



Biosafety Level 4 Laboratory Consultant

Biosafety Program

Community Initiatives Bureau

March 16, 2023

I. Overview

The Boston Public Health Commission (BPHC) is the local public health department for the City of Boston. BPHC's mission is to protect, preserve, and promote the health and well-being of all Boston residents, particularly the most vulnerable.

The BPHC's Biosafety Program is seeking a Biosafety Consultant to assist the Biosafety Program in providing oversight and regulation of biological research laboratories in the City of Boston, including Boston University's National Emerging Infectious Diseases Laboratories (NEIDL) Biosafety Level 4 (BSL-4) and Animal Biosafety Level 4 (ABSL-4) facility. Individuals, environmental health and safety (EH&S) consulting teams, and companies are invited to submit a proposal in response to this RFP.

In December 2017, BPHC issued a permit to the NEIDL to conduct research in the Biosafety Level 4 (BSL-4) and Animal BSL-4 (ABSL-4) facility. The United States Centers for Disease Control and Prevention (CDC) Federal Select Agent Program issued a registration to the NEIDL to conduct research involving biological select agents and toxins at Biosafety Level 3 (BSL-3)/Animal Biosafety Level 3 (ABSL-3), and BSL-4/ABSL-4 laboratories.

The BPHC's Biosafety Program regularly inspects the permitted labs to monitor compliance with the BPHC's regulations; identify deviations from acceptable laboratory safety, biocontainment, or biosecurity practices, and recommend program improvements. The Biosafety Consultant will participate in these scheduled site inspections at the NEIDL as support to the Biosafety Program.

The Biosafety Consultant will review institutional training modules and records, review and verify compliance with written institutional policies and standard operating procedures (SOPs) and provide guidance to BPHC and the Boston Biosafety Committee on the NEIDL facility operations.

The Biosafety Consultant will review new research protocols and protocol amendments, facilitate the Boston Biosafety Committee meetings, and submit written summaries of discussions and recommendations of the Committee. The Biosafety Consultant will also facilitate the Boston Biosafety Working Group (quarterly) meetings, as needed, and submit written summaries of discussions and recommendations to the BPHC's Biosafety Program Office. The Biosafety Consultant will hold regular meetings with NEIDL and BPHC staff.

As part of BPHC's efforts to have an equitable procurement process, BPHC will consider and encourage Certified Unrepresentative Businesses Enterprises (CUBE) that includes; Minority-owned Business Enterprises (MBE), Women-owned Business Enterprises (WBE), Veteran-owned Business Enterprises (VBE), Disability-owned Business Enterprise (DOBE), Lesbian Gay Bisexual Transgender Business Enterprises (LGBTBE), Minority Non Profit (MNPO), Women Non Profit (WNPO), Minority Women Non Profit (MWNPO) and local businesses to apply to this RFP

II. Scope of Service

The Biosafety Program seeks a qualified Biosafety Consultant to support various aspects of the oversight and regulation of the biological research laboratories in Boston including:

1. Inspect BSL-4/ABSL-4 Suit Laboratory Facility:

In collaboration with the BPHC Biosafety Program Team, conduct laboratory inspections (at least 2 annual routine and any non-routine inspections required due to unexpected circumstances) of the BSL-4/ABSL-4 laboratory spaces and supporting areas.

- a. Complete BU NEIDL BSL-4 Visitor Training and Suit Training and getting medical clearance by BU's Research Occupational Health Program (ROHP) to access the BSL-4/ABSL-4 laboratory facilities
- b. Verify inventory records of biological select agents and toxins (BSATs) and other high-risk agents (Risk Group 3 or 4 Agents);
- c. Tour the BSL-4/ABSL-4 related facilities (e.g., HVAC, Effluent Decontamination System (EDS), tissue digester, etc.).
- d. Complete the required BU NEIDL BSL-4 Suit Training and obtain BU Research Occupational Health Program (ROHP) medical clearance to enter the biocontainment facility.
- e. Participate in interviews of the BU NEIDL personnel and review their training records and relevant SOPs, as part of the lab inspection.
- f. Submit a written inspection report, including completed standardized facility inspection checklists to verify that the BSL-4/ABSL-4 laboratories follow acceptable national biosafety, biocontainment and security practices.

2. Review Work Practices and Documents/Records:

- a. As requested by the BPHC Biosafety Program Team, review institutional training modules and records and laboratory work practices to verify compliance with NEIDL written institutional policies and procedures, biosafety/biocontainment plan, security plan, incident response plan, and Select Agent requirements as part of the inspection process and on an ad hoc basis.
- b. Provide guidance to BPHC and the Boston Biosafety Committee on the NEIDL facility operations.

3. Review Research Projects/Protocols:

- a. Review BU NEIDL's BSL-4/ABSL-4 and BSL-3/ABSL-3 new research projects and protocol amendments, in collaboration with the BPHC's Biosafety Program Team and the Boston Biosafety Committee (BBC).
- b. Provide a risk assessment and public health and safety concerns of the proposed research.
- c. Review the minutes of the Institutional Biosafety Committee (IBC) meeting(s) at which the research protocols/amendments submitted to BPHC were reviewed.
- d. Review inactivation validation procedures (SOPs), data and records to ensure compliance with

- e. Submit written comments to the BPHC Biosafety Team on the reviewed documents.

4. Participate in BU NEIDL Emergency Response Drills/Exercises Planning:

- a. Participate in the planning and execution of emergency response drills and exercises (at least three per year) conducted at the BU NEIDL and coordinated by the City of Boston emergency responders.
- b. Submit written comments/feedback on the NEIDL drills/exercises and After-Action Reports to the BPHC Biosafety Program Team after each drill/exercise.

5. Facilitate Committee Meetings:

- a. Facilitate the **Boston Biosafety Committee (BBC)** meetings (held quarterly either virtually or in- person at the BPHC offices,1010 Massachusetts Avenue, Boston, MA 20118) and submit written summaries of meeting discussions and recommendations of the Committee.
- b. Facilitate the **Boston Biosafety Working Group (BSWG)** meetings (held quarterly either virtually or in-person at the BPHC offices) and submit written summaries of discussions and recommendations to the BPHC’s Biosafety Program Team.

III. RFP Timeline	
Monday, March 15, 2023	RFP Legal Notice publication in The Boston Globe
Thursday, March 16, 2023	Request for Proposal available online at - BPHC RFPs and Bids Boston.gov at 10AM EST . RFP will also be disseminated via email to relevant networks.
Tuesday, March 28, 2023	Questions are due via email by 5:00 PM EST to smuchohi@bphc.org Subject: Vendor Name – Questions for RFP Biosafety Level 4 Laboratory Consultant
Friday, March 31, 2023	Responses to questions will be available for viewing at BPHC RFPs and Bids Boston.gov by 5:00 PM EST
Wednesday, May 3, 2023	Proposal due by 5:00 PM EST via email to: biosafety@bphc.org and procurement@bphc.org Subject: Vendor Name - RFP Biosafety Level 4 Laboratory Consultant Proposal
Thursday, May 11, 2023	Notification of Decision: Desired date for notification of award to proposer, however, BPHC has the discretion to extend this date without notice. The contract(s) results from this RFP shall be in effect when all necessary contract documentation is fully executed by BPHC and awarded vendor(s).

Thursday, July 01, 2023	Contract Period Begins
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IV. Minimum Qualifications

Qualified respondents must have one or more staff members assigned to this contract who meet(s) the following requirements. The successful applicant may have the required skills and experience shared between two team members (please specify and provide supporting documents in the response to this RFP).

Education and Experience:

- Doctoral degree in biomedical sciences (e.g., Cell Biology, Microbiology, Molecular Biology, Genetics, Virology, etc.), public health, infectious diseases or any other relevant scientific field.
- Must have a minimum of 2 years of relevant experience working in a maximum-containment (BSL-4/ABSL-4) laboratory facilities or 5 years of relevant experience working in high-containment (BSL-3/ABSL-3) laboratory facilities. Relevant experience working in academic/research laboratory settings in the United States is preferred, but international experience will be considered.
- At least one team member who is trained and qualified to wear a BSL-4 suit, enter the BSL-4/ABSL-4 laboratory space, and spend at least 4 hours inside the lab.
- Experience conducting inspections or audits of maximum-containment facilities for regulatory compliance is desired. Hands-on practical training such as BSL-4 suit training, orientation to BSL-4 facility, and BSL-4/ABSL-4 work practices, policies and procedures are critical qualifying experience.
- Knowledge of the complex design features, operations and maintenance, and regulatory compliance requirements of the BSL-4/ABSL-4 Laboratories in the United States.
- Knowledge of the United States CDC/USDA Federal Select Agent Program regulatory requirements.
- Current knowledge of, and skill in applying and interpreting, applicable federal, state and local regulations, standards, and guidelines, and institutional policies and procedures such as Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC), Gain-of-Function (GOF) Research, and Research involving Enhanced Potential Pandemic Pathogens (ePPP).
- Must obtain and maintain annual medical clearance through the BU's Research Occupational Health Program (ROHP) to access the BSL-4/ABSL-4 laboratory facilities
- Must pass a background check to access BU NEIDL BSL-4/ABSL-4 Suit Labs.
- Ability to obtain and maintain Security Risk Assessment and a Suitability Assessment to access Biological Select Agents and Toxins (BSATs) required by the United States CDC/USDA Federal Select Agent Program.
- Strong written, verbal and interpersonal communication skills
- Ability to explain complex technical information effectively to diverse groups.
- Ability to wear a BSL-4 suit and walk around/stand for at least 4 hours inside the biocontainment during facility walkthrough and inventory verification.

Professional Certifications and Registrations:

- Registered Biological Safety Professional (RBP), ABSA International, is required.
- Certified Biological Safety Professional (CBSP), ABSA International, is preferred.

V. Proposal Requirements

Proposal must be submitted as a single PDF document not to exceed 10 pages (excluding the appendix) in single spaced 12-point font with 1-inch margins consisting of the following:

1. Description of the applicant (individual or organization) including relevant experience related to BSL-4/ABSL-4 or BSL-3/ABSL-3 research facilities such as inspecting or regulating such facilities, managing reviewing research projects/protocols. Please note the minimum qualifications above in preparing this document. Include any other relevant details in subject matter expertise, and experience facilitating professional working groups and preparing technical reports.
2. Names, contact information, and brief biographical sketches of personnel who will be involved in supporting the contract. This must include the name(s) and relevant qualifications of the person(s) who will conduct the on-site inspections of the BSL-4/ABSL-4 lab spaces, including entry into the maximum biocontainment facility.
3. Detailed 2-year project budget from July 1, 2023 through June 30, 2025, including costs for specific activities in the scope of service. Include the hourly rate or per-activity rate, travel, and all other related expenses. **The total budget must not exceed \$40,000 per fiscal year inclusive of all direct and indirect costs.**
4. Names and contact information of three relevant professional references. Include brief description of services provided to these professional references.
5. An appendix (not included in the page limit) containing curriculum vitae/resumes of key personnel on the contract.

VI. Period of Performance and Location

The Biosafety Consultant is expected to perform services between July 1, 2023 through June 30, 2025 under the terms and conditions of the contract. Locations of activities will include:

- On-site meetings at BPHC offices at 1010 Massachusetts Avenue, Boston, MA 02118.
- On-site inspections at the BSL-4/ABSL-4 facility at Boston University Medical Campus (BUMC), 620 Albany Street, Boston, MA 02118.
- Virtual or in-person committee meetings (Boston Biosafety Committee and Boston Biosafety Working Group)
- Email correspondence and submission of written reports and documents/records for review

Hours will normally be between 9am-5pm Monday to Friday. The Boston Biosafety Committee quarterly meetings are held from 5:30-7:00 pm on a weekday. The Boston Biosafety Working Group quarterly meetings are held from 1:00–2:30 pm on a weekday.

The Biosafety Consultant must be able to attend unscheduled meetings or respond to laboratory incidents or emergencies during the evenings or weekends/public holidays at the BPHC offices, the BU NEIDL, or virtually, as needed.

Qualified respondents must meet the following reporting requirements:

- Preparation and submission of written laboratory inspection reports
- Preparation and submission of written committee meeting notes and summaries
- Preparation and submission of written assessments of research protocols and document reviews
- Timely submission of invoices for services provided

VII. Submission Instructions

Please submit your Proposal by email to biosafety@bphc.org and procurement@bphc.org a single PDF file attachment on or before **Wednesday, May 3, 2023 at 5:00PM EST.**

Proposals must be received by Wednesday, May 3, 2023 at 5:00 PM EST.