

Specialist Review Action within LSRTIS

The Specialist Review actions are performed within the LSRTIS Module, under the Serial Release Heading, Action Sheet Subheading. APHIS Form 2008s (2008s) reviewed by the Biologics Compliance Assistant (BCA) and found to need special attention are forwarded on to the Specialist assigned to the firm or the Program Coordinator (PC). This is usually initiated between 12 p.m. and 3 p.m. CST.

The PC is responsible to determine if the Specialist of the Firm is not available to review their 2008s.

- If the Specialist is out of the office for more than 24 hours, the PC is responsible for review.
- If a Specialist is teleworking, they are responsible for reviewing the 2008s received from the NCAH Portal.
- The hard copy 2008s should be reviewed by the PC if the Specialist is out of the office for the day.

I. To perform a Specialist Review:

- a. Click on the Specialist Review Tab within the Serial Release Action Sheet dashboard.
- b. Usually the Specialist will choose their assigned firms by clicking on the “toggle visibility” under the Primary Establishment category.
- c. The Reason will be listed in the Action Sheet (I/NT, EOD, Rebottling, Review Hold, Legal Hold, Prelicense, R&R, Transfer, Short Dating, Veterinary Services Memorandum No. 800.62 V.I.D.). For ease of finding, use the Search within the Action and type any info, such as serial #.

Primary Establishments(0):
(Toggle Visibility)

Backup Establishments(29):
(Toggle Visibility)

Show 50 entries

PRTL	Entry	Est	Product	Serial Number	Reason	Audit	Reference Slip	Outline	Review	Serial Spec	2008 / Serial Stat
Y	04/19/2016 12:37:56	999	500400	TESTT 2	I/NT	Audit	Reference Slip	Outline	Review	Serial Spec	2008 / Serial Stat
Y	04/13/2016 16:08:08	999	950000	94320036	Other	Audit	Reference Slip	Outline	Review	NA	2008 / Serial Stat
Y	01/21/2016 15:06:45	999	264853	TESTJAN19	I/NT	Audit	Reference Slip	Outline	Review	Serial Spec	2008 / Serial Stat
N	12/18/2015 12:57:09				I/NT	Audit	Reference Slip	Outline	Review	Serial Spec	2008 / Serial Stat
N	01/08/2016 09:32:55	999	500400	08JAN3	Transfer Request	Audit	Reference Slip	Outline	Review	Serial Spec	2008 / Serial Stat

Showing 1 to 5 of 5 entries (filtered from 29 total entries)

The 2008s can be sorted at this point for those received via Portal or those that were received hard copy. Portal submissions should be reviewed first.

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- d. The following actions can be performed by the Specialist:
 - i. **Perform an Audit:**
 1. See **ICWI0075**, *Audits and Reference Slips for IC Documents*
 2. **Once audited, the 2008 will move to BCA Ready for Approval and can be moved on for Signature.**
 - ii. **Add a Reference Slip:** The person who initiated the reference slip should be the one who prints the hard copy and attaches to the 2008. Click on the “2008” link on the Action sheet for:
 1. See **ICWI0075**, *Audits and Reference Slips for IC Documents*
 2. The 2008 will still need to be reviewed at this point to move out of the Specialist Review area (see Section v. Review).
 - iii. **View Outline:**
 1. This link brings the user to the SharePoint site for Outlines of Production – Licensed and Prelicense Products. The user will have to find the specific outline of production for the firm/product.
 - iv. **View Serial Spec Sheet:**
 1. This link brings up the Serial Spec Sheet (Mock 2008), if one has been created.
 2. This document is either created or updated within the Serial Release subheading, Serial Spec Sheet.
 3. Refer to **ICWI0057**, *Serial Spec Sheets (formerly known as Mocks)* on updating or creating new Serial Spec sheets within LSRTIS.
 - v. **Review:**
 1. This link brings up a new window in which the Specialist can do the following:
 - a. The Specialist can choose an APHIS Disposition, if the default disposition is not desired (i.e., Unsat based on firm’s results) – See **ICWI0130**, *APHIS Dispositions and Associated Information on Form 2008s*.
 - b. The Specialist can mark the 2008 as a Process Deviation by choosing the LOV (Equipment Deviation, Production Deviation, Testing Deviation). Choose this anytime there is a manufacturing deviation.
 - c. The Specialist should choose if they Mock Checked the 2008 by selecting the toggle – business practice: this should be done if you initial off on the 2008.
 - d. Enter any review comments.

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- e. The Specialist can also choose to have the firm perform **Release Requirements** (see **Section viii** for items to consider for release requirements).
 - i. With the selection of the toggle switch, the Release Criteria LOV, due date for the firm to perform the release requirement, and comments to further explain the requirement(s).

****These will be sent directly to the firm via the ENSR process with release of the serial. Ensure this is the wording you want the Firm to see.**
 - ii. Ensure this information is relayed to the BCA for the firm so the same comments are typed on the 2008s hard copy as well.
 - iii. These requirements remain in the Misc. tab within the Serial Release Action Sheet until they have been completed.
 - iv. To Edit the release requirement, search for the 2008. Within the Release Criteria category, click on the link “Edit Serial Release Criteria.” Update the info or enter a completion date if the establishment has completed the request, then click on “Update Release Criteria” link.
- f. Click on “Save” which will move the 2008 out of the Specialist Review area. The link for the serial stat is also located on this page.

Specialist Review

Establishment: 999
Product: 500400
Serial #: TESTT 2

APHIS Disposition: Other - Transfer Approved

Process Deviation

Mock Checked?

Review Comments

Release Criteria Required?

Save

vi. View 2008 history:

1. The 2008 link brings up all the information regarding the 2008 and the history of actions done with this 2008. Attachments also appear here (Audits/Reference Slips).

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2. This link is critical to open if a 2008 has been received from the Portal, as it will now contain the test data file from the firm and other attachments both from the firm and uploaded from CVB.
3. The Specialist Check Out option is also available here. This removes the Review option on the Action Sheet within Specialist Review area. It informs other Specialists that this 2008 is in the process of being reviewed by whomever checked it out, unless otherwise stated. The Specialist Check Out is usually done on 2008s received from the Portal.

The screenshot displays two sections of the LSRTIS interface. The top section, titled "Attachments", includes a sub-header "Add Attachment To Aphis 2008" and a table with columns "Attachment" and "Type". A single row shows a redacted attachment name with a ".pdf" extension and the type "Portal Test Data File" with the source "FROM PORTAL". The bottom section, titled "Action History", features a table with columns "Action", "Employee", "Timestamp", and "Info". It lists five actions performed by "Ennis, Lynn" on 2016-05-31, including logging in, initial review, updates, marking for specialist review, and a final review status. Below the table is a row of action buttons: "Edit", "Specialist Check Out", "Specialist Review", "Serial Spec", "Edit ENSR Data", and "Delete".

Attachment	Type
[REDACTED].pdf	Portal Test Data File FROM PORTAL

Action	Employee	Timestamp	Info
Aphis 2008 Logged In	NCAH-Portal, NCAH-Portal	2016-05-27 14:01:41.0	Aphis 2008 info received through NCAH Portal, submitted by [REDACTED]
Initially Reviewed By BCA	Ennis, Lynn	2016-05-31 07:00:24.0	
Aphis 2008 Updated	Ennis, Lynn	2016-05-31 07:03:36.0	
Aphis 2008 Marked For Specialist Review	Ennis, Lynn	2016-05-31 07:03:54.0	
2008 Review - Not Reviewed	Ennis, Lynn	2016-05-31 07:03:54.0	

vii. View Serial Stat:

1. This link brings up the Serial Status for actions and 2008s associated with this Firm/Product/Serial. It details any information within the LSRTIS application that is associated with this serial number.
2. The link within the serial Stat "Export Profile" is a printer friendly version of the serial stat, without the action history.

viii. Items to Consider for Release Requirements:

1. Safety issue – consider submission of adverse event reports – can use Epidemiologist Scott Taylor as a resource
 - Monthly
 - Quarterly
 - Annually

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2. Potency issue – consider potency tests – work with CVB-Lab SME for fraction to determine best course
 - If the potency tests uses animals, requesting potency tests is discouraged, but not prohibited.
 - Frequency should be related to perceived risk that the product will not maintain required potency throughout shelf-life.
 - If stability has not been demonstrated, more frequent potency intervals would be appropriate; work with the Reviewer.
 - If a change in the production or testing process has been approved, this also could cause a stability issue and warrant more frequent potency intervals.

II. Additional Information to Review

- a. When a firm submits hard copy information, such as bench records or cover letters with 2008s, they are scanned and entered into the Mail Log System. This mail log number will be entered into the Remarks section on the Form 2008 by the CVB staff.
- b. Upon Review of the 2008, this mail log should be closed out by the Specialist as well. Choose **Workflow Completed – No Records Management** to close out this mail log item.