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# CVB Inspection and Compliance Manual

Last Modified:

This policy manual represents the Center for Veterinary Biologics (CVB) current thinking on these topics. It does not create or confer any rights for, or on any person, and does not operate to bind CVB or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the CVB staff responsible for implementing these policies.

## 1. INTRODUCTION

- Mission
  - [CVB Mission Statement](#)
  - [CVB-IC Mission Statement](#)
  - [CVB Product Monitoring Mission Statement](#) (10.66 KB)
  - [CVB Product Monitoring Strategies](#) (10.57 KB)
- History

## 2. AUTHORITIES FOR THE BIOLOGICS PROGRAM

- [Virus-Serum-Toxin Act](#) (16.44 KB)
- VS Memo 800.1

## 3. INSPECTION OF ESTABLISHMENTS - Principles (In process)

- VS Memo 800.8
- [Record Audit Inspections](#) (4.29 MB) CVB-SOP-5116 (May 6, 2022)
- [Pre-Inspection Activities](#) (3.4 MB) CVB-SOP-0034 (October 14, 2022)
  - [Process for Prelicensing Inspection Requests](#) (2.08 MB) CVB-WI-0093 (February 11, 2020)
  - [Process for Prelicensing Inspection Requests \(Inspection Approval and Scheduling\)](#) (1.03 MB) CVB-WI-5219 (February 11, 2020)
  - [Prelicensing Inspection for New Establishments/Products](#) (2.1 MB) CVB-WI-5217 (February 11, 2020)
  - [Requesting International Inspections](#) (966.36 KB) CVB-WI-0080 (December 14, 2018)
  - [International Inspection Checklist](#) (190.04 KB) ICFRM0045 (December 2, 2013)
  - [Pre-Inspection Blueprint Worksheet](#) (9.37 KB) ICFRM0001 (July 3, 2008)
  - [IC Pre-Inspection Packet Checklist - LSRTIS Information and Preparation](#) (2.59 MB) CVB-WI-0076 (September 10, 2020)
  - [Scheduling and Approval of Inspections in LSRTIS](#) (958.77 KB) CVB-WI-0119 (July 12, 2019)
  - [Inspection Items to Consider \(electronic desk file on the Mail Log\)](#) (211.12 KB) ICWI0067 (June 11, 2015)
- [The Inspection Proper](#) (59.21 KB) ICSOP0013 (August 30, 2012)
  - [VS Memo 800.91](#) (May 13, 1999)
  - [Cross References](#) (38.39 KB) (August 18, 2005)
  - [Daily Inspection Notes](#) (143.88 KB) CVB-FRM-0084 (June 1, 2009)
    - [Inspection Tools - Requested Documents and Observations](#) (270.07 KB) ICWI0035 (August 18, 2017)
    - [Inspection, Processes Observed Worksheet](#) (83.14 KB) ICFRM0026 (April 17, 2015)
    - [Inspection, Requested Document Worksheet](#) (108.99 KB) ICFRM0027 (August 18, 2017)
    - [Inspection Product Check-off Sheet](#) (195.52 KB) CVB-FRM-0083 (January 26, 2024)
  - On-site Inspection Meeting Sign-In Sheet
  - [Exemptions to 9 CFR 109.1 and 109.2](#) (79.93 KB) ICWI0028 (June 12, 2013)
  - [Inspection Techniques & Report Citing of 9 CFR 114.8\(d\) & 102.5\(c\)\(1\)](#) (192.23 KB) ICWI0237 (July 26, 2018)

- [Inspection: Findings related to 9 CFR 114.11 and Out of Cooler Episodes](#) (1.03 MB) CVB-WI-0081 (August 12, 2022)
- [CVB Inspection and Compliance Policy Concerning Compliance to Title 9 CFR 113.53 - Ingredients of Animal Origin Testing](#) (1.81 MB) CVB-WI-0083 (August 11, 2021)
- [Evaluation of Electronic Record Keeping and Compliance with Title 9, Code of Federal Regulations, Part 116](#) (169.9 KB) ICSOP0046 (June 23, 2017)
  - [Items to Consider in Evaluating Electronic Records and Digital Data](#) (66.54 KB) ICWI0146 (December 01, 2017)
- [Assessing Compliance with the Requirement of State Veterinarian Approval](#) (872.81 KB) CVB-WI-5215 (February 25, 2023)
- [Refusal of Entry for Inspection, Assault, and Bribery Procedures - ICSOP0028](#)
  - [Refusal of Entry Related to Inspections and Investigations](#) (13.08 KB) ICWI0113 (December 17, 2010)
- [Post-Inspection Activities](#) (32.65 KB) ICSOP0015 (December 27, 2010)
  - [BCA Process for Finalization of Inspection Reports](#) (926.25 KB) CVB-WI-0121 (April 1, 2020)
  - [Routing of Inspection Reports - For Specialist](#) (401.16 KB) CVB-WI-0136 (January 16, 2024)
  - [Inspection Report - Closing Action Items in LSRTIS](#) (827.27 KB) ICWI0059 (December 17, 2014)
  - [General Guidelines for Violations Attachment Report Format](#) (1.46 MB) CVB-WI-0095 (August 20, 2021)
- [Processing Administrative Inspection Reviews](#) (1.4 MB) CVB-SOP-0028 (November 4, 2019)
  - [Processing Incoming Administrative Inspection Review \(AIR\) Documents by CVB](#) (1.85 MB) CVB-WI-0144 (October 28, 2022)
- [Biologics Forms](#)

#### **4. INVESTIGATION AND PROCESSING ALLEGED VIOLATIONS OF THE VIRUS-SERUM-TOXIN ACT** (3.95 MB) **CVB-SOP-0037 (July 21, 2020)**

- [VBI Procedures](#) (294.01 KB) ICWI0016 (August 3, 2017)
- [Investigation Procedures Following a Report of Potential Lack of Efficacy Report for a Rabies Vaccine](#) (135.56 KB) ICWI0006 (August 4, 2017)
- [Tests Requested to Assist Investigations - Processes and Responsibilities](#) (193.48 KB) CVBSOP0101 (May 30, 2014)

- [Investigation Procedures Following a Report of a Disease Outbreak in an SPF Flock which Supplies SPF Eggs or Chickens for use in Vaccine Production](#) (1.09 MB) CVB-WI-0122 (May 20, 2021)
- [Veterinary Biologics Investigation Summary Sheet](#) (97.97 KB) ICFRM0016 (May 20, 2016)
- [UPS Tracking of Regulatory Letters](#) ICWI0316 (March 16, 2016)
- [Writing a Report of Investigation](#) (140.19 KB) ICWI0416 (May 18, 2016)
- [Work Flow for Initiating a Regulatory Action or Regulatory Correspondence Using the Mail Log System and Portal](#) (256.25 KB) CVB-WI-0155 (August 14, 2023)
- [IC Chain of Custody Form](#) (83.92 KB) ICFRM0108 (April 19, 2017)

## 5. PHARMACOVIGILANCE OF VETERINARY BIOLOGICAL PRODUCTS

- Receiving Adverse Event Reports at the CVB - CVB-SOP-0038
  - [Adverse Event Report Form](#)
  - Entering and Verifying Adverse Event Reports in PV-Works - CVB-WI-0123
  - [CVB Inspection and Compliance Procedure for Generating Case Summaries from PV Works System](#) (1.88 MB) CVB-WI-0127 (September 05, 2019)
  - [Reviewing, Coding and Assessing Adverse Event Reports from the Public in PV-Works](#) (5.72 MB) CVB-WI-0124 (August 10, 2021)

## 6. PROCESSING SERIAL RECORDS

- [VS Memo 800.53](#) (647.56 KB) (June 27, 2014)
- [Processing Serial Records](#) (1.91 MB) CVB-SOP-0032 (May 20, 2021)
  - [Serials Ready for Conditional Action](#) (51.79 KB) ICFRM0010 (April 28, 2017)
  - [Conditional Serial Release](#) (146.93 KB) ICWI0410 (April 28, 2017)
  - [Unit of Measure Use and Conversion for Data Entry into LSRTIS](#) (10.39 KB) ICWI0710 (March 18, 2011)
  - [Hold Management Process for APHIS Form 2008s](#) (745.13 KB) CVB-WI-0158 (May 20, 2021)
    - [Mandatory 2008 Review \(Mock Management\) in LSRTIS](#) (417.25 KB) CVB-WI-0085 (May 20, 2021)
  - [QA Process for Serial Release](#) (923.73 KB) CVB-WI-0162 (March 29, 2022)
  - [Log APHIS Form 2008](#) (208.69 KB) CVB-WI-0163 (January 2, 2020)

- Mock Checks in LSRTIS Phase II
- Review Hold Release Document - ICFRM0024
- [Processing Inventory Transfers](#) (962.98 KB) CVB-WI-0147 (July 12, 2022)
- [Extension of Dating - Process](#) (153.92 KB) ICWI0107 (July 6, 2017)
  - [Extension of Dating Worksheet - Process](#) (690.5 KB) CVB-WI-0117 (November 7, 2022)
- [Rebottling/Reprocessing - Process](#) (431.54 KB) CVB-WI-0106 (March 8, 2021)
  - [Rebottling Worksheet](#) (75.75 KB) ICFRM0006 (January 20, 2017)
- [Shortened Dating - Process](#) (1020.9 KB) CVB-WI-0130 (April 5, 2022)
- [Mail Receipt, Process, and Distribution for CVB - IC Hard Copy Submission](#) (255.84 KB) ICWI0910 (March 14, 2017)
- [Ready for Signature Action in LSRTIS \(Specialist and BCA duties\)](#) (1.42 MB) CVB-WI-0088 (August 12, 2021)
- [Processing APHIS Form 2008s for Tests Completed - UNSATISFACTORY and IF the Manufacturer challenge of the CVB Laboratory Results](#) (1.35 MB) CVB-WI-0091 (July 12, 2022)
- [APHIS Dispositions and Associated Information on Form 2008s](#) (2.46 MB) CVB-WI-0129 (May 5, 2022)
- [Audits and Reference Slips for IC Documents](#) (1.01 MB) CVB-WI-0104 (March 22, 2024)
- [Items to Consider for No Tests Regarding the Wet Chick Safety Test, 9 CFR 113.207\(a\)](#) (1.52 MB) CVB-WI-0133 (August 19, 2021)
- [LSRTIS Special Test Request Procedures for Inspection and Compliance](#) (496.91 KB) ICSOP0043 (July 10, 2017)
  - [Special Test Requests Initiated by Inspection and Compliance Staff](#) (1.01 MB) CVB-WI-0116 (February 19, 2020)
- [Processing of the APHIS Form 2007 by the CVB-IC](#) (135.3 KB) CVB-SOP-0045 (January 25, 2024)
  - [Receiving and Updating Establishment Personnel Data](#) (1.33 MB) CVB-WI-0086 (June 13, 2023)
- [Processing of APHIS Form 2008s for Prelicensing Serials, Outline Changes, or Technology Transfers](#) (632.79 KB) CVB-WI-0108 (February 11, 2021)
  - [Processing of APHIS Form 2008s for Prelicensing Serials related to Firm Mergers](#) (379.96 KB) ICWI0042 (May 16, 2013)
- [BCA Initial Review](#) (1.26 MB) CVB-WI-0164 (July 12, 2022)
- [BCA Ready for Approval](#) (1.29 MB) CVB-WI-0165 (March 8, 2022)

- Processing CVB References and Reagents
  - [Reference and Reagent Review and Release](#) (133.43 KB) CVBSOP3001 (June 5, 2015)
  - [Processing CVB Reference and Reagent Test Reports](#) (991.98 KB) CVB-WI-0167 (June 6, 2022)

**7. [PRODUCT SAMPLING](#) (2.25 MB) **CVB-SOP-0040 (January 13, 2020)****

- Reference Slip - Product Sample Submission
- [Inspection - On Site Sampler Training and Portal Submission](#) (2.14 MB) CVB-REF-5105 (March 8, 2021)

**8. [PRODUCT DESTRUCTION](#) (111.61 KB) **ICSOP0005 (June 27, 2011)****

**9. [PROCESSING FACILITY DOCUMENTS](#) (226.24 KB) **ICSOP0018 (October 6, 2017)****

- [Facility Documents: Biologics Compliance Assistant \(BCA\) Preliminary Review](#) (2.26 MB) CVB-WI-0109 (August 22, 2022)
  - [Facility Document Form Plot Plan/Plot Plan Legend - Preliminary Review \(BCA\)](#) (66.3 KB) ICFRM0018 (November 16, 2017)
  - [Facility Document Form Blueprint/Blueprint Legend - Preliminary Review \(BCA\)](#) (134.94 KB) ICFRM0019 (November 16, 2017)
- [Facility Documents: Specialist Review and Outgoing Correspondence](#) (608.74 KB) ICWI0083 (February 7, 2018)
  - [Facility Document Correspondence](#) (152.5 KB) ICTEM0045 (October 12, 2017)
  - [Facility Documents; Specialist Review, including Electronic Processing](#) (4.91 MB) CVB-WI-0115 (October 3, 2019)
- [Finalization of Facility Document Submission](#) (376.92 KB) ICWI0084 (July 3, 2018)
- General Information
  - [Listing Fractions in Facility Documents](#) (91.69 KB) ICWI0029 (October 14, 2016)
  - [Exemptions to 9 CFR Parts 109.1 and 109.2](#) (79.93 KB) ICWI0028 (June 12, 2013)
  - [General Guidelines on Designating a Building or Area Separate and Apart](#) (82.75 KB) ICWI0004 (May 25, 2017)

- [Items to Consider Regarding Facility Documents for Autologous Therapeutic Biologics](#) (367.01 KB) ICWI0082 (September 29, 2017)
- [Items to Consider When Processing Preliminary Drawings](#) (926.72 KB) CVB-WI-0131 (November 25, 2019)
- [VS Memo 800.78](#) (827 KB)
  - OMB form (as attached to CVB Notice 17-11)
  - Directions for use of OMB form (as attached to CVB Notice 17-11)
  - [Instructions for Completing the Center for Veterinary Biologics Inspection and Compliance Facility Document Submission Worksheet](#) (476.9 KB) ICWI0134 (December 26, 2017)

## **10. PROCESSING AUDITS FOR APHIS FORMS 2008 and 2071 (In process)**

- Approval of Alternate Form 2008 - ICWI0002

## **11. INSPECTION OF A FOREIGN ESTABLISHMENT (In process)**

## **12. DEPOSITION, SUBPOENAS, INFORMAL CONFERENCE AND LEGISLATIVE INQUIRY PROCEDURES**

- [Subpoena Procedures](#) (181.28 KB) ICSOP0024 (July 26, 2018)

## **13. SAFETY AND HEALTH**

## **14. INSPECTION AND COMPLIANCE POLICIES**

- [Compliance Policy for Issuing Regulatory Actions](#) (245.83 KB) ICSOP0105 (April 20, 2017)
- [APHIS Mandated Stop Distribution and Sale Procedures](#) (430.77 KB) CVB-WI-0073 (May 20, 2021)
- [CVB - IC Policy and Procedures when the Licensee/Permittee has been Granted an Animal Safety Testing Exemption Under VS Memo 800.116](#) (245.77 KB) ICWI0052 (June 26, 2014)
- [CVB Inspection and Compliance Policy Concerning Response to Firms and the Queue Process](#) (317.86 KB) CVB-WI-0150 (May 20, 2021)
- [Processes for Evaluating Compliance with Requirements of VS Memo 800.210 and VS Memo 800.57](#) CVB-WI-5218 (August 16, 2021)
- [Items to Consider when Approving a Third-Party Cold Storage for Autogenous Biologics - VS Memo 800.69](#) (1.25 MB) CVB-WI-5291 (March 8, 2022)

- [Items to Consider for Autogenous Vaccines in Relation to VS Memo 800.69 and 9 CFR 113.113](#) (1.98 MB)CVB-WI-5304 (November 10, 2022)

## **15. GENERAL OFFICE GUIDELINES**

- [Outgoing Correspondence](#) (132.23 KB) ICSOP0011 (April 28, 2017)
  - [CVB-IC Mail/Filing](#) (14.67 KB) ICWI0111 (August 14, 2013)
- [General Inspection and Compliance Correspondence Guidance](#) (163.81 KB) ICSOP0042 (April 4, 2016)
- [Receipt of Submissions from CVB-PEL](#) (211.6 KB) CVB-WI-5209 (August 30, 2019)
- [Inspection and Compliance Correspondence \(LSRTIS, Mail Log Procedures\)](#) (4.19 MB) CVB-SOP-0049 (May 10, 2022)
  - [BCA Entry and Review of Incoming Correspondence](#) (1.15 MB) CVB-WI-0100 (March 29, 2022)
  - [IC Inbox Queue](#) (111.4 KB) CVB-WI-0102 (August 7, 2023)
  - [Linking Documents Within the LSRTIS Mail Log System](#) (202.11 KB) ICWI0074 (September 1, 2016)
  - [Audits and Reference Slips for IC Documents](#) (1.01 MB) CVB-WI-0104 (March 22, 2024)
  - [Mail Log Work Flow for Correspondence for Inspection and Compliance: Section Leader Review](#) (1.16 MB)CVB-WI-0105 (March 8, 2022)
  - [Mail Log Work Flow for Correspondence for Inspection and Compliance: Biologics Specialist Review](#) (1.02 MB) CVB-WI-0139 (May 20, 21)
- Inspection and Compliance Weekly Report to the President Examples CVB-WI-0125
- [Program Coordinator Duties](#) (109.47 KB) CVB-WI-0090 (August 23, 2023)

## **16. REFUSAL OF ENTRY, ASSAULT AND BRIBERY PROCEDURES**

- USDA Secretary's Memorandum 4430-2
- USDA Departmental Regulation 4200-001
- USDA Handbook on Workplace Violence Prevention and Response
- APHIS Form 259-R, Workplace Incident Report
- USDA Ethics Training

## **17. GENERAL COMPUTER GUIDELINES**



- CVB Inspection and Compliance Policy Concerning Email Message Regarding Trade Secrets Act - CVBWI0215

## **18. EXPORT ACTIVITIES**

- [Export Certificates and Certificates of Licensing and Inspection](#) (395.91 KB) ICSOP0044 (July 5, 2018)
- [Entry and Primary Review of Export Documents \(APHIS Form 2017 and Certificates of Licensing and Inspection\)](#) (592.02 KB) ICWI0068 (July 6, 2018)
- [Secondary Review of Export Documents \(APHIS Form 2017 and Certificates of Licensing and Inspection\)](#) (400.39 KB) ICWI0069 (July 6, 2018)
- Finalization and Mailing of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection) - ICWI0070
- [Export Information](#) (128.65 KB) ICWI0063 (November 01, 2016)
- [Submitting Letter to the U.S. Department of State Office of Authentications](#) (550.36 KB) CVB-WI-0094 (March 7, 2019)
- [Audits and Reference Slips for IC Documents](#) (1.01 MB) CVB-WI-0104 (March 22, 2024)

## **19. MISCELLANEOUS**

- The Inspection and Compliance Review Process for Veterinary Biologics Program Documentation Intended for Publication - ICSOP0002
- Calculation and Reporting of Inspection and Compliance Workload Indicators - ICSOP0027
  - Workload Indicator Calculations for On-Site Inspections - ICWI0127
  - Workload Indicator Calculations for Product Inspection - ICWI0227
  - Workload Indicator Calculations for Compliance - CVB-WI-0149
  - Monthly Workload Indicator Calculations for Pharmacovigilance - CVB-WI-0153
  - Workload Indicator Calculations for Imported Product - CVB-WI-0156
  - Workload Indicator Calculations for Policy Documents - ICWI0927
  - Tracking Customer Service using LSRTIS Phone Log - CVB-WI-0141
- [Processing United States Veterinary Permits for Importation and Transportation of Controlled Materials and Organisms and Vectors \(VS Form 16-6A MAR 95\)](#) (320.28 KB) ICSOP0032 (March 22, 2018)
  - [Review, Electronic Filing, and Disposal of United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors \(VS Form 16-6A\)](#) (186.06 KB) ICWI0032 (March 23, 2018)

- Center for Veterinary Biologics Inspection and Compliance Biologics Specialist Training Plan - ICFRM1001
- [Processing CVB Reference and Reagent Test Reports](#) (94.06 KB) ICWI3001 (November 16, 2011)
- Nonconforming Work-AIRs - ICWI0020
- Training Plan for BCAs - ICFRM0021

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