

Approved: 11-25-2016

**SUBJECT: CONDUCT AND APPROVAL OF SELECT AGENT AND TOXIN WORK AT
DEPARTMENT OF ENERGY SITES**

PURPOSE AND SCOPE

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) directs the Secretary of Energy and the Administrator of the National Nuclear Security Administration to expand, enhance, and intensify research relevant to the rapid detection and identification of select agents and toxins likely to be used in a bioterrorism attack or other select agents and toxins that may cause a public health emergency.

In meeting its obligations under the Public Health Security and Bioterrorism Preparedness and Response Act, the Department of Energy (DOE) places a high priority on occupational health, safety and security and emergency management, as well as its responsibility for protecting the public and environment from any hazards resulting from these activities.

The purpose of this policy is to establish the Department's expectations for the establishment and operation of DOE research laboratories that utilize select agents and toxins (as regulated by the United States Department of Health and Human Services and the United States Department of Agriculture), hereinafter called LABS; and to assess future policy needs through the DOE Biosurety Executive Working Group for the operation, coordination, and oversight of these LABS.

This policy cancels DOE P 434.1A, *Conduct and Approval of Select Agent and Toxin Work at Department of Energy Sites*, dated 11-7-13.

POLICY

The Department will not authorize any biosafety level (BSL)-4 activities at LABS or allow BSL-4 operations to be conducted at DOE facilities or on DOE sites.

BSL-3 labs will follow current DOE procedures and policy. If necessary, DOE will establish additional specific guidance to ensure safe construction and operation of BSL-3 LABS. Any new line item construction of BSL-3 LABS must be conducted in accordance with DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, Chg 2, dated 5-12-16. The heads of the Program Secretarial Office (PSO) are expected to formally approve the construction of any new BSL-3 research laboratory intended for conducting research on or otherwise utilizing select agents and toxins.

The Department will not authorize any laboratory operations with select agents and toxins, including those which may be part of classified Strategic Partnership Projects (formally known as Work for Others) or similar projects, without the head of the DOE field element being fully informed of the details of the operations.

All research activities performed by DOE or DOE contractors in LABS will comply with all applicable DOE regulations and directives as well as other applicable federal, state, and local regulations. Appropriate oversight of biological facilities should be conducted within the framework of existing DOE regulations and directives, including 10 CFR Part 851, DOE Policy 450.4A, DOE Order 226.1B, and DOE Order 450.2 (see References).

All research activities involving Dual Use Research of Concern (DURC) should be reviewed with consideration of the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, as well as the complementary United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, which addresses institutional oversight to ensure DURC is identified and risk mitigation measures are implemented, where applicable. DURC includes important research vital to improving public health, agriculture, and the environment, and to strengthening our national security and economy; however, it may be directly misapplied to create dangerous pathogens for employment as weapons, bypass or diminish the effectiveness of medical countermeasures, or threaten in other ways the health and safety of humans, animals, plants, and the environment.

The DOE Biosurety Executive Working Group will be expected to ensure that a cooperative relationship is developed with the United States Department of Health and Human Services and the United States Department of Agriculture (USDA) in their regulatory oversight of DOE select agent and toxin activities. The DOE Biosurety Executive Working Group, in concert with the Department of Homeland Security and other federal agencies utilizing DOE laboratories, should develop a long-term strategy for research activities involving select agents and toxins.

DOE will ensure that any agency requesting work be responsible for all costs incurred by DOE contractor(s) performing work for that agency for which DOE is required to reimburse the contractor(s). Such costs include any and all third party liability costs incurred by the contractor and reimbursed by DOE in accordance with the "Insurance-litigation and claims" clause (DEAR 970.5228-1) contained in DOE's contract with the contractor. To the extent that DOE may incur any liabilities in regard to the performance of the work directly, DOE will ensure that the agency requesting the work will reimburse DOE for such liabilities.

The heads of DOE field elements are expected to ensure full implementation of this policy at the respective field facility.

APPLICABILITY

This Policy applies to the development, construction, and operation of DOE research laboratories utilizing select agents and toxins.

REFERENCES

- Public Law 91-190, *National Environmental Policy Act (NEPA) of 1969*, as amended, codified at 42 U.S.C. Sections 4321-4347.
- 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins.
- 9 CFR Part 121, *Possession, Use, and Transfer of Select Agents and Toxins*.

- 42 CFR Part 73, *Select Agents and Toxins*.
- 42 CFR Part 1003, *Civil Money Penalties, Assessments and Exclusions*.
- 48 CFR 970.5228-1, *Insurance - Litigation and Claims*.
- 10 CFR Part 851, *Worker Safety and Health Program*.
- *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. 5th Edition. Centers for Disease Control and Prevention.
- United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>.
- DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy*, dated 4-25-11.
- DOE Policy 450.4A, *Integrated Safety Management Policy*, dated 4-25-11.
- DOE Order 450.2, *Integrated Safety Management*, dated 4-25-11.
- DOE Order 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, Chg 2, dated 5-12-16.

BY ORDER OF THE SECRETARY OF ENERGY:



ELIZABETH SHERWOOD-RANDALL
Deputy Secretary