

Items to Consider in Evaluating Electronic Records and Digital Data

This information is to be used as a tool in evaluating electronic records and digital data to ensure compliance with title 9, *Code of Federal Regulations* (9 CFR), part 116. The information was compiled from multiple sources into one document to provide an easy accessible tool to use on inspections or when reviewing firm submissions.

Utilize Veterinary Services Memorandum No. 800.122 (Memo 800.122) as guidance as well as ICSOP0046, *Evaluation of Electronic Record Keeping and Compliance with title 9, Code of Federal Regulations, part 116*. Sections of the Memo 800.122 are referenced below. Violations to be referenced are listed if noncompliance found.

Any system that is used to document any aspect of a veterinary biological product falls under these requirements. Some of the systems may be procurement, Select Agent Program (SAP), NCAH Portal, and distribution.

I. ITEMS TO AUDIT

- a. **Proceed through each section and determine if the firm has complied or not. Yes = complied, No = Not compliant**
- b. **If not compliant, a violation of the referenced 9 CFR section may be appropriate.**
 - a) Memo 800.122 Section III. A. **Location/ownership of server(s)** where information stored.
 - a. Is the server at an alternate (unlicensed) location?
 - i. If yes, has the firm requested the alternate location?
 - ii. Has the vendor been recently audited?
 - b. Is the information filed in the facility documents?

Violation: 9 CFR 116.1(c)

- b) Memo 800.122 Section III. B. (1). Is the system reliable (**Reliability**)?
 - a. Was the system tested and testing documented prior to deployment?
 - b. Did the Management/appropriate official approve the final use of the product and is it documented?
 - c. Do the records conform to the Outline of Production?
 - d. Is date, time, user identified?
 - e. Is the unit of measure identified?
 - f. Is there a change control process and are changes documented?
 - g. Is there documentation to substantiate a change to the data through change control?

Violation: 9 CFR 116.1(a)(1)

Items to Consider in Evaluating Electronic Records and Digital Data

- c) Memo 800.122 Section III. B. (2). Is the system authentic? (**Authenticity**)
 - a. Is access controlled by a means that allows the tracking of entries to a specific person, at a specific date, and time?
 - b. Does the system have unalterable computer generated date and time stamps, independent from operator entries? This action documents actions such as create, modify, and delete and is not altered without documentation to substantiate and describe the change.
 - c. If electronic signatures are used, is there a written policy concerning use and acceptance?
 - d. Is access allowed only for those that need access?
 - e. Is there is a written protocol or procedure for access process?

Violation: 9 CFR 116.1(a)(2)

- d) Memo 800.122 Section III. B. (3 and 4). (**Integrity**)
 - a. Is the server(s) secure and limited to physical access? (This may be in vendor audit by firm.)
 - b. Is the system controlled through complex passwords, key card access, or other equivalent means?
 - c. Is there an audit trail that allows reconstruction of the course of events relating to the creation, modification, and/or deletion of the electronic records?
 - d. Are roles assigned/deleted and documented in the system for specific functions as a part of Access Control?
 - e. Is training provided to the employee on their role and system security process with continuing training established and documented (i.e., do not share passwords/login)?
 - f. Are certification and re-certification approvals of employee roles performed on intervals determined by the firm?
 - g. Is the system audited periodically for compliance by in house personnel or by a vendor?

Violation: 9 CFR 116.1(a)(3)

- e) Memo 800.122 Section III. B. (5). (**Usability**)
 - a. Are all electronic records retained for a period of two years after expiration date of a product?
 - b. Are all records retrievable and are readable?
 - c. Are older versions of software readable?

Violation: 9 CFR 116.8

Items to Consider in Evaluating Electronic Records and Digital Data

II. Regulatory Actions

- a. **Any violation that reveals that the Outline of Production was not followed or cannot substantiate that the Outline of Production was followed is a serious violation.**
- b. **See ICSOP0105, *Compliance Policy for Issuing Regulatory Actions*.**