GUIDANCE ON THE INVENTORY OF BIOLOGICAL MATERIAL

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Introduction

The Federal Experts Security Advisory Panel (FESAP) was charged with providing guidance on the long-term storage and inventory of biological material. This document closely follows the guidance provided to the Select Agent regulatory community to ensure consistency in sample storage and inventory controls. An accurate and current inventory should be maintained for biological materials (i.e., infectious agents/toxins, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms).

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Definitions that apply to this document

Biological Agent – Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or other living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

Toxin – Toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or recombinant or synthesized molecules, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

Recombinant Nucleic Acids – (1) Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell or (2) molecules that result from the replication of those described in (1) above.

Synthetic Nucleic Acids – (1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules or (2) molecules that result from the replication of those described in (1) above.

Long-term storage

Long-term storage is the placement of biological materials in a system designed to ensure viability for future use, such as in a freezer or other storage container or lyophilized materials. In addition to freezers and other storage containers, the system selected by the entity to preserve specimens for future use can be appropriate to specific agents, and therefore can include, but is not limited to, refrigerators, liquid nitrogen tanks, and room temperature storage units. Long-term storage materials are not part of an ongoing experiment, have not been accessed for a significant period, or in accordance with entity policies.

All biological materials stored long-term are kept in a secure location.

Indicators of long-term storage materials

a) The material is in a highly concentrated state and would not be used in its present state without dilution to a less concentrated state.
    1. Example: A vial containing a high concentration of bacteria is removed from storage and used to inoculate several tubes of broth, and then the vial is returned to storage.
    2. Example: A vial containing a high concentration of bacteria is removed from storage to make additional aliquots (vials) of highly concentrated bacteria from the original stock(s).
    3. Example: Subcultures of highly concentrated bacteria or high titer viruses (plates, broth cultures, cell culture tubes, flasks, etc.) are used to replace the original seed stocks for experiments to be performed within a specified amount of time (e.g., 30 calendar days or in accordance with entity policy).

b) The material is not part of an ongoing experiment and will not be used for any work by the entity within a defined period (e.g., 30 calendar days or in accordance with entity policy).
    1. Example: A vial of material is not planned for use for any entity research project, diagnostic procedure, quality control or other laboratory activity within the defined period.

c) The material is not consumed within a defined period by the entity (e.g., 30 calendar days or in accordance with entity policy).
    1. Example: A vial of material is received by the laboratory but there are no plans to use the contents of the vial for any work within the defined period.
    2. Example: An aliquot is collected from an experimental protocol that is preserved for future analysis.

d) The material is placed in an environment where there is infrequent access to the environment.
    1. Example: Viruses are placed in a liquid nitrogen tank that is only accessed infrequently by a member of the laboratory (e.g., 30 or more calendar days).

Working stock

Working stocks may be defined as material, which is part of an ongoing experiment, accessed frequently, or are not stored for an extended period. All working stock materials must be kept and used in a location registered and/or approved in accordance with entity policy.

Indicators of working stock materials

a) The material has been diluted from a concentrated state and placed into multiple aliquots in the less concentrated form for immediate use (e.g., within 30 calendar days or as needed by the ongoing experiment).
b) The material is part of an ongoing experiment and will be used for work by the entity within a period as defined by experimental protocol.
c) The material is consumed as part of an ongoing experiment within a defined period by the entity (e.g., 30 calendar days or as dictated by the ongoing experiments).
d) The material is placed in an environment where there is frequent access to the material, such as a refrigerator or incubator in an active laboratory to support ongoing experiments.

Inventory and record maintenance

An entity is responsible for maintaining an accurate and current inventory of all biological material. Institutional policies and procedures should dictate what samples are inventoried, how they are recorded, and how long records must be maintained. Consideration should be given to implementing an electronic inventory tracking system and access should be limited to only those individuals approved to handle the biological material. If an entity has archived specimens that are accessed infrequently, the container may be sealed with tamper-proof material (e.g., security tape) following inventory verification, and the sealed container can be verified during self-audits. The types of material that should be inventoried will vary from institution to institution but at a minimum the following types should be tracked:

a) Infected animals and animal tissues

b) Infected arthropods

c) Infected plants

Labeling Guidance

The guidance below is to enhance material accountability through:

- The establishment of standards for labeling samples that are flexible and not overly prescriptive.
- The minimization of the potential for orphaned materials through enhanced awareness of non-select agent and toxin collections through a qualitative inventory process.
- The definition of working stocks to distinguish them from long-term inventory.

Labels on agent or toxin containers (e.g., tubes) should:

- Be legible.
- Be indelible and able to survive surface decontamination with an appropriate disinfectant and the time and temperature extremes expected during storage.
- Be permanently affixed to the container.
- Contain enough information for a rapid, visual assessment of the contents by a knowledgeable viewer, including (at a minimum):
    - Agent or toxin name
        - Agent strain or toxin isoform (if such information changes the risk, such as an attenuated strain)
    - Date of creation
    - A clear indication of whether the agent is inactivated or not (lack of information will lead to a presumption that the agent is viable, or the toxin is in a toxic form)
    - Name of Principle Investigator (PI) or responsible individual (although this could be included in the inventory records instead, it may be beneficial for laboratories to include this on labels to quickly identify who the responsible PI is or who generated/owns the samples and help resolve any issues with the samples)