

## Special Test Requests Initiated by Inspection and Compliance Staff

### Background:

Special Test Requests (STR) related to issues observed during the review of information on the APHIS Form 2008 (Form 2008). The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) uses the Form 2008 information utilizing a risk assessment to determine the need for check testing. In addition, STRs may be initiated in conjunction with a Veterinary Biologics Investigation (VBI).

### I. Instructions for STRs initiated due to Review of an APHIS Form 2008:

Specialist or Program Coordinator (PC) will review all Form 2008s with test results coded as Inconclusive (I) or No Test (NT). Depending on the explanation provided, the Specialist may consider requesting a Special Test prior to marketing determination of the serial.

1. The Specialist will contact the Laboratory Test Agent Contact to discuss the results observed on the Form 2008. Agent Assignments can be found on the LSRTIS system.

Provide the following information to the Agent Contact prior to a discussion via email, along with the test data for the serial in question (scanned Form 2008 for hard copy or reference to the NCAH Portal entry). Include the Product Specialist (Jeanette Watson) on this email.

- |                       |                                   |                         |              |
|-----------------------|-----------------------------------|-------------------------|--------------|
| a. <b>Purpose</b>     | <b>Proposed Test(s) Conducted</b> | <b>Fraction(s)</b>      | <b>Issue</b> |
| b. <b>Test Method</b> | <b>Reagents Requested</b>         | <b>Section/Employee</b> |              |

The discussion with the Agent Contact should be face to face or by phone and include the following points:

- a. Availability of CVB-Laboratory resources to perform the test in question; personnel, media, cells, equipment;
- b. The merits of the test requested, including reproducibility and ruggedness of the test;
- c. Does CVB have sufficient experience with the test – due to limited resources, we do not routinely perform all Section V testing.

If it is determined testing is not the appropriate route, requesting the firm's bench records for the fraction in question is an acceptable method to further investigate the situation. This may be done by auditing the Form 2008 back to the firm, or contacting them to submit via the 2048 submission in NCAH Portal or email is acceptable means.

2. If the serial is not to be tested by CVB, the normal process for the Form 2008s should be followed as documented in **ICSOP0010, Processing Serial Records**.
3. If the serial is to be tested as part of an investigation, follow procedures in **CVBSOP0101, Tests Requested to Assist Investigations – Processes and Responsibilities**.
4. If the serial is to be tested after discussion as specified in item 1, the Specialist will enter the Special Test Request using the testing information provided by LSRTIS or the Laboratory Test Agent Contact.

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### To enter an STR in LSRTIS:

- a. Choose the Testing Module within LSRTIS, Special Requests heading
- b. Choose “+Create Special Request” within the Special Request screen
- c. Purpose is mandatory (*Problem, Complaint, Extension of Dating, Reprocessed, Rebottling* are normally used for Inspection and Compliance)
- d. Establishment is mandatory – choose which establishment number from the list of choices
- e. Product Code – enter only 1 product code per STR
- f. Serial Number – enter only 1 serial number per STR
- g. Comments relevant to the STR testing purpose
- h. Choose “Create”
  - i. within the selection, the Establishment and Product Codes are automatically filled in, but the testing category, type, agent, and section may be added to further define the search
  - ii. choose the test(s) to be added by selecting the toggle box
  - iii. choose “Add Tests” icon

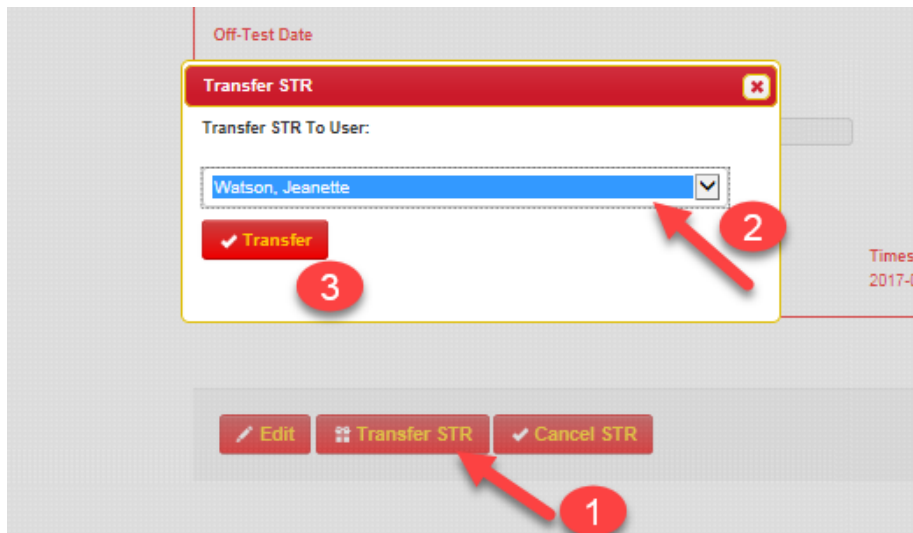
*At this point the STR is initiated*

5. The Specialist may print the STR and initials.

### To Print the STR:

- a. Right-click on the screen
- b. Choose “Print” or “Print Preview”
- c. Print the select document

**Note: If you are the PC, please make a copy of the STR for the Specialist assigned to the firm. Also transfer the STR to make the Specialist assigned to the firm as the Responsible Party.**



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6. You may review the serial/Form 2008 within the Specialist Review area of LSRTIS, and the Form 2008s will move to Laboratory Actions until the testing has been verified. THE SERIAL WILL NOT BE RELEASED UNTIL AFTER TESTING IS COMPLETED AND VALIDATED.

\*However, if you leave the Form 2008 in Specialist Review until the testing is complete, you must be aware of the email from the LSRTIS System when the STR is complete to move the Form 2008 on to the Biologics Compliance Assistant (BCA) for finalizing.

7. The Specialist may scan the Form 2008 in question and email this to the Laboratory Test Agent Contact along with the STR# – if it was received hard copy.

8. Give the STR printout and Form 2008 back to the BCA for filing in the pending drawer.

9. When the CVB Laboratory responds to the STR with validated test results, the BCA will pull the Form 2008 and STR information from the pending drawer and provide to the Specialist for review of the test report.

- a. Withholding marketing release of serials based on testing after initial release, must be approved by an IC Section Leader or Director. Any other inquiries should be directed to the Specialist who requested the STR, Product Specialist, or Section Leader.
- b. If the Specialist will be out for an extended period of time, the BCA will provide info to the Product Specialist to sign off on the Form 2008.

### **Instructions for STRs initiated due to an Investigation:**

See current version of **CVBSOP0101** for procedures.

## **II. For STRs not initiated by Inspection and Compliance staff:**

The Form 2008s should be submitted to IC following procedures in Veterinary Services Memorandum No. 800.53, *Release of Biological Products*.

- a. Form 2008s that are initiated from Technology Transfer requests, Preliminary License serials, and Outline of Production change requests, may be requests that come from Policy, Evaluation, and Licensing (PEL). The firm should submit Form 2008s with the appropriate disposition (Other – Preliminary License, or Other – Outline Change). The Reviewer should respond to the automatic email they get with submission of the Form 2008, to the BCA with the acceptability of those serials for the request.
- b. It is assumed that the STR will be entered prior to IC receiving the Form 2008 from PEL, so the system will hold up release within Laboratory Actions of the Serial Release module.
- c. The ENSR process will not change for STRs initiated by PEL, as PEL informs the manufacturers of test results through other means.