

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Policy/Procedure

**Delegation of Authority for Center for Veterinary
Biologics-Inspection and Compliance**

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Date: 09Feb16

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Entered into CVB Quality Management System by: <u>/s/Linda S. Snively</u> <u>09Feb16</u> Linda S. Snively Date Quality Management Program Assistant
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Delegation of Authority for Center for Veterinary Biologics-Inspection and Compliance

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Delegation of Authority for Center for Veterinary Biologics-Inspection and Compliance

1. Purpose and Scope

The purpose of this document is to provide guidelines to employees of the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) Program staff concerning authorities that have been delegated by the Inspection and Compliance Management Team (ICMT) to others who have been designated as Acting. The scope of this document does not cover employees of the Information Management Unit (IMU) or the Safety and Security Unit (SSU).

Positions that require Actings to be designated and the times they are to be available, either in person or via teleworking:

- IC Director (M-F 9 a.m. – 3 p.m.)
- Section Leaders (M-F 9 a.m. – 3 p.m.)
- Program Coordinator (M-F 8 a.m. – 4 p.m.)

The CVB-IC Program Support Assistant (PSA) is notified of Acting designations and sends an email notification to CVB All in advance for scheduled absences. Only full day absences require a delegated Acting.

2. Procedures

2.1 Time and Attendance/Leave

- CVB-IC Section Leaders approve time and attendance and leave.
- CVB-IC Section Leaders are responsible for adding leave, flex time, and telework days to the IC calendar if over 4 hours.
- Leave requests are handled through Web TA and only Section Leaders, the IC Director, the Assistant Director, or the CVB Director should approve for the current or subsequent pay periods. Leave requests may be granted for the current pay period by an Acting who has previously been assigned the “Supervisor” role in WebTA. This is not the same as a WebTA delegation of authority. To be designated as a supervisor requires additional clearance from Marketing and Regulatory Programs Business Services (MRPBS).

Requests for leave beyond the following pay period will be held for the supervisor to approve upon their return to the office. If there is an unusual circumstance and approval is needed prior to the supervisor’s return, the leave request is forwarded to the next level of management.

2.2 Personnel Actions

- Actings are responsible for reporting all performance concerns to the supervisor.

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- Any employee is required to report unethical practices to their supervisor or other authority at any time under the *Standards of Ethical Conduct for Employees of the Executive Branch*. To further emphasize, any Acting is required to report misconduct or unethical practices to their immediate supervisor, the IC Director, or the CVB Director.
- Serious or dangerous conduct issues must be immediately reported to the next higher level of management.
- Actings do not take personnel actions without management direction.

2.3 Meeting Attendance

- The Acting Section Leader attends all ICMT meetings during the Section Leader's absence unless informed otherwise.

2.4 Communications

- Actings are responsible for keeping management and subordinates informed of appropriate information and situations, including situations that affect their availability.

2.5 Training Approval

- The Section Leader evaluates training requests and recommends training to the IC Director.
- Actings do not approve training requests unless on a long term detail (90 days or more).
- Training requests are reviewed and approved by the ICMT. Input from the Directorate is sometimes necessary.

2.6 Workload Indicators

- If the Section Leader or responsible person is not available to provide monthly workload indicators, it is their responsibility to recruit someone who can provide the data or make arrangements with the IC Director for an extension to the deadline. Information on completing workload indicators is located on info (\\iaamvsfs11\CVB Specific\notes\cvb-ic\IC Workload Indicators).

2.7 Procurement Requests (PRs)

- Office purchases are approved through the Section Leader.
- All procurement requests in excess of \$500 go to the IC Director.
- Except where otherwise noted, Actings do not approve procurement requests unless detailed in the position for 90 days or longer.

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- The CVB-IC PSA is responsible for forwarding all procurement requests to the Acting IC Director. If that individual is not already a purchase approver in the procurement system, they are to work with a member of the CVB Directorate for approval.

2.8 Travel

- Travel authorizations and vouchers (including international travel) are approved by the IC Director or Acting IC Director. In the event the IC Director or Acting is not available, CVB Directorate support staff may obtain a next higher level approval for travel authorizations.
- International Travel Notifications are approved by the IC Director or Acting prior to the IC PSA sending to the appropriate personnel.
- The IC Director or Acting will sign the Decision Memorandum for creation of new Cooperative Service Agreement (CSA) trust funds in support of international inspections.

2.9 Inspection Approvals

- The Inspection Section Leader provides a list of sites to be inspected each fiscal year; approves all inspections in LSRTIS and adds them to the IC calendar; and provides the information to the CVB Financial Technician for inclusion in the CVB Travel plan.
- Only IC Management may approve inspections in LSRTIS. If needed, the Compliance Section Leader or the IC Director may approve in-depth, special, and follow-up inspections.
- The Inspection Section Leader or Acting is contacted by Policy, Evaluation, and Licensing (PEL) by means of the process outlined in **ICWI0012**, *Requesting Special Inspections*, for prelicense or special inspections. Actings must further discuss these inspections with the IC Director.
- The Inspection Section Leader assigns personnel to international inspections.
- The IC Director will gather information for the CSA Information Document and works with the Biologics Specialist and the CVB Management and Program Analyst to finalize the CSA.
- The IC Director will approve the international inspection budget prior to sending on to the permittee. In the event the IC Director is not available in a reasonable time frame, CVB Directorate staff may approve the proposed budget.

2.10 Inspection Report Review

- The Section Leader or the Acting Section Leader for the Inspection Team Leader is responsible for the initial review.

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- The Inspection Section Leader or their Acting conducts the policy review of the Inspection Report.
- The final review of the completed Inspection Report is performed by the Inspection Section Leader or Acting Inspection Section Leader. This includes initialing the front page of the Inspection Report and the yellow copy of the cover letter.

2.11 Serial Release

- Early or Conditional Releases
 - These actions are authorized by any IC Section Leader or Product Specialist.
 - Acting IC Section Leaders may authorize these actions as well.
- Hold Release
 - See **Section 2.17**, Regulatory Notifications.
- The Product Specialist designates the Program Coordinator (PC).

2.12 Export Certificates/Certificates of Licensing and Inspection

- The Export Manager is responsible for review and validation of Export Certificates and Certificates of Licensing and Inspection.
- The Acting Export Manager reviews and validates Export Certificates and Certificates of Licensing and Inspection.

2.13 Investigations

- The Compliance Section Leader or Investigation Manager assigns Veterinary Biologic Investigations (VBIs).
- The Acting Compliance Section Leader does not assign VBIs. The order of succession for assigning VBIs is as follows: 1) Investigation Manager, 2) IC Director.

2.14 Regulatory Notifications

- The Compliance Section Leader signs all APHIS-mandated stop distribution and sale letters, hold release notifications, letters of warning, and infraction notices.
- The Acting Compliance Section Leader does not sign hold release notifications, APHIS-mandated stop distribution and sale letters, letters of warning, and infraction notices. The order of succession for signing these letters and initialing the yellow copies is as follows: 1) Investigation Manager, 2) other IC Section Leader, 3) IC Director, 4) Acting IC Director following consultation with the PEL or CVB Director.
- The Compliance Section Leader reviews all letters of advice for policy.

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- The Acting Compliance Section Leader does not review letters of advice for policy. The order of succession for reviewing these letters and initialing yellow copies is as follows: 1) Investigation Manager, 2) other IC Section Leader, 3) IC Director.
- Voluntary stop distribution and sales are confirmed by the Biologics Specialist for the firm through an acknowledgement letter.

2.15 Final Review of All Other Correspondence

- All outgoing correspondence (yellow copy) other than Inspection Reports and Regulatory Notifications must be initialed by an IC Section Leader or the IC Director.
- Acting Section Leaders may not do this final review.

2.16 Pharmacovigilance

- The Senior Biologics Epidemiologist is responsible for the Adverse Events Report (AER) database. In the Senior Epidemiologist's absence, an acting is appointed for day-to-day Epidemiologist duties but only those properly trained and with access will run AER reports.

3. Summary of Revisions

Version .06

- **1:** Changed the hours the Director needs to be in office.
- **1:** Removed Export Manager and Senior Biologics Epidemiologist as positions requiring an Acting.
- **2.1:** Changed verbiage clarifying that Actings who are not a Section Leader, IC Director, Assistant Director, or CVB Director cannot approve leave for the current or following pay period

Version .05

- **1:** "Does not cover employees of the Safety and Security Unit (SSU)" has been added.
- **1:** "Senior Biologics Epidemiologist as a position requiring an Acting" has been added.
- **2.1:** Minor changes to wording
- **2.3:** Removed Expanded Management Team (ECVBMT)

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- **2.5:** Removed ECVBMT
- Removed Sections 2.8 – 2.10
- **2.12:** Incorporated LSRTIS and changes to wording
- **2.14:** Added Product Specialist
- **2.19:** Added Senior Biologics Epidemiologist Acting Role

Version .04

- The Contact information has been updated.
- This document has been updated to better reflect the procedures needed to meet the needs of the Inspection and Compliance Unit.

Version .03

- The Program Coordinator has been added to the list of positions needing Actings.
- This document has been updated to better reflect the procedures needed to meet the needs of the Inspection and Compliance Unit.
- The section on “Country Clearance” has been removed from the document.
- The section on “CVB Administrative Directorate Responsibilities not Covered by Acting”.
- References to the Assistant Director have been removed from the document as this position is no longer under the Inspection and Compliance Unit.

Version .02

- Table of Contents has been added.
- **1** Hours changed to reflect more accurate business needs.
- **2.1** “Personnel Actions” has been separated out into its own section.
- **2.10** “Access to Email Groupings” has been added.
- **2.14** “Inspection Report Review” has been added.

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- **2.18** “Regulatory Notifications” has been added.
- **2.19** “Final Review of All Other Correspondence” has been added.
- Further clarification of duties allowed/not allowed for Actings have been added throughout the document.