Potentially Hazardous Biological Materials Management Plan - Phase I

Clean sweep of all NIH laboratories, clinical spaces, offices associated with laboratories – To Be Completed by September 30, 2014.

This clean sweep applies to all NIH owned or leased or contractor-operated laboratory spaces or facilities (e.g. off-site "freezer farms" and animal facilities) including RML, NIEHS, Frederick, Poolesville, etc.

Phase I. Workplan

Step 1. No later than July 11, the DDIR will inform the SDs of the need to execute a comprehensive search of all NIH laboratory spaces including all refrigerators, freezers (all types), cold rooms, cabinets, shelves, drawers, and storage rooms for potentially hazardous biological materials. There should be special emphasis on regulated materials such as Select Agents and Toxins, but other potentially hazardous biological materials such as infectious agents, non-regulated toxins, poisons, venoms, explosive materials, etc. should also be included.

Step 2. SDs will inform all PIs and other personnel in their ICs of the need to immediately commence a comprehensive search of laboratory and associated spaces including cabinets, drawers, shelves and all refrigerators, freezers (all types), cold rooms and storage rooms. SDs will instruct personnel to label materials properly that are maintained and appropriately discard all materials that are no longer needed, including unneeded materials left by former trainees and investigators. For identifiable clinical samples collected under IRB-approved protocols, special rules apply. Unidentified materials (unlabeled with uncertain contents) should be autoclaved twice. After double autoclaving, Medical Pathological Waste should be placed in a Medical Waste (MWP) ("Burn Box") and dropped off at designated pickup locations. Any materials discharged to the drain must comply with NIH environmental standards for waste water discharge (see attached Waste Disposal Guide). No materials that are the subject of ongoing investigations or concerns should be destroyed. For materials thought possibly to include select agents, please contact the Division of Occupational Health and Safety (DOHS) in the Office of Research Services (ORS).

Step 3. SDs will assign responsible individual(s) to search common areas (such as cold rooms, instrument rooms, and freezers) and ensure that these areas are surveyed completely.

Step 4. Good laboratory practice indicates that a central list should be maintained by each PI of the nature of materials in each box, rack, or similar container in all storage areas in or around the laboratory or laboratory offices. This will require that the entire contents of each storage container be visually surveyed. All human pathogenic organisms that require BL2 level

containment and above, and biological toxins, venoms, or poisons (please see attached list of such compounds) must be recorded and inventoried as to location and reported to DOHS via an electronic registration system.

Step 5. PIs will be responsible for all spaces assigned to them and must survey all material and discard materials no longer needed.. Regulated but unregistered materials that may be found, such as Select Agents, must be turned over to Division of Occupational Health and Safety (DOHS) and All human pathogenic organisms that require BL2 level containment and above, and biological toxins, venoms, and poisons (please see attachment) must be recorded and inventoried as to location and reported to DOHS via an electronic registration system.

Step 6. PIs will sign an attestation that all potentially hazardous biological materials are properly labeled, stored, inventoried and any unlabeled materials were destroyed or turned over to DOHS. The attestations shall be collected and verified by the Scientific Director to make sure no areas were missed. (Attestation form is attached)

At this time, PIs should also ensure that all hazardous chemicals are properly labeled and stored or use this opportunity to contact the ORF Division of Environmental Protection for the proper disposal of unneeded or expired chemicals and chemical waste. This Division has been alerted to the need for possible expansion of service during this period and will assist promptly.

Step 7. PIs will sign, date and affix stickers to rooms and equipment indicating that under counter and upright freezers and refrigerators, cold rooms, laboratory doors and other closed spaces have been surveyed. **This includes freezers located in freezer farms (including those containing historical collections) or other leased or contracted space on and off campus.** (Stickers will be provided by DOHS)

Step 8. SDs will ensure and attest to OIR that all PIs in their IC have completed this clean sweep by **September 30, 2014.** (Attestation forms are attached).

Step 9. DOHS will perform systematic compliance checks of all the laboratory spaces, all freezers and refrigerators, cold rooms, dry storage areas, etc. including review of the inventories for potentially hazardous biological materials.

Step 10. For registered areas**,** DOHS will provide follow-up compliance checks of storage areas during annual surveys of registered laboratories (those conducting infectious disease and recombinant nucleic acid research). Safety specialists will document compliance checks in PI Dashboard.

Reminder

As a reminder, failure to comply with the requirements for select agents and toxins can lead to disciplinary actions including removal for an initial offense.

Select Agents and Toxins[1]: biological agents and toxins that could pose a severe threat to public health and safety, to animal health, or to animal products. See list attached. This plan is not limited to these Select Agents, but also includes all hazardous biological materials as defined above.

Select Agents and Toxins List

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at: http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html.

HHS AND USDA SELECT AGENTS AND TOXINS
7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	**OVERLAP SELECT AGENTS AND TOXINS**
Abrin	*Bacillus anthracis* *
Botulinum neurotoxins*	*Bacillus anthracis* Pasteur strain
Botulinum neurotoxin producing species of *Clostridium**	*Brucella abortus*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]	*Brucella melitensis*
	Brucella suis
	*Burkholderia mallei**
Coxiella burnetii	*Burkholderia pseudomallei**
Crimean-Congo haemorrhagic fever virus	Hendra virus
Diacetoxyscirpenol	Nipah virus
Eastern Equine Encephalitis virus[3]	Rift Valley fever virus

Ebola virus*
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus[3]
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
- Far Eastern subtype
- Siberian subtype

Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**
Venezuelan equine encephalitis virus[3]
*Francisella tularensis**

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus[3]
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum[3]
Mycoplasma mycoides[3]
Newcastle disease virus[2,3]
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

1 C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.
2 A virulent Newcastle disease virus (avian paramyxovirus serotype 2) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.
3 Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus , west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13

Potentially Hazardous Biological Materials Management Plan – Phase 2

(retyped from the original)

Introduction

The NIH has embarked upon a comprehensive search of all research facilities to ensure that there are no select agents, toxins or hazardous biological materials improperly stored on our campuses. This effort is being referred to as "Clean Sweep" and is part of Phase 1 of the NIH Potentially Hazardous Biological Materials Management Plan. Phase 2 of this Plan addresses policy review and revision, potential changes to the NIH Table of Penalties and establishment of management responsibilities at all levels. Scientists often maintain materials for many years; sometimes for historical purposes but in many cases materials are abandoned or no longer needed or even useful. Phase 2 of the Work Plan is aimed at changing the research culture to one of accountability and responsibility in dealing with biological materials. The phase 2 Work Plan outlines the steps to be taken to ensure that responsibility and accountability for potentially hazardous biological materials becomes fully established as an expectation for NIH scientists and for the conduct of research at NIH. The Phase 2 Work Plan products and policies will apply to all NIH owned or leased or contractor-operated laboratory spaces or facilities (e.g. off-site "freezer farms" and animal facilities) including RML, NIEHS, Frederick, Poolesville, etc.)

Phase 2. Work Plan

Step 1. Review and draft revisions for NIH Policy Manual Chapter 3035 – Working Safely with Hazardous Biological Materials will be completed. The revision will:

- expand responsibilities, at all levels, with regard to work with and management and storage of potentially hazardous biological materials at the NIH;
- institute and require upkeep of a central NIH inventory of potentially hazardous biological materials including Select Agents and Toxins, other potentially hazardous biological materials such as infectious agents handled at Biosafety Level 2 and above, non-regulated toxins, including poisons and venoms, and human blood, body fluids and tissues;
- require registration of potentially hazardous biological materials in storage (currently registration is only required when active work is being performed); and
- establish a requirement for disposition of materials when a scientist, post-doctoral fellow, student, etc. leave the NIH.

Step 2. NIH will review the NIH Table of Penalties to determine if failure to fully implement provisions of revised MC 3035 or failure to maintain adequate control of potentially hazardous biological materials warrants disciplinary action(s). Should it be determined that disciplinary actions are warranted, the Table of Penalties will be modified by the NIH Office of Human Resources.

Step 3. The Director, Division of Occupational Health and Safety, will work with the Deputy Director of Intramural Research to develop and implement, in all institutes performing biological research, a "check out" procedure for departing scientists that ensures all biological materials are transferredto another responsible party or destroyed prior to leaving NIH. Procedure will ensure that the NIH central database has been adequately updtate to reflect he transfer of responsibility, destruction, or other disposition of the materials.

Step 4. In order to ensure that controls remain in place and are adequate:

- The NIH Division of Occupational Health and Safety will perform and document assurance checks of inventories maintained by registered laboratories (laboratories performing infectious disease and recombinant nucleic acid research, research using human or nonhuman blood and body fluids, or select agent laboratories) annually.
- Institute Health and Safety Committees will perform and document assurance checks of inventories maintained by non-registered laboratories annually.