

	REQUEST	NIH RESPONSE
1	An updated security and incident response plan to address appropriate security and safety of select agents, or potential select agents, after identification in unregistered areas and during transfer between unregistered space and registered space.	Please see Attachment 1 for the revisions to the NIH security and incident response plans.
2	A copy of the completed "Phase 2" of NIH's plan, currently in development, aimed to address review and revision to NIH policies, potential changes to the NIH Table of Penalties, and establishment of enhanced management responsibilities at all levels of NIH. If the plan is not completed by August 22, 2014 please indicate when it will be completed and provide the completed plan by that date.	Please see the DRAFT Phase 2 Plan, Attachment 2 . The Plan is currently under review by NIH Management, Human Resources and Office of Acquisition and Logistics Management. There are proposed dates for completion of the items on the draft work plan. The draft work plan was submitted to NIH Management on August 13 th for review. Until NIH Management has reviewed and approved the work plan, we cannot provide a completion date. NIH will keep the CDC/DSAT advised and provide a copy of the approved work plan.
3	Please clarify how the Biological Material Survey Attestation and the Phase I of the NIH Potential Hazardous Biological Materials Management Plan will address identification and the accountability for biological materials where ownership is not clear or unknown (e.g. the current incident where there was no Principal Investigator or other personnel specifically assigned to account for the collection containing Variola virus).	As it states in the Phase 1 work plan "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." Inventories will be uploaded into the centralized NIH database. In addition, NIH Policy Manual Chapter - 3035 Working with Hazardous Biological Materials is being revised to insure all inventories have a responsible party and that materials are transferred to another responsible party when an investigator leaves the NIH.
4	In addition, please provide the date by which NIH/DOHS will provide documentation that it has completed under Phase I of the NIH Potential Hazardous Biological Materials Management Plan the systematic compliance checks of all the laboratory spaces, all freezers and refrigerators, cold rooms, dry storage areas, etc. and has reviewed all	Our working estimate of storage units that require quality assurance checks exceeds 100,000. These checks will begin on October 1, 2015. Our working goal to complete the checks within 6 months but NIH must take as long as necessary to thoroughly complete the task. At this time the actual size of the effort is unknown.

August 22, 2014

NIH Response to CDC Entity Request for Information dated August 8, 2014
(Subject Inspection Dates: July 7-9, 2014)

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	inventories for potentially hazardous biological materials and the results of these checks with respect to select agents and toxins.	

Annual Review

The Incident Response Plan has been prepared in compliance with the *Possession, Use, and Transfer of Select Agents and Toxins, Final Rule*. The RO must review the plan on an annual basis, after any drill or exercise is conducted, and after any incident.

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Potentially Hazardous Biological Materials Management Plan - Phase 2

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. No later than **October 31, 2014**, review and draft revision of 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 such as 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. leaves the NIH.

Step 2. No later than **October 15, 2014**, 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. No later than **November 1, 2014**, Office of Management will engage NIH Office of Acquisition Management and Policy to ensure that:

- contract language is developed to ensure that biological materials are stored and tracked meeting the intent of NIH policies described in the revised manual chapter;
- contracts are appropriately modified to require appropriate management, storage and tracking of biological materials by contractors and sub-contractors; and
- contractors will enter storage holdings of biological materials into the NIH central database using the NIH Inventory spreadsheet.

Step 4. No later than **December 1, 2014**, develop and implement, in all Institutes performing biological research, a “check out” procedure for departing scientists, post-doctoral fellows, visiting scientists, students, etc., that ensures that all biological materials are transferred to another responsible party or destroyed prior to leaving NIH. Procedure will ensure that the NIH central database has been adequately updated to reflect the transfer of responsibility, destruction, or other disposition of the materials.

Step 5. 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.

T. Notification of Select Agent Discovery (Non-Diagnostic / Non-Clinical)

The discovery of a potential select agent(s) or toxin(s) in an unregistered space on the NIH Bethesda campus is a serious matter and must be immediately reported to the NIH Select Agent Responsible Official (RO) or an Alternate Responsible Official (ARO). If an ARO receives the information, (s)he must report the information to the RO as soon as he or she is available. The RO will investigate the situation and determine if the material meets the definition of a select agent or toxin or if the material is suspect and requires transfer to another facility (e.g., CDC, Atlanta) for testing. Based on the RO's findings, the material may be transferred and secured in the registered SAP laboratory in Building [REDACTED]. Alternately, depending on the quantity, volume, storage particulars, material state, etc., the material may be secured in place until transfer arrangements can be made (e.g., locked freezer, locked room, guard/sentry, etc.). If the RO decides that the material should be secured in Building [REDACTED] the RO or an ARO will complete a chain-of-custody form between the SAP and the IC finding the material. If the decision is made to transport the material to Building [REDACTED] triple-packaging will be used and the material will be transported directly to Building [REDACTED] Room [REDACTED]. The RO will notify the CDC of select agent discovery according to 42 CFR 73.

U. Notification of Theft or Loss of Select Agent or Toxins

Upon the discovery of a *theft or loss* of a select agent or toxin, laboratory personnel must immediately notify the NIH RO. NIH SAP will immediately notify CDC DSAT and appropriate law enforcement agencies of such an incident, as stipulated in 42 CFR §73.19.

1) The *theft or loss* of a select agent or toxin must be reported immediately by telephone, fax, or email. The following information must be provided:

- i) Name of select agent or toxin and identifying information (e.g. strain)
- ii) An estimate of the quantity lost or stolen
- iii) An estimate of the time during which the theft or loss occurred
- iv) The location (building, room) from which the theft or loss occurred, and
- v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss, as follows:

1.

[REDACTED]

[REDACTED] cell

2.

[REDACTED]
FBI - [REDACTED]

Annual Review

The Physical Security Plan for this facility has been prepared in compliance with the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* and the *Possession, Use, and Transfer of Select Agents and Toxins, Final Rule*. The RO must review the plan on an annual basis, after any drill or exercise is conducted, and after any incident.

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locked select agent freezer and must make a record in the select agent inventory. NIH SAP will communicate such actions to the CDC file manager.

XIII. Notification of Select Agent Discovery (Non-Diagnostic / Non-Clinical)

The discovery of a potential select agent(s) or toxin(s) in an unregistered space on the NIH Bethesda campus is a serious matter and must be immediately reported to the NIH Select Agent Responsible Official (RO) or an Alternate Responsible Official (ARO). If an ARO receives the information, (s)he must report the information to the RO as soon as he or she is available. The RO will investigate the situation and determine if the material meets the definition of a select agent or toxin or if the material is suspect and requires transfer to another facility (e.g., CDC, Atlanta) for testing. Based on the RO's findings, the material may be transferred and secured in the registered SAP laboratory in Building [REDACTED]. Alternately, depending on the quantity, volume, storage particulars, material state, etc., the material may be secured in place until transfer arrangements can be made (e.g., locked freezer, locked room, guard/sentry, etc.). If the RO decides that the material should be secured in Building [REDACTED], the RO or an ARO will complete a chain-of-custody form between the SAP and the IC finding the material. If the decision is made to transport the material to Building [REDACTED], triple-packaging will be used and the material will be transported directly to Building [REDACTED] Room [REDACTED]. The RO will notify the CDC of select agent discovery according to 42 CFR 73.

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Upon the discovery of a *theft or loss* of a select agent or toxin, laboratory personnel must immediately notify the NIH RO. NIH SAP will immediately notify CDC DSAT and appropriate law enforcement agencies of such an incident, as stipulated in 42 CFR §73.19.

1) The *theft or loss* of a select agent or toxin must be reported immediately by telephone, fax, or email. The following information must be provided:

i) Name of select agent or toxin and identifying information (e.g. strain)

ii) An estimate of the quantity lost or stolen

iii) An estimate of the time during which the theft or loss occurred

iv) The location (building, room) from which the theft or loss occurred, and

v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss, as follows:

1.

[REDACTED]

[REDACTED] cell

Annual Review

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and activities.

U. Notification of Select Agent in Diagnostic Isolate

If a diagnostic isolate is identified as containing a select agent, it must be stored or destroyed. The laboratory must immediately notify the NIH RO of the discovery of a select agent or toxin contained in a specimen presented for diagnosis or verification, including Tier 1 agents. The NIH RO will immediately report this event to CDC DSAT and shall submit a Form 4.

V. Notification of Select Agent Discovery (Non-Diagnostic / Non-Clinical)

The discovery of a potential select agent(s) or toxin(s) in an unregistered space on the NIH Bethesda campus is a serious matter and must be immediately reported to the NIH Select Agent Responsible Official (RO) or an Alternate Responsible Official (ARO). If an ARO receives the information, (s)he must report the information to the RO as soon as he or she is available. The RO will investigate the situation and determine if the material meets the definition of a select agent or toxin or if the material is suspect and requires transfer to another facility (e.g., CDC, Atlanta) for testing. Based on the RO's findings, the material may be transferred and secured in the registered SAP laboratory in Building [REDACTED]. Alternately, depending on the quantity, volume, storage particulars, material state, etc., the material may be secured in place until transfer arrangements can be made (e.g., locked freezer, locked room, guard/sentry, etc.). If the RO decides that the material should be secured in Building [REDACTED] the RO or an ARO will complete a chain-of-custody form between the SAP and the IC finding the material. If the decision is made to transport the material to Building [REDACTED] triple-packaging will be used and the material will be transported directly to Building [REDACTED] Room [REDACTED]. The RO will notify the CDC of select agent discovery according to 42 CFR 73.

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1) The *theft or loss* of a select agent or toxin must be reported immediately by telephone, fax, or email. The following information must be provided:

- i) Name of select agent or toxin and identifying information (e.g. strain).
- ii) An estimate of the quantity lost or stolen.
- iii) An estimate of the time during which the theft or loss occurred.
- iv) The location (building, room) from which the theft or loss occurred.
- v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss, as follows:

1. [REDACTED]
Responsible Official

Annual Review

The Physical Security Plan for this facility has been prepared in compliance with the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* and the *Possession, Use, and Transfer of Select Agents and Toxins, Final Rule*. The RO must review the plan on an annual basis, after any drill or exercise is conducted, and after any incident.

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via a [REDACTED] reader and is limited only to individuals registered with the select agent program who are authorized to enter that space. The package is secured inside a BSC until such time when an authorized recipient arrives to accept the package by completing an intra-facility transfer form directly from the RO or ARO.

A shipment is considered an unexpected shipment if it is: 1) a select agent shipment is delivered to Building [REDACTED] Room [REDACTED] without prior notification from the sender; or 2) a select agent shipment is delivered to a destination other than Building [REDACTED] Room [REDACTED]

If an unexpected select agent shipment is delivered to Building [REDACTED] Room [REDACTED] the RO or ARO must complete a chain-of-custody and secure the package inside the BSC in Room [REDACTED]. If an authorized recipient is unable to retrieve the unexpected select agent shipment, the RO and/or AROs must store the contents of the select agent package in the triple-locked select agent freezer and must make a record in the select agent inventory. The RO or ARO must immediately notify the CDC of the unexpected shipment and briefly describe how the package or package contents were secured. NIH SAP will coordinate with the sender and the ultimate recipient to identify why the unexpected shipment was sent, as well as to determine the ultimate disposition of the agent. NIH SAP will communicate such actions to the CDC file manager.

Prior to receiving any select agent shipment, NIH SAP will request that the sender include a "Notice for Unintended Receipt" with the package. The individual responsible for preparing the shipment will include a "Notice for Unintended Receipt" with the package. The "Notice for Unintended Receipt" will contain the names and contact information of the NIH RO and AROs. It will instruct unintended recipients to secure the package and immediately notify the NIH RO or AROs in case of accidental delivery. If a select agent shipment is delivered to a destination other than Building [REDACTED] Room [REDACTED] an unintended recipient will be informed to secure the package and immediately contact the RO or an ARO using the information provided.

The RO or ARO must complete a chain-of-custody and transfer the package to Building [REDACTED] Room [REDACTED]. The package must be transported in such a way as to contain any potential leakage (e.g. by ensuring a secondary container is intact or through the use of a biohazard bag). The RO or ARO will secure the package inside the BSC in Room [REDACTED]. The RO or ARO must immediately notify the CDC of the mistakenly delivered shipment and briefly describe how the package or package contents were secured. NIH SAP will coordinate with the sender and the ultimate recipient to identify why the shipment was mistakenly delivered, as well as to determine the ultimate disposition of the agent. If an SRA-approved recipient is unable to retrieve the package, the RO and/or AROs must store the contents of the select agent package in the triple-locked select agent freezer and must make a record in the select agent inventory. NIH SAP will communicate such actions to the CDC file manager.

XIII. Notification of Select Agent Discovery (Non-Diagnostic / Non-Clinical)

The discovery of a potential select agent(s) or toxin(s) in an unregistered space on the NIH Bethesda campus is a serious matter and must be immediately reported to the NIH Select Agent Responsible Official (RO) or an Alternate Responsible Official (ARO). If an ARO receives the information, (s)he must report the information to the RO as soon as he or she is available. The RO will investigate the situation and determine if the material meets the definition of a select

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iv) The location (building, room) from which the theft or loss occurred, and

v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss, as follows:

1. [REDACTED]
[REDACTED] cell

2. [REDACTED]
FBI - [REDACTED]
[REDACTED]
[REDACTED]

Alternate 1: [REDACTED]

