



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Items to Consider when Approving a Third-Party Cold Storage for Autogenous Biologics □ VSM 800.69

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Notes:

Items to Consider when Approving a Third-Party Cold Storage (will be referred to as 3rd Party Facility in this work instruction) for Autogenous Biologics – VSM 800.69

1. The firm must submit a written request to the CVB-IC for each 3rd Party Facility prior to use. If conditions do not change, CVB-IC only need to provide one-time approval for each 3rd Party Facility. This permission does not transfer from licensee to licensee. The request should address the following issues:
 - a. Temperature control during shipment to the 3rd Party Facility – including documentation
 - b. Temperature control at the 3rd Party Facility – including documentation
 - c. Temperature control during shipment to the herd/flock/veterinarian – including documentation
 - d. Tracking and distribution of serials at the 3rd Party Facility – including documentation
 - e. Permission for CVB to inspect the 3rd Party Facility
 - f. Quality agreement or process for notifying the firm regarding quality or issues impacting quality (The licensed firm may have routine audits of the 3rd party facility and have these available for CVB upon request.)
2. Shipment of autogenous products to the 3rd Party Facility may only occur after the serial is released, either 3-day release for first serials or CVB release for subsequent serials.
3. Once a 3rd Party Facility is approved, this approval is further documented in a Plot Plan Legend Addendum as a more centrally located source of information. The addendum should include the address for the 3rd party facility, the Mail Log number of the approval and permission to inspect the facility.
4. The licensed establishment is responsible for all compliance related to the maintenance and distribution of the autogenous serials by the 3rd Party Facility in accordance with the regulations. This includes but is not limited to 9 CFR 113.113(a)(2),(3) and (4), 114.11 and 116.2. Records confirming compliance should be available for review during inspection at the licensee and 3rd party facility.
5. All documents will be available and supplied for inspection. If the 3rd Party Facility refuses to supply documents, the privileges and regulatory flexibility of 3rd Party facility distribution will immediately be revoked for that distribution site.
6. Once approved 3rd Party Facility will be entered into LSRTIS
7. Recalled, returned, or expired autogenous serials.
 - a. If the testing of a first serial indicates contamination or safety issues after the 3rd day of observation, the serial may be quarantined at the e 3rd Party Facility until a retest (if performed) has been done and a final determination has been made. This is only if the 3rd Party Facility has appropriate quarantine procedures.
 - b. If the serial has already been shipped to the herd, the unused inventory should be returned to the licensee, not the 3rd Party Facility.

c. Inventory of expired serials at the 3rd Party Facility can be destroyed by the 3rd Party Facility if processes and documentation is in place. If the 3rd Party Facility is not equipped to handle or do destruction, the serials will be shipped back to the firm for destruction. The firm shall be responsible for and maintain all documentation.