Sources Sought (SS)

Title: NIAID Biocontainment Sterilizers (Autoclaves)
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Post Date: May 8, 2023
Response Date: May 18, 2023
Classification Code: 6640 – Laboratory Equipment and Supplies
NAICS: 339113 Autoclaves, Laboratory-type (Except Dental), Manufacturing

Introduction

This is a Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding the availability and capability of all qualified sources to perform a potential requirement.

Project Summary

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Intramural Research (DIR) is seeking to acquire eleven (11) biocontainment sterilizers (autoclaves) models that are compatible with existing building infrastructure for a three-year phased lifecycle replacement acquisition project in the Biosafety Level 3 (BSL-3) laboratories located in the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases at NIH. The sterilizers are a critical component and act as a secondary barrier between two classified zones of the BSL-3 laboratories, playing a vital role in the safe processing, decontamination, neutralization, and sterilization of bio-contaminated waste exiting the individual BSL-3 high containment laboratory suites.

Specifically, NIAID, DIR is seeking eleven (11) biocontainment sterilizer units with associated supplies and services that must meet all required minimum characteristics listed below:

1. Sterilizer net weight shall not exceed 2194 lbs (10 units) and 3549 lbs (1 extra capacity unit) by hydrostatic test.
2. Shall provide and install a chamber with a physical method to steam sterilize and disinfect and various biological wastes and other items by reaching and maintaining 121.0°C/ 249.8°F for at least 30 minutes with a pressure of at least 15.0 Pounds per square inch (PSI)/103.4 kilopascal (kPa).
3. Shall have password protected initiation of the following operational cycle settings from an electronic human-machine interface (HMI).
    a. Liquid Cycle – for liquid media, non-flammable liquids, aqueous solutions, and liquid biological wastes.
    b. Solids or Dry Cycle – for glassware, dry hard items, metal items with porous parts, and other porous materials.

    c. Wrapped Goods or Pre-vacuum Cycle – for glassware that must be sterilized upright or can trap air, pipette tip boxes, sharps decontamination, biohazard waste decontamination in autoclave bags (wet or dry).
4. Shall have double doors as to allow installation with one door on the BSL-2 "cold" side of the chamber and one in the BSL-3 "hot" high containment area.
5. Shall be designed for operation via HMI from either of the double doors and have engineering safeguards to ensure that both doors are never open at the same time (Pass-through autoclave).
6. A hard-wired interlock shall be provided to prevent both doors from opening simultaneously.
7. Shall have double doors that are fully automatic and electrically operated with safety features that prevent doors from closing if obstructed by an object.
8. Shall be floor mounted and able to be recessed and biologically sealed into the high containment wall space.
9. Shall provide custom engineered wall frames that meet the dimensional requirements needed to fit the existing high containment wall space to provide a true biological sealing.
10. Shall provide units that fit in existing spaces which are 22.6 sqft and 4' 4 ⅜" in depth.
11. Shall provide units that accommodate the following existing dimensions:
    a. A wall frame height of 78⅞"
    b. A wall frame width of 48"
    c. A wall frame depth of 3' 3'⅜"
    d. A chamber flange width of 40⅛"
12. Control Panels installed above the chamber to create more space for servicing.
13. Shall provide and install a biological sealing flange with lagged wall frame, stainless steel, and bolted to wall. The seal must be 6mm thick butadiene rubber gasket material using stainless steel clamping bars, nuts, and lock washers. Must provide an airtight seal capable of preventing passage of airborne microorganisms between classified zones of the facility. Any necessary penetrations shall be through potted conduit fittings. Must include HEPA filtration for pneumatic signals though the biological seal for decontamination of the door air system and piping to provide for safe filter replacement. Must be able to demonstrate no leakage through the sealing flange with a pressure differential of 0.22psig in Gas tightness tests.
14. Shall have a unit power requirement of 460-480V, 3Ph, 60Hz
15. Shall have a control system power requirement of 100-120V, 60Hz
16. Shall provide orientable unit side service access to include (9 of 11 including the 1 extra capacity) units with right side service and (2 of 11) units with left side service.
17. Shall have a B&R Industrial Automation Control System or equivalent for both BSL-3 "hot" high containment and BSL-2 "cold" sides of the unit including a 9-11" color touch screen HMI on both BSL-3 "hot" high containment side and BSL-2 "cold" side. The BSL-3 "hot" high containment side to shall show chamber pressure/vacuum and process steam supply pressure. The BSL-2 "cold" side shall show chamber pressure/vacuum.

18. Shall have a Multi-flow - Dual sterilizer control with possibility to start a cycle on any side and possibility to unload on any side upon a successful sterilization process.
19. Shall have a control system that fully controls the machine and is developed according to Good automated manufacturing practice (GAMP) guidelines.
20. Shall have control panels installed above the chamber to create more space for servicing units.
21. Shall provide and install Remote located control and electrical panels which will be 50+ feet away from the units.
22. Shall have a 4”-5” fascia printer to capture operational data
23. Shall provide a usable chamber dimension of 26” wide, 26½” high, and 39⅜” deep and equating to a chamber volume of 16.6 cubic feet for 10 units.
24. Shall provide usable chamber dimensions of 26” wide, 26½” high, and 51¼” deep and equating to a chamber volume of 21.5 cubic feet for 1 extra capacity unit.
25. Shall provide for a condensate return connection to capture non-product contact steam.
26. Shall provide for a chilled water recirculation connection to use chilled water to reduce potable water consumption up to 75%.
27. Shall provide for a compressed air connection for instrument air/pneumatics.
    a. Unit shall have one common compressed air connection for both process air and instrument air.
    b. Unit shall provide chamber pressure equalization after drying vacuums through an atmospheric air sterile grade air filter.
    c. Unit shall provide process air used for pressure equalization after drying vacuums as well as for support pressure during cooling.
28. Shall include incoming media pressure gauges.
29. Shall include a jacket pressure gauge.
30. Shall include a chamber pressure sensor.
31. Shall include a chamber temperature sensor.
32. Shall include a jacket temperature sensor.
33. Shall include a load temperature sensor for liquid load.
34. Shall include one 2” tri-clamp chamber port to accommodate temperature sensors for validation.
35. Shall include an emergency stop button in the front fascia that will stop the cycle and take the machine to a safe state.
36. Shall include a chamber and door plate made from solid high quality 316L stainless steel with internal surfaces highly polished to Ra<0.5µm (20µin).
37. Shall include internal surfaces highly polished to Ra< 0.5 µm (20 µin).
38. Shall include radiused internal corners of the chamber and a chamber floor that slopes to a central drain.
39. Shall have a supporting jacket for the unit made from 304 stainless steel.
40. Shall have door reinforcements made from corrosion protected carbon steel SA516 Gr60/EN10028-2 1.0425.

41. Shall include a stainless steel mesh strainer to protect the drain port from blockage by debris as well as protecting the components in the drain line from clogging
42. Shall have a sterilizer chamber insulated with chloride free mineral wool encased by rigid sheet aluminum cladding.
43. The front fascia of the sterilizer unit shall be constructed of 304 stainless steel and designed to support frequent cleaning of external surfaces.
44. The unit shall have instrumentation mounted in a stainless steel panel placed above the chamber door.
45. Doors shall be constructed for sealing by parylene coated silicone rubber gaskets with both air and steam capacity. The door gasket shall be pushed against the back of the door by compressed air and retracted by vacuum. Steam shall be utilized when pressurizing door gasket for redundancy in pressurization media. A backup tank shall be provided for door gasket pressure.
46. Shall provide a chamber leak rate test at manufacturing facility to meet regulatory standards.
47. Shall provide for effluent sterilization process to entrap potentially contaminated discharge until successful completion of the sterilization cycles.
48. Shall include automatic filter intrusion test (WIT) of effluent retention filter. This is used to automatically test and dry the chamber effluent retention filter in place.
49. Shall include standard process and non-process piping that consists of stainless steel piping and automatic valves. The piping and components shall be welded, connected threaded, or adjoined with flanged fittings.
50. Process valves shall be pneumatically operated piston globe valves for extended life and limited maintenance.
51. Shall have a highly efficient liquid ring vacuum pump protected by a upstream condenser provided to effectively remove air from within the chamber. The vacuum pump shall be mounted on vibration dampers and connected with flexible hoses in order to protect against vibration. Water to the vacuum pump shall be sealed, recirculated, and cooled.
52. The drain discharge for the unit shall be cooled to reduce the effluent temperature to an average of 60°C/140°F or less.
53. A 0.2 µm sterile grade filter shall be provided as vent filter for equalization of chamber pressure after post sterilization drying vacuum.
54. Shall be provided with stainless steel filter housing with 0.2 µm sterile filter to support air pressure.
55. For effluent cycles, an effluent retention filter system shall be provided to ensure that exhaust from the chamber is sterile before discharge to drain.
56. For effluent retention cycles the door gasket shall be sealed by steam instead of compressed air.
57. Shall have diaphragm pressure gauges & switches on the chamber.

58. Shall include isolation valves and ports for decontamination (fumigation) of effluent, a drain piping system, and air signals through the barrier to allow for safe maintenance or emergency service.
59. Shall include a vacuum decontamination support cycle.
60. Shall have a hard-wired interlock that will prevent the drain valve and BSL-2 “cold” side door from opening before a successful sterile phase.
61. Shall include a high pressure alarm that will prevent the safety valve from opening.
62. Shall provide a closed bonnet safety valve to including bursting disc.
63. Shall provide withdrawable shelves for the chamber specifically designed for easy loading and unloading of the sterilizers without using external trolleys.
64. Shall provide extra top shelf placed on top of provided withdrawable shelf in the chamber to give an extra level of product loading.
65. Shall provide service to disconnect plumbing, mechanical and electrical services on the existing machines.
66. Shall provide service to remove, haul away, and properly dispose of existing “old” units that are being replaced with “new” units.
67. Shall provide service to install and level new units.
68. Shall provide service to install biological seals that are industry tested.
69. Shall provide service to commission new units and provide necessary documentation including warranty information.
70. Shall provide onsite training for 120 staff. Shall provide details on how the training will be provided: mode and duration of training, learning objectives and outcomes, learning materials provided, and contributions to Standard Operating Procedure (SOP) modifications.
71. Shall provide service to program software – including the transfer user information such as names and passwords from old units to the new units. Shall provide service to customize software to require user password after selecting cycle and before starting the cycle.

Anticipated Period of Performance

It is anticipated that an award will be made on or about July 5, 2023. Delivery of the biocontainment sterilizers will be required in defined quantities per phase over the duration of the three-year project.

Capability Statement/Information Sought

If your organization has the potential capacity to provide eleven biocontainment sterilizers which meets the minimum requirements and performance capabilities listed above, please provide the following information:

1. Organization name, address, point of contact, email address, website address, telephone number, UEI number
2. Company location(s) and number of years company has been in business

3. Type of business (e.g., 8(a), HUBZone, Other than Small, etc.) pursuant to the applicable NAICS code
4. Type of ownership for the organization
5. Identification of any Best-In-Class contract vehicles including Government Wide Acquisition Contracts (GWAC) (e.g., GSA schedule) they may possess or are aware of that would support this possible requirement. If your organization does not provide the products/services under a GWAC, please identify availability as OPEN MARKET ONLY.
6. Tailored capability statement addressing the capability of the autoclaves to meet NIAID's minimum requirements. Capability document shall be no more than six pages.
7. Place of manufacture for the autoclaves and components
8. Evidence that the organization is an authorized reseller or manufacturer of the autoclaves. Authorized resellers shall identify the Original Equipment Manufacturer (OEM) of the equipment proposed in their capability statement. Only Original Equipment Manufacturer (OEM) products are acceptable.
9. A of history of the organization's installations in high containment facilities in the United States.
10. Please describe any customary commercial contract terms or conditions that you feel would make any resulting contract more effective if applicable.
11. Published price lists for your products. If commercially available list pricing is not available, provide a Rough Order of Magnitude.
12. What does the organization view as the top 3 risks to completing the resulting contract.

Submission Instructions

Interested businesses who consider themselves qualified to provide the above listed biocontainment sterilizers are invited to submit a response to this Sources Sought Notice by May 18, 2023, at 3:00 PM EST. All responses under this Sources Sought Notice shall be emailed to seth.schaffer@nih.gov.

Disclaimer and Important Notes

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and

solicitation may be published in SAM.gov. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).