Background - See current version of **ICSOP0035**, *Processing of the APHIS Form 2007* by the Center for Veterinary Biologics-Inspection and Compliance.

# I. Receipt of APHIS Form 2007 (Form 2007) through the NCAH Portal (see Appendix I)

#### A. Receipt:

All Form 2007s are received by CVB-IC. If Form 2007s are received by CVB-PEL, in the case of establishments in the prelicensing phase, hard copies are given to CVB-IC for initiation of the work flow.

No Mail Logs for Form 2007s will be initiated by CVB-PEL. If a 2007 is received from the firm via NCAH Portal 2049s, this will be returned to the firm and instructed to re-enter into the 2007 module of the NCAH Portal.

If a submission is received from the NCAH Portal, the submission will be directly routed to the CVB-IC Inbox in Mail Log. This inbox should be monitored daily. The Biologics Compliance Assistant (BCA) assigned to the firm will "self-assign" the Mail Log item.

## B. BCA Review (Review of Form 2007 for sufficiency)

- 1. Is the form Complete/Sufficient?
  - If Okay, go on to Step B.2.
  - If not, return to the firm with Approval set to No, and reason(s) in the Remarks.
- **2.** Is the submission requesting for an employee to be a <u>Liaison or Alternate</u>?
  - Child loop to the Reviewer should be initiated (Liaison Approval Request).
  - The Reviewer will review and Approve or Deny within the Mail Log (if initiated from the NCAH Portal), with Response "Acknowledged by <name>" or if denied, state reason in the Response. This is done by Editing the Mail Log record.
- **3.** Is the submission *inactivating* a Liaison or Alternate?
  - Child loop to the Reviewer should be initiated (Liaison Approval Request).
  - The Reviewer will NOT have to Approve or Deny within the Mail Log as this automatically is set to Approve (YES).
- **4.** Is the submission requesting for an employee to be a <u>Sampler</u>?
  - The Mail Log should be submitted to the Specialist.
  - The Specialist will review and Approve or Deny within the Mail Log (if initiated from the NCAH Portal), by Editing Mail Log item #xxxx,

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with Response "Acknowledged by <name>" or if denied, state reason in the Response.

- If Denying confer with IC Section Leaders first.
- The request from the firm should have documentation that the employee had been trained in accordance with Veterinary Services Memorandum (VSM) No. 800.59.

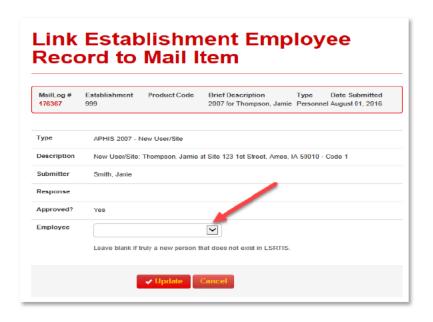
#### 5. All other Form 2007s

- The Mail Log should be routed to the Specialist.
- The Specialist should then review the information for completeness and validity of the Form 2007.
- The Specialist will review and Approve or Deny within the Mail Log (if initiated from the NCAH Portal), by Editing Mail Log item #xxxx; no Response is needed unless the Form 2007 is denied.
  - If Denying confer with IC Section Leaders first.
- **6.** The Specialist will then return the Form 2007/Mail Log to the BCA under the Mail Log action of Finalization for entry into LSRTIS.

#### C. Finalization

 New Form 2007: These Form 2007 may now be automatically updated (as of September 2016).

To perform the automatic update, click on the "Set to Employee link" in the Mail Log record. Then in the Employee field, either choose an existing employee record in LSRTIS, or leave blank if a new record should be created.



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- 2. <u>Modified Employee Information 2007:</u> No manual LSRTIS entry is needed, LSRTIS will automatically update upon completion (and a portal push) of the Mail Log for those Form 2007s that have "Yes" for the Approval status.
- 3. <u>Inactivate User 2007</u>: No LSRTIS entry is needed. LSRTIS will automatically update upon the firm submission to the CVB.
- D. Work Flow Complete No Records Management

#### **II. Receipt of Hard Copy Form 2007s** (See Appendix II)

- A. When a hard copy Form 2007 and cover letter are received by CVB-IC, the BCA stamps the Form 2007 with the date received in the office and hand writes the establishment number, "Pers. Corr," and the responsible Specialist in the upper right corner of the cover letter, if applicable. They add the Mail Log number to the Box 6 on the form.
- B. The Submission is entered into the Mail log.
- C. BCA Review (**Review of Form 2007 for sufficiency**)
  - 1. Is the submission requesting for an employee to be a <u>Liaison or Alternate</u> Liaison?
    - Draft Liaison authorization letter in accordance with the Template Liaison Approval Letter and upload into the Mail Log item.
    - Child loop to the Reviewer will be initiated (Liaison Approval Request).
    - The Reviewer will review and Approve or Deny by accepting the letter as is, or re-drafting the letter with their response.
    - Upon Finalizing the Mail Log, the BCA will gather the Reviewer's signature and mail the letter to the firm.
  - 2. Is the submission *inactivating* a Liaison or Alternate Liaison?
    - Child loop to the Reviewer (Liaison Approval Request).
    - The Reviewer will NOT have to Approve or Deny the request, unless they take exception with the request.
  - 3. Is the submission requesting for an employee to be a <u>Sampler</u>?
    - The Mail Log is submitted to the Specialist.
    - The Specialist will review and Approve or Deny by drafting a Sampler request letter. Requests for Sampler authorization must be granted by the Specialist prior to LSRTIS entry. The most current version of ICTEM0023, Sample Authorization Letter, should be utilized.
    - The request should have documentation that the employee had been trained in accordance with VSM 800.59.

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## 4. All other Form 2007s

- The Mail Log should be routed to the Specialist.
- The Specialist should then review the information for completeness and validity of the Form 2007.
- The Specialist will review the Form 2007 and initial/date the hard-copies.
  - o If the Specialist returns the Form 2007 unprocessed, the reason must be documented in a letter.
  - The only field that may be filled in or corrected by the Specialist or BCA is Block 1.D, Establishment License Number. This is usually only required for prelicensing firms.
  - o If the firm is reporting other types of changes to its personnel roster, the Specialist reviews the Form 2007 and/or organizational chart. If it is acceptable, a response letter is not required. The Specialist initials the top right-hand corner of the organizational chart and returns the submission to the appropriate BCA. The Specialist initials and dates Box 6 on the Form 2007.
- 5. The Specialist will then return the Form 2007/Mail Log to the BCA under the Mail Log action of Finalization for entry into LSRTIS.

#### **D.** Finalization

- Hard copy Form 2007s:
  - The BCA will create a child loop to the activity "Pending LSRTIS 2007 Entry" until they are ready to enter the information into LSRTIS and close the child loop 2. Once entered, the BCA writes the word "Entered" on the Form 2007, initials/dates.
- Finalization of any attached letter to be done at this point.
- **III. Manual LSRTIS Entry:** To access the Establishment Employee module, login to LSRTIS and choose the Licensing drop-down.
  - A. Before Updating Personnel in LSRTIS:
    - 1. Under Licensing, run an "Establishment Employee Search" report on LSRTIS.
    - 2. If Employee exists in LSRTIS, follow instructions "Current Employees."
    - 3. If Employee does not exist in LSRTIS, follow instructions "New Employees."
  - B. <u>Current Employee</u>: After running the "Establishment Employee Search" report and verifying that the employee is in LSRTIS, follow the directions below. For all changes:
    - 1. Click "Show" next to the employee's name
    - 2. Verify that Employee Info, Contact Info, and Establishment Employee Education Info are correct

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- 3. If it is not correct, click on "Edit" and update the information that needs to be corrected, then click on "Update."
- C. To Add or Remove Role(s):
  - 1. Under Establishment/Roles, click on "Show" for the correct Est. number
  - 2. Click on the Edit button
  - 3. To Add Role, click on drop down, choose role, and click on +Add Role
  - 4. To remove a role, click on red X by the role to be removed
  - 5. If applicable, enter the mail log item(s) associated with the update
  - 6. After complete click on "√ Update"
- D. To Add Establishment:



- 1. Under Establishment/Roles, click on Add New Establishment/Role
- 2. Fill in Establishment, Site, Year Employed at Firm, Job Title, Most Recent 2007 Date (date signed by employee), Mail Log Item and Add Roles
- Click on "√Create"
- E. To Remove/Inactivate Establishments:
  - 1. Under Establishment/Roles, click on "Show" for the correct Est. number
  - 2. Click on Edit and unmark "Active" box
  - 3. Click on "√ Update"
- F. To Inactivate Employee (if only assigned to one firm): In the Show Establishment Employee screen, click "Inactivate" at the bottom of the screen. This will inactivate both the employee and their associated establishment/roles.
- G. To verify any of the actions above, click on the Employee's name (within the blue box) and verify that the actions taken match the information on the Form 2007 and correspondence.
- H. <u>New Employee</u>: After running the "Establishment Employee Search" report and verifying that the employee is not in LSRTIS, follow the directions below.
  - 1. Click on the "Create Establishment Employee" link on the top left of the page
  - 2. Enter Establishment Employee Info to include comments
  - 3. Enter Establishment Employee Contact Info, if applicable

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- 4. Enter Establishment Employee Education Info
- 5. Click "Create"
- 6. Under Establishment/Roles (last category of the page) click the link "Add New Site/Role"
- 7. Enter the Establishment information to include Mail Item #. If there is a role, remember to click "+Add Role" after you have selected the role.

To verify information, follow steps in Section II.G.

### IV. Filing

- A. No hard copy files will be maintained for NCAH Portal submissions.
- B. Hard copy Files not CAH Portal submissions
  - 1. Superseded Form 2007: If the Form 2007 supersedes a Form 2007 currently on file, the BCA removes the superseded Form 2007 from the Active Personnel file. The BCA marks through it with a diagonal line and labels it as "Superseded," along with their initials and date. The BCA then staples the superseded Form 2007 to the cover letter and files this packet in the Personnel Correspondence file for the firm.
  - 2. Obsolete Form 2007: The BCA removes the obsolete Form 2007 from the Active Personnel file. The BCA marks through the Form 2007 with a diagonal line and labels it as "Obsolete," along with their initials and date. The BCA then staples the obsolete Form 2007 to the cover letter and files this packet in the Personnel Correspondence file for the firm.
- C. General information regarding filing of Hard Copy Form 2007
  - 1. The BCA files the Form 2007 in the firm's Active Personnel file in alphabetical order.
  - 2. Approved Sampler: Files the yellow file copy of the Sampler authorization letter in the Personnel Correspondence file.
  - 3. Files organizational charts, if submitted, in the Personnel Correspondence file.

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Appendix I

Inactive 2007: Automatic LSRTIS U<sub>I</sub> upon submission of I

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Source Document: Veterinary Services Memorandum No. 800.63, Personnel at Licensed Establishments

Appendix II

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Source Document: Veterinary Services Memorandum No. 800.63, Personnel at Licensed Establishments