



VETERINARY SERVICES MEMORANDUM NO. 800.122

Animal and Plant
Health Inspection
Service

Veterinary Services

1400 Independence
Ave, SW

Washington, DC
20250

TO: Veterinary Services Leadership Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: for Jack A. Shere
Deputy Administrator

SUBJECT: Electronic Recordkeeping and Compliance with 9 CFR Part 116

I. PURPOSE

This memorandum provides guidance to licensees and permittees that intend to utilize electronic records for documenting activities associated with the manufacturing of veterinary biological products.

II. BACKGROUND

Title 9, *Code of Federal Regulations* (CFR), part 116 requires complete accountability of all activities within each establishment. The records must be detailed and include, but are not limited to, items listed in 9 CFR 116. The regulations in 9 CFR 116 are suitable for both written and electronic recordkeeping. Licensees and permittees previously adhered to the regulations by printing out an electronic record and authenticating the paper document to satisfy the requirements of 9 CFR 116. This memorandum is intended for licensees and permittees that desire to utilize an electronic record system to document activities as required by 9 CFR 116; electronic recordkeeping that demonstrates controlled reliability, authenticity, integrity, security, and usability are compliant with the requirements of 9 CFR 116.

III. POLICY

- A. Records are maintained on licensed premises unless an alternative location or an electronic service provider is authorized by the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC).
 1. The server used for storing the information, whether partial or complete information, must be maintained at the licensed or permitted site, or approved foreign manufacturing site in the case of imported products or other location(s) authorized by the CVB.

2. Alternatively, requests for utilizing an electronic service provider for electronic records may be submitted to the CVB-IC as an addendum to the plot plan legend. The request for utilizing an electronic service provider should include:
 - a. the location and identity of the electronic service provider;
 - b. the proposed process to audit the provider for compliance;
 - c. the audit of the provider.
- B. The following types of record management controls are required to ensure that electronic information systems can provide adequate and proper documentation of activities for as long as the information is required by the regulations:
 1. Reliability controls must be in place to ensure records adequately represent activities at the establishment. The electronic record generated represents the activity intended and is accurate, complete, and has not been altered inappropriately.
 2. Authenticity controls must be in place to protect against unauthorized additions, deletions, alterations, or concealment. The record shall show the creator, the date and time, and alteration.
 3. Integrity controls must be in place that allow audit trails providing evidence that records are complete and unaltered; access procedures to the system are in place and periodically audited.
 4. Security controls must be in place to ensure access to the system and servers are controlled; access to the system by personnel not employed by the licensee or permittee is controlled and auditable.
 5. Usability controls must be in place to ensure records can be located, retrieved, presented, and interpreted throughout the life cycle according to the regulations.
- C. The electronic recordkeeping system is the responsibility of the licensee or permittee. Failure to comply with 9 CFR 116 may result in regulatory action.

IV. IMPLEMENTATION/APPLICABILITY

This memorandum is effective immediately.