



November 24, 2008

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 08-19

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

TO: Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS
State Veterinarians

FROM: Richard E. Hill, Jr. /s/ Richard E. Hill
Director

SUBJECT: Electronic Maintenance of Paper Records

I. PURPOSE

The purpose of this notice is to inform interested parties that records required by Title 9, Code of Federal Regulations (9 CFR), Part 116, may be archived electronically.

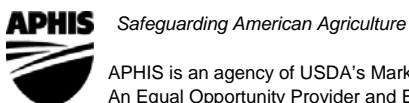
II. ACTION

All applicable records and reports must be retained by licensees or permittees in original form for inspection as provided in 9 CFR 115.1(a) from the date of the completion of the record. After 3 years, documents may be electronically archived, using a system that ensures an exact duplicate of the printed material in the original document (including color), duplexing (both sides archived), authenticity and maintains evidentiary information including but not limited to handwriting, signatures and initials. Documents larger than a standard page (e.g., large labels) should be scanned at the original size. Suitable electronic documents may be retained for the period of time required by 9 CFR 116.8 or longer.

All electronic archiving must ensure integrity and backward compatibility so that older electronic files may be retrieved. Electronic records must be printed to paper as requested by the Center for Veterinary Biologics-Inspection and Compliance (CVB). Firms may request permission to create electronic archives by submitting a plan to the CVB for review and approval.

The plan for electronic archiving should minimally include:

- The method to be used (including software and version);
- The range of dates included in the electronic archive including when older records will be deleted;



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- Verification of tamper proof electronic archives, backward compatibility of the archiving software and printing capability of the archiving software including the method used to validate these processes;
- The individual(s) having final responsibility for electronic archiving;
- The types of records to be archived;
- The location of the electronic archives. Records must be stored in a secure area and the storage location must be specified in the blueprint legends. If records are stored at an alternate location, the firm must submit an addendum to the plot plan legend listing the location of the records and the condition of their storage. The firm must also permit inspection of records stored at an alternate location in accordance with 9 CFR 116.1(c)