

## QA Process for Serial Release

The purpose of this document is to provide guidance on the quality assurance process for serial release. This process is performed daily after the Biologics Specialist who has been assigned Program Coordinator (PC) duty for the week has electronically and physically signed the APHIS Form 2008s (Form 2008s) that the Biologics Compliance Assistants (BCAs) have prepared for release. This document is to be used as a reference while performing this duty.

### BCA Processing of Form 2008s

1. BCAs pull the hard copy Form 2008s that are appearing in their “BCA Ready for Approval Section” and prepare the hard copy Form 2008s to forward on both physically and electronically to the PC to approve for sale/distribution.
2. The PC signs (both electronically and physically) and returns all of each BCA's Form 2008s that have been approved to the Lead BCA or other designee.
3. The Lead BCA or their designee does a search on the Form 2008s processed and signed for the day. Under the “Serial Release tab,” select “Serial Search.” At the bottom of the screen choose “With an Action Of”=APHIS 2008 signed by Specialist.  
“Action Timestamp” From=current date To=current date
  - Choose “Search,” select “Generate Pdf Report”
4. The Lead BCA compares the data on the generated report against the physical copy of the Form 2008s and checks for the following to make sure the paper matches the report:
  - EST. #
  - APHIS Disposition
  - Product Code
  - Serial #
  - APHIS Representative’s signature is on both copies of the Form 2008s
  - Firm disposition matches
  - Title and date are stamped on both copies
  - All comment and FFMs in remarks have been adequately addressed
  - Testing is attached to Form 2008s correctly if applicable
  - BCA’s initials are at the top on IC’s copy to indicate who logged it in
  - 100% Mock Check has been done on the products that require it
5. After the QA process has been completed, the Lead BCA initials and dates the list of serial releases for the day and returns the Form 2008s to the appropriate BCAs to prepare for mailing. If discrepancies/issues are found on the list, the Lead BCA follows up with the appropriate personnel to resolve the issues.

The QA’d list is then given to the designated mail checker for that day to record the double check of the other BCAs’ and Export Document Examiner’s outgoing mail. Once the outgoing mail has been verified on the “List of Released Serials,” the list is then filed in “List of Serials Released” notebook under the appropriate month. These files are currently located in the pending firm request file cabinet in the drawer below the firm requests.