1.0 PURPOSE

To ensure compliance with federal regulations, including the U.S. Patriot Act, U.S. Department of Health and Human Services (HHS) 49 CFR Part 73, and U.S. Department of Agriculture (USDA) 9 CFR Part 121 and 7 CFR Part 331, which govern the storage, use, and shipment of biological materials, LSUHSC must maintain an accurate inventory of the type and location of biological materials. Biological materials are defined as any biologically-derived materials or materials which, either by accident or design, contain biological agents. Examples include bacteria, fungi, parasites, rickettsidal agents, viral agents, prions, genetically modified organisms/micro-organisms, toxins of biological origin, transgenic animals or plants, human blood and body fluids, human or primate cell cultures, recombinant DNA, or any other biological agents which might pose a risk to health and safety or the environment.

2.0 SCOPE

This policy applies to all LSUHSC personnel who work with or store biological materials.

3.0 RESPONSIBILITIES

3.1 Environmental Health & Safety Department (EH&S) shall:

- Provide technical support to assist departments in maintaining an accurate inventory.
- Provide training for data entry into the biological inventory database.
- Perform random laboratory inspections to ensure inventory accuracy.
- Assist departments in complying with all applicable federal rules and regulations.
- Monitor inventory for infectious agents, recombinant materials, toxins, select agents, and other biological materials of interest.
3.2 Department Heads shall:
- Notify EH&S of the addition or deletion of personnel that use or store biological materials.
- Ensure compliance with all applicable federal rules and regulations.

3.3 Principle Investigators (PI)/Supervisors shall:
- Maintain their On Site biological inventory.
- Designate one or more laboratory personnel to be trained and responsible for the laboratory’s biological materials inventory.
- Update/delete authorized users.
- Update the inventory when biological material(s) is added, no longer used, or when there is a significant change in the quantity of any biological material.

4.0 IMPLEMENTATION

4.1 Inventory Overview
The On Site Biological Safety Assistant program is a web-based inventory database that manages biological materials data, generates reports, and provides online training. The program allows PIs/Supervisors to access and monitor their biological materials inventory.

4.2 Inventory Implementation

EH&S Department shall:
- Assign security settings for Department Head and each PI/Supervisor to have access limited to only their biological materials inventory.
- Assign security settings to other designated users to have access to their PI/Supervisor biological materials inventory.

PI/Supervisor shall:
- Provide list of authorized users to EH&S and update as users are added or deleted.

4.3 Inventory Access
Department Heads, PIs/Supervisors, and other authorized users can access and monitor their own biological materials inventory by going to the EH&S website and log onto the Web Inventory Control site by using their LSUHSC user name and password.

4.4 Inventory Maintenance
- Personnel will update their biological materials inventory when:
  - New biological materials are added to the inventory.
  - Biological material is no longer used or kept in the laboratory.
○ When there is a significant change in quantity of biological materials.

- The On Site Bio Assistant User’s Manual provides instructions on adding and deleting biological materials.

4.5 Shipping Biological Material
The shipment of biological materials is regulated by multiple agencies, including the Department of Transportation (DOT), Department of Commerce (DoC), U.S. Postal Service (USPS), International Air Transport Association (IATA), Federal Aviation Authority (FAA), and International Civil Aviation Organization (ICAO).

Prior to the shipment of biological materials, personnel shall ensure that materials are properly packaged, shipping documents are completed correctly, and any required permit or license is obtained. For a summary of the shipping rules that apply, consult Appendix C of the Centers for Disease Control and Prevention’s (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL, 5th edition).

4.6 Commerce Control List
Export control laws are federal regulations that control the conditions under which certain information, technologies, and commodities can be transmitted overseas. The laws are implemented by the Department of Commerce through its Export Administration Regulations (EAR). The laws prohibit the unlicensed export of certain materials or information for reasons of national security or protection of trade. The CCL is a list of items which includes commodities, software, and technology that are found in the EAR subject to the jurisdiction of the Department of Commerce. In order to comply with EAR, personnel must consult the CCL prior to shipping biological materials overseas. Coordinate with EH&S before shipping any biological materials on the CCL.

5.0 TRAINING
Training on data input onto the On Site Biological Assistant System will be provided by EH&S on request. The On Site Biological Safety Assistant Users Manual is available on the EH&S web site.

6.0 RECORDKEEPING
EH&S will maintain training records for the current fiscal year plus the previous three fiscal years.

7.0 INSPECTIONS AND PROGRAM REVIEW
Program effectiveness will be assessed annually by EH&S.
8.0 REFERENCES

- CDC, Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
- Department of Commerce, Export of Etiologic Agents of Humans, Animals, Plants and Related Materials, 15 CFR 730 to 799
- DOT, Hazardous Materials Regulations, 49 CFR 171-180
- HHS, Use, and Transfer of Select Agents and Toxins, 49 CFR 73
- IATA, Dangerous Goods Regulations
- National Institutes of Health (NIH), Guidelines for Research Involving Recombinant DNA Molecules
- U.S. Patriot Act, U.S. H.R. 3162, Public Law 107-56
- USDA, Select Agents, Final Rule, 9 CFR Part 121 and 7 CFR 331
- OSHA, Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030