Serial Release - BCA Initial Review

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Source Document: CVB-SOP-0032, Processing Serial Records

BCA Initial Review is a step for review of data entry of the record both for the NCAH Portal and internally entered documents received hard copy. This process is usually done between 10 a.m. and 2 p.m. Anything received after 2:00pm will be held for the following business day.

The Biologics Compliance Assistant (BCA) will select the **Serial Release** within the LSRTIS module and then select **Action Sheet** option. Use tab, "BCA Initial Review."

Do not move 2008s that are in the categories of Unlicensed, Technology Transfer, or Outline of Production change without confirmation from the PEL Reviewer. See CVB-WI-0108.

A. View APHIS Form 2008 (Form 2008) entries by clicking on (Toggle Visibility) to open either **Primary Establishments**, firms assigned to the BCA or **Backup Establishments**, all other firms. The Form 2008s will be sorted based on the establishment disposition entered, then by Firm/Product/Serial Number. The user may sort on PRTL column and Entry time stamp also.

Do not move 2008s that are hardcopy (Marked as "N" in the PRTL column) unless you have the hard copy to look at (in the office).

B. Review of Form 2008 – Locate Serial to Review under Serial Action Sheet

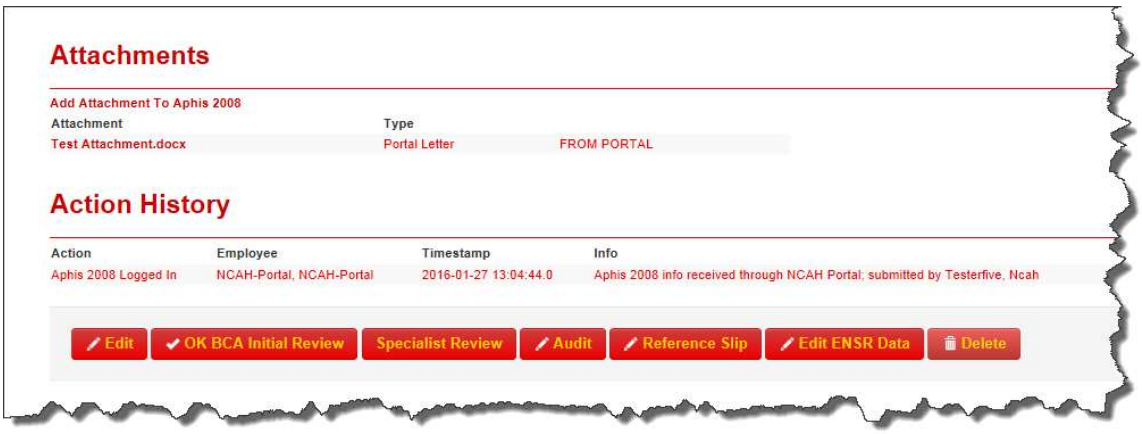
Click on "2008" link.

1. Review Blocks 2-8 and 10-12 to ensure the submission is complete and correct; also review the data entry for correctness.
   a. If the APHIS Form 2008 is not used as a Test Data File, ensure License/Permit #, Est. Name, Product Code, Serial Number, Expiration Date, Test Reference, Test Dates, Results, Conclusion, and Remarks are complete and correct.:
   b. If a 2008 is a NCAH Portal Submission (marked as Y in the PRTL column), ensure the License Status is "Active." If not Active, contact the Product Manager.
   c. Ensure data entered matches the specifics (listed above) for the serial.

d. Ensure there is a Portal Test Data File received for those Form 2008s that need one. Mandatory for all Firm Dispositions except: File for Information, For Further Manufacture, Inventory Correction, and Expiration Date Correction. Autogenous serials that are marked as 1st serials do not require a test data file either. (Note: Autogenous serials that have less than 50 containers still need a test data file, just no samples).

e. Items required on the Test Data file: (Find the firm guidance within the 2008 portal user guide # 5, USDA APHIS | NCAH Portal User Guides). If information is entered in both test data file and portal and it does not match, the serial should be audited back to the firm.
   - Establishment #,
   - Product Code,
   - Serial #,
   - Test Reference identification (can be 9CFR or Outline section),
   - date started and date concluded,
   - All test results, including validity and controls requirements, and the test conclusion. (the BCA may audit at this point if these are missing from the test data file)
   - Also include any explanations for No Test and/or Inconclusive results in remarks
   - Expiration date of the serial is also requested.

2. If no corrections are needed and the Form 2008 does not need to be sent to Specialist for Review, click on "OK BCA Initial Review" – this will move the record to 2008 Review or BCA Ready for Approval (2008s that do not need samples).



3. Firm data should NOT be corrected.

4. If the serial needs to be sent onto the Specialist, choose the "Specialist Review" option within the 2008 view.

C. Determine if the Form 2008 should be sent for **Specialist Review.** [redacted]

[redacted]

D. If the record should be sent to Specialist review:

1. LSRTIS - click **Specialist Review** on Serial Action Sheet screen (or within the 2008 link) and select the correct item from the list of values (LOV). Click √Send to Specialist. Comments may be added here as well.

2. Hardcopy – place in folder for review (if applicable)

[redacted]

E. Auditing an APHIS Form 2008

If there is a technical error or the Form 2008 is incomplete and the information cannot be changed or added, the Form 2008 should be audited. This can be done at any time during the serial release process prior to signature of the Form 2008 (hard copy and LSRTIS). See CVB-WI-0104, Audits and Reference Slips for IC Documents, within LSRTIS for the auditing process.