

Facility Documents: BCA Preliminary Review

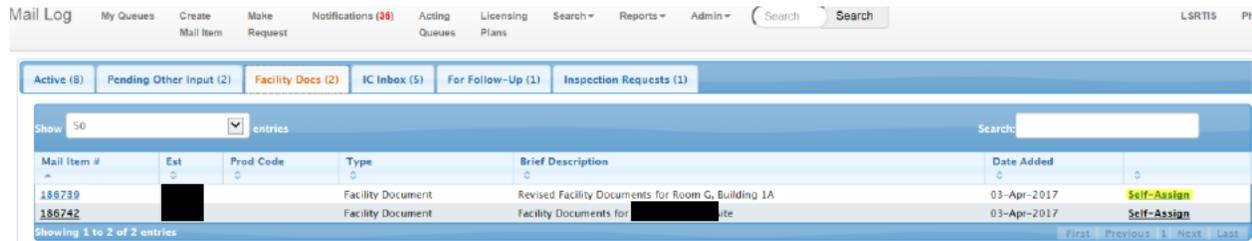
Facility documents can be submitted as hard copy or received electronically through the NCAH Portal.

	Electronic Submission	Hardcopy Submission
ML Creation	Automatic through Portal	ICWI0910
Version Identification	Required	Recommended – can use supersedes date
FDS form Used	No	Yes
Summary of Changes	Required only for drawings *	Required for all documents
Signature of Liaison/Alternate	No	Required on plot plans and blueprints
Two copies	No	Yes

*A summary of changes will be required for the first electronic submission for legends and addenda. Once a document has been filed electronically, a summary of changes is not required.

Submissions are reviewed first in/first out. The CVB's 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 mail log (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. Hard Copy Review:

- a. *Ensure proper data entry into LSRTIS – see ICWI0910, 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 Facility Document Submission Worksheet (FDS). 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.*

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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 exception noted in Section C.3.a.
- d. For all legends and addenda submitted, page numbers should be provided next to each entry under Column B.

2. Electronic Submission Review:

- a. Open ML and go to Documents Tab.
- b. Open File and ensure it matches the Type: for example, if the document you open is a document and it is a blueprint, make sure the Type is _Blueprint.

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

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 a capsulated 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. below.
3. A Summary of Changes is not required for the corresponding document(s) if:
 - a. It's a new site or building.
 - b. The legend or addendum have already been approved electronically and are on file with the CVB.

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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 mail log, i.e., ████_Discrep_ML123456 and identify as “internally routed”
3. Do document compare, if applicable. (See Section F. below)
4. Submit to Specialist
5. 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 below)
2. Submit to Specialist

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

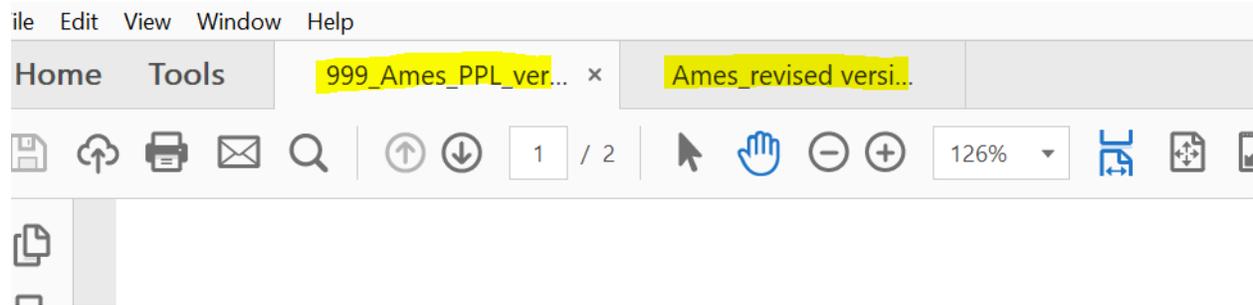
The BCAs will use the comparison aspect of Adobe Acrobat to generate a document compare report which the Specialist will use to evaluate the revisions of the submitted facility documents as compared. NOTE – This is only for legends and addendums - not applicable to drawings, such as blueprints or plot plans. ****IF this is the first electronic submission, this function should not be used.**

1. Go to CVB File Room SharePoint Site – Facility documents
2. Locate the currently filed document (legend/addendum) needed to compare to active submission, identify ML# (the example below is ML 177863)
3. Go to that ML, 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		

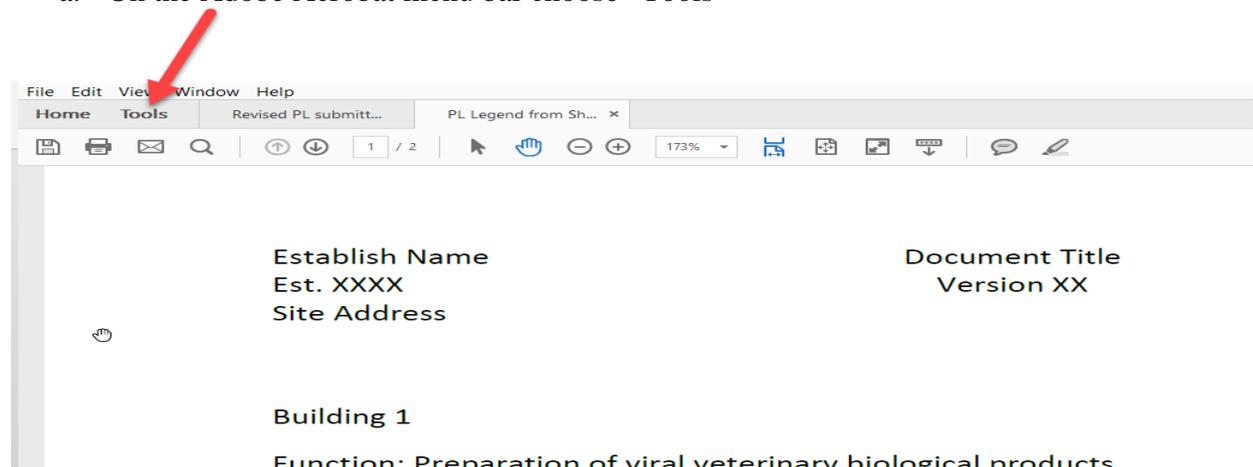
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4. Go to the Active ML, Document Tab and open the submission. Now both should be opened on the PDF window.

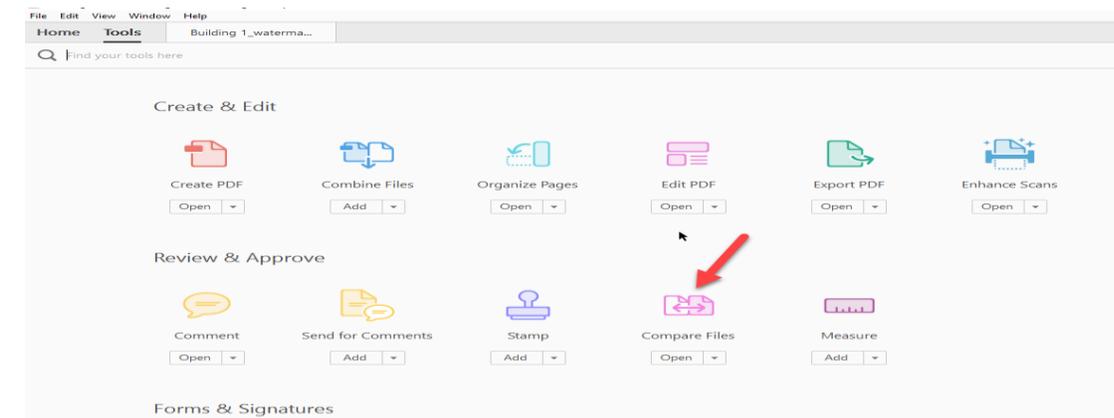


5. Document Comparison

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

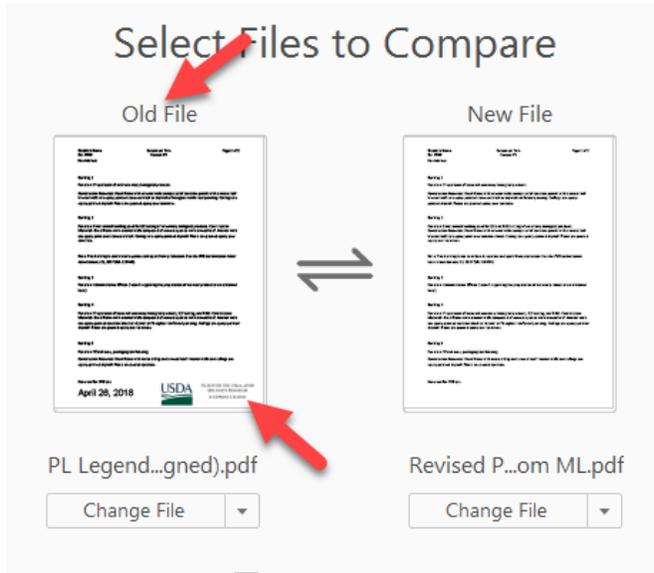


b. Choose “Compare Files”



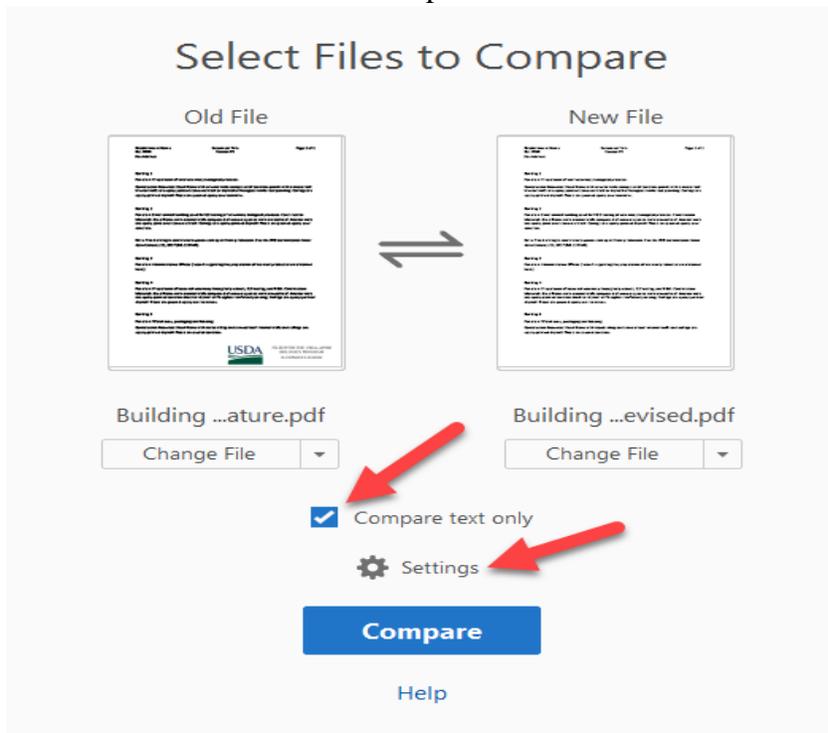
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- c. Make sure the “Old File” is the IC Clean Copy document. Should have CVB’s stamp and date on it. If it isn’t, select the arrows in the middle to switch files around.



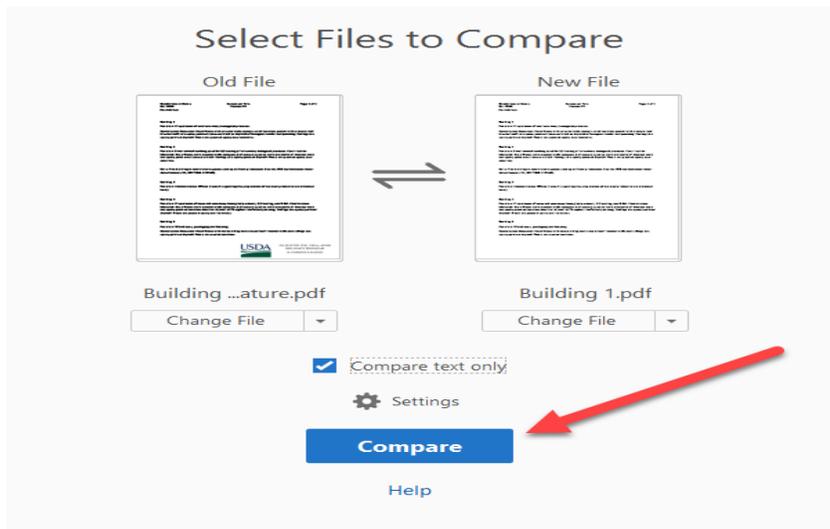
- d. Check the box “Compare text only”. Click OK.

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

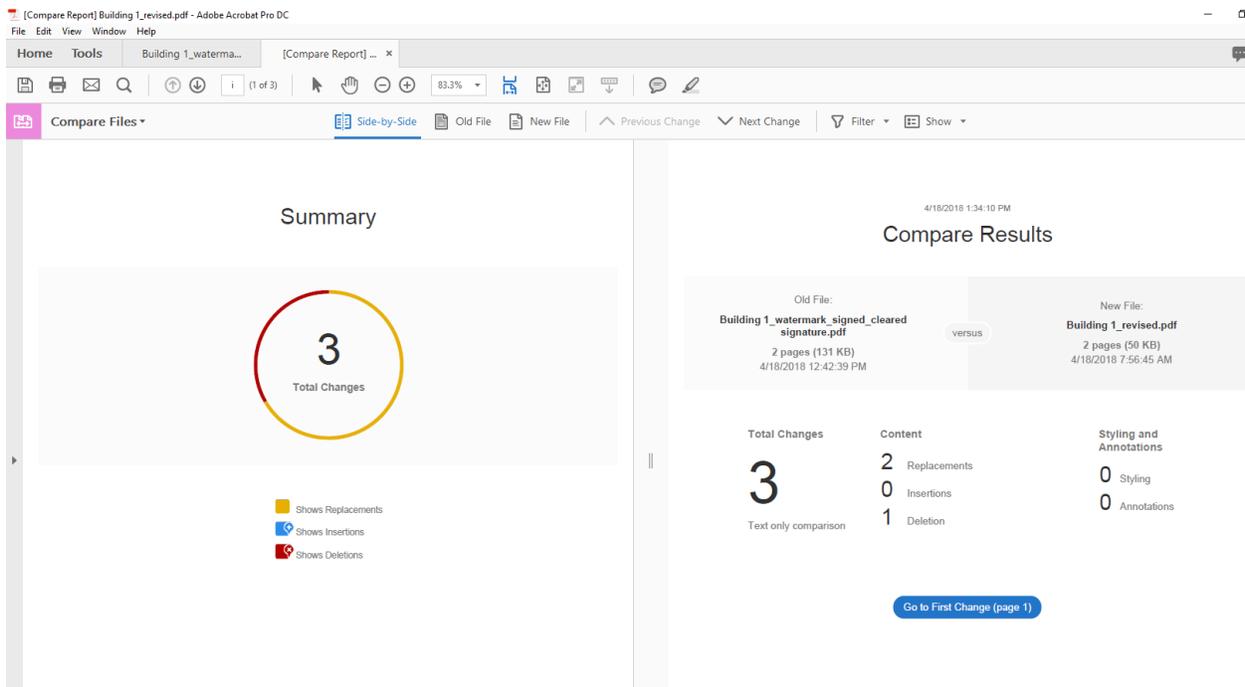


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e. Click Compare



f. This will generate the “Compare Report”.



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

Est. ##_Primary Site_Document_Compare_ML#

Example: █████_██████_BPLBldg2_Compare_ML11111.

If it is an ancillary site:

Est. ##_Primary Site_Ancillary Site_Document_Compare_ML#

█████_██████_██████_PPL_Compare_ML11111.

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

G. If submission is incomplete, return unprocessed.

1. For hard copies:
 - a. Sign and date the FDS
 - b. Place ✓ in Block 9C “Documents Returned” of FDS
 - c. Scan FDS and attach to the ML, identify document type “Outgoing General Correspondence”
 - d. Use **ICTEM0045** to create response to firm as to why submission is being returned unprocessed. Customarily, give the firm 1 month to respond.
 - e. Attach to the ML and identify as “Outgoing Enclosure”
 - f. Move forward in mail log to Section Leader – Final Authorization
 - g. Send the hard copy FDS, **ICTEM0045**, and facility document submission back to firm, see **ICSOP0011**, *Outgoing Correspondence*.

2. For electronic submissions:
 - a. Use **ICTEM0049** to create response to firm as to why submission is being returned unprocessed. The resubmission date is customarily 1 month from current date.
 - b. Sign the response electronically
 - c. Attach to ML and identify as “Outgoing General Correspondence”
 - d. Move forward in mail log to Section Leader – Final Authorization

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

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 mail log; i.e., *124_Discrep_ML123456* and identify as “Internally Routed”.