



June 4, 2012

[REDACTED] Responsible Official  
[REDACTED]

Bethesda, MD 20892  
Fax: (301) 480-0701

**Subject: Opportunity to Show Cause why the Select Agent Registration of the National Institutes of Health (Registration #C20110919-1265) should not be suspended or revoked**

Dear [REDACTED]

The National Institutes of Health (NIH) is being provided the opportunity to show cause why the registration of the NIH (Registration #C20110919-1265) should not be suspended or revoked. Based on observations noted during the May 1-4, 2012 inspection of the NIH, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has significant concerns regarding the compliance of the NIH with the requirements of 42 CFR Part 73. Section 73.8 of the select agent regulations provides that an entity's registration may be suspended or revoked for failure to meet the requirements of the select agent regulations.

Specifically, DSAT has significant concerns regarding the biosafety, security, administrative oversight, and record keeping practices observed during recent inspections of the NIH Select Agent Laboratories and Program. These concerns are detailed below (cited Observations can be found in the Site Visit Inspection Report submitted under separate cover):

**(1) Biosafety {42 CFR 73.12}**

NIH is not currently working with or storing select agents safely. In developing and implementing its written biosafety plan, NIH has not appropriately incorporated the biosafety standards, procedures, and practices found in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition. Specifically:

- o NIH failed to ensure that the biosafety and containment procedures were sufficient to contain the select agents, as required under section 73.12 (b) of the select agent regulations (Observation #6).
  - i. The biosafety and containment procedures used for the propagation of *Bacillus anthracis* pX01- pX02+ vegetative cells and spore preparations were insufficient to contain the select agent. Based on the observations of DSAT inspectors of the equipment and facility features of rooms 1A09 and 2A08 in Building 6A, NIH allowed propagation of *Bacillus anthracis* in rooms with insufficient containment practices to contain the agent, a departure from recommended biosafety standards in the BMBL 5<sup>th</sup> edition [BMBL: (BSL-2), (BSL-3), Section VIII-A *Bacillus anthracis*].
  - ii. NIH failed to implement procedural safeguards sufficient to ensure secondary containment of the Risk Group 4 (RG4) viruses stored in a BSL2 laboratory, a departure from recommended biosafety standards in the BMBL 5<sup>th</sup> edition [BMBL: (BSL-4) B6].
  - iii. NIH failed to implement a Virulent Newcastle disease virus (vNDV) quarantine policy for individuals accessing vNDV for inventory purposes during the May 2012 site visit. This

policy is a USDA enhancement for laboratories manipulating or storing vNDV to ensure that individuals do not come into contact with susceptible avian species following access to vNDV [APHIS/VS Standard Section A(2) adopted from BMBL: Appendix D: Agriculture Pathogen Biosafety: Virulent Newcastle Disease Virus].

**(2) Security {42 CFR 73.11}**

NIH failed to implement provisions of the NIH security plan to safeguard select agents against unauthorized access, theft, loss or release in violation of section 11 of the select agent regulations. Specifically:

- During the May 2012 CDC site visit, DSAT inspectors discovered that [REDACTED] possesses vials of regulated *Bacillus anthracis* vials mislabeled as "Ames 35" stored in non-registered locations in an unsecured manner (Observation #1).
- NIH failed to limit access to select agents to individuals with access approval from the HHS Secretary or the Administrator as required under section 73.11 (d)(1) of the select agent regulations. A review of electronic access records and interviews of NIH personnel conducted by DSAT inspectors revealed NIH lacks an effective security access control system resulting in unauthorized access to select agents. As a result, non-SRA cleared individuals had access to *Bacillus anthracis*. This failure, (Observation #5), highlights the lack of procedures in place, or in practice, for the control of access to select agents as required under 73.11 (c)(2) and 73.11(c)(7) .

**(3) Registration {42 CFR 73.7} and Restricting Access to Select Agents {42 CFR 73.10}**

NIH conducted work with select agents that had not been approved by DSAT and failed to restrict access to select agents to personnel approved by the HHS Secretary or the Administrator. Specifically:

- NIH discovered unauthorized work and storage of *Bacillus anthracis* Ames 34 in nonregistered laboratory and equipment areas for 4 principal investigators ([REDACTED] and [REDACTED] not listed on the entity's certificate of registration at the time the work was conducted (Observation #1).
- [REDACTED] and laboratory personnel conducted work with *Bacillus anthracis* without the knowledge of the NIH Responsible Official and DSAT access approval following their July 2009 removal from the NIH certificate of registration (Observation #1).
- NIH failed to request approval by DSAT for the *Bacillus anthracis* spore preparations directed by [REDACTED] (Observation #6).
- NIH failed to provide control of *Bacillus anthracis* to prevent unauthorized access as required by section 73.10 of the select agent regulations. During the May 2012 CDC site visit, it was determined that NIH failed to prevent approximately 15-20 individuals from gaining access to *Bacillus anthracis*. None of these individuals had a security risk assessment conducted by the Attorney General, nor approval from the HHS Secretary or the Administrator (Observation #4).

**(4) Responsible Official (RO) {42 CFR 73.9}**

The NIH RO has not ensured compliance with the requirements of the select agent regulations (Observations #2 and #3). Specifically:

- The RO failed to limit the use and storage of select agents to registered rooms per section 73.7,
- The RO failed to request (and/or receive approval for) modified select agent activities and personnel changes prior to allowing related activities to be conducted with select agents in accordance with section 73.7,

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- The RO failed to ensure compliance with the select agent regulations during annual inspections of select agent registered laboratories based on documentation provided in April 2012 per section 73.9(a)(5),
- The RO failed to restrict access to select agents per section 73.10,
- The RO failed to implement security access control provisions per sections 73.11(c)(2), 73.11(c)(7), 73.11(d)(1), and 73.11(d)(3),
- The RO failed to ensure sufficient biosafety and containment procedures to contain the select agent(s) per section 73.12(b), and
- The RO failed to ensure an accurate, current inventory for each select agent held in long-term storage as required under section 73.17 (a)(1).

(5) Record-keeping {42 CFR 73.17}

- NIH failed to ensure an accurate current inventory for select agents held in long-term storage as required under section 73.17 (a)(1) of the select agent regulations (Observation #7).
- NIH has not implemented procedures to ensure that records and databases created pursuant to the select agent regulations were accurate, had controlled access, and their authenticity verified, as required under section 73.17 (b) of the select agent regulations. Specifically:
  - i. The failure of NIH to maintain current and accurate select agent inventory records went undetected, because NIH had not implemented robust procedures to verify the accuracy of inventory held in long-term storage for [REDACTED] (Observations #7, 8).
  - ii. NIH failed to maintain accurate security access control databases, used for granting personnel access to registered laboratory space (Observations #4, 5).

In lieu of taking steps to immediately suspend or revoke the certificate of registration, DSAT is willing to allow the NIH to participate in a Performance Improvement Plan Program (PIPP) under the conditions enumerated below. If the NIH desires to participate in the PIPP, within fourteen (14) days of the date of this letter, the NIH must:

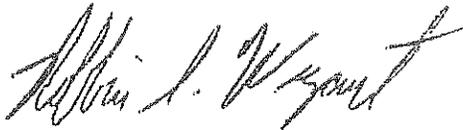
1. Provide to DSAT a written performance improvement plan describing how the NIH will resolve the discrepancies identified and specified in the site visit inspection report, including milestones for resolution of these discrepancies;
2. Implement the plan immediately upon approval by DSAT;
3. Provide to DSAT bi-weekly progress reports detailing milestones completed;
4. Agree to notify DSAT immediately of any situation that impacts the plan;
5. Agree to resolve all discrepancies identified in the site visit inspection report in accordance with the approved plan; and
6. Provide to DSAT written confirmations as discrepancies are corrected.

Should the NIH decline to participate in the PIPP, all discrepancies noted in the Site Visit Inspection report must be resolved, and a letter documenting the resolution thereof, must be submitted to DSAT no later than thirty (30) calendar days of the receipt of this letter.

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Please be reminded that DSAT retains the authority to conduct announced or unannounced inspections at any time to ensure compliance with the select agent regulations (See section 73.18). Resolution of all discrepancies will be confirmed by an onsite verification inspection by DSAT.

If you have any questions concerning this correspondence, please contact [REDACTED] at [REDACTED]



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