



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Process for Prelicensing Inspection Requests (Inspection Approval and Scheduling)

Document Number: CVB-WI-5219

Revision: 02

Previous Number:

Vault: CVB-Released

Section/Area: CVB-WI-IC

Effective Date: 11 Feb 2020

Notes: *This is a spin off of CVB-WI-0093 (but utilized by IC Staff)*

IC Process for Review and Approval of Prelicensing Inspection Requests (includes Inspection Scheduling by Specialist)

Source Document: CVB-SOP-0035, The Inspection Proper

The Center for Veterinary Biologics – Policy, Evaluation, and Licensing (CVB-PEL) requests prelicensing inspections based on information received from the applicant. The inspection is to determine if the personnel, facilities, equipment, and processes are appropriate for the product considered for licensure. The request to inspect is not made by the applicant.

I. Documents required prior to approval of a prelicensing inspection:

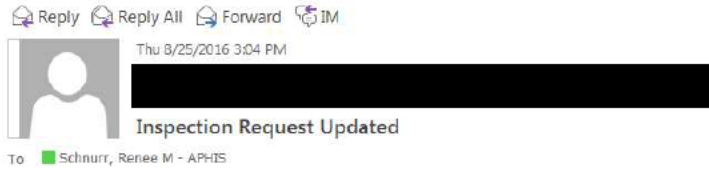
1. APHIS Form 2001, 2003, or 2005
 - a. Addresses of all manufacturing, testing, and storage sites should be entered in LSRTIS
 - b. Sites should be marked as Active
2. Draft or Final Outline of Production (OP) with PEL comments
3. Facility Documents
4. APHIS Form 2007
5. Summary Information Format for the Importation of Veterinary Biological Products into the United States (for permittees only)

See CVB-WI-0093 for PEL's guidance on when to request an inspection for additional information, if needed.

II. How to Approve a Prelicensing Inspection:

1. Inspection and Compliance Section Leader – Review Request
 - a. The Inspection Section Leader (SL) will be notified of a request – it is in a Tab in the Mail Log (ML) queue, labeled Inspection Requests.
 - b. The ML is “self-assigned” and moved to Inspection Section Leader ML queue.
 - c. The request is reviewed by the SL.
 - i. If **APPROVING** –
 - a) Edit ML Brief Submission Description – add APPROVED and initials
 - b) Move ML forward to “Workflow completed – No Records Management. Click “OK.”

c) The Requestor will receive an email.



Hello!

Inspection Request (ML# 176507) has been accepted by the Inspection Section Leader. The inspection request has been placed in the recommended inspection list until it has been scheduled by Inspection and Compliance.
Comments: null

[https://\[redacted\]](https://[redacted])

- d) At approval, this will move automatically to the Recommended for Inspection tab, and no longer show in ML queues.
- e) If a Specialist and Biologics Compliance Assistant (BCA) are not assigned, SL will assign and designate both roles in LSRTIS for the prelicensed entity.
- ii. If **DENYING** –
 - a) Edit ML Brief Submission Description – add DENIED and initials
 - b) Move ML forward to “Workflow completed – No Records Management. Click “Cancel.”
 - c) The Workflow Log will indicate the request was not approved.

Info	Documents	Workflow Log	Notifications	Phone Logs	Detailed Database Action Log		
Activity	Assigned Individual	Queue Entry	Queue Exit	Exit By	Approval	Routing Comment	Return Comment
Inspection Requests Pool		08/25/2016 14:40:48	08/25/2016 14:49:47	Schnurr, Renee			
Inspection Requests Pool	Schnurr, Renee	08/25/2016 14:49:47	08/25/2016 14:51:21	Schnurr, Renee	No		
Workflow completed–no records management	Schnurr, Renee	08/25/2016 14:51:21	08/25/2016 14:51:21				

d) The SL will also discuss this action with the Reviewer who requested the inspection. No email is sent as this should be a discussion.

- iii. If request is not complete –
 - a) SL will work with Reviewer and manufacturer to ensure all documents are in order and the timing is correct for the purpose intended.
 - b) Once all information is complete – the SL will move through Step 3.a above.

- 2. Specialist – Schedule Inspection once it is approved by Section Leader
 - a. The Inspection Module will show requested info in the Recommended Inspection TAB.
 - i. The ML #, hyperlink to the actual ML request from PEL.
 - ii. The Est #, hyperlink is a summary of the request from PEL

- b. The Specialist will contact the entity and schedule a time for the inspection.
 - i. This Phone Log will be attached to the Inspection Request ML – use hyperlink in Recommended Inspection TAB module.
 - ii. The Specialist will Schedule the inspection in LSRTIS
- c. The SL will approve the inspection in LSRTIS
 - i. The SL will place the inspection on the IC calendar under the format of Specialist Name – Est. # (type of inspection) City, State or Country
 - ii. At the time of approval the Reviewer assigned to the firm will receive an email notification.



Tue 8/23/2016 9:59 AM

Inspection approved

To: Schnurr, Renee M - APHIS; Houer, Paul - APHIS; Coyle, Daniel C - APHIS; Rippke, Byron - APHIS; Coyle, Bonnie M - APHIS; Schmellik Sandage, Connie S - APHIS; Yearry, Teresa J - APHIS; Karil, Steven A - APHIS

Follow up. Start by Tuesday, August 23, 2016. Due by Tuesday, August 23, 2016.

Hello!

A Request for Inspection has been Approved!

Establishment: [REDACTED]
Site: [REDACTED] - Manufacturing Site
Inspection Type: Special
Special Inspection Type: Prelicensing
Travel Out Date: September 19, 2016
Travel Back Date: September 22, 2016
Team Leader: Schnurr, Renee
Team Members:

III. Search for Inspection Request or Scheduled Inspection

Information regarding Inspection Request can be retrieved either through the ML Module or the LSRTIS Inspection Module.

ML Module – Use Master Search in ML

1. Enter Establishment (if searching for a specific entity)
2. Enter “Inspection Requests Pool” under Activity.
3. Approved? Yes/No

Activity:

Approved?

Assigned Individual:

Queue Entry - From: To:

Queue Exit - From: To: OR No Queue Exit Date

Exit By:

This will give you a listing of related ML # and Status. Completed means an action has been taken and ML has been closed. If a ML is still Active – please contact the Inspection SL.

NOTE: The requestor is not going to be in the search – but he/she will show in the “Detailed Database Action Log.”

Initiate ▾ Notifications (24) Licensing Plans Searching ▾ Reports ▾ Admin ▾ (Search) Search LSRTIS Phone DVI

Mail Log #	Establishment	Product Code	Brief Description get there!	Type	Date Submitted
131410	[REDACTED]			Inspection Request	September 14, 2015

Info Documents Workflow Log Notifications Phone Logs Detailed Database Action Log

Timestamp	Action Taken	User	Info	Attachment
09/14/2015 14:51:26	Create Mail Log Item	Ludemann, Larry	Request created	
09/14/2015 14:56:17	Update Mail Item	Ludemann, Larry	Mail Log Item updated	
09/14/2015 16:09:21	Move Item to Another Queue	Watson, Jeanette	Mail Log Item moved	

The inspection Status can be determined by searching in LSRTIS-IC-Inspections.

1. Inspections Dashboard – Inspection Search: Enter Establishment Number and click on Search
2. Click on Info for the inspection you are interested in.

Show 50 entries Search:

	Est	Type	Location	Status	Team Leader	Team Members	Start Date
Info	[REDACTED]	In-Depth	[REDACTED]	Denied	Yeary, Teresa	Yeary, Teresa; Schnurr, Renee	05/29/2012
Info	[REDACTED]	In-Depth	[REDACTED]	Completed	Yeary, Teresa	Yeary, Teresa; Schnurr, Renee	05/29/2012
Info	[REDACTED]	In-Depth	[REDACTED]	Pending Inspection	Koski, Danielle	Yeary, Teresa	09/19/2016
Info	[REDACTED]	In-Depth	[REDACTED]	Cancelled	Yeary, Teresa		04/15/2015
Info	[REDACTED]	In-Depth	[REDACTED]	Cancelled	Yeary, Teresa		04/15/2015
Info	[REDACTED]	Special – Miscellaneous	[REDACTED]	Completed	Yeary, Teresa	Fry, Alethea	02/03/2016

Showing 1 to 6 of 6 entries First Previous 1 Next Last

3. This brings up the Show Inspection screen that includes information regarding the inspection, including an Action History of requests, modifications, and approvals.