United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Evaluation of Electronic Record Keeping and Compliance with Title 9, Code of Federal Regulations, Part 116

Date: **June 23, 2017**

Number: ICSOP0046.02

Supersedes: ICSOP0046.01, August 25, 2016

Contact: Daniel C. Coyle, (515) 337-6124

Approvals:

/s/Steven A. Karli Date: 05Jul17
Steven A. Karli, Director
Inspection and Compliance
Center for Veterinary Biologics

United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

INTERNAL USE ONLY

Entered into CVB Quality Management System
by: /s/Linda S. Snavely 05Jul17
Linda S. Snavely Date
Quality Management Program Assistant

Evaluation of Electronic Record Keeping and Compliance with Title 9, Code of Federal Regulations, Part 116

Table of Contents

Evaluation of Electronic Record Keeping and Compliance with Title 9, Code of Federal Regulations, Part 116

1. Purpose and Scope

The purpose of this document is to provide guidance and policy for the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) Biologics Specialist Inspectors concerning the evaluation of electronic records maintained by the Licensee or Permittee.

Title 9, *Code of Federal Regulations* (9 CFR), part 116, requires complete accountability of all activities within each establishment. The records must be detailed and must include, but are not limited to, items listed in 9 CFR 116. The regulations are suitable for both written and electronic record keeping.

This document is to be used by IC personnel to assist in determining Reliability, Authenticity, Integrity, and Usability of electronic recordkeeping systems, hereafter referred to as "the system."

2. Procedures

2.1 Records are maintained on licensed premises unless authorized by the Administrator (CVB-IC) to be maintained at an alternate location [9 CFR 116.1(c)].

2.1.1 The server used for storing the information, whether partial or complete, must be maintained at the licensed or permitted site, or approved foreign manufacturing site in the case of imported products.

Requests for alternative locations, or secure cloud system provider, may be submitted to CVB-IC, as allowed for in 9 CFR 116.1(c) as an addendum to the plot plan legend. Information that should be considered when systems are maintained off licensed premises includes controls for data integrity, reliability of the system, ability to retrieve needed information, and record retention. Cloud based solutions must meet the same security requirements for data availability, integrity, reliability, and authenticity. The licensee or permittee must be able to demonstrate how the cloud based system is compliant.

2.1.2 The locations or ownership of back up or other multiple systems used in the storage of the records must also be identified and comply with the requirements set forth in this document.

2.2 Reliability – Records adequately represent activities at the establishment [9 CFR 116.1(a)(1)]. Controls are in place to ensure documentation is accurate and complete for the steps performed in the development and preparation of veterinary biological products according to the filed Outline of Production.

2.2.1 The system used for records is developed and tested in Information Technology environments separate from the production environment prior to deployment for use (production environment).

i. The system is tested and reviewed against manufacturing processes and regulatory documents (i.e., label approvals, license restrictions, outlines of production, etc.) to ensure critical steps, identification of material, amounts added or removed, unit of measure, date and time are adequately recorded.
ii. The system was approved by the Licensee or Permittee management prior to use of the system in the production environment.

2.2.2 Changes to pre-defined sequence of events must have appropriate management approval.

2.2.3 Changes to the system/records must go through a Change Control process to assure appropriate steps have been taken to assure all changes are in accordance with regulatory and statutory requirements for preparation, and distribution of veterinary biological products prior to implementation in the production environment.

i. Changes to programming code
ii. Changes to hardware
iii. Changes to software

2.3 Authenticity – Records are legible and indelible, verified by initials or signature of the person immediately responsible for the action taken [9 CFR 116.1(a)(2)]. Controls to protect against unauthorized additions, deletions, alterations, and concealment are in place.

2.3.1 Only one employee can use the electronic document at one time. Read access is acceptable for open documents, but write access should be limited to only the person working on the document.

2.3.2 Data entry errors must include information on who made the correction, when the correction was made, and why the correction was made.

2.3.3 Unalterable computer generated date and time stamps, independent from operator entries. This action documents actions such as create, modify, and delete.

2.3.4 A written policy in place regarding acceptability of electronic signature and data entry.

2.4 Integrity – Records shall be completed by the licensee or foreign manufacturer [9 CFR 116.1(a)(3)]. Controls, such as audit trails, to ensure records are complete and unaltered.

Definition: Audit trails refer to the secure time stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and/or deletion of an electronic record.

2.4.1 Security of the system must be under control.

i. The physical access to server and system must be controlled.
ii. The access to the system from outside of network must be controlled.
iii. The access from a remote location to the system must be controlled.

2.4.2 Roles are assigned in the system for specific functions as a part of Access Control.

i. Training must be provided to the employee on their role and process required to maintain system security with continuing training established.
ii. Certification and re-certification of employee roles must be performed on intervals determined by the Licensee or Permittee.
iii. A process of assignment of roles and a periodic review of the roles is performed.
iv. Access for employees no longer employed is addressed in the system appropriately.

2.4.3 A structured new employee and reoccurring training on the security of the system, employee responsibilities and management oversight, regarding security procedures is in place.

2.4.4 The system allows for an audit trail (including user identification, date, and time) for all critical entries.

2.4.5 Access to the system must be controlled through complex passwords, key card access, or other equivalent means.

2.4.6 There must be a process in place for periodic established review of audit trails by the establishment.

2.5 Usability – All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after expiration date of a product or longer as may be required by the Administrator [9 CFR 116.8]. Mechanisms are in place to ensure records can be located, retrieved, presented, and interpreted throughout the lifecycle according to the regulations.

2.5.1 Records are retrievable.

i. Archived records are complete and can be accessed and read.
ii. Audit trails must be available.

2.5.2 Upgrades in software versions, changes in hardware, addition of new equipment, and new programming codes do not inactivate or render records unusable.

2.5.3 Information retrieved is understandable.

3. Regulatory Actions

3.1 The use of electronic record keeping that does not comply with the requirements of 9 CFR 116 may constitute a risk to the final product.

3.2 The severity of the violation requires a risk evaluation by the Biologics Specialist and may require CVB Management input.

4. Summary of Revisions

Version .02

- 2.1.1 and 2.1.2 – revised
- Deleted 2.6 – no APHIS Form 2007 needed.