

# Select Agent Inventory Requirement

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# Regulatory Requirement

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## 42 CFR § 73.17, 7 CFR § 331.17, & 9 CFR § 121.17 Records

- (a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part.
- (b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified.
- (c) All records created under this part must be maintained for three years and promptly produced upon request.



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# Records Requirements

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**Such records must include:**

- **Accurate, current inventory for each select agent held in long-term storage**
- **Includes certain viral genetic elements, recombinant nucleic acids, and recombinant organisms**



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# Long Term Storage

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Placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials



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# Long Term Storage

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Phrases not found in 42 CFR § 73:

- “Working Stocks”
- “Reference Stocks”
- “Seed Stocks”



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# Types of Inventory Records (Select Agents)

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1. The name and characteristics of the agent  
(*strain designation, GenBank Accession number, etc.*)
2. The quantity acquired from another individual or entity  
(*containers, vials, tubes, etc., date of acquisition, and the source*)
3. Where the agent is stored, (*building, room, and freezer*)
4. Identity of person who removes the material from storage



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# Types of Inventory Records- 2

## (Select Agents)

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5. Time and date when material is removed from storage
6. If material is returned to storage, by whom?
7. The identity of the select agent used and purpose of use



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# Types of Inventory Records (Toxins)

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1. The name and characteristics of the toxin
2. The number of containers, vials, tubes, etc., acquired and the total quantity of material e.g., milligrams, milliliters, grams, etc., initially acquired
3. The date of acquisition
4. The source of the toxins
5. The current amount presently in your possession



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# Types of Inventory Records (Toxins)

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6. When a toxin is used, the identity of the toxin, the purpose of use, the quantity used, the date and the identity of the user must be recorded.
7. The location where the toxin is stored, e.g., building, room, and freezer must be recorded.
8. If a toxin is destroyed, the quantity of toxin destroyed, the date of such action, and by whom must be recorded



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# Long-term Storage Criteria

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## Concentration:

The select agent (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.



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# Long-term Storage Criteria

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## Storage Time:

The select agent 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).



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# Long-term Storage Criteria

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## Storage Time:

The select agent is not consumed within 30 calendar days of receipt or creation by the entity.



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# Long-term Storage Criteria

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## Intent to Extend Viability:

The select agent 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.



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# Long-term Storage Criteria

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## Infrequent Access:

The select agent is placed in an environment where there is infrequent access to the environment.



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# Tissue Samples

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Tissue culture fluids and tissue specimens obtained from animals or plants experimentally infected with select agents or toxins do not need to be identified as long term storage material unless:

1. The materials are prepared with the intent to store for a long period of time or,
2. There is no specified date established when the materials will be used.



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# Long Term Storage of Tissue Samples

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If the tissue culture fluids and tissue specimens are classified by the entity as long term storage material:

- 1) no requirement for a vial-by-vial inventory of such materials
- 2) but, these materials must be labeled with:
  - the date placed in storage,
  - the agent contained in the fluids or tissue, and
  - a reference identification that is recorded in written record (inventory record, research notes, etc.)



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# Questions ?



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