

**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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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 (pending as of August 2016).

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 Licensing, Serial Release, and Testing Information System (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

2.1 BCA: Biologics Compliance Assistant

2.2 IC: Inspection and Compliance

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- 2.3 **PEL:** Policy, Evaluation, and Licensing
- 2.4 **Specialist:** Biologics Specialist
- 2.5 **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.
- 2.6 **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-PEL: 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 CVB-PEL in accordance with the current version of **ICWI0055**, *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.

5. Procedures

5.1 Follow **ICWI0055** for workflow procedures in Receiving and Updating Establishment Personnel Data for both LSRTIS – Establishment Employees and Mail Log entry.

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.

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5.3 Filing:

The BCA files the Form 2007 in the firm's Active Personnel file in alphabetical order, if they are received hard copy. **Approved Sampler:** Files the yellow file copy of the Sampler authorization letter in the Personnel Correspondence file. Files organizational charts, if submitted, in the Personnel Correspondence file.

Form 2007 information received through the NCAH Portal are not kept hard copy.

5.4 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 .03

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

Version .02

- The Contact information has been updated.