



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

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Facility Documents: Biologics Compliance Assistant (BCA) Preliminary Review

Document Number: CVB-WI-0109

Revision: 02

Previous Number: ICWI0081.04

Vault: CVB-Released

Section/Area: CVB-WI-IC

Effective Date: 22 Aug 2022

Notes:

Facility Documents: Biologics Compliance Assistant (BCA) Preliminary Review

Source Document: CVB-SOP-0039, *Processing Facility Documents*

Facility Documents can be submitted as Hard Copy or received electronically through the NCAH Portal.

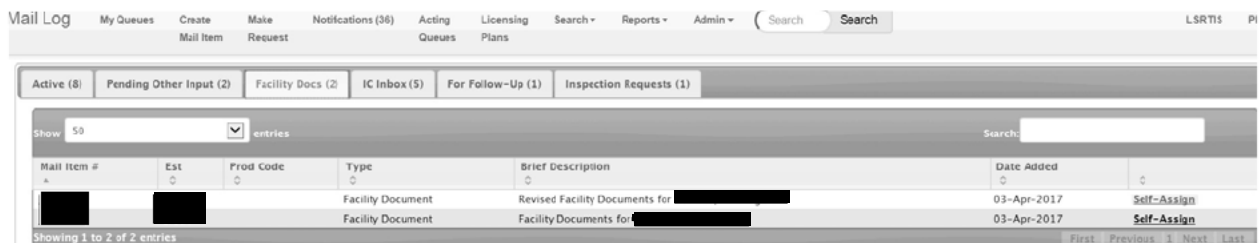
	Electronic Submission	Hard Copy Submission
Mail Log (ML) Creation	Automatic through Portal	CVB-WI-0159
Version Identification	Required	Recommended – can use supersedes date
Facility Document Submission (FDS) form Used	No	Yes
Summary of Changes	Required only for drawings and first electronic submissions of Legends and Addenda	Required for all documents
Signature of Liaison/Alternate	No	Required on Plot Plans and Blueprints
Two copies	No	Yes

A Summary of Changes is **not required** for the corresponding document(s) if:

- a. It's a new site or building (Check SharePoint for previously filed electronic documents and the establishment's License to determine which sites have been approved for use).
- b. The Legend or Addendum have already been approved electronically and are on file with the Center for Veterinary Biologics (CVB).

Submissions are reviewed on a first in/first out basis. The CVB goal is to conduct preliminary review within 10 working days of entry into LSRTIS. Once the firm starts submitting electronically for a site, they cannot return to submitting with Hard Copies.

A. The BCA self-assigns a Facility Document. This moves the ML to the BCA's *Active Queue* under the activity Review (BCA).



B. The BCA will verify the documents submitted are identified correctly under the *Documents* tab or the Hard Copies received.

1. Electronic Submission Review:

- a. Open the ML and go to *Documents* Tab.
- b. Open File and ensure it matches the Type: for example, if the document you open is a PDF document and it is a Blueprint, make sure the Type is labeled “Blueprint.”

2. Hard Copy Review:

- a. *Ensure proper data entry into LSRTIS – see CVB-WI-0159, Mail Receipt, Process, and Distribution for CVB-IC Hard Copy Submission.*
- b. *Review submission against the incoming Hard Copy Center for Veterinary Biologics Inspection and Compliance FDS. Export Document Examiner (EDE) fills out the Hard Copy FDS sheet, scans it in, and attaches it to the ML. Place a √ in the CVB USE ONLY column, verifying the document has been received. If the document is not part of the submission, do not √ the box. If there are any documents included that are not listed on the FDS, document in Box 5 – Miscellaneous Documents Type.*

4. DOCUMENTS SUBMITTED		
[A] Type of Document	[B] Comments	CVB USE ONLY
Plot Plan		<input checked="" type="checkbox"/>
Plot Plan Legend		<input checked="" type="checkbox"/>
Blueprint	Building 1	<input checked="" type="checkbox"/>
Blueprint Legend	Building 1, pages 1-20	<input checked="" type="checkbox"/>
Addendum - Fraction List	Building 1, pages 1-3	<input checked="" type="checkbox"/>
Summary of Changes (required)		<input checked="" type="checkbox"/>

- c. A Summary of Changes is required for all Hard Copies with the exceptions noted above.
- d. For all Legends and Addenda submitted, page numbers should be provided next to each entry under Column B.

If during initial review, the submission is found to be incomplete, the submission (whether electronic or Hard Copy) may be returned unprocessed by the BCA. See Section G.

C. Perform preliminary review – for both electronic and Hard Copy submissions

- 1. The BCA reviews the documents using the **Facility Document Review Aid**, which is an encapsulated guidance document created from title 9, *Code of Federal Regulations* (9 CFR), part 108, and Veterinary Services Memorandum No. 800.78. *See attachment.*
- 2. Establishment name and site address
 - a. The site shown should match the submission information.

- b. Only one site location, as listed on a Plot Plan, is permitted per ML submission. There may be multiple buildings and documents associated with a single site.
If more than one site is submitted per ML, return the submission without further review (See Section G).

D. If discrepancies are found during preliminary review

1. Create a review attachment identifying specific document(s) and brief description(s) of discrepancy
2. Attach to ML, i.e., [REDACTED] and identify as “internally routed”
3. Submit to Specialist as Review (Specialist)
4. Provide Hard Copies of submission if received through USPS.

E. If no discrepancies are found, there is no need for a discrepancy attachment.

1. Do document compare, if applicable. (See Section F)
2. Add comment “No discrepancies found” in Comment section prior to sending to Specialist
3. Submit to Specialist as Review (Specialist)

F. Electronic Document Compare for Legend and Addendum Submissions via the NCAH Portal

The BCA will use the comparison aspect of Adobe Acrobat to generate a document compare report which the Specialist will use to evaluate the revisions of the submitted Facility Documents as compared. NOTE – This is only for Legends and Addendums - not applicable to drawings, such as Blueprints or Plot Plans.

****If this is the first electronic submission, this function should not be used.**

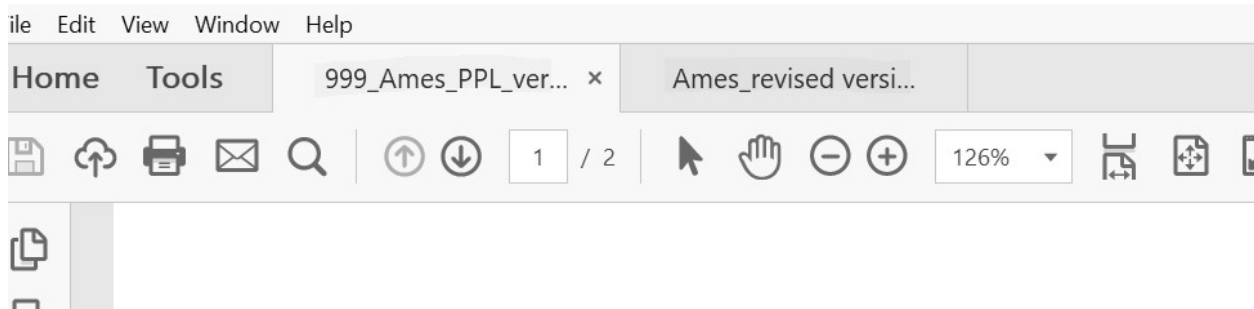
1. Go to the CVB File Room in SharePoint Site and select Facility Documents
2. Locate the currently filed document (Legend/Addendum) needed to compare to active submission, identify ML# [REDACTED]

3. Click the ML hyperlink, select Documents Tab, and open the **IC Clean Copy**

Doc ID	Type	File Name	Create Date	Comments	Hard Copy
177863 - 3	_Plot Plan Legend	Ames - 1st electronic submission.pdf	06/04/2018		
177863 - 4	IC Clean Copy	999 Ames PPL version 1 cleancopy.pdf	06/04/2018		
177863 - 5	Outgoing Enclosures	999 Ames PPL 1-REV.pdf	06/04/2018		
177863 - 6	Outgoing General Corr.	180530-1.pdf	06/04/2018		

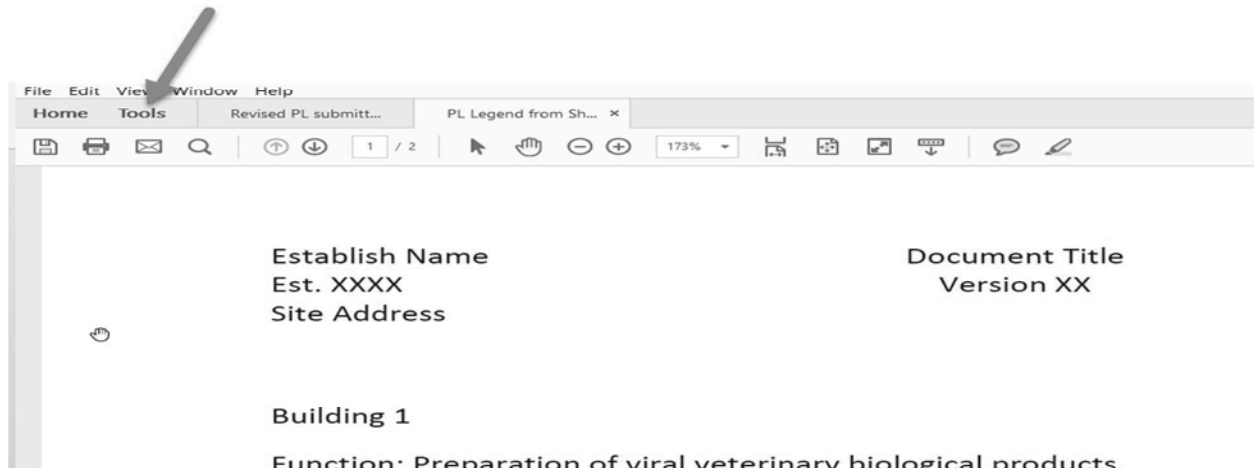
Showing 1 to 4 of 4 entries

4. Go to the Active ML, Document Tab and open the submission. Now both should be opened as PDFs.



5. Document Comparison

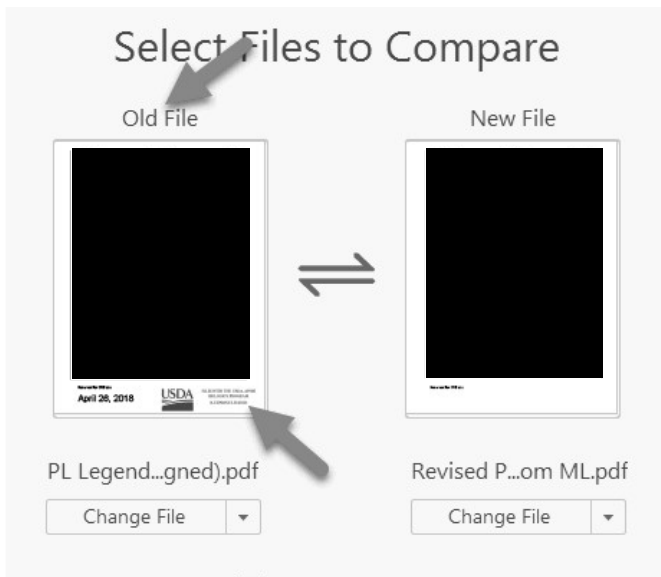
a. On the Adobe Acrobat menu bar choose “Tools”



b. Choose “Compare Files”



c. Make sure the “Old File” is the IC Clean Copy document. The IC Clean Copy should have the CVB stamp and date on it. If it isn't, select the arrows in the middle to switch files around.

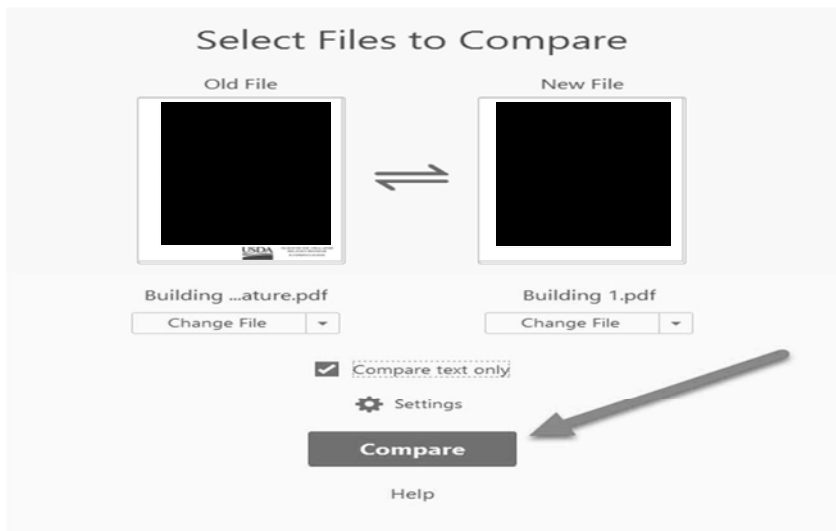


d. Check the box “Compare text only” and click OK.

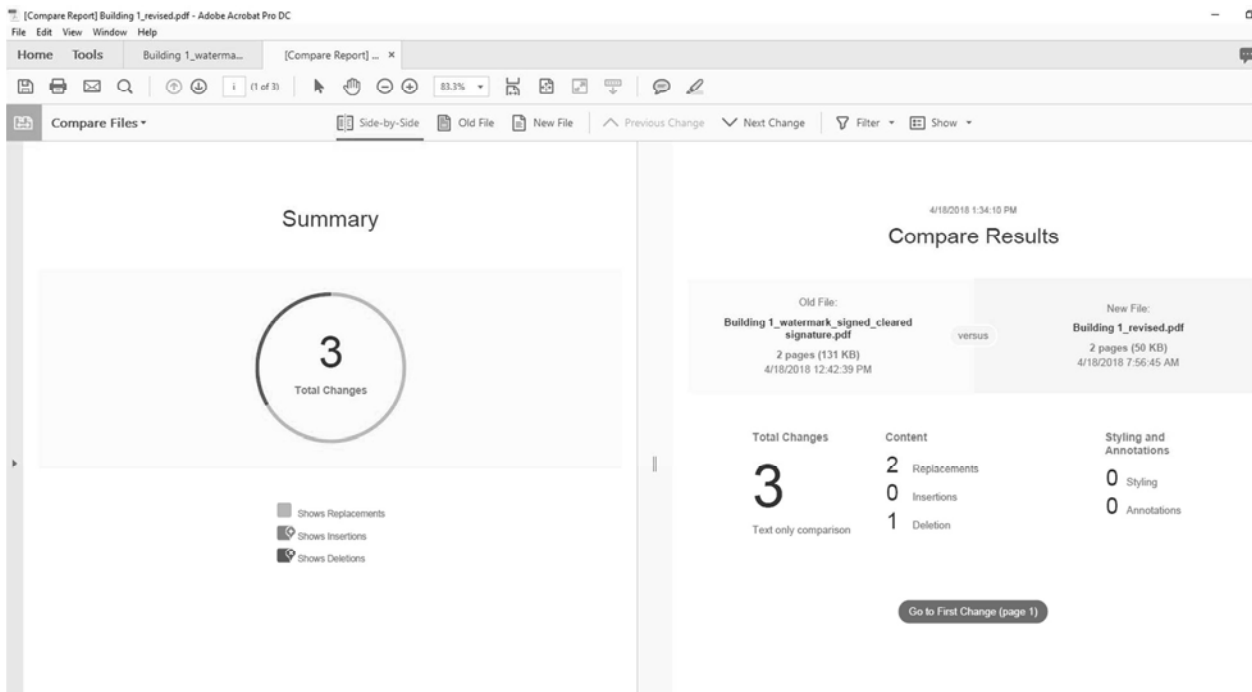
As a double check, you can click on “Settings” to make sure that text is the only box check the show in report area.



e. Click Compare



f. This will generate the “Compare Report.”



g. Go to File and “Save As” to *F:\Facility Doc Compare* folder using nomenclature below.

Designation – this includes Building number or Addendum designation.

EXAMPLES:

A) If the document is for Building 2, the designation would be “Bld2.”
123_Ames_Roland_BPL_Bld2_Compare_ML12345

B) If the document is Addendum A, Fraction List for Building 2, the designation would be “Bld2_A.”
123_Ames_Roland_BPLA_Bld2_A_Fraction_Compare_ML12345

C) If the document is an Addendum A, Fraction List that covers multiple buildings, the designation would not include the Building number in the name but would in the comment field.
123_Ames_Roland_BPLA_A_Fraction_Compare_ML12345

To name the document, use the following tables as guidance:

Document	Code	Building Number
Plot Plan	PP	NO
Plot Plan Legend	PPL	NO
Plot Plan Legend Addendum	PPLA	NO
Plot Plan Addendum	PPA	NO
Blueprint	BP	In Name of Document
Blueprint Legend	BPL	In Name of Document
Blueprint Legend Addendum - single building	BPLA	In Name of Document
Blueprint Legend Addendum - multiple buildings	BPLA	In Comments
Blueprint Addendum	BPA	In Name of Document

Addendum Type	Abbreviation
Fraction List	Fraction
Decontamination Procedures	Decon
Biocontainment & Biosafety Practices	BB
Exemptions to 9 CFR 109	109
Movement of Materials Between Licensed Premises	Movement
Storage of Master Seed off Licensed Premises	MSS
Alternative Location for Storage of Records	RS
Other Precaution Against Contamination Most BPA and PPA are related to mitigating cross-contamination	CC
Other	Other

Add the “Compare Report” to the ML identified as “Compared Document”

G. If submission is incomplete, return unprocessed.

1. For electronic submissions:
 - a. Use CVB-TEM-0042 to create a response to firm as to why the submission is being returned unprocessed. The resubmission date is customarily 1 month from the current date.
 - b. The BCA moves forward to Finalization and self-assigns
 - c. Sign the response electronically
 - d. Select *Return Unprocessed* as a TAG in the ML on *Info* tab
 - e. Fill out "Follow-Up" information on *Info* tab and enter "Follow-up Due Date" and "Follow Up By"
 - f. Update the Submission Response on the *Info* tab of the ML: select date for "Date of Letter/2015" and "Date Mailed." Select Portal under "Shipment Type."
 - g. Attach to the ML and identify as "Outgoing General Correspondence"
 - h. Move forward in the ML to the Section Leader – Final Authorization

2. For Hard Copies:
 - a. Sign and date the FDS
 - b. Place ✓ in Block 9C "Documents Returned" of FDS
 - c. Scan the FDS and attach to the ML. Identify document type as "Outgoing General Correspondence"
 - d. Use CVB-TEM-0042, *Facility Document Correspondence*, to create a response to the firm as to why the submission is being returned unprocessed. Customarily, give the firm 1 month to respond.
 - e. Attach to the ML and identify as "Outgoing Enclosure"
 - f. Select *Suppress Response from Portal* and *Return Unprocessed* as a TAG in *Info* tab in the ML
 - g. If returning via USPS (Certified Mail Receipt)
 1. Grab "Green Card" and White CERTIFIED MAIL RECEIPT (CMR) USPS label from Hive
 2. Use a First-Class USDA-APHIS manilla or white envelope (depending on size of documents being returned)
 3. Print three return address labels from the DYMO printer (select using *Liaison Return Labels* from the Address Book drop down in DYMO program)
 - a. Place one label in Box 1 of Green Card
 - b. Place one label in box under "OFFICIAL USE" on white CMR
 - c. Place one label on the front of the First-Class envelope
 4. Remove perforated portion of USPS CMR to keep
 5. Place CMR Sticker in upper right-hand corner of the First-Class envelope
 6. Place tracking number sticker in Box 2 of Green Card
 7. Write ML #, Est. #, BCA's Initials, Date, and VBI # (if applicable) somewhere on the Green Card and white CMR. This way, when the Green Card is returned, the EDE knows which BCA to return to.
 8. Check the "Certified Mail/Certified Mail Restricted Delivery" as well as "Signature Confirmation/Signature Confirmation Restricted Delivery" options in Box 3 of Green Card.

9. Remove the stickers on the back of the Green Card and place on the back of the First-Class envelope.
- h. If returning via UPS
 1. Sign on to UPS Campus Ship website (account will need to be created by NCAH Shipping Department)
 2. Enter the Establishment's Mailing address and address to the firm's Liaison
 3. Select "UPS Next Day Air" and check "Receive Confirmation of Delivery" box
 4. Ensure all information is correct and print the shipping label
 5. Use the UPS folder found in BCA Hive
- i. Fill out "Follow-Up" information on *Info* tab and enter "Follow-up Due Date" and "Follow Up By"
- j. Update the Submission Response on the *Info* tab of the ML: select date for "Date of Letter/2015" and "Date Mailed," select US Certified Mail or UPS under "Shipment Type," and enter Shipment Tracking Number.
- k. Move forward in ML to Section Leader – Final Authorization
- l. Send the Hard Copy FDS form, CVB-TEM-0042, and Facility Document submission back to the firm, see **CVB-SOP-0033**, *Outgoing Correspondence*.

This will close the ML – **any resubmission should reference the original ML.**

Facility Document Review Aid

PLOT PLAN

1. Scale indicated [108.3(a)]
2. Boundaries marked [108.3(b)]
3. Buildings identified [108.3(d)]
4. Use of adjacent property [108.3(e)]
5. Compass point [108.3(f)]
6. Date of Preparation [108.3(g)]
7. Signature of Liaison/Alternate [108.3(h)]**
8. Summary of Changes [108.6(a)]
9. Two copies [108.7]**

PLOT PLAN LEGEND

1. Legend identified by site [108.5]
2. Pages numbered [108.5]
3. Buildings identified [108.5(a)(1)]
4. Construction material included [108.5(a)(2)]
5. Summary of Changes [108.6(a)]**
6. Two copies [108.7]**

PLOT PLAN LEGEND ADDENDUM

1. Legend identified by site [108.5]
2. Pages numbered [108.5]
3. Addendum has unique identification [108.5]
4. Summary of Changes [108.6(a)]**
5. Two copies [108.7]**

BLUEPRINT & BLUEPRINT ADDENDUMS

1. Scale indicated [108.4(a)]
2. Rooms identified [108.4(e)]
3. Stationary equipment identified [108.4(f)]
4. Compass point [108.4(h)]
5. Building number included [108.4(i)]
6. Date of preparation [108.4(j)]
7. Signature of Liaison/Alternate [108.4(k)]**
8. Summary of Changes [108.6(a)]
9. Two Copies [108.7]**

BLUEPRINT LEGEND

1. Legend identified by building/floor [108.5]
2. Pages numbered [108.5]
3. Rooms identified [108.5(b)(1)]
4. Summary of Changes [108.6(a)]**
5. Two copies [108.7]**

BLUEPRINT LEGEND ADDENDUM

same as Plot Plan Legend Addendum

**See chart on Page 1 for requirements.

If discrepancies are found in document review, create one attachment identifying specific document(s) and brief description(s) of discrepancy. Attach to ML, [REDACTED] and identify as "Internally Routed".