Processing Incoming Administrative Inspection Review (AIR) Documents by CVB

The process below outlines steps and responsible individuals related to receiving the AIR from the manufacturers and the steps to route the information within the CVB.

Export Document Examiner/Office Clerk/Student

A. Receipt of Incoming AIR documents:
   1. Upon receipt of the hard-copy AIR Submittal form (**ICTEM1004**) that is signed by the firm representative, enter this into the mail log (ML), and scan all documents and upload to the ML item. Route this to the Lead Biologics Compliance Assistant (BCA), or acting.
   2. Upon receipt of the electronic AIR submission through the NCAH Portal from the firms, the ML is directly routed to the IC Inbox pool. No data entry is required.

Lead BCA

3. Check CVB.IC.Distribution email box daily for hard copy AIR submission
   a. Save the Attachment(s) to the F drive (FS11\Firms\AIR In Process\Est. #).
      - Suggestion – copy all the attachments from the email and paste into the selected folder
   b. Save the PDF'd incoming email to the same folder

4. Go to ML (see submittal sheet for ML number)
   a. Append the attachments to the ML item – attach as incoming corr.
   b. Append the PDF'd incoming email as well – attach as incoming corr.

5. For electronic Portal submissions – check the IC Inbox pool
   a. Self-assign any AIR Correspondence documents.

6. Send child loops with the activity "AIR Updates" to responsible individuals for updates, if needed:

   a. Biologics Compliance Assistant responsible for the firm
      1. Personnel

   b. Records Management –
      1. Active Labels
      2. Special Outlines (if inactivated/changes needed)
      3. Outlines of Production Review (if inactivated/changes needed)

   c. Product Specialist/Biologics Specialist
      1. APHIS Form 2008s (Form 2008s) without Samples
      2. Outline of Production Review

Author: Jeanette M. Watson
Issue Date: 29Sep17
Source Document: Title 9, *Code of Federal Regulations*, part 116.5; CVBSOP0027, *Processing Administrative Inspection Reviews*

3. Special Outline of Production Review
4. Samples without Form 2008s

d. Legal Instruments Examiner/Program Assistant
   1. Licensed/Permitted Products
   2. Pre-licensing Activity
   3. Establishment Site Information
   4. Master Seeds
   5. Master Cells
   6. Potency References

To send a child loop, choose "Initiate Child Workflow" with the activity "AIR Updates." Select the first person assigned to a document. In the routing comments, enter the report name(s) assigned to the individual, Initiate, then Yes for "*Are you sure?*". For subsequent child loops, go to the Pending Other Input tab to find the ML item and open it. Repeat the process to initiate child workflow. A message of "*You are initiating a child loop for an activity that is already open. Do you wish to continue?*" – choose OK.

The **ICTEM1004** is held until all child loops are closed. See **Section E**.

Responsible Individuals – respond to ML

B. Review information for needed program/LSRTIS updates or comments made by the firms.
C. Enter and/or Archive appropriate documents
   Refer to appropriate guidance for entry or archiving of files
   1. Inspection and Compliance Quality Manual
   2. CVB Program Information
   3. Policy, Evaluation, Licensing (PEL) Reviewer-Support Staff Info
   4. PEL Support Staff Manual

D. Once data has been updated, the responsible individual will close their child loop by choosing "Complete My Child Workflow." A return comment may be entered, if needed.

Lead BCA

E. Once all child loops are closed, the ML will return back to the Active queue under current activity – BCA Review. Route the ML to the Product Specialist, using the activity "Finalization." Hard copy submittal sheet returned to the Product Specialist.

Product Specialist

F. If questions or if there are actions based on the information submitted by the firm, the Product Specialist will respond and the activity will be marked as "Specialist Review."

1. Product Specialist will contact firms for questions/issues that come up.
2. Will send letters to firm, if necessary, with a new mail log item or request more info from submitter (for portal submissions).
3. Informationally link the two mail logs together.

G. Product Specialist will send the ML to "Workflow completed, No Records Management" if no further action needed by firm or CVB personnel.