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 <b>only</b> 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).

Mail Log	My Queues	Create Mail Item	Make Notific Request	ations (36)	Acting Licensi Queues Plans	ng Search <del>-</del>	Reports +	Admin -	Search	Search		LSRTIS F
Active (8)	Pending Othe	er Input (2)	Facility Docs (2)	IC Inbox (5	i) For Follow-U	p (1) Inspecti	ion Requests ()	1)				
Show 50		۲	entries								Search:	
Mail Item	# Es	st Pro	od Code	Туре		Brief Description	1				Date Added	
^	0	¢ (		<b>\$</b>		¢					0	0
186739				Facility Docum	ent	Revised Facility D	ocuments for R	oom G, Buildi	ng 1A		03-Apr-2017	Self-Assign
186742				Facility Docum	ent	Facility Document	ts for	lite			03-Apr-2017	Self-Assign
Showing 1	to 2 of 2 entries											Previous 1 Next Last

**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.

[B] Comments							
	<ul> <li>Image: A start of the start of</li></ul>						
	<ul> <li>✓</li> </ul>						
Building 1	<ul> <li>✓</li> </ul>						
Building 1, pages 1-20	<ul> <li>✓</li> </ul>						
Building 1, pages 1-3	<ul> <li>✓</li> </ul>						
	<ul> <li>✓</li> </ul>						
	[B] Comments [B] Comments Building 1 Building 1, pages 1-20 Building 1, pages 1-3						

- 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.

#### 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 - <u>not</u> applicable to drawings, such as blueprints or plot plans. \*\*IF this is the <u>first electronic submission</u>, this function <u>should not</u> 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)

Info Doci	Ifo Documents Workflow Log Notifications Phone Logs Detailed Database Action Log						
Show <sup>50</sup>		entries	Search:				
Doc ID \$	Туре ≎	File Name ≎		Create Date ≎	Comments ≎	Hard Copy ≎	
<u> 177863 - 3</u>	_Plot Plan Legend	Ames - 1st electronic submi	ission.pdf	06/04/2018			
<u> 177863 - 4</u>	IC Clean Copy	999 Ames PPL version 1	999 Ames PPL version 1 cleancopy.pdf 06/04/2018				
<u> 177863 - 5</u>	Outgoing Enclosures	999 Ames PPL 1-REV.pdf		06/04/2018			
<u> 177863 - 6</u>	Outgoing General Corr.	<u>180530-1.pdf</u>		06/04/2018			
Showing 1 to 4 of 4 entries First Previous 1 Next						t Last	

3. Go to that ML, Documents Tab, and open the IC Clean Copy

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



b. Choose "Compare Files"



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.

Old File		New File
And the And the And	-	
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April 26, 2018	No. John Inda Land	Kest Re.
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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.



#### e. Click Compare

Suildingature.pdf   Change File     Compare text only	Old File		New File
Buildingature.pdf Building 1.pdf Change File Chang		$\rightarrow$	
Change File Change	Buildingature.pdf		Building 1.pdf
Compare		Compare text o	nly
		Compare	

#### f. This will generate the "Compare Report".

🗾 [Co File	[Compare Report] Building 1_revised.pdf - Adobe Acrobat Pro DC = 6 ddt View Window Help								
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8	Compare Files • Ei Side-by-Side DId File DId File New File	vious Chan	ange 🗸 Next Change 🛛 $\nabla$ Filter 🔹 🎛 Show 👻						
	Summary		4/182018 1:34-10 РМ Compare Results						
Þ	3		Old File:         New File:           Building 1_watermark_signed_cleared signature.pdf         Building 1_revis           2 pages (131 KB)         2 pages (30 F 4/18/2018 12:42:39 PM	ed.pdf KB) 45 AM					
			Total Changes Content Styling a Annotatic Replacements	nd ons					
	Shows Replacements		Text only comparison 1 Deletion 0 Annot	3 lations					
			Go to First Change (page 1)						

 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#

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  $\sqrt{\text{ in Block 9C "Documents Returned" of FDS}}$
  - 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]\*\*

#### ICWI0081.04 Author: Sharon Mundt Issue Date: 25Jun18 Source Document: ICSOP0018, *Processing Facility Documents*

# 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".

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