Receiving and Updating Establishment Personnel Data

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

Background - See current version of **CVB-SOP-0045**, *Processing of the APHIS Form 2007 by the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC)*.

I. Receipt of APHIS Form 2007 (Form 2007) through the <u>NCAH Portal</u> *(see Appendix I)*

A. Receipt:

All Form 2007s are received by the CVB-IC. If Form 2007s are received by the CVB-Policy, Evaluation and Licensing (PEL), in the case of establishments in the prelicensing phase, Hard Copies are given to the CVB-IC for initiation of the workflow.

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

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

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

1. Is the form Complete and accurate?
   - Fields that must be filled out: Name, Est #, Site Address, Title, Year Employed
   - If acceptable, go on to Step B.2.
   - If it is unacceptable, return to the firm with Approval set to "No", and enter the reason(s) in the Remarks. The close the ML select Workflow Completed, No Records Management.

2. The BCA should search for the employee's record (either with the same firm or a different firm). *See Section C if applicable*.
   - If a record is found to be an exact match that is inactive, the records should be linked.
   - If a record is found, with another active firm, discussion with the IC management team should be held to determine if shared employee status is permissible. Letters should be on file with both establishments if there is not license documentation on file (APHIS Form 2001 or 2003).
   - If a record is found, within the same firm, these may be returned unprocessed for the firm to resubmit as a "Modify" or "Reactivate" Form 2007. See NCAH Portal guidance, <u>Qualifications of Veterinary Biologics Personnel</u>, Guide # 4.

3. Is the submission requesting for an employee to be a <u>Liaison or Alternate</u>?
   - A Child loop to the Reviewer should be initiated (Liaison Approval Request).

- The Reviewer will review and Approve or Deny within the ML (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 ML record.
- Move on to Step 7.

4. Is the submission *inactivating* a <u>Liaison or Alternate</u>?
   - A Child loop to the Reviewer should be initiated (Liaison Approval Request).
   - The Reviewer will NOT have to Approve or Deny within the ML as this automatically is set to Approve (YES).
   - Move on to Step 7.

5. Is the submission *inactivating* other than <u>Liaison or Alternate</u>?
   - Move on to Step C. Finalization.

6. Is the submission requesting for an employee to be a <u>Sampler</u>?
   - The ML should be submitted to the Specialist.
   - The Specialist will review and Approve or Deny within the ML (if initiated from the NCAH Portal), by Editing ML and entering in the Approval area: item #xxxxxx, with Response "Acknowledged by <name>" or if denied, state the reason in the Response.
     - If Denying – confer with the IC Section Leaders first.
   - The request from the firm should have documentation attached that the employee had been trained in accordance with Veterinary Services Memorandum (VSM) No. 800.59.

7. <u>All other Form 2007s</u>
   - The ML 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 ML (if initiated from the NCAH Portal), by Editing Mail Log item #xxxxxx; no response is needed unless the Form 2007 is denied.
     - If Denying for reasons other than format of submission – confer with the IC Section Leaders first.

8. The Specialist will then return the Form 2007/ML to the BCA under the ML action of "Finalization" for entry into LSRTIS.

C. Finalization

1. <u>New Form 2007:</u> These Form 2007s may now be automatically updated (as of September 2016).

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

Questions on whether an employee is the same can be addressed with the assigned Biologics Specialists.

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 ML 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. Workflow Completed – "No Records Management"

II. Receipt of <u>Hard Copy</u> (HC)Form 2007s *(See Appendix II)*

A. When a HC Form 2007 and cover letter are received by the CVB-IC, the BCA or alternate, will scan the Form 2007s.

B. The Submission is entered into the ML and the scanned documents are uploaded as incoming submission.

C. BCA Review **(Review of Form 2007 for sufficiency).**

1. Is the submission requesting for an employee to be a <u>Liaison or Alternate Liaison</u>?
   - Draft Liaison authorization letter in accordance with the Template,

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CVB-TEM-0039, *Liaison/Alternate Approval Letter* and upload into the ML item and add to the ML item.

- A 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 ML, the BCA will obtain the Specialist's signature and mail the letter to the firm.

2. Is the submission *inactivating* a <u>Liaison or Alternate Liaison</u>?
- A 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 ML 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 **CVB-TEM-0028**, *Sample Authorization Letter*, should be utilized.
- The request should have documentation that the employee had been trained in accordance with VSM 800.59.

4. <u>All other Form 2007s</u>
- The ML 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 HCs.
  - o If the Specialist returns the Form 2007 unprocessed, the reason must be documented in a letter
  - o The only field that may be filled in or corrected by the Specialist or BCA is Block 1.D, Establishment (Est.) 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/ML to the BCA under the ML action of Finalization for entry into LSRTIS.

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D. Finalization
- HC Form 2007s:
  The BCA will create a Child loop to the activity "Pending LSRTIS 2007 Entry" if Prelicense, or 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 must 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. Current Employee: 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
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 ML 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".

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2. Fill in Establishment, Site, Year Employed at Firm, Job Title, Most Recent Form 2007 Date (date signed by employee), ML Item and Add Roles
3. 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
 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 ML #. 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 HC files will be maintained for the NCAH Portal submissions.

 B. HC Files – not the NCAH 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 HC 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.

V. Consultants for Licensed Manufacturers

A. When a firm representative has submitted official correspondence allowing a consultant to be able to communicate to the CVB on behalf of the firm, the CVB should file this information within the ML.
- PEL Reviewers should tag this correspondence as "Authorized Consultant."

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Appendix I

jmw, 8/3/2022

CVB-WI-0086.05
Issue Date: 13Jun23

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Receiving and Updating Establishment Personnel Data

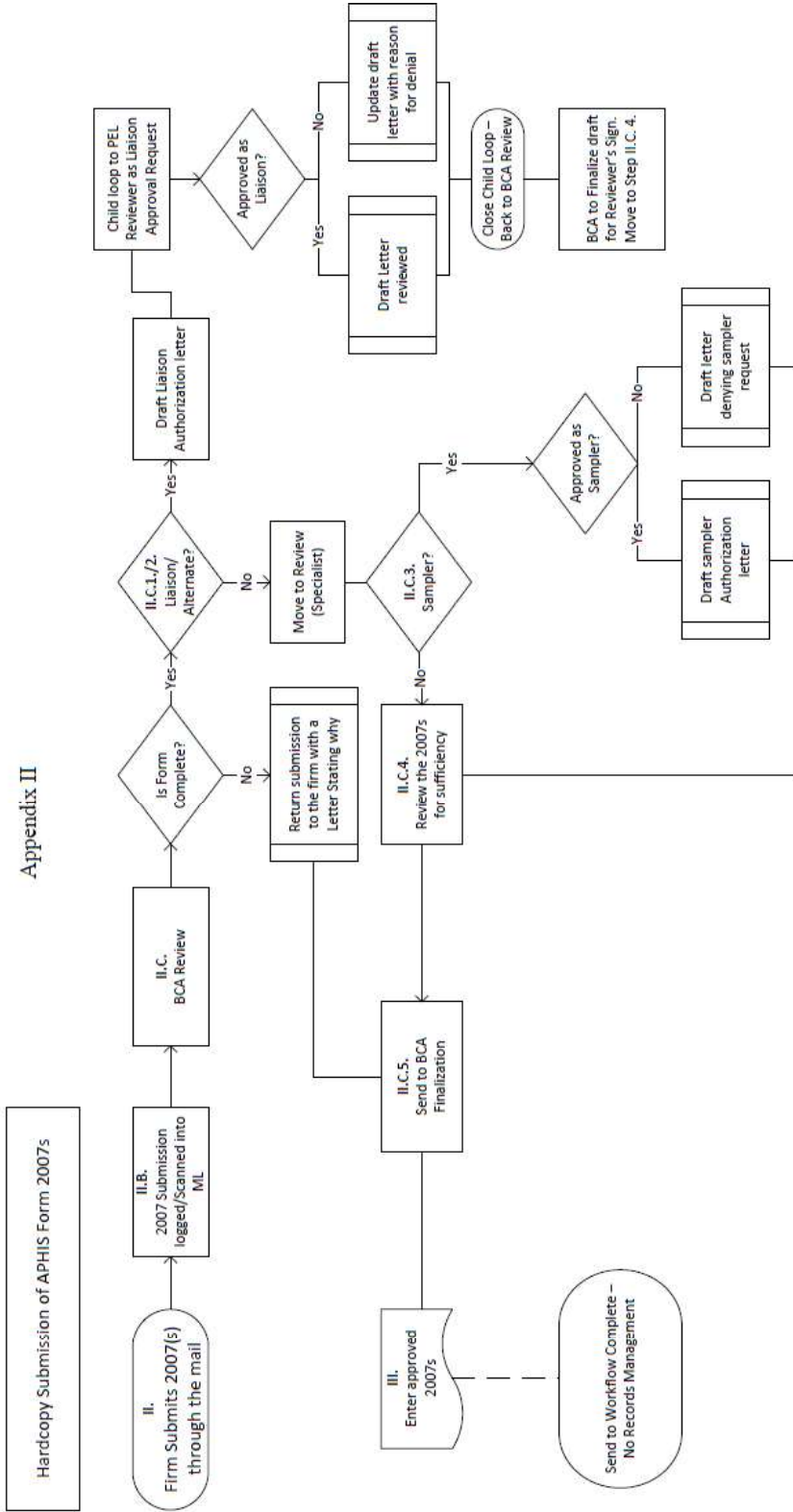## Appendix II

II.
Firm Submits 2007(s) through the mail

II.B.
2007 Submission logged/Scanned into ML

II.C.
BCA Review

Is Form Complete?
- No → Return submission to the firm with a Letter Stating why
- Yes → II.C.1./2. Liaison/ Alternate?

II.C.1./2. Liaison/ Alternate?
- Yes → Draft Liaison Authorization letter → Child loop to PEL Reviewer as Liaison Approval Request
- No → Move to Review (Specialist) → II.C.3. Sampler?

Approved as Liaison?
- Yes → Draft Letter reviewed
- No → Update draft letter with reason for denial

Close Child Loop – Back to BCA Review

BCA to Finalize draft for Reviewer's Sign. Move to Step II.C. 4.

II.C.3. Sampler?
- Yes → Approved as Sampler?
- No → II.C.4. Review the 2007s for sufficiency

Approved as Sampler?
- Yes → Draft sampler Authorization letter
- No → Draft letter denying sampler request

II.C.4. Review the 2007s for sufficiency

II.C.5. Send to BCA Finalization

III.
Enter approved 2007s

Send to Workflow Complete – No Records Management

Hardcopy Submission of APHIS Form 2007s

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