Receipt of Bench Records in Response to a Firm Submission

Background:

Testing and production bench records are often requested in response to firm submissions, including but not limited to:
- Serials submitted for consideration for marketing
- Reprocessing
- Non-conformity to the filed Outline of Production

Requests for bench records can be via a telephone conversation, email, audit request, or written correspondence. Bench records can be received by fax, email, or hard copy.

NOTE: Submission of bench records related to **an investigation** follows the process documented in **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act.*

Instructions:

1. Requests must be documented. This can done several ways depending on the method of request:
    a. Telephone requests are documented in the Customer Service Database
    b. Email requests are printed and provided to BCA for filing
        General Correspondence when more than one product code is involved
        Product Correspondence when only one product code is involved
    c. Audit Form – self explanatory
    d. Written Correspondence – use process outlined in **ICWI0236,** *Work Flow for Correspondence for Inspection and Compliance: Using the Mail Log System*

2. Receipt of bench records
    a. Fax – scan and attach to ML, see 3.b.
    b. Email – create pdf and attach to ML, see 3.b.
    c. Audit – scan or maintain as hard copy. If you are going to use a child loop to PEL Reviewer or Laboratory, easier to scan and attach to ML, see 3.b
    d. Written Correspondence – use process outlined in **ICWI0236** – the original ML should be informationally linked to the bench record ML. If you are going to use a child loop to PEL Reviewer or Laboratory, easier to scan and attach to ML, see 3.b.

3. Create Mail Log Item
    a. Enter the following:
        1. Establishment, Product, and Serial Number
        2. Submission Type (General Correspondence if more than one code, Product Correspondence if only one product code)
        3. Date Submitted
        4. Brief Description – Bench records requested (date and method of request, phone, email, audit, correspondence).

        5. Submission Subtype: Bench Records related to 2008
   b. Attach bench records under Create Document Record
        1. Uploaded File
        2. Document Type – Incoming Submission (core)
   c. If not scanning hardcopy – use purple folders
        1. Hard Copy selected under Create Document Record
   d. Move Forward to Review (Specialist)

4. Specialist to review bench records and determine if the information provided meets the request placed by the IC request.
   a. Document your review and decision in all applicable fields for Mail Log
   b. Move Forward – Initiate Child Workflow for PEL, either the Reviewer or the Lab
   *Request Misc. Info from CVB Employee

5. Once Child Loop is finished and information has been discussed, the Specialist will make a decision about the APHIS Form 2008
   a. In LSRTIS, finish Specialist Review, add appropriate note and push to BCA; remember to hand back purple folder with 2008 for processing.
   b. Tag ML as Regulatory Flexibility (if appropriate)
   c. If follow-up is needed, add that to the Follow-Up section of ML
   d. Move Forward to Finalization and BCA responsible for the firm

6. BCA marks: Workflow completed – no records management