SMG 2130.8

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

SAFETY AND OCCUPATIONAL HEALTH PROGRAMS

HAZARDOUS BIOLOGICAL AGENTS AND TOXINS

Biosecurity and Inventory Control

Effective Date: January 13, 2016

1. BACKGROUND AND PURPOSE

In pursuit of the agency's mission, FDA employees perform scientific research and analyses in laboratories located throughout the United States. FDA employees handle, analyze, manage, and conduct research on a variety of materials and devices which may present biological, chemical, radiological, and physical risks.

Within the Occupational Safety and Health Program series of Staff Manual Guides, this Guide serves to outline FDA's biosecurity policy as applied to hazardous biological agents and toxins (HBATs). Good biosecurity practices include provisions to maintain an accurate inventory of HBATs to ensure that HBATs can be located when necessary and inventory discrepancies (e.g., misplaced or unreported HBATs) are easily and quickly identified and resolved.

The purpose of this Staff Manual Guide is to establish policies and responsibilities for the biosecurity and inventory control of HBATs used or stored in FDA laboratories. This Staff Manual Guide also establishes an audit process for both HBAT storage areas and HBAT inventories, as well as procedures for discrepancy reporting and remediation. These policies require that FDA employees account for laboratory personnel turnover and changes,

and to properly destroy all HBATs that are not assigned to a current qualified FDA employee, in accordance with this Staff Manual Guide.

2. SCOPE

This policy relies on and references the regulations regarding the possession, use, and transfer of Biological Select Agents and Toxins (BSATs), as governed by the Federal Select Agent Program. In the event that this policy appears to be inconsistent, the Federal Select Agent Regulations govern.

Radioisotope use is regulated by the Nuclear Regulatory Commission (NRC). NRC regulates medical, industrial, and academic uses of nuclear materials through a combination of regulatory requirements; licensing; safety oversight, including inspection and enforcement; operational experience evaluation; and regulatory support activities. HBATs (defined in section 5.I) containing radioisotopes are governed by the NRC and are not addressed in this policy.

This policy is applicable only to those HBATs classified at risk group 2, risk group 3, or risk group 4 (defined in section 5.M), and to the equipment or rooms wherein these agents are stored.

This policy sets the minimum requirements for HBAT biosecurity and FDA employee qualifications. However, additional requirements may be prescribed by the individual Centers/Offices.

Under the Center/Office's Occupational Safety and Health Officer's supervision, the inventory requirements of this policy may be temporarily suspended in the event of exigent circumstances (e.g. a malfunctioning storage unit). The Occupational Safety and Health Officer must notify the Office of Employee Safety and Environmental Management when such circumstances exist.

This policy supplements other occupational safety and health standards issued by the FDA, including SMG 2130, all chapters.

3. POLICY

It is the policy of the FDA to secure and inventory (section 3.G) HBATs that are used in agency biomedical research and regulatory analyses in compliance with the most current versions of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guide,[1] the NIH Guidelines,[2] Institutional

[1] http://www.cdc.gov/biosafety/publications/bmbl5/. Last accessed August 7, 2015.

[2] https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/

Biosafety Committee,[3] or Federal Select Agent Program (FSAP) requirements.[4]

Unless subject to a Material Transfer Agreement, HBATs assigned to, or acquired by, FDA supervisors and employees in the course of their employment are property of the United States Government and are for official laboratory use only.

Upon request, FDA supervisors and employees must be able to identify the storage location(s) for all assigned HBATs.

For the purposes of this policy, a qualified FDA employee is one who has: (1) successfully completed the training specified in section 3.I of this policy, (2) fully met all biosafety and biosecurity requirements established by their Center/Office for HBAT laboratory or location entry, and (3) been approved by management to: (a) enter that laboratory or location, and (b) handle and conduct experiments with HBATs. Centers/Offices may further define the requirements and the mechanisms to determine if an FDA employee is qualified to work with HBATs.

HBATs must be controlled and secured at all times by current qualified FDA employees.

To ensure that all HBATs are properly controlled and stored, the Center/Office Occupational Safety and Health Officer will conduct annual visual inventory audits (section 3.H.i) of areas used to store HBATs.

In coordination with the Director of Laboratory Science and Safety and the Office of Employee Safety and Environmental Management, each Center/Office must develop policies and procedures to implement this Staff Manual Guide within nine (9) months of issuance of this document. Centers/Offices may supplement and expand upon the policy and procedures to meet their specific needs through issuance of written standard operating procedures (SOPs), so long as those SOPs support, and do not conflict with, this SMG.

A. Custodians of HBATs

Supervisors (defined in section 5.N) to whom qualified FDA employees report are the custodians of and are ultimately responsible for all HBATs within their area of responsibility.

[3] https://fda.sharepoint.com/sites/OC-intranet-OC-OCS-OLS-OSH/SitePages/Biosafety.aspx#institutional-biosafety-committee

[4] http://www.selectagents.gov/. Last accessed August 7, 2015.

The supervisor, with the approval of his or her supervisor, may designate appropriate officials (e.g. team leader, principal investigator, etc.) to perform the responsibilities described in this policy.

B. Assignment of HBATs

Supervisors must assign HBATs stored in FDA laboratories to a qualified FDA employee.

For the purposes of employee transitions or to maintain the biosecurity of an HBAT, supervisors may temporarily assign an HBAT to themselves, if qualified. All self-assignments must be immediately reported to the Occupational Safety and Health Officer.

Any HBATs not so assigned ("orphaned HBATs") must be properly destroyed in an appropriate fashion and overseen by the safety officer.

In accordance with this policy, qualified FDA employees may store and conduct experiments with working stocks of an HBAT that is not assigned to them with the approval of the FDA employee assigned the HBAT. However, the FDA employee assigned the HBAT retains responsibility for the storage and inventory requirements of the archival stock.

C. The arrival of new laboratory staff

Centers/Offices must develop policies and procedures that guide the arrival of new laboratory staff. These policies and procedures must include:

- a centralized electronic database(s) to facilitate documenting assigned HBATs and space within shared and single-user storage units;
- the documented assignment of empty and clear storage spaces within shared storage units, or an entire storage unit as they become available;
- the documented assignment or transfer of initial stores of HBATs, including notification to, or application with, the Institutional Biosafety Committee under the relevant biosafety protocol, if applicable;
- the immediate update of all inventory records and signage related to the specific storage space and HBATs, if applicable;
- any other provisions the Center/Office deems necessary in order to qualify a new laboratory employee to work in its laboratories; and

- the training of inventory, biosecurity, and secure storage procedures.

In the case where an arriving employee wishes to transfer HBATs from their previous institution to the FDA, the following must occur:

- the arriving employee must obtain approval from both their new supervisor and the Occupational Safety and Health Officer;

- any required regulatory permits are obtained;

- the arriving employee ensures that a Material Transfer Agreement is executed between the employee's previous laboratory or institution and FDA (Appendix 2);

- copies of the executed Material Transfer Agreement must be submitted to the Center/Office's Technology Transfer point of contact, Occupational Safety and Health Officer, and the FDA Technology Transfer Program, Office of the Commissioner;

- the Occupational Safety and Health Officer works closely with the arriving employee to ensure a safe and secure transfer of the material;

- the arriving employee's supervisor takes custody of the material and properly assigns the material to the employee;

- the arriving employee immediately updates the inventory records; and

- the arriving employee immediately notifies both their supervisor and the Occupational Safety and Health Officer when the transfer is complete and inventory records are updated.

D. The departure of laboratory staff

Centers/Offices must develop policies and procedures that guide the departure of laboratory staff. These policies and procedures must include:

- providing an adequate amount of time for the departing FDA employee to complete the departure process;

- the documented re-assignment of all HBATs from the departing FDA employee to a current qualified FDA employee, or else the proper destruction of the orphaned HBATs;

- the documented transfer of HBAT custody from the departing FDA supervisor to a current qualified FDA supervisor, or else the proper destruction of the orphaned HBATs;

- the immediate update of all inventory records, documentation (notify issuing agency if permitted material), and signs related to the specific storage space and HBATs;

- the documented transfer of vacated and clear storage spaces from the departing FDA employee's responsibility;

- a thorough sweep of the storage unit(s) assigned to the departing FDA employee to ensure that all HBATs are properly controlled; and

- discrepancy reporting, as in section 3.H.ii.

In the case where a departing employee wishes to transfer HBATs from the FDA to their new laboratory or institution, the following must occur:

- the departing employee must obtain approval from both their current supervisor and the Occupational Safety and Health Officer;

- the departing employee ensures that a Material Transfer Agreement is executed between the employee's new laboratory or institution and FDA (Appendix 2);

- copies of the executed Material Transfer Agreement must be submitted to the Center/Office's Technology Transfer point of contact, Occupational Safety and Health Officer, and the FDA Technology Transfer Program, Office of the Commissioner;

- the Occupational Safety and Health Officer works closely with the departing employee to ensure a safe and secure transfer of the material to the new laboratory or institution;

- the supervisor immediately updates the inventory records; and

- the supervisor immediately notifies the Occupational Safety and Health Officer when the transfer is complete and inventory records are updated.

E. Physical laboratory moves

Center/Office policies on physical laboratory moves must include procedures for:

- laboratory personnel to vacate all storage space within the original space completely;

- the packing and security of HBATs during the physical move;

- the Center/Office Occupational Safety and Health Officer to conduct a thorough sweep, including a visual inventory audit (section 3.H.i), of all previously occupied storage units in the original space to ensure that all HBATs have been properly removed or reassigned to a current FDA employee prior to the new laboratory personnel moving into the space;

- when applicable, the documented assignment of empty and clear storage space in the new physical location to incoming researchers;

- immediately updating all inventory records, documentation, and signs related to the specific storage space and HBATs;

- a visual inventory audit (as defined in section 3.H.i) of all storage space in the new laboratory space within 90 days of the completion of the move-in; and

- discrepancy reporting, as in section 3.H.ii.

F. Minimum Requirements for HBAT Storage

1. All supervisors with HBATs in their custody are responsible for ensuring that storage units housing HBATs must:

    - be secured at all times or be located in an appropriately secured laboratory and accessible only to qualified personnel, in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guide and the policies of the Center/Office, and

    - be externally labeled with:

        - a biohazard sign,

        - the name and contact information of the supervisor responsible for the equipment, and

        - a unique identification number for the storage unit (for example, an FDA barcode number).

2. Minimum requirements for working stock HBAT storage. Supervisors with HBATs in their custody are responsible for ensuring that all:

    - HBATs within a storage unit must be recorded in a current posted overview inventory (section 3.G.i); and

- individual working stocks must be labeled properly and legibly with at least:

    - the HBAT identification,
    - name of owner (may be initials), and
    - date of creation.

3. Minimum requirements for archival stock storage. Supervisors with HBATs in their custody are responsible for ensuring that all:

    - HBATs are recorded in an inventory as described below (section 3.G.ii),

    - HBATs are organized in a manner to facilitate inventory and auditing,

    - HBATs stored after the issuance of this policy are properly and legibly labeled with at least:

        - the identification of stored HBAT,
        - name of owner (may be initials), and
        - date of creation.

4. Shared storage units

    When using shared storage units or shared facilities, such as freezer farms, cold rooms, etc., the Center/Office laboratory must have policies in place for how space (e.g. shelves or racks) in shared storage units are assigned, inventoried, and audited.

G. Minimum Requirements for Inventories

As part of an effective biosecurity program, laboratories must maintain an accurate electronic inventory of all the HBATs that are stored in FDA laboratories.

Databases that contain the inventory of HBATs should be current, complete, readily available, easily searchable, and stored securely with adequate backup provisions.

In line with the level of the biosecurity risk, all transfers of HBATs between laboratories or storage equipment are to be immediately recorded and controlled, as determined by the Office of Employee Safety and Environmental Management and the Office of Security Operations.

Inventories must be established within sixty (60) days of the issuance of Center/Office policies pursuant to this Staff Manual Guide and a memorandum certifying the establishment of inventories must be submitted to the Director of Laboratory Science and Safety with a copy to the Office of Employee Safety and Environmental Management.

1. A posted overview inventory of storage units housing HBAT working stocks includes, at a minimum:

    - a general listing of all HBATs or diagnostic material, including risk group (defined in Section 5.M), stored within the equipment. This includes, but is not limited to, known HBAT-containing cultures, specimens, and other sources (e.g. infected tissues/ samples or animals);

    - the term “samples containing unknown [risk group] HBATs,” or language to that effect, if applicable;

    - the responsible FDA employees or supervisors who are assigned the listed material; and

    - the contact information for the FDA employee who serves as the primary responsible party for the equipment, and/or the supervisor responsible for the equipment.

2. Central databases containing inventories of archival stock storage include, at a minimum:

    - the Center/Office;

    - building and room location of the equipment where HBATs are stored;

    - the identification number of the equipment, if applicable;

    - the type of equipment (room temperature cabinet, -80°C, -20°C, etc.);

    - the contact information for the FDA employee who serves as the primary responsible party for the equipment, and/or the supervisor responsible for the equipment;

    - the HBAT name, risk group, and other relevant details relevant to risk group determination (i.e., if relevant, strain) of the HBAT(s) stored in the equipment;

- the responsible FDA employee who is assigned the HBAT;

- the location of the HBAT within the archival stock storage unit to include at a minimum, the box (if applicable), rack, and storage unit identifier information (additional level of information, such as vial-by-vial inventory may be deemed necessary, at the discretion of the PI, Division, Office, or Center/Office);

- an option to include comments; and

- any additional inventory requirements as prescribed in the Scientific Collection Management and Access Policy Staff Manual Guide, if applicable.

H. Compliance

Auditing will be the primary mechanism to determine compliance with this policy. Any discrepancies discovered during an audit or reported by an employee must be appropriately documented and reported (Appendix 3).

The Occupational Safety and Health Officer for a Center/Office has the authority to ensure the remediation of discrepancies and compliance with this policy for that Center/Office.

The first audit must be completed within one year of the issuance of Center/Office policies.

The Occupational Safety and Health Officer will conduct the annual audits.

1. Minimum Requirements for Auditing

- The Occupational Safety and Health Officer must develop procedures for annual visual inventory audits of HBAT storage units, labeling practices, and inventories within that Center/Office.

- The supervisor, or designated official (see sections 3.A and 5.N) must be present during all audits.

- Visual inventory audits should include an inspection of:

  - all unassigned storage units or areas within shared storage, as identified by the supervisor in the database, to ensure that they remain empty and clear;

- the exterior of all storage units to ensure that all units have a posted sign that clearly displays the minimum information outlined in section 3.F.i;

- randomized sample of the inventory records of HBATs stored within the storage equipment to ensure general compliance with the requirements;

- an item-by-item visual audit of any, and all, self-assigned HBATs to ensure proper storage and record keeping; and

- a randomized item-by-item visual audit of an appropriately sized sample of the HBATs stored within the equipment to ensure proper labeling and storage.

- The Occupational Safety and Health Officer may conduct directed, more extensive audits and inspections if there is evidence that indicates noncompliance or at Center/Office discretion.

- The results of all audits are to be maintained by the Occupational Safety and Health Officer.

2. Discrepancy reporting and remediation

   Centers/Offices must develop (and update as needed) policies and procedures to report (to the Occupational Safety and Health Officer) and effectively remediate instances of non-compliance.

   A summary of all discrepancy reports must be sent to the Director of Laboratory Science and Safety and Office of Employee Safety and Environmental Management annually in order to evaluate the effectiveness of this policy.

   Procedures for the immediate remediation of an inventory discrepancy, security breaches, or release of materials are to include:

   - properly securing the HBAT in an approved archival stock storage unit,

   - entry of the HBAT into the current inventory of a laboratory,

   - editing of the HBAT inventory to make it current and true, and

   - proper destruction of an orphaned HBAT (if applicable).

However, if (a) HBATs are discovered in an unassigned storage location, (b) if risk group 3 or risk group 4 HBATs are discovered in an assigned storage location, but are not declared in the inventory, (c) HBATs are recorded in the inventory, but cannot be physically located (i.e. the HBATs are missing), or (d) BSATs are discovered in non-select agent registered laboratories or cannot be physically located, then:

- the Occupational Safety and Health Officer must be immediately notified;

- in the case of the discovery of BSATs, the Center/Office Responsible Official, the Director of Laboratory Science and Safety, the Chief Scientist, and the Chief Operating Officer must be immediately notified (refer to Appendix 1);

- an immediate complete vial-by-vial visual inventory audit of all material in the storage unit is to be performed by the Occupational Safety and Health Officer;

- a visual inventory audit (see section 3.H.i) of affected storage units will occur once every quarter for a period of one year; and

- the discovery of the discrepancy and the subsequent remediation must be reported to the Director of Laboratory Science and Safety and the Office of Employee Safety and Environmental Management by the Occupational Safety and Health Officer. The following information should be provided in the discrepancy report to the Director of Laboratory Science and Safety and the Office of Employee Safety and Environmental Management (Appendix 3):

- the name of the HBAT and any identifying information (e.g., strain or other characterization information),

- an estimate of the quantity (for biological toxins) or number of vials (for pathogens) identified,

- assessment of the integrity of the primary container (e.g. intact) of the material,

- the location of the discovery and the level of security of the location,

- whether any individuals were potentially exposed to the HBAT and any other hazards posed by the discovery, and

- any immediate actions taken in response to the discovery.

3. Compliance

   To ensure proper compliance after inventory control problems have been discovered, the Occupational Safety and Health Officer may recommend an increase to the number and scope of audits (section 3.H.i) and trainings (section 3.I) as necessary until the FDA employee, or laboratory, is in full compliance with this policy.

   If an FDA employee repeatedly fails to comply with this policy, and the policy and procedures issued by the Center/Office, then the supervisor, in conjunction with the Center/Office, must reassign the HBATs in order to maintain biosecurity. Non-compliance may lead to administrative action up to, and including, removal from the Federal service. Consistent compliance may be rewarded.

   In the rare case of repeated, and willful, laboratory noncompliance with this policy, and the policies and procedures issued by the Center/Office, the Chief Scientist, in consultation with the Director of Laboratory Science and Safety and the involved Center/Office leadership, may permanently or temporarily transfer the custody of HBATs from the noncompliant laboratory to a compliant laboratory.

I. Training

   Within six (6) months after the issuance of Center/Office policies and procedures, the Occupational Safety and Health Officer, with assistance from the Director of Laboratory Science and Safety and ESEM Training Manager, Office of Employee Safety and Environmental Management, will develop training manuals, standard operating procedures, and training for their Center/Office on this policy and those policies and standard operating protocols developed by the Center/Office pursuant to this Staff Manual Guide. These materials are to be reviewed annually and updated as needed. Employees will be given the opportunity to provide comments and feedback on each training.

   In addition to Center/Office requirements, all FDA employees who conduct research using HBATs, and their supervisors, must complete training on this policy annually in order to be considered “qualified” to work with HBATs, as defined in section 3.

4. RESPONSIBILITIES

A. The Office of the Chief Scientist

The Office of the Chief Scientist provides agency oversight of this policy. Upon the recommendation of the Director of Laboratory Science and Safety, the Chief Scientist, in consultation with the involved Center/Office leadership, may permanently or temporarily transfer the custody of HBATs from laboratories that repeatedly fail to comply with this policy to other laboratories. The Chief Scientist may also order the material destroyed in an appropriate fashion if deemed necessary.

B. Director of Laboratory Science and Safety

Within the Office of the Chief Scientist, the Director of Laboratory Science and Safety ensures that the Occupational Safety and Health Officers oversee and ensure compliance with this policy. The Director of Laboratory Science and Safety serves as the agency's senior laboratory scientific advisor to the FDA Commissioner and FDA Chief Scientist.

The Director of Laboratory Science and Safety: (1) has full authority to ensure that discrepancies and noncompliance are corrected in a timely manner by appropriate Center/Office personnel; (2) will coordinate efforts amongst the Centers/Offices to develop policies and SOPs based upon this Staff Manual Guide; (3) in conjunction with the Office of Employee Safety and Environmental Management, may conduct independent audits of the documented inventories of the laboratory's archival stock and working stock storage units to ensure compliance with this policy; and (4) will ensure that documented discrepancies will be reconciled by a physical audit of the suspect storage location.

Annually, the Director of Laboratory Science and Safety will evaluate the effectiveness of this policy by reviewing all discrepancy reports submitted by the Occupational Safety and Health Officer in order to determine if this policy is in need of revision. The Director of Laboratory Science and Safety will establish time-frames and the format of the summary report.

C. Office of Employee Safety and Environmental Management

In addition to its existing roles and responsibilities, the Office of Employee Safety and Environmental Management assists the Director of Laboratory Science and Safety to provide oversight for the Centers to ensure that they are in compliance with the biological safety requirements described in this SMG. Any discrepancy brought to the attention of the Office of Employee Safety and Environmental Management must be immediately reported to the Director of Laboratory Science and Safety.

D. FDA Centers/Offices

Center/Office Directors and Associate Commissioner for Regulatory Affairs (ACRA) ensure compliance with this policy and through oversight of an Occupational Safety and Health Officer, as defined in Staff Manual Guide 2130.1. The Center/Office Director and ACRA is responsible for developing and implementing Center/Office-wide policies and procedures to support their individual laboratory programs, as long as those policies are consistent with this Staff Manual Guide. Policies and procedures must be posted to the Center/Office's intranet.

E. Occupational Safety and Health Officer

The Occupational Safety and Health Officer must immediately report to the Director of Laboratory Science and Safety and the Office of Employee Safety and Environmental Management discrepancies involving (1) HBATs that are discovered in an unassigned storage location; (2) if risk group 3 or risk group 4 HBATs are discovered in an assigned storage location, but are not declared in the inventory; (3) HBATs or BSATs that are recorded in an inventory, but cannot be physically located (i.e. the HBATs are missing); (4) security breaches, (5) the inadvertent release of HBATs outside the laboratory environment, or (6) accidental exposures of FDA employees to HBATs.

The Occupational Safety and Health Officer is responsible for overseeing annual audits.

The Occupational Safety and Health Officer is also responsible for maintaining an electronic database of qualified employees within their Center/Office to ensure that employees maintain their current qualification in order to continue to work with HBATs.

Annually, the Occupational Safety and Health Officer must submit to Director of Laboratory Science and Safety and the Office of Employee Safety and Environmental Management a summary of all discrepancy reports.

F. Laboratory Directors and Supervisors

It is the responsibility of the supervisor (see sections 3.A and 5.N) to ensure FDA employees to whom HBATs are assigned comply with the Staff Manual Guide and related policies and provide these employees with a detailed list of all related policies and pertinent sections. Within their area of responsibility, supervisors are responsible for:

- all HBATs;
- the complete contents (including non-HBATs) of all storage units that contain HBATs;
- the assignment of HBATs to a qualified FDA employee;
- providing or updating the list of employees on their staff who are currently fully qualified to work with HBATs to the Occupational Safety and Health Officer;
- ensuring and verifying that FDA employees are trained regarding policies for the proper storage and labeling, use, inventory practices, and disposal of the HBATs under their control;
- overseeing the transition of arriving and departing FDA employees (as it pertains to HBAT assignment), entire laboratory moves, and the transfer of HBATs between FDA employees;
- verifying that no HBATs under their control are stored in non-approved storage units, unassigned storage units, or unassigned spaces within storage units;
- ensuring that information about storage units is documented;
- maintaining personal training, credentialing, and/or certifications needed to access BSL-2 or BSL-3 facilities and storage units housing HBATs;
- accompanying and supporting the Occupational Safety and Health Officer during audits;
- encouraging FDA employees to report any discrepancies or unsafe practices with respect to biosafety and biosecurity to them, or the Occupation Safety and Health Officer;
- immediately reporting to the Occupational Safety and Health Officer any inventory discrepancy, storage equipment failure, security breaches, or inadvertent release of materials;
- ensuring FDA employees comply with this policy by taking appropriate action, including disciplinary action;
- promoting a culture that encourages and rewards proper HBAT biosecurity and inventory practices; and

G. FDA Employees

It is the responsibility of the FDA employee to properly inventory, safely store and secure, and comply with all policies, rules, and regulations that apply to the assigned HBATs.

FDA employees are responsible for:

- complying with this and Center/Office-issued biosecurity policies;
- handling only those HBATs for which they are qualified;
- maintaining appropriate qualifications to work with assigned HBATs, including all relevant biosafety and biosecurity training, Occupational Health and Safety consultation, and approval by management to work with HBATs;
- verifying upon assignment that the storage areas they have been assigned are clear and free of any HBATs;
- completing an initial full inventory of all assigned HBATs within thirty (30) days of FDA employment start date (new FDA employees);
- maintaining an accurate and up-to-date inventory of assigned HBATs;
- promptly reporting to their supervisor and the Occupational Safety and Health Officer, any inventory discrepancy, storage equipment failure, security breaches, or release of materials; and
- under oversight from their supervisor, facilitating the transfer of all HBATs in their custody to another qualified FDA employee prior to separating from the laboratory.

5. DEFINITIONS

A. Archival Stock

HBATs are considered archival stock if the material is stored in a manner to ensure the viability of the HBATs for future use. Storage of archival stock can be appropriate to specific HBATs, and therefore can include, but is not limited to, cryogenic storage, freezers, refrigerators, and room temperature storage units.

Archival stock storage units must adhere to the minimum requirements for both archival stock storage (section 3.F) and inventories (section 3.G).

Characteristics of materials stored in archival stock storage units:

- The material is in a concentrated state and must be diluted prior to use in an experiment.
- The material is not part of an active experiment.
- The material is stored in an environment that is accessed infrequently.

B. Audit

An audit is defined as a systematic and independent examination of data, statements, records, operations and performances to insure compliance with this Staff Manual Guide. For the purposes of this Staff Manual Guide, the minimum requirements for auditing are outlined in section 3.H.

C. Biological Select Agents and Toxins (BSATs)

BSATs are biological agents and toxins that have been deemed by the U.S. Department of Health and Human Services (HHS) or by the U.S. Department of Agriculture (USDA) to pose a severe threat to public, animal or plant health, or to animal or plant products. These biological agents are divided into three broad categories: (1) HHS select agents and toxins (affecting humans); (2) USDA select agents and toxins (affecting agriculture); and (3) overlap select agents and toxins (affecting both). For more information, see 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

D. Biological Agent

Biological agents include bacteria, viruses, fungi, and other microorganisms. They have the ability to adversely affect animal, human, or plant health in a variety of ways.

E. Biological Toxins

A biological toxin is a poisonous substance produced within living cells or organisms. Biological toxins can be small molecules, peptides, or proteins that are capable of causing disease.

F. Biosafety levels

A biosafety level is the level of the biocontainment precautions required to work with HBATs in an enclosed laboratory. The levels of containment range from the lowest biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4). In the United States, the Centers for Disease Control and

Prevention (CDC) and the National Institutes of Health (NIH) through the Biosafety in Microbiological and Biomedical Laboratories guide have specified the requirements for each of these levels.

G. FDA Center/Office

The terms, “FDA Center/Office” or “Center/Office,” are used to refer to one of FDA’s core operating components—namely the Office of Regulatory Affairs, the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, Center for Tobacco Products, the National Center for Toxicological Research, and other agency components that conduct scientific research and regulatory analyses, including offices within the Office of the Commissioner.

H. FDA Employee

For the purposes of this policy, an FDA employee is a government employee, contractor, visiting scientist, or guest worker, whether paid or volunteer, whose position description includes laboratory support, analysis, or research.

I. Hazardous Biological Agents and Toxins (HBATs)

HBATs include biological agents and biological toxins categorized at risk group 2, or higher (defined in section 5.M). The term “HBAT” also includes recombinant and synthetic nucleic acids derived from risk group 2, or higher, microorganisms. HBATs must be contained in Biosafety Level 2 (BSL-2) facilities, or higher. While the definition of HBATs includes BSATs as defined in 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73, storage, use, and transfer of BSATS at FDA are governed under the Federal Select Agent Program permit issued to the Center/Office.

J. Inventory

An electronic catalog of all HBATs within a particular archival stock storage unit as defined in section 3.G, minimum requirements for inventories.

K. Laboratory

For the purposes of this policy, a laboratory is any place, situation, set of conditions, or the like, within an establishment that provides controlled conditions in which scientific or technological research, experiments, and measurements involving HBATs may be performed. Centers/Offices may

further refine this definition as necessary in order to effectively develop policies and procedures in support of the Staff Manual Guide.

L. Occupational Safety and Health Officer

Within each Center/Office, the Occupational Safety and Health Officer is an individual appointed by a Center Director, the Associate Commissioner for Regulatory Affairs (ACRA) or the Deputy Chief Operating Officer (acting on behalf of all Offices of the Commissioner's program offices except ACRA) to be responsible, on a full-time basis, for developing, implementing, and maintaining an effective and comprehensive occupational safety and health program in their respective program office or Center/Office. For the purposes of this policy, the Occupational Safety and Health Officer may designate a safety and health officer at each establishment in order to effectively ensure compliance with this policy.

M. Risk Group

HBATs are categorized in risk groups based on the pathogenicity of the organism, modes of transmission and host range of the organism. The risk group may be influenced by existing levels of immunity, density and movement of host population, presence of appropriate vectors and standards of environmental hygiene. For the purposes of this policy, risk groups are determined by the Institutional Biosafety Committee, Biosafety in Microbiological and Biomedical Laboratories (BMBL) guide, NIH Guidelines, or World Health Organization Laboratory Biosafety Manual.

N. Supervisor

A supervisor is an individual employed by an agency having authority in the interest of the agency to hire, direct, assign, promote, reward, transfer, furlough, layoff, recall, suspend, discipline, or remove employees or contractors, to adjust their grievances, or to effectively recommend such action. The supervisor, in consultation with his or her supervisor, may designate appropriate officials (e.g. team leader, principal investigator, etc.) to perform the responsibilities described in this policy.

O. Working Stock

HBATs are considered working stock if the materials are part of an ongoing experiment. HBATs classified as working stock are not required to be included in inventories of archival stock storage units.

Storage units that contain working stocks must adhere to the minimum storage requirements for working stocks (section 3.F) and overview inventories (section 3.G).

Indicators of working stock materials:

1. The material has been diluted from a concentrated state for use in an active experiment.

2. The material is stored in an environment where there is frequent access to the material, such as a refrigerator, cabinet, or incubator in an active laboratory.

6. EFFECTIVE DATE

The effective date of this Staff Manual Guide is January 13, 2016.

7. Document History – SMG 2130.8, Hazardous Biological Agents and Toxins: Biosecurity and Inventory Control

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	09/25/2015	N/a	OC/OCS	Walter Harris, FDA Chief Operating Officer

APPENDIX 1

To: Center Directors
Office of the Commissioner Executive Leaders
Laboratory Safety Practices and Policies Workgroup (LSPPW)

From: Dr. Stephen Ostroff, Acting Chief Scientist /s/
Walter Harris, Deputy Commissioner for Operations /s/

Re: Notification Procedures for Discovery of Biological Select Agents or Toxins[1]

Date: September 10, 2014

The ongoing inventory of specimens in FDA's laboratories remains a high priority for the agency due to its visibility of this effort resulting from recent incidents in HHS laboratories. Thank you for your continuing cooperation on this activity. Even after the September 30, 2014 deadline to complete the inventory, there will be ongoing requirements for inventory management and control. **It is especially important that any suspected or confirmed biological specimen or toxin on the CDC or USDA select agent list that is found in an inappropriate/unregistered storage location be immediately notified to the Office of the Commissioner.** This notification should occur through a Center's Responsible Official or a member of a Center's senior leadership. Immediate notification will help to determine a course of action and assure appropriate parties are made aware of the finding.

As co-chairs of the Laboratory Safety Practices and Policies Workgroup, one or both of us should be immediately notified (preferably by telephone or through email) of the finding:

- Dr. Stephen Ostroff, Acting Chief Scientist (LSPPW Co-Chair)
- Walter Harris, Deputy Commissioner for Operations (LSPPW Co-Chair)

The following individuals will serve as back-ups if neither of us can be reached.

- Kristine Leiphart, Deputy Chief Operating Officer

- Carmen Maher, Deputy Director, Office of Counterterrorism and Emerging Threats

As much of the following information should be provided:

[1] The Director for Laboratory Safety was not an established position at the time this memorandum was issued.

- The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

- An estimate of the quantity (for toxins) or number of vials (for pathogens) identified;

- The status (e.g. intact) of the material

- The location of the discovery and the security of the location;

- Whether any individuals were potentially exposed to the agent and any other hazards posed by the discovery;

- Any immediate actions taken in response to the discovery

Thank you for your continued work protecting the safety and health of our employees and the public at large.

APPENDIX 2 - MATERIAL TRANSFER AGREEMENT

Considerations regarding the use of the Material Transfer Agreement[1] (MTA) for situations involving the arrival or departure of employees and the transfer of hazardous biologic agents and toxins:

1. The “provider” and the “recipient” must be an entity, and not an individual. As such, the employee may not sign and execute the document on his/her behalf.

2. Unless otherwise agreed upon in writing, the provider of the materials is the owner of the materials to be transferred.

3. A detailed vial-by-vial list of materials must be attached as an appendix to the MTA. Any materials that have patent protection must be noted. FDA has a right to retain a stock of any material invented or generated by an employee of the FDA as part of their official duties.

4. Copies of the executed document must be delivered to the following:

    a. Center/Office’s Technology Transfer point of contact;
    b. Occupational Safety and Health Officer; and
    c. FDA Technology Transfer Program, Office of the Commissioner.

5. All physical movements of materials must be coordinated through the Occupational Safety and Health Officer.

6. The description of research should indicate why the material is to be transferred between entities and how the material is to be used at the recipient entity.

[1] For more information about, and points of contact for, the FDA Technology Transfer Program, see: https://fda.sharepoint.com/sites/OC-Intranet-OC-OCS-Technology-Transfer

APPENDIX 3 - DISCREPANCY REPORTING FORM

To be filed when (1) HBATs are discovered in an unassigned storage location, (2) if risk group 3 or risk group 4 HBATs are discovered in an assigned storage location, but are not declared in the inventory, (3) HBATs are recorded in the inventory, but cannot be physically located (i.e. the HBATs are missing), or (4) BSATs are discovered in non-select agent registered laboratories or cannot be physically located.

1. Name
2. Date
3. Center/Office
4. Building
5. Room location
6. Name of FDA employee who is assigned the HBAT (if known)
7. Name of supervisor who has custody of the HBAT
8. The name of the HBAT and any identifying information (e.g., strain or other characterization information),
9. BSAT: yes or no
10. Risk Group: 2, 3, or 4
11. An estimate of the quantity (for biological toxins) or number of vials (for pathogens) identified
12. Assessment of the integrity of the primary container (e.g. intact) of the material
13. The location of the discovery and the security of the location
14. Whether any individuals were potentially exposed to the HBAT and any other hazards posed by the discovery
15. Any immediate actions taken in response to the discovery
16. Routing and signatures (non-BSAT discovery):

a. Occupational Health and Safety Officer, or the Office of Employee Safety and Environmental Management (for Office of the Commissioner matters)

b. Director of Laboratory Science and Safety

17. Routing and signatures (BSAT discovery):

a. Federal Select Agent Program Responsible Official
b. Occupational Health and Safety Officer, if applicable
c. The Office of Employee Safety and Environmental Management
d. Director of Laboratory Science and Safety
e. Chief Scientist
f. Chief Operating Officer

18. Copies to:

a. Center Director
b. Office Director
c. Supervisor
d. FDA employee assigned the material