BIOSAFETY

I. Purpose

This Directive and the accompanying Instruction establish the authorities, responsibilities, requirements, and procedures for Biosafety in all activities conducted or sponsored by the Department of Homeland Security (DHS). This Directive adopts the principles of the current edition of the U.S. Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health *Biosafety in Microbiological and Biomedical Laboratories* and its recommendations for standards, practices, equipment, and facilities for biological laboratory activities, as well as the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) and other related guidance listed in Part III.

II. Scope

This Directive applies to all activities conducted, sponsored, or funded by DHS through a contract, grant, cooperative agreement, other transaction, or other arrangement. Its scope includes all activities involving bacteria, viruses, toxins, nucleic acids, tissue/sera samples, and other biologically derived materials (collectively, "Biological Materials"). This includes all activities conducted at DHS-owned laboratories and at non-DHS Research Institutions, including subcontractors and sub-awardees.

III. Authorities

A. Title 6, United States Code (U.S.C.), Section 182, Responsibilities and Authorities of the Under Secretary for Science and Technology

B. Title 7, Code of Federal Regulations (CFR), Part 331, Possession, Use, and Transfer of Select Agents and Toxins

C. Title 9, CFR, Part 121, Possession, Use, and Transfer of Select Agents and Toxins

D. Title 9, CFR, Part 122, Organisms and Vectors

E. Title 29, CFR, Part 1910, Bloodborne Pathogens

F. Title 29, CFR, Part 1910, Hazard Communication

G. Title 29, CFR, Part 1910, Occupational Exposure to Hazardous Chemicals in Laboratories

H. Title 42, CFR, Part 72, Interstate Shipment of Etiologic Agents

I. Title 42, CFR, Part 73, Select Agents and Toxins

J. Title 49, CFR, Part 172, Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans

K. Title 49, CFR, Part 173, Shippers-General Requirements for Shipments and Packaging

L. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

IV. Responsibilities

A. The ***Under Secretary for Science and Technology*** is the DHS Biosafety Coordinating Official and is responsible for directing, ensuring, and supporting Department-wide implementation of and compliance with this Directive and the accompanying Instruction.

B. The ***Compliance Assurance Program Manager (CAPM)*** serves as the head of the Compliance Assurance Program Office, which is responsible for developing and implementing the Department's Biosafety compliance program.

C. The ***Director of the Office of National Laboratories*** has oversight and management of DHS-owned laboratory operations and coordinates with the Laboratory Directors to ensure compliance with this Directive, the accompanying Instruction, and all Authorities in Part III.

D. ***Laboratory Directors*** manage the daily operation of DHS-owned and/or operated biological laboratories, including serving as or designating an institutional official who is responsible for ensuring compliance with this Directive, the accompanying Instruction, and all Authorities in Part III.

E. ***DHS Component Heads*** are responsible for supporting Department-wide implementation of and compliance with this Directive and the accompanying Instruction.

V. Policy and Requirements

All DHS personnel conduct themselves in accordance with the responsibilities set forth in this Directive and the accompanying Instruction, as well as with any subsequently developed and approved policy, procedure, or guidance to ensure Biosafety compliance in all DHS activities.

A. ***Policy***:

1. DHS is committed to ensuring that DHS laboratories and Research Institutions conducting DHS-sponsored activities meet the highest ethical and regulatory standards for Biosafety compliance.

2. The cardinal principle for safety in DHS-sponsored activities involving Biological Materials is to minimize the potential for exposure of workers, the environment, and the community to these materials.

3. DHS has an ethical and moral obligation to rigorously adhere to established regulations and practices for storing, handling, and working with potentially hazardous Biological Materials, and is responsible for ensuring that all infectious disease Research sponsored by the Department is conducted safely and securely.

B. ***Requirements:***

1. Each facility conducting DHS-sponsored activities involving Biological Materials designates an institutional official who is responsible for ensuring compliance with this Directive, the accompanying Instruction, and all Authorities in Part III.

2. All activities conducted or sponsored by DHS involving Biological Materials are carried out in accordance with this Directive, the accompanying Instruction, and all Authorities in Part III.

3. All personnel who work directly with, or may have potential exposure to, Biological Materials in connection with activities conducted or sponsored by DHS are provided initial and annual Biosafety training commensurate with their duties, and are subject to oversight by the entity's Biosafety Officer and other relevant institutional and/or DHS officials, as applicable.

4. All DHS personnel who work directly with infectious Biological Materials or animals possibly infected with diseases transmissible to humans (i.e. zoonotic diseases) are offered immunization if a Food and Drug Administration-licensed vaccine is available.

5. All high-containment laboratories, regardless of select agent registration status, have policies and procedures in place to actively monitor and account for all hazardous Biological Materials, from receipt or identification through transfer or final disposition.

6. All Biological Mishaps and incidents of serious or continuing noncompliance with this Directive, the accompanying Instruction, and/or the requirements established by the Authorities in Part III, involving any DHS Component, facility, or sponsored Research Institution, are reported within 72 hours both to the CAPM and to the Research Institution's Biosafety Officer. No action, administrative or disciplinary, may be taken against a person for the act of reporting such mishaps or incidents of serious or continuing noncompliance.

7. All Biological Materials utilized in activities conducted or sponsored by DHS are prepared for shipment, labeled, and shipped in accordance with applicable federal, state, and local laws and regulations including 42 CFR 72, 49 CFR 172 and 173, and 9 CFR 122.

VI. Questions

Any questions or concerns regarding this Directive should be addressed to the Compliance Assurance Program Manager in the Science and Technology Directorate.

R C Deyo

Russell C. Deyo
Under Secretary for Management

6/22/16

Date