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United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Processing of the APHIS Form 2007 by the Center for Veterinary Biologics-Inspection and Compliance

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INTERNAL USE ONLY

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1. Purpose

This document describes procedures for processing the APHIS Form 2007 (Form 2007), *Qualifications of Veterinary Biologics Personnel*, by the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC). The Form 2007 is required by title 9, *Code of Federal Regulations* (9 CFR), part 114.7(a), and is further explained in Veterinary Services Memorandum (VSM) No. 800.63 and on the CVB Website.

2. Background

All Form 2007s should now be initially submitted to the Inspection and Compliance (IC), with the incorporation of VSM 800.63.

Initially, a Form 2007 was submitted for each designated person at an establishment. If a responsible person was associated with multiple establishments or permittees, a Form 2007 for each establishment or permittee was required to be filed with CVB. For the remainder of the standard operating procedure and applicable work instructions, the phrase "employee" will include designated person, responsible person, authorized person, and any other reference to Veterinary Biologics personnel. If a section applies to only one type of employee, it will be noted.

With the implementation of the LSRTIS in October 2010, the information previously tracked in a Microsoft Access database was migrated into LSRTIS. Each employee had a separate record for each establishment for which they were employed. Employees that had a name change had their record updated; however, if that employee changed either sites or establishments, a new record was created.

In August 2014, LSRTIS 2014 was implemented. The rewrite of this environment provided an opportunity for all records related to one employee to be combined, thereby showing a complete history of employee's work history related to veterinary biologics. There is one establishment employee record and many associated establishment/site records for that employee. LSRTIS 2014 also links the employee record to the Mail Log records associated with the submission of the Form 2007.

In April 2016, the NCAH Portal was implemented. The NCAH Portal allows the manufacturers to enter information (including personnel data) which, if acceptable, will populate LSRTIS. This information is utilized for their access to the Portal.

3. Definitions

3.1 BCA: Biologics Compliance Assistant

3.2 IC: Inspection and Compliance

3.3 PEL: Policy, Evaluation, and Licensing

3.4 Specialist: Biologics Specialist

3.5 Form 2007: APHIS Form 2007 – The official form submitted by biologics manufacturers to file the biographical summaries of the regulatory Liaison and all persons responsible for any phase of preparation or initial distribution of a biological product.

3.6 LSRTIS: Licensing, Serial Release, and Testing Information System. This database system is the information management system used by the CVB for serial information and processing.

4. Responsibilities

4.1 CVB-IC: CVB-IC receives all Form 2007s, new and revised. Form 2007s for an addition, change, or deletion of the Liaison or Alternate Liaison is forwarded to PEL-Reviewer in accordance with the current version of CVB-WI-0086, *Receiving and Updating Establishment Personnel Data*.

4.2 BCA: The BCA performs a preliminary review of the Form 2007 and enters the data from the Form 2007 into LSRTIS or updates an existing record. The BCA also forwards the Form 2007s to the Specialist for review and finalizes any required correspondence back to the firm.

4.3 Specialist: The Specialist reviews the Form 2007s and associated correspondence. Once completed, the documents are returned to the appropriate BCA. The Specialist authorizes government sampler when requested by the manufacturer.

4.4 PEL-Reviewer: The Reviewer approves liaisons and alternate liaisons through a child loop activity “Liaison Approval Request”.

5. Procedures

5.1 Follow CVB-WI-0086 for workflow procedures in Receiving and Updating Establishment Personnel Data for both LSRTIS – Establishment Employees and Mail Log entry.

5.1.1 Access to NCAH Portal is determined by roles assigned on the Form 2007. See the NCAH Portal User Guide 2, NCAH Portal Roles and Privileges.

5.2 Newly licensed Firms:
Assurances that the establishment and addresses (sites) are entered properly into LSRTIS must be conducted. This information initiates the ability to enter site information for an establishment employee record.

New firms may need to have NCAH Portal access provided. Follow procedures on the CVB Website for guidance:
https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/sa_ncah_portal_guidance/ct_vb_ncah_portal_access

CVB does not accept copies of APHIS Form 2007s, original "wet-signature" is needed for firms that cannot utilize the NCAH Portal. Communication with the firm may be needed as they may not be familiar with expectations of filling out APHIS Forms.

5.3 Filing:

5.3.1 All Form 2007s are either received through the NCAH Portal and the official record is kept with the Mail log, or if it is received hard copy, then it is scanned and that record becomes the official file.

5.3.2 Requests for liaisons or alternate liaison that were submitted hard copy, or those entities without NCAH Portal access will need to be responded to through official correspondence. Use the most current version of CVB Template, CVB-TEM-0039, *Liaison/Alternate Liaison Approval Letter*.

5.4 Consultants for Licensed Manufacturers
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."

5.5 Retention:
Obsolete Form 2007 information has a retention time of 10 years after the termination of the entity or individual.

Correspondence relating to personnel or Form 2007s should be retained as long as the referenced Form 2007 is still active.

6. References

6.1 Title 9, *Code of Federal Regulations*, part 114, section 7, Personnel at Licensed Establishments, current version

6.2 Veterinary Services Memorandum No. 800.63, Personnel at Licensed Establishments

7. Summary of Revisions

Version CVB-SOP-0045.02

- Updated document numbers through the document
- Document number has changed from ICSOP0035 to CVB-SOP-0045.

Version ICSOP0035.03

- The Contact information has been updated.
- Removed all procedures as these have been incorporated into work instructions.
- Removed the IC-OAA duties.

Version ICSOP0035.02

- The Contact information has been updated.
- Information pertaining to the NCAH Portal role access has been added.