DRAFT

STATEMENT OF WORK (SOW)

FACILITY ENVIRONMENTAL MONITORING

NIH
10 CENTER DR
BETHESDA, MD 20892

June 13, 2017

TABLE OF CONTENTS

1.0 INTRODUCTION

1.1. The mission of the Clinical Center (CC) (defined as Warren Grant Magnuson Building (Bldg 10), Ambulatory Care Research Facility (ACRF) and Clinical Research Center (CRC)) is to provide clinical research servicing the needs of the NIH Intramural Research Program by providing a safe and effective environment for the care and treatment of patients participating in structured biomedical research protocols. It consists of 3.5 million square feet of mixed occupancy space in three congruent buildings on the NIH campus. The Clinical Center (CC) is a 200 bed clinical research hospital. The CC employs approximately 2,000 employees, across 30 different departments. Refer to Enclosure 1 for a list of publications applicable to this Performance Work Statement (PWS). For definitions of terms used throughout this document see Enclosure 2.

2.0. BACKGROUND

2.1. The NIH Clinical Center serves as the nation's premier research hospital for conducting clinical research to improve the health of humankind. The Clinical Center also serves as the national resource for clinical research by fostering dynamic interactions with outside partners; developing diagnostic and therapeutic interventions; enhancing systems to ensure the safe, efficient, and ethical conduct of clinical research; training clinical researchers; and leading the clinical research response to the nation's emerging public health needs. The Clinical Center Complex of the National Institutes of Health (NIH) is located in Bethesda, Maryland. The Clinical Center is the hospital of the NIH consisting of 200 inpatient beds, 90 day hospital stations and numerous specialty ambulatory care areas. Adjacent to the hospital facilities are research laboratories.

3.0 OBJECTIVES:

3.1 To provide a documented environmental monitoring program, implemented through standard operating procedures that describe in detail the procedures and methods used for monitoring temperature, relative humidity, particulates, and viable microorganisms in controlled environments (air, surface and personnel). The program includes sampling sites, frequency of sampling, and investigative and corrective actions to be followed if action levels or regulatory limits are exceeded.

The purpose of this procedure is to provide instructions for the microbiological workup of the environmental monitoring cultures collected in pharmaceutical and cell therapy manufacturing facilities following USP <797>, ISO 9001, and ISO 17025. The manufacturing of pharmaceutical and cell based therapies requires a system for monitoring environmental conditions as mandated by FDA regulations (211.42 Design and construction features, 1271.195 Environmental control and monitoring, 211.46 Ventilation, air filtration, air heating and cooling, and 211.113 Control of microbiological contamination). Regulation 211.113 requires that SOPs "prevent objectionable microorganisms in drug products. . .". FDA guidance provides further clarification that objectionable organisms "relates to microbial contaminants that, based on microbial species, numbers of organisms, dosage form, intended use, patient population, and route of administration, would adversely affect product safety". The purpose of this project is to establish a service contract with a microbiology testing lab that is capable of culturing, incubating, enumerating, and identifying bacteria and fungi in the environmental contaminants as per the FDA guidelines.

The technical aspects include culturing of air and surface samples at two temperatures and enumerating and identifying all isolates grown on culture.

Environmental monitoring programs should provide information to demonstrate that engineering controls, sanitation practices, and processes as a whole can provide a "state control" indicating a consistently stable environment where microbial burden is maintained at an acceptable level. The program should be capable of detecting adverse trends in microbial burden and populations in a timely manner.

Proactive environmental monitoring for microbial burden should facilitate in data trending analysis and identification of the microbial source such as equipment failure, sanitation practices, and personnel habits or training deficiencies. Proactive trending with results available close to the time of collection can assist with corrective action of the environment prior to a potential adverse effect of the product. The protocol describes the equipment, sample sites, lab analysis (including media, culture, incubation, method of identification), data collection and reporting, statistical analysis, risk assessment, and response to exceed concern levels of detail.

4.0 SCOPE OF WORK

This document serves to outline the scope of work for execution of a viable microbial environmental monitoring program for product production and testing facilities on the NIH Campus.
The scope of work for the product production and testing facilities environmental monitoring includes:

-
- Quality control testing of media
- Supply of microbiological media
- Incubation and culture analysis of environmental monitoring samples
- Bacterial and fungal identification performed in house or subcontracted as requested by NIH

Independently and not as an agent of the Government, the contractor shall provide all necessary services, supervision, and labor, not otherwise provided by the Government, as needed to perform services as specified in this document in accordance with all terms, conditions, general and special contract requirement, specifications, exhibits, etc. contained within the contract document or incorporated by reference.

5.0 PERIOD OF PERFORMANCE

The period of performance shall be for one (1) Base Year of 12 months and four (4) 12-month option years. The period of Performance reads as follows:

Base Year:	October 1, 2017	thru	September 30, 2018
Option Year I	October 1, 2018	thru	September 30, 2019
Option Year II	October 1, 2019	thru	September 30, 2020
Option Year III	October 1, 2020	thru	September 30, 2021
Option Year IV	October 1, 2021	thru	September 30, 2022

5.1. Quality Control: The contractor shall develop and maintain an effective quality control program to ensure services are performed in accordance with this PWS. The contractor shall develop and implement procedures to identify, prevent, and ensure non-recurrence of defective services. The contractor's quality control program is the means by which they assure themselves that their work complies with the requirement of the contract. The contractor shall conduct a quality assurance program that is computer

based and able to produce reports, as requested. This program will be used to help evaluate the contractor's performance. The NIH reserves the right to perform unannounced audits as a measurement of quality control.

5.2 Government Quality Assurance

1. Inspection Criteria – How should the products or services be delivered?
   By email and electronic files (to include reports and data) downloadable from the website with capability to transmit results into a Government approved system.

2. Acceptance Criteria – How will you know you got what you paid for?
   The reports of the environmental monitoring will indicate the testing has been conducted adequately. All quality measurements including controls must be documented and provided to NIH in reports routinely or upon requested.

6.0 PLACE OF PERFORMANCE

Equipment and onsite sampling will be conducted by the NIH in several pharmaceutical and cell production facilities, as well as the sterility testing lab. Cultures will be sent to entity foe microbiological culture and microbial identification.

7.0 WORK REQUIREMENTS

The following is a list of anticipated tasks which are required to complete baseline monitoring and room qualification in several NIH manufacturing facilities as well as routine dynamic and static environmental monitoring:

Meeting:
- Onsite meeting at the inception of the contract
- Inspection of testing facility
- Audit and review of test records
- Audit and review of test method validations and performance including media qualification, identification test platforms and acceptability criteria, instrument maintenance etc.

Shipping:
- Coordinate shipping, handling, supplies, and returns
- Ensure stability of cultures during shipping
- Ensure timely receipt of cultures and handling in lab
- Ensure timely shipping at appropriate temperature of qualified media to NIH for EM testing
- Media must be shipped to multiple facilities on NIH campus upon request

Testing:
- Collaborate with NIH to accomplish required incubation and reading of samples
- Collaborate with NIH to establish acceptable identification criteria and reporting methods including validation/qualification of test platform.
- Identify all isolates to the species level using a test platform approved by NIH. Genus level identification acceptable in certain circumstances.

- Keep isolates subcultures for 1 week after providing results to NIH in case further investigation is required.
- Perform all culture manipulation (smear preparation and subculture) in a clean BSC. Cleaning procedures must be deemed acceptable by NIH.
- Perform smears and relevant biochemicals in addition to microbial identification platform to ensure validity and correlation of the identification result.
- Electronic specimen tagging to ensure continuity of specimen handling through pre-analytical, analytical, and post-analytical phases.

Report:

- Assemble, review, and analyze data from testing into report format for large dataset analysis
- Provide results within 1 day for culture negative sign outs.
- Provide enumeration results within 1 day for culture positive sign outs with breakdown of colony types (bacteria, yeast, mold) with Gram stain description for bacteria and Lactophenol cotton blue (and/or macroscopic morphology) description of fungi.
- Provide microbial identification to the record within 1 day of result receipt
- If microbial identification is outsourced, identification must be provided to NIH within 14 days of original culture receipt.
- Provide certificate of analysis for media relating to sterility and growth promotion

8.0 DELIVERABLES

- Provide colony forming units per plate including breakdown of colony types (bacteria, yeast, mold)
- Smear results per isolate
- Identification of all colonies to the species level (genus acceptable in certain circumstances)
- EM samples 8000 per year projected to 25,000 per year
- EMPQ samples approximately 3000 projected/year

The contractor should include an option for a sampling service to include the following:

- Routine sampling service performed by contractor on-site with a qualified technician on a regular weekly basis
- Non-routine sampling service performed by contractor with a qualified technician available for planned, non-routine sampling such as EMPQ/dynamic monitoring with 72 hours' notice
- A sampling kit that includes calibrated equipment and qualified media (for use by NIH staff to sample the facility)

8.1. Quality Control Plan (QCP). Within one (1) week of contract award, the contractor shall submit a QCP to the CO. The QCP shall cover every aspect of the contractor's operation under the contract and for each subsequently awarded task order. The purpose of the QCP is to monitor, analyze, and improve quality, management and compliance with contract performance standards. Subsequently awarded task orders may require modifications to the QCP. The QCP must be reviewed annually and data may be requested and audited by the NIH, as requested.

8.2. Transition Plan. Within one (1) week of contract award, the contractor will provide a Transition Plan that will detail what steps will be taken to minimize any decreases in productivity and to prevent possible negative impacts on services. The Contractor shall develop procedures to ensure that all HCPs are available, at no additional cost to the Government, during the phase-in / phase-out periods to ensure that services are provided in accordance with contract/task order terms and conditions. During the phase-in

period, the Contractor shall become familiar with requirements in order to commence full performance of services on the contract or task order start date, as applicable.

8.3. Quarterly Reports. The contractor shall submit a written report to the CO and COR identifying all current task orders and the distribution of performance between the prime and subcontractors, monthly fill rates, turnover rates, credential submissions, patient complaints, and back fill support. The period of the report will be the previous quarter and will be due on the 10th calendar day after the quarter ends. If the fill rate or turnover rate does not meet the requirements stated in the contract/ task order, an explanation must be provided, as well as measures to meet fill and turnover rate standards and requirements. The contractor shall submit additional reports to the CO as requested for use in monitoring contractor performance. The CO may request additional information at any time.

8.4 Contractor Representative. In addition to the requirement discussed at paragraph 3.1.2, the contractor shall notify the COR and CO in writing should the CR be absent and is not available to the government. Designated CR(s) shall be available via email and cell 365 days a year.

9.0 Alert Limit (USP<797> and ISO)

	ISO5	ISO7	ISO8 & Buffer Rooms
Air	>1	>10	>100
Surface	>3	>5	>100
Fingertip	>3	NA	NA
Swab			

10.0Notification

- Provide courtesy phone call to submitting laboratory for colony counts above alert limits
- Provide courtesy phone call to submitting laboratory immediately for laboratory errors and/or corrected reports.

11.0 GENERAL INFORMATION

Administrative

11.1.3. The Contracting Officer's Representative (COR) will be the CO's authorized representative in administering the contract. The contractor's representative shall be available to discuss any problems that the contractor's personnel may be experiencing during the performance of this contract. Problems experienced by the Government with the contractor's performance will be discussed and resolved. Unresolved problems will be referred to the CO for resolution.

11.1.4. The contractor shall abide by all NIH CC standards, regulations, rules, and procedures including requirements for any licensure, credentialing and quality assurance requirements. Such regulations include, but are not limited to, general safety, fire prevention, waste disposal, infection control, JC, and patient safety initiatives.

11.1.5. Media and Other Inquiries. The contractor shall not respond to any media inquiries, requests for interviews or comments or provide any public response to media inquiries. The contractor shall not speak to the media on behalf of the Government. Any inquiries from the media or third party inquiries received shall be immediately relayed to the COR who will relay them to the NIH Public Affairs Officer for coordination.

11.5. Safety Requirements

11.5.1. The contract shall maintain safety and health standards compliant with requirements of the Occupational Safety and Health Administration (OSHA).

11.6. Security Requirements

11.6.1. NIH CC is a restricted campus. An identification badge is required for access for entry into buildings and is also shown to the Security Police/Sentry when entering/exiting the NIH Campus.

Since the contract employee(s) under this contract have access to and/or process information requiring protection under the Privacy Act of 1974, these positions are considered "IT Sensitive" positions. Compliance with Executive Order (EO) 10450 and OMB Memorandum M-05-24 is mandatory for IT Sensitive positions. Therefore, a National Agency Check for Trustworthiness (NACT) is required for each contract employee(s) under this contract. Each individual will be fingerprinted and required to complete the appropriate forms, usually a Standard Form 85-P, Questionnaire for Public Trust Positions. The contractor is responsible for obtaining the Standard Form 85-P, Questionnaire for Public Trust Position. The contractor shall advise their employees that a favorable report is required as a condition of employment under this contract. The contractor shall apply for the NAC within three (3) workdays after start of performance for each contract employee. The government will be responsible for all costs associated with the NAC. Offerors shall be advised adjudication constraints may prevent non-U.S. Citizens from performing in a timely manner. No waivers will be contemplated.

11.6.5. Safeguarding Material and Confidentiality of Information

11.6.5.1. The contractor shall be responsible for safeguarding all Government property provided or obtained in connection with this contract. The contractor shall safeguard information of a confidential or sensitive nature. Neither the contractor nor any of its contract HCP shall disclose or cause to be disseminated any information concerning NIH that could result in or increase the possibility of a breach in security or interrupt the continuity of operations or which breaches the requirements of the Federal Privacy Act of 1974. However, the contractor may be required to provide testimony in legal or administrative procedures. Such participation must be consistent with the disclosure requirements imposed in this contract and coordinated with the contracting officer.

11.6.5.2. The contract under this contract shall have access to and/or process information requiring protection under the Privacy Act of 1974. These positions are considered "Automated Data Processing (ADP) Sensitive" positions. Contractor shall comply with Executive Order (EO) 10450 and OMB Memorandum M-05-24.

11.6.5.3. Unless otherwise specified, all financial, statistical, personnel, medical, patient and/or technical data which is furnished, produced or otherwise available to the contractor during the performance of this contract are considered confidential information and shall not be used for purposes other than performance of health care services under this contract. The contractor shall not release any of the above information without prior written consent of the CO. The contractor and contract shall prepare medical

records, forms and documents as required, in accordance with the regulations and established guidelines listed in the contract and those established by the NIH Director.

11.6.5.4. The contractor shall abide by federal and local NIH regulations and requirements concerning the nature of privileged communication between patients and the HCP as may be necessary for security and personnel reliability programs. They shall also abide by federal and local regulations concerning the confidentiality of patient records, to include but not limited to the Privacy Act of 1974 and the Health Insurance Portability & Accountability Act (HIPAA) of 1996. All regulations referenced are available for review from the COR, or the CO. All medical records and reports will remain the property of the Government.

11.11. Contractor Furnished Supplies/Services

11.11.1. Unless specified otherwise by each individual task/Call order, the contractor shall furnish all personnel and services to comply with the requirements of this contract. Requirements for contractors to furnish equipment or supplies will be addressed in each applicable task/call order.

11.12. NIH Clinical Research Center Hours of Operation

11.12.1. The Clinical Center hospital and Ambulatory Care Research Facility operates 24 hours a day, 365 days a year (366 days during leap years) including holidays.

11.12.2. Holidays. The following is a list of legal federal holidays. Any of the federal holidays falling on a Saturday will be observed on the preceding Friday; holidays falling on a Sunday will be observed on the following Monday. Contract employees may be required to work on legal holidays as determined by the NIH department chief or COR as specified in each Task/Call order.

New Year's Day, January 1st
Martin Luther King's Birthday, 3rd Monday in January
President's Day, 3rd Monday in February
Memorial Day, Last Monday in May
Independence Day, July 4th
Labor Day, 1st Monday in September
Columbus Day, 2nd Monday in October
Veteran's Day, November 11th
Thanksgiving Day, 4th Thursday in November
Christmas Day, December 25th

11.12.4. Closures. During anticipated closure of the facility due to NIH declared training holidays, Presidential Executive Order or unplanned closure of the facility or campus due to natural disasters, emergencies, severe weather, acts of God or otherwise, the contractor will only be paid for the actual hours worked. The NIH Campus may designate training days. These training days may close certain departments. Staffing may be limited in certain areas due to low census. Contract employees may be required to work during training days.

11.19. Unauthorized Services

The Contractor shall not undertake any action that will increase the price of the contract without the written approval of the Contracting Officer. Any such unauthorized action taken by the contractor or any Contractor employee, which might be construed to be approved by the Government, shall be the responsibility of the Contractor and shall be resolved by the Contractor at no expense to the Government. Third party claims resulting from such unauthorized actions shall also be resolved by the Contractor without expense to the Government.

12.0. QUALITY CONTROL

12.1. The contractor shall have a planned and systematic quality control process and Quality Control Plan (QCP) covering every aspect of the contractor's operation under the contract/task order, as applicable. Contractor shall implement its QCP for monitoring, analyzing, and improving quality, management and compliance with contract performance standards. The QCP shall specifically address and correct deficiencies identified by the contractor or which are brought to its attention by the Government.

13.0 AUDITS

Contractor shall allow NIH or NIH contractor to audit facilities, systems and documentation, as they relate to environment monitoring testing, at mutually agreed upon times. In the event observations are issued, contractor shall issue responses within 15 business days to all observations in writing. Where the contractor commits to a corrective action, a description and timeframe for completion will be included in the written response.