.16.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.16.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.17 CLIN 16: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-110-01.

4.4.17.1 Temperature Mapping

4.4.17.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.17.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.17.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.17.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.17.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.17.2 Cycle Development

4.4.17.2.1 CLIN 16 model is identical both CLIN 10 and CLIN 14. CLIN 16 cycle configuration comprise the requirements of both CLIN 10 and 14. Provided both CLIN 10 and CLIN 14 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 and CLIN 14 can be used for CLIN 16. If cycle development from CLIN 10 and CLIN 14 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 and CLIN 14 must be performed for CLIN 16.

4.4.17.3 Cycle Validation Five (5) Successful Runs

4.4.17.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. and 4.4.15.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.17.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.17.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.17.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.17.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to

establish quality parameters.

4.4.18 CLIN 17: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-150-01.

4.4.18.1 Temperature Mapping

4.4.18.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.18.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.18.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.18.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.18.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.18.2 Cycle Development

4.4.18.2.1 CLIN 17 model is identical both CLIN 10 and CLIN 14. CLIN 17 cycle configuration comprise the requirements of both CLIN 10 and 14. Provided both CLIN 10 and CLIN 14 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 and CLIN 14 can be used for CLIN 17. If cycle development from CLIN 10 and CLIN 14 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 and CLIN 14 must be performed for CLIN 17.

4.4.18.3 Cycle Validation Five (5) Successful Runs

4.4.18.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. and 4.4.15.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.18.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.18.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.18.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.18.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.19 CLIN 18: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-030-01.

4.4.19.1 Temperature Mapping

4.4.19.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.19.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.19.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.19.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.19.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.19.2 Cycle Development

4.4.19.2.1 CLIN 18 model is identical both CLIN 10 and CLIN 14. CLIN 18 cycle configuration comprise the requirements of both CLIN 10 and 14. Provided both CLIN 10 and CLIN 14 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 and CLIN 14 can be used for CLIN 18. If cycle development from CLIN 10 and CLIN 14 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 and CLIN 14 must be performed for CLIN 18.

4.4.19.3 Cycle Validation Five (5) Successful Runs

4.4.19.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. and 4.4.15.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.19.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.19.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.19.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.19.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.20 CLIN 19: The contractor shall provide PQ validation for Getinge model GEB6913 ARB Serial Number 0011126505-190-01.

4.4.20.1 Temperature Mapping

4.4.20.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.20.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.20.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.20.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.20.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.20.2 Cycle Development

4.4.20.2.1 CLIN 19 model is identical both CLIN 10 and CLIN 14. CLIN 19 cycle configuration comprise the requirements of both CLIN 10 and 14. Provided both CLIN 10 and CLIN 14 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 10 and CLIN 14 can be used for CLIN 19. If cycle development from CLIN 10 and CLIN 14 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 and CLIN 14 must be performed for CLIN 19.

4.4.20.3 Cycle Validation Five (5) Successful Runs

4.4.20.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.11.2.2. and 4.4.15.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.20.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.20.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.20.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.20.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.21 CLIN 20: The contractor shall provide PQ validation for Getinge model GE 6610 ARB-2 Serial Number 0011126506-010-01.

4.4.21.1 Temperature Mapping

4.4.21.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.21.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.21.1.3 The run parameters will be as recommended by the 3M Attest

Challenge Pack.

4.4.21.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.21.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.21.2 Cycle Development

4.4.21.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.21.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) special glassware and tools, and (1) laundry configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.21.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.21.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.21.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.21.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.21.3 Cycle Validation Five (5) Successful Runs

4.4.21.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.21.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.21.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.21.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.21.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.21.3.5 The contractor shall provide a report of the cycle validation results to

include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.22 CLIN 21: The contractor shall provide PQ validation for Getinge model GE122222 ARB-2 Serial Number 0011126502-050-01.

4.4.22.1 Temperature Mapping

4.4.22.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.22.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.22.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.22.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.22.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.22.2 Cycle Development

4.4.22.2.1 CLIN 21 and CLIN 1 models are identical except that CLIN 21 has an additional (1) glassware and tools, (1) rodent caging, and (1) animal carts and bins configurations. Provided CLIN 1 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 1 can be used for CLIN 21. If cycle development from CLIN 1 is used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 10 must be performed for CLIN 13.

4.4.22.2.2 The contractor shall complete cycle development of (1) glassware and tools, (1) rodent caging, and (1) animal carts and bins configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.22.2.3 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.22.2.4 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.22.2.5 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional

measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.22.2.6 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.22.2.7 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.22.3 Cycle Validation Five (5) Successful Runs

4.4.22.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.2.2.2 and 4.4.22.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.22.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.22.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.22.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.22.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.23 CLIN 22: The contractor shall provide PQ validation for Getinge model GE122222 ARB-2 Serial Number 0011126502-070-01.

4.4.23.1 Temperature Mapping

4.4.23.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.23.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.23.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.23.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.23.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.23.2 Cycle Development

4.4.23.2.1 CLIN 22 model is identical both CLIN 1 and CLIN 21. CLIN 22 cycle configuration comprise the requirements of both CLIN 1 and 21. Provided both CLIN 1 and CLIN 21 cycle development results were successful and receives agreement from Technical POC, the

results from the cycle development CLIN 1 and CLIN 21 can be used for CLIN 22. If cycle development from CLIN 1 and CLIN 21 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 1 and CLIN 21 must be performed for CLIN 22.

4.4.23.3 Cycle Validation Five (5) Successful Runs

4.4.23.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.4.2.2. and 4.4.22.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.23.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.23.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.23.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.23.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.24 CLIN 23: The contractor shall provide PQ validation for Getinge model GE122222 ARB-2 Serial Number 0011126502-010-01.

4.4.24.1 Temperature Mapping

4.4.24.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.24.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.24.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.24.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.24.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.24.2 Cycle Development

4.4.24.2.1 CLIN 23 model is identical both CLIN 1 and CLIN 21. CLIN 23 cycle configuration comprise the requirements of both CLIN 1 and 21. Provided both CLIN 1 and CLIN 21 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 1 and CLIN 21 can be used for CLIN 23. If cycle development from CLIN 1 and CLIN 21 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 1 and CLIN 21

must be performed for CLIN 23.

4.4.24.3 Cycle Validation Five (5) Successful Runs

4.4.24.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.4.2.2. and 4.4.22.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.24.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.24.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.24.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.24.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.25 CLIN 24: The contractor shall provide PQ validation for Getinge model GE122222 ARB-2 Serial Number 0011126502-030-01.

4.4.25.1 Temperature Mapping

4.4.25.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.25.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.25.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.25.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.25.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.25.2 Cycle Development

4.4.25.2.1 CLIN 24 model is identical both CLIN 1 and CLIN 21. CLIN 24 cycle configuration comprise the requirements of both CLIN 1 and 21. Provided both CLIN 1 and CLIN 21 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 1 and CLIN 21 can be used for CLIN 24. If cycle development from CLIN 1 and CLIN 21 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 1 and CLIN 21 must be performed for CLIN 24.

4.4.25.3 Cycle Validation Five (5) Successful Runs

4.4.25.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each

cycle and configuration described in 4.4.4.2.2. and 4.4.22.2.3. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.25.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.25.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.25.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.25.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.26 CLIN 25: The contractor shall provide PQ validation for Getinge model GE122222 ARB-2 Serial Number 0011126502-130-01.

4.4.26.1 Temperature Mapping

4.4.26.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.26.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.26.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.26.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.26.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.26.2 Cycle Development

4.4.26.2.1 CLIN 25 model is identical both CLIN 1 and CLIN 21. CLIN 25 cycle configuration comprise the requirements of both CLIN 1 and 21, and the addition of (1) liquid configuration. Provided both CLIN 1 and CLIN 21 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 1 and CLIN 21 can be used for CLIN 25. If cycle development from CLIN 1 and CLIN 21 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 1 and CLIN 21 must be performed for CLIN 25.

4.4.26.2.2 The contractor shall complete cycle development for (1) liquid configuration. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.26.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.26.2.4 The cycle development shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. The development will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for the configured profile.

4.4.26.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.26.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.26.3 Cycle Validation Five (5) Successful Runs

4.4.26.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.4.2.2. and 4.4.22.2.3 and 4.4.26.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.26.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.26.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.26.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.26.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.27 CLIN 26: The contractor shall provide PQ validation for Getinge model GE122222 ARB-2 Serial Number 0011126502-150-01.

4.4.27.1 Temperature Mapping

4.4.27.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.27.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 24 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.27.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.27.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.27.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.27.2 Cycle Development

4.4.27.2.1 CLIN 26 model is identical both CLIN 1 and CLIN 21. CLIN 26 cycle configuration comprise the requirements of both CLIN 1 and 21, and the addition of (1) liquid configuration. Provided both CLIN 1 and CLIN 21 cycle development results were successful and receives agreement from Technical POC, the results from the cycle development CLIN 1 and CLIN 21 can be used for CLIN 26. If cycle development from CLIN 1 and CLIN 21 are used, the contractor will indicate that in the report. Otherwise, the cycle development requirements listed in CLIN 1 and CLIN 21 must be performed for CLIN 26.

4.4.27.2.2 The contractor shall complete cycle development for (1) liquid configuration. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.27.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.27.2.4 The cycle development shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. The development will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for the configured profile.

4.4.27.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.27.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.27.3 Cycle Validation Five (5) Successful Runs

4.4.27.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.4.2.2. and 4.4.22.2.3 and 4.4.26.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.27.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.27.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.27.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.27.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.28 CLIN 27: The contractor shall provide PQ validation for Getinge model GEQ6610 ARC-2 Serial Number 0011126507-020-01.

4.4.28.1 Temperature Mapping

4.4.28.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.28.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.28.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.28.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.28.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.29 CLIN 28: The contractor shall provide PQ validation for Getinge model GEQ6610 ARC-2 Serial Number 0011126507-010-01.

4.4.29.1 Temperature Mapping

4.4.29.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.29.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.29.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.29.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.29.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.29.2 Cycle Development

4.4.29.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.29.2.2 The contractor shall complete cycle development of (1) special glassware and tools configuration. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.29.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.29.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35

minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.29.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.29.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.29.3 Cycle Validation Five (5) Successful Runs

4.4.29.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.29.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.29.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.29.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.29.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.29.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.30 CLIN 29: The contractor shall provide PQ validation for Getinge model GEQ6610 ARC-2 Serial Number 0011176970-040-01.

4.4.30.1 Temperature Mapping

4.4.30.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.30.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.30.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.30.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.30.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.30.2 Cycle Development

4.4.30.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for

each autoclave profile.

4.4.30.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) special waste, (1) laundry, (1) special glassware and tools, and (1) liquid configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.30.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.30.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.30.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.30.3 Cycle Validation Five (5) Successful Runs

4.4.30.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.30.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.30.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.30.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.30.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.30.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

4.4.31 CLIN 30: The contractor shall provide PQ validation for Getinge model GEQ6610 ARC-1 Serial Number 0011176971-010-01.

4.4.31.1 Temperature Mapping

4.4.31.1.1 The contractor shall complete empty chamber temperature mapping. The government and the contractor shall agree on the number and location of temperature data logging equipment.

4.4.31.1.2 Temperature mapping will include 3M Attest Challenge Pack at least 8 predetermined locations based on the autoclave model. 3M Attest Challenge Packs will be provided by the government.

4.4.31.1.3 The run parameters will be as recommended by the 3M Attest Challenge Pack.

4.4.31.1.4 The contractor shall provide a Standard Operating Procedure (SOP) for the temperature mapping.

4.4.31.1.5 The contractor will provide a report of the temperature trends for the entire test period, a diagram identifying any cold spots in the autoclave chamber, and the results of the biological indicators and chemical/steam integrators from the 3M Attest Challenge Packs.

4.4.31.2 Cycle Development

4.4.31.2.1 Prior to cycle development the government and the contractor shall agree on the location and interpretation of the BIs, CIs, and temperature loggers and shall agree on the load configuration for each autoclave profile.

4.4.31.2.2 The contractor shall complete cycle development of (1) mixed PPE, lab, and sharps waste, (1) special waste, (1) laundry, (1) special glassware and tools, and (1) liquid configurations. This task shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.31.2.3 This task shall establish initial cycle parameters based on similar applications, applicable standards and or Getinge cycle development guide.

4.4.31.2.4 The contractor will provide a report for the cycle development which shall identify when $1x10^6$ spore reduction is achieved and the time when BIs and CIs will begin to pass/fail given a constraint on temperature. It will also include the use of temperature probes at the center of each package and provide graphical temperature data trends that support the achievement of ≥121°C continuously for at least 35 minutes. The cycle development report will include additional measures to identify the additional time or temperature increase required to achieve a sterility assurance level for each configured profile.

4.4.31.2.5 The contractor shall provide a Standard Operating Procedure (SOP) for cycle development.

4.4.31.2.6 The contractor shall provide a report of the cycle development results to include temperature trends for each cycle profile configuration and biological indicator and chemical/steam integrator results.

4.4.31.3 Cycle Validation Five (5) Successful Runs

4.4.31.3.1 Once the final parameters for the cycle have been determined, the contractor shall complete 5 consecutive successful runs for each cycle and configuration described in 4.4.31.2.2. This task shall include at the minimum the items listed below and shall be coordinated and reviewed in conjunction with the Technical POC.

4.4.31.3.2 Cycle verification will include running the developed cycle using CIs, BIs, and temperature data logging equipment to demonstrate efficacy as described in the general product requirements section.

4.4.31.3.3 The contractor shall recover all BIs and CIs and process and interpret results.

4.4.31.3.4 The contractor shall provide a Standard Operating Procedure (SOP) for cycle validation.

4.4.31.3.5 The contractor shall provide a report of the cycle validation results to include temperature trends for each cycle profile configuration

and biological indicator and chemical/steam integrator results. The trend data shall depict standard deviation upper and lower control limits to establish quality parameters.

PART 5
DELIVERABLES SCHEDULE

5.1 CLIN 1- 30

5.1.1 The contractor shall provide a schedule for the completion of work within 30 days of the being awarded the contract.

5.1.2 The contractor shall verify that the operational requirements are met.

5.1.3 Contractor shall provide shadowing opportunities to NBAF personnel directly associated with system functions for up to three (3) personnel throughout the course of service. This shall not impede on the production or work of the contractor but will provide visualization of the process in its entirety. The frequency and the scheduling of the shadowing will be determined and coordinated with and in conjunction with the contractor.

5.1.4 The contractor shall provide a daily update of the preliminary data from the previous day to the Technical POC/designee and receive approval before work on the new day can be initiated.

5.1.5 The contractor shall provide a weekly update of the work completed to the COR by the close of business on the first workday of the following work week.

5.1.6 CLIN1-CLIN 4 must be completed within 60 days after being awarded the contract. The deliverable must include a report specified in CLIN1-CLIN4.

5.1.7 CLIN 5-CLIN 30 must be completed within 210 days of being awarded the contract.

5.1.8 The contractor shall provide the government with all the reports as specified in CLIN1-CLIN30 30 days before the end of the performance period to allow for ample feedback and adjustments.

5.1.9 All required tasks for this Performance Work Statement shall be completed no later than 210 days after the contract is awarded.