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CVB Inspection and Compliance Manual

Last Modified:

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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](#) (237.3 KB) CVB-FRM-0082 (April 29, 2025)
 - [Scheduling and Approval of Inspections in LSRTIS](#) (958.77 KB) CVB-WI-0119 (July 12, 2019)
- [The Inspection Proper](#) (5.95 MB) CVB-SOP-0035 (March 8, 2022)
 - [VS Memo 800.91](#) (May 13, 1999)
 - [Cross References](#) (38.39 KB) (August 18, 2005)
 - [Daily Inspection Notes](#) (257.36 KB) CVB-FRM-0084 (April 29, 2025)
 - [Inspection Tools – Requested Documents and Observations](#) (191.62 KB) CVB-WI-0074 (December 21, 2023)
 - [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](#) (134.55 KB) CVB-WI-0135 (October 22, 2024)
- [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](#) (1.36 MB) CVB-SOP-0036 (March 08, 2022)
 - [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 CVB-WI-0095
- [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](#) (602.09 KB) CVB-WI-0122 (December 21, 2023)

- UPS Tracking of Regulatory Letters CVB-WI-0148
- [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 CVB-WI-0155](#) (979.39 KB) (August 30, 2024)
- [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)
 - [Serial Release - Conditional Serial Release](#) (538.23 KB) CVB-WI-0151 (July 20, 2020)
 - [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)
 - Mock Checks in LSRTIS Phase II
 - [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](#) (114.57 KB) CVB-WI-0106 (September 13, 2024)
 - [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)
- [Serial Release - APHIS Dispositions and Release Criteria On Form 2008s](#) (883.08 KB) CVB-WI-0129 (September 12, 2024)
- [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](#) (763.73 KB) CVB-WI-0086 (September 10, 2024)
- [Processing of APHIS Form 2008s for Prelicensing Serials related to Firm Mergers](#) (379.96 KB) ICWI0042 (May 16, 2013)
- [Serial Release - BCA Initial Review](#) (484.86 KB) CVB-WI-0164 (March 22, 2024)
- [BCA Ready for Approval](#) (1.29 MB) CVB-WI-0165 (March 8, 2022)
- Processing CVB References and Reagents
 - [Reference and Reagent Review and Release](#) (145.3 KB) CVB-SOP-3001 (September 18, 2024)
 - [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)

- [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)

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)
- [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

- [General Inspection and Compliance Correspondence Guidance](#) (142.48 KB) CVB-SOP-0046 (January 22, 2024)
- [Receipt of Submissions from CVB-PEL](#) (211.6 KB) CVB-WI-5209 (August 30, 2019)
- [Inspection and Compliance Correspondence \(LSRTIS, Mail Log Procedures\)](#) (421.25 KB) CVB-SOP-0049 (August 6, 2024)

- [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—This chapter is intentionally blank.

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
- 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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