



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

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Serial Release - Conditional Serial Release

Document Number: CVB-WI-0151

Revision: 02

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Vault: CVB-Released

Section/Area: CVB-WI-IC

Effective Date: 20 Jul 2020

Notes:

Serial Release - Conditional Serial Release

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

A Conditional Release allows authorized users to release a serial prior to the completion of testing or the sample selection period and is granted when there is an emergency need (only product available, expedite export, national program disease) and on the condition that the serial is subject to immediate recall by the Center for Veterinary Biologics (CVB) if tested and found unsatisfactory. Samples and APHIS Form 2008 (Form 2008) must be received by the CVB prior to a serial being considered for Conditional Release. A written request from the firm (letter) must accompany the Form 2008 being considered for a conditional release. This letter may be either submitted as a mail log through the NCAH portal or as an attachment to the serial requested for conditional release.

For those who are not portal enabled, a fax of a letter can be accepted to expedite the process, but a hard copy original signature letter must follow. The fax will be destroyed and the original letter becomes CVB-Inspection and Compliance's (CVB-IC) official copy for filing.

Conditional Release

Conditional Release creates an additional parallel path to the normal Form 2008 workflow (first leg). The normal workflow (final leg) will not be affected.

1. Requesting/Authorizing the Conditional Release:
 - a. The Specialist will determine the type of release required depending on the sample status (within the at-risk period or on test).
 - b. Within LSRTIS, the Specialist will choose "Conditional Release" within the LSRTIS laboratory action subcategory.
 - c. A notification to the IC Section Leader should occur.
2. Approving the Conditional Release:
 - a. The IC Section Leader, or designate, will Approve the Conditional Release.
 - b. Select either "Approved" or "Denied" depending on the action needed within LSRTIS, Product Manager Review Tab, Conditional Releases.
 - The first leg of the conditional release Form 2008 will then move to BCA Ready for Approval area, if approved by Section Leader.
 - If the conditional release is Denied, the "first leg" Form 2008 will be complete and no further action is necessary for the first leg. The "final leg" or now the original Form 2008 will wait for the at-risk window or testing to be complete.
3. Processing the Conditional Release:
 - The Biologics Compliance Assistant (BCA) makes two copies of the Form 2008 (if it came in hard copy). This will be the "first leg" of the conditional release. Check "Other" in Block 16 of the Form 2008 if hard copy.
 - If the serial is under test by our lab, type on the hard copy Form 2008, "May be released, subject to immediate recall should this serial, now under test by

APHIS, be found unsatisfactory. See letter from _____ dated _____.”
This should also be entered as a Release Criteria within LSRTIS. See below.

- If the serial has not been selected for testing and still is in the testing selection timeframe, type on the Form 2008 or Release Criteria, “May be released, subject to immediate recall should this serial, if tested by APHIS, be found unsatisfactory. See letter from _____ dated _____.” See below.
- Ensure this is entered as a Serial Release Requirement in LSRTIS, so it shows in the ENSR (Electronic Notification of Serial Release).
 - Under the Serial Stat, “Serial Info” category – choose “Release Criteria Required” – Add Info link.

Serial Info

Most Recent Expiration Date	██████████
Release Criteria Required?	No Add Info
Destruction Info	Add Destruction Info



- Choose the toggle of “Release Criteria Required?”
- Fill in Criteria of “Conditional Release”
- Choose Due date of either off test date or end of at risk window
- Comments – add what you type on the Form 2008 (above bullets under 3.b.)

4. Releasing the Conditional Release:

- a. The first leg of the conditional release should be in BCA Ready for Approval. Ensure the APHIS Disposition shows “Other - Conditional Release Granted” in the Action Sheet. Approve the Form 2008.
- b. The Form 2008 should move to Ready for Signature. The Specialist will sign the “first leg” of the conditional release both electronically and hard-copy (if applicable).
- c. If hard copy:
 - Stamp the photocopy of the Form 2008 with the appropriate stamps in Blocks 18 and 19, and then give to the initiating Specialist for signature.
 - Mail photocopy of Form 2008 to firm, Contact the firm of Conditional Release action, and document the contact on in the Phone Log.
 - Drop file the CVB photocopy with original Form 2008 and any other paperwork in the corresponding product code file in the pending 2008 file drawer.

5. Releasing the Original Form 2008:

- a. Once testing has been verified or the at-risk window complete, the “final leg” of release of the electronic Form 2008 will move to BCA Ready for Approval area, which can be approved and moved on for Signature by the Specialist.

- b. Once the serial comes up for final release in BCA Ready for Approval, pull the previous photocopy and paperwork from the pending drawer (if applicable). This is the “final leg” of the conditional release.
- c. Complete the APHIS disposition (Block 16) on the original Form 2008: The APHIS disposition of the serial on the Action Sheet will be based on either the Firm’s disposition or CVB Laboratory testing results.
 - If the serial was tested as “SAT” by our lab, check “SAT” and “Other”, and type, “This completes the conditional release granted per Specialist name on initial date of conditional release”
or
 - If the serial was not tested and the Action Sheet shows to release as “Not to Be Tested,” check “NBT” and “Other,” and type, “This completes the conditional release granted per Specialist name on initial date of conditional release”.
 - Complete the Release Requirements in LSRTIS (so it does not show up on the ENSR report). This will show in the Serial Stat again.
 - Choose the “Edit Serial Release Criteria”

Serial Info

Most Recent Expiration Date	[REDACTED]
Release Criteria Required?	Yes Edit Serial Release Criteria
Release Criteria	[REDACTED]
Due Date	[REDACTED]
Completion Date	
CVB User	[REDACTED]
Release Comments	Serial [REDACTED] to be tested for potency 6 months prior to expiration
Destruction Info	Add Destruction Info



- Fill in the “Completion Date” with the date of Release of final Leg.
- d. Ensure the Form 2008 has the appropriate APHIS Disposition.
- e. Give the Form 2008 to the Program Coordinator for signature with any other serials up for release that day. (Clip “first leg” copy to the original Form 2008.)

Signature Manifest**Document Number:** CVB-WI-0151**Revision:** 02**Title:** Serial Release - Conditional Serial Release**Effective Date:** 20 Jul 2020

All dates and times are in Central Standard Time.

CVB-WI-0151 01 Conditional Serial Release**Review for Doc Format**

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QM Program Asst	27 Apr 2020, 01:46:21 PM	Approved

Section Leader Final Approval

Name/Signature	Title	Date	Meaning/Reason
DANIEL COYLE (DCOYLE)	CVB COMPLIANCE SEC LDR	28 Apr 2020, 12:46:40 PM	Approved

Final Quality Check and Assign Training

Name/Signature	Title	Date	Meaning/Reason
MARK PAGALA (MPAGALA)	Assistant Director	30 Apr 2020, 08:35:46 AM	Approved

Minor Changes: CVB-WI-0151 02 Serial Release - Conditional Serial Release**Review for Doc Format**

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QM Program Asst	03 Jun 2020, 10:12:09 AM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
MARK PAGALA (MPAGALA)	Assistant Director	20 Jul 2020, 03:48:31 PM	Approved