



VETERINARY SERVICES MEMORANDUM NO. 800.113

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Washington, DC
20250

TO: VS Management Team (VSMT)
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: John R. Clifford /s/ John R. Clifford 9/17/08
Deputy Administrator
Veterinary Services

SUBJECT: Production, Testing and Storage of Master Seed and Master Cell Stocks at
Alternate Locations

I. PURPOSE

The purpose of this memorandum is to provide guidance regarding production, testing, and storage of Master Seeds and Master Cell stocks at locations other than the facility licensed to sell and distribute the related veterinary biologic.

II. DEFINITIONS

Applicable 9 CFR Definitions

- A. Master Seed (MS) 9 CFR 101.7(a) – An organism at a specific passage level which has been selected and permanently stored by the producer from which all other seed passages are derived within permitted levels.
- B. Master Cell Stock (MCS) 101.6(d) – The supply of cells of a specific passage level from which cells for the production of biologics originate.

III. BACKGROUND

Seed and cell stocks prepared for designation and use as an MS or MCS may be produced at the licensed establishment that manufactures the products or obtained from other sources such as other licensees, research and development firms, and universities.

In the case of products that are imported to the United States for distribution and sale, the MS and MCS are often produced and stored at a foreign manufacturing facility. Refer to VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale, for more information.



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Since products must be produced from the designated passage levels of MS and/or MCS, this material may be stored at several different locations within the licensed facility and/or, with APHIS permission, portions may even be stored off licensed premises.

IV. GUIDELINES

- A. The use of MS and MCS produced and/or tested by other sources or stored at alternate locations is permissible. The following guidelines are applicable to such MS or MCS:
 1. The licensee is responsible for maintaining copies of all records pertaining to the source and/or characterization of the MS and MCS.
 2. MS and MCS obtained from other sources must be shipped to the licensed facility accompanied by any applicable permits. Permit restrictions must be followed, and documentation related to the movement of the organism or cell stock must be maintained.
 3. Once the MS and MCS are located at the licensed establishment, the licensed establishment assumes all responsibility for the MS and MCS and compliance with applicable regulations. Starting inventory received by the licensee must be documented and all uses of this material recorded.
 4. The licensee is responsible for all 9 CFR-required testing of the MS and MCS, including any testing performed by contractors. Records (including bench records) of all 9 CFR-required testing used to support MS and MCS approval must be maintained by the licensed firm. The MS and MCS reports, submitted as per Veterinary Services Memorandum 800.109, should be submitted by the licensed firm.
- B. Storage of MS and MCS off licensed premises – A licensee must request APHIS permission to store a portion of the MS and MCS at a secure, alternate location. The request should be submitted to CVB Inspection and Compliance regarding storage at sites other than the licensed establishment. The request should include the following information:
 1. Identification of the MS and MCS, including a description of the storage containers,
 2. Amount of inventory to be stored at alternate storage location,
 3. How the containers of MS and MCS are to be secured and made tamper evident,

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4. Storage conditions for MS and MCS containers, and
5. An addendum to the plot plan legend including the following information:
 - a. Name and address of alternate storage location.
 - b. Permission to inspect off-site location by APHIS inspectors or foreign inspectors acting on behalf of APHIS. If the storage site is at another licensed facility, both establishments must submit a request for an exemption to 9 CFR 114.3(b). The licensee receiving the MS and/or MCS for storage must update their facility documents to include the storage of this material.