Guidance on the Definition of "Long Term Storage" as Used in the Select Agent Regulations

The purpose of this document is to provide additional explanation for the term "long term storage" used in 42 C.F.R. Part 73.17 (1), 7 C.F.R. Part 331.17(1) and 9 C.F.R. Part 121.17(1).

This section of the regulations includes the requirement for an accurate inventory and is stated as, "Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as a freezer or lyophilized materials) including:"

> (i) The name and characteristics (e.g., strain designation, GenBank Accession number, etc.);
> (ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source;
> (iii) Where stored (e.g., building, room, and freezer);
> (iv) When moved from storage and by whom and when returned to storage and by whom;
> (v) The select agent used and purpose of use;
> (vi) Records created under Section 16 of 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (Transfers);
> (vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient; and
> (viii) Records created under Section 19 of 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (Notification of theft, loss, or release)"

The information that follows is intended to further assist entities working under the select agent regulations in meeting the requirements for accurate inventories of materials in long term storage.

Long-term storage: The select agent or toxin meets one or more of the following criteria:

1. The material (bacteria, fungus, virus, toxins, genetic) is in a highly concentrated state and would not be used in the present state without dilution into a less concentrated state.
    a. Example: A vial containing a high concentration of bacteria is removed from storage and used to inoculate several tubes of broth then the vial is returned to storage.
    b. Example: A vial containing a high titer of virus is removed and diluted into multiple aliquots. The original vial is considered long term storage material and the aliquots "working material" in this example.

2. The material (bacteria, fungus, virus, toxins, genetic) will not be used for any work by the entity within a defined period of time (e.g., no work with the material within 30 calendar days).
    a. Example: A vial of, bacteria, fungus, virus, toxin, is not planned for use for any entity research project, diagnostic procedure, quality control or other laboratory activity with a period of 30 calendar days or less.
3. The material (bacteria, fungus, virus, toxin, genetic) is not consumed within 30 calendar days of receipt or creation by the entity.
    a. Example: A vial of bacteria is received by the laboratory. There are no plans to use the contents of the vial for any work performed by the laboratory within the next 30 calendar days.
4. The material (bacteria, fungus, virus, toxin, genetic) is placed in an environment that is designed to extend the viability of the material for longer than the expected natural viability of the material.
    a. Example: Bacteria that have a natural viability of 3 days under permissive growth conditions are placed in liquid nitrogen to extend the viability for greater than 3 days.
    b. Example: Fungi are placed in tubes with an overlay to prevent a reduction of viable organisms.
5. The material (bacteria, fungus, virus, toxin, genetic) is placed in an environment where there is infrequent access to the environment.
    a. Example: Viruses are placed in a liquid nitrogen tank that is only accessed by a member of the laboratory every two months.

Tissue Samples:

Tissue culture fluids and tissue specimens (i.e., samples) collected from animals or plants experimentally infected with select agents or toxins do not need to be identified as long term storage material, unless the materials are prepared with the intent to store for a long period of time, or if there is no specified date established when the materials will be used. If tissue culture fluids and tissues specimens are classified by an entity as long term storage material, there is no requirement for a vial-by-vial inventory of such materials as is required for high concentration seed stock. There is a requirement to label these materials with the date placed in storage, the agent contained in the sample, and a reference identification that is recorded in a written record (inventory record, research notes, etc.). Example: Specimens are grouped according to the experimental protocol, typically by the day post- infection, and placed in secondary containers with the protocol designation and select agent/toxin identity clearly marked on both the primary and secondary containers.

If entities wish to ensure samples from animals experimentally inoculated with select agents are no longer subject to select agent requirements, documents which verify samples are free, inactivated, or attenuated of regulated select agent material should be available and provided to the Federal Select Agent program for review upon request. Samples collected from animals that are presumed to have been naturally infected (i.e., not intentionally introduced) would not be considered select agent material and required

to be handled as restricted material until the samples have been confirmed to contain select agent material.

Additional Requirements:

Any material determined to be long term storage must be maintained in a secure location and detailed, accurate records must be kept. Any material determined to not be long term storage does not require detailed, accurate records however the entity must have mechanisms in place to control the distribution of the material and to track the creation of the working material from material in long term storage. The entity is required to provide records, if requested, that document the stock source of production quantities of agents.

The entity should have protocols in place for the transfer and accountability of inventories when the investigator responsible for the inventory departs the entity as a result of change in employment, retirement, death, sabbatical, or other reasons for no longer having an active role in the entity.

Note: To facilitate inventory accountability for large long term storage collections vials of materials can be recorded and grouped into tamper proof containers and audits made of intact containers rather than audits of individual vials.