CDC Requirments Document

**Liquid Nitrogen Freezers (LN2s) MVE 1426F with Magnetic Lock, TEC-3000 compatibility**

Procurement Requirements

**Purpose**

- Replacement of existing LN2s MVE 1426F-CDC with Magnetic Lock MVE 1400 system, TEC-3000 compatibility that are at end-of-life for use in the Viral Special Pathogens Select Agent Program (BSL-4 environment).
- Provide long-term, secure, monitored storage for Tier 1 Select Agents in compliance with CDC Select Agent Program and CDC high-containment laboratory requirements.

**Scope**

- This document covers functional, security, monitoring, installation, validation, service, documentation, and procurement evaluation criteria for the MVE 1426F-CDC LN2 vapor-phase freezer(s) to be purchased and installed in a BSL-4 laboratory.

1. **Functional Requirements**
    - Freezer Type: MVE 1426F-CDC Vapor-phase liquid nitrogen (LN2) freezer modifed with magnetic lid lock MVE 1400 system adapted for mounting on MVE 1426F to meet CDC requirements suitable for long-term storage of biological materials, explicitly rated for Tier 1 Select Agents, with mounted Magnetic lock lid system, .
    - Capacity: Vendor must specify model and make of the proposed freezer, gross and net sample capacity (number of racks/tubes/boxes) and rack configuration options. The Freezers must be compatible with existing systems and be a MVE 1426F-CDC with magnetic lock system, TEC-3000 monitor able to communicate with e-control system and .
    - Temperature Performance:
        - Nominal operating temperature range: vapor-phase LN2 storage temperatures typical for cryogenic storage.
        - Hold time: specify empty and loaded hold time at the stated LN2 fill schedule (vendor to provide data).

    - Uniformity: vendor to provide temperature uniformity and stability specifications and supporting test data.

- Lid/Access:
    - Locking lid must be mounted and magnetic
    - Lid design should minimize frost/ice and LN2 loss during normal use.

2. **Security and Physical Modifications**

- Mounted and compatible Magnetic Locking (Maglock) Lid System for use on :
    - MVE 1426F-CDC freezer must be modified with magnetic lid lock MVE 1400 system (factory or post-sale modification by qualified personnel) with a welded-on magnetic locking system that meets CDC Select Agent Program physical security requirements.

3. **Monitoring, Alarms, and Interfaces**

- Monitoring System:
    - MVE 1426F-CDC Freezer must include a monitoring system capable of communicating with CDC's in-house monitoring system. Vendor must document communication protocol, network interface (e.g., Ethernet, RS-232/485), data formats, and any middleware required.

- Temperature Probe and Valve Monitoring:
    - Temperature probe B shall be relocated into the fill valve and wired into the fill valve alarm software so that a stuck valve condition is detected and alarms are generated in a timely manner. Vendor must describe probe placement, wiring, and logic for the alarm.

- High-Containment Alarm Integration:
    - MVE 1426F-CDC Freezer must communicate with the laboratory's High Containment (BSL-4) alarm system using a TEC 3000 monitor.

4. **Service, Installation, and Personnel Requirements**

- Service Personnel:
    - Vendor must provide trained service representatives who are authorized and capable of installing and servicing these modified LN2 freezers.

- On-Site Installation:

    - Vendor to provide documentation of successful IQOQPQ following installation.

- Warranty:
    - State warranty coverage period for equipment and modifications, including labor and parts. Specify remedies for defects discovered during warranty period.

5. **Compliance and Documentation**

- Regulatory Compliance:
    - Equipment must be commercial off-the-shelf (COTS) modified as necessary to meet CDC specialized high-containment laboratory requirements and Select Agent Program standards.
    - Vendor must declare conformity with applicable safety standards and provide supporting documentation (e.g., materials, pressure/vacuum ratings, CE/UL listings if applicable).

6. **Acceptance Criteria and Testing Protocol**

- Acceptance tests to be completed before final acceptance and payment:
    - Visual inspection and verification of physical modifications (welded magnetic lock).
    - Temperature uniformity and stability tests with instrumentation traceable to NIST (or equivalent); vendor to supply calibration certificates.
    - Alarm integration verification: exercise alarms and demonstrate notification to CDC'S in-house monitoring system and BSL-4 alarm system; demonstrate probe B functionality (simulate stuck valve).
    - Security test: lock operation, and access control behavior.
    - Documentation review: all manuals, schematics, and IQOQPQ reports delivered and approved.

7. **Procurement Evaluation Criteria**

- Technical compliance: ability to meet functional, security, and monitoring requirements.

- Proven experience: vendor track record of supplying and servicing LN2 freezers in high-containment environments; references required.
- Integration readiness: demonstrated capability to integrate with CDC'S in-house monitoring system and BSL-4 alarm systems, including sample interface documentation.
- Total cost of ownership: equipment cost, modification costs, spare parts
- Delivery and lead time: within 3 months of the contract signature.