



**Animal and Plant  
Health Inspection  
Service**

**Veterinary Services**

**Center for Veterinary  
Biologics**

**1920 Dayton Avenue  
PO Box 844  
Ames, IA 50010**

**(515) 337-6100**

## **Facility Documents; Specialist Review, Including Electronic Processing**

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**Author: DMURTLE**

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**Release Date: 03 Oct 2019**

**Notes:**

## **Facility Documents; Specialist Review, including Electronic Processing**

Source Document: Veterinary Services Memorandum 800.78 and title 9, *Code of Federal Regulations*, part 108

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## I. BACKGROUND

The main objective in the Specialist's review and assessment of facility document submissions is to determine if the facility construction and arrangement, along with the established processes and procedures regarding preparation of licensed or permitted biological product, appear to effectively work together to ensure consistent manufacturing of products and to mitigate contamination of licensed or permitted product. The Specialist should become familiar with both title 9, *Code of Federal Regulations* (9 CFR), part 108, and Veterinary Services Memorandum (VSM) 800.78 in order to conduct a meaningful review. The submitted document(s) should be reviewed in its entirety even though there may have only been a few changes.

## II. SPECIALIST REVIEW (SECONDARY REVIEW CONSIDERATIONS)

Below is a listing of some of the items each Specialist should consider when reviewing facility documents. Keep in mind that depending on the type of licensed/permitted product prepared at the facility and processes and procedures established to mitigate cross contamination of product will likely differ significantly. For example, licensed establishments preparing injectable vaccines will likely have established more safeguards to protect product against cross-contamination than the manufacturer of diagnostic test kits which do not require final sterility testing. In performing your review, ask yourself the question – *Does the facility appear appropriate for the intended activities and use as described in the filed Outline(s) of Production?*

### A. FACILITY DOCUMENT SUBMISSION TYPE (as determined by the Specialist)

- New Address – sites not currently included on the establishment license
- Prelicensing – self explanatory
  1. Licensee – Has an APHIS Form 2001 been submitted to Policy, Evaluation, and Licensing (PEL)?
  2. Permittee – Has an APHIS Form 2005 or a special outline been submitted?
  3. Diluent – Not technically required, but is site listed in a special outline?
  4. Does the site require an inspection prior to adding it to the establishment license?
    - a. Prelicensing – requires an inspection
    - b. New Address for Production – requires an inspection unless there are extenuating circumstances. This will be at the discretion of the Section Leader, Inspection.
    - c. New Address for Testing or Distribution – depends, but can be approved without an inspection. There must be a statement from the firm indicating the personnel are trained (if new to the process) and

equipment is adequate to provide similar results. May require technology transfer with testing by Center for Veterinary Biologics (CVB).

- New Building – new construction on a site listed on the establishment license
- Remodeled Facility – construction which moves walls, areas, or an addition
- **Does the building require an inspection prior to filing the facility documents?**
  1. Production – YES  
Requires an inspection unless there are extenuating circumstances (rare). This is at the discretion of the Section Leader (SL), Inspection.
    - a. New or remodeled facilities can be used AT RISK prior to an inspection.
    - b. Product made in a new or remodeled facility IS NOT eligible for consideration for marketing prior to assessment of the facility, equipment, personnel, and processes. Samples and APHIS Form 2008s should be held until after the inspection results are documented (unless an inspection was not required per SL, Inspection discretion)
    - c. Equipment and processes should be validated prior to an inspection.
  2. Testing, Distribution – depends, but can be approved without an inspection as long as the personnel, equipment, and processes are the same.
- Revision – usually due to an update from the firm or inspection findings.

## B. ITEMS TO CONSIDER WHEN REVIEWING THE FACILITY DOCUMENTS

1. Determine if there is adequate **separation of production areas** from non-production areas. **CVB-WI-0066**, *General Guidelines on Designating a Building or Area Separate and Apart*, may apply in making this determination.
2. Does the level of control regarding mitigation of cross contamination appear appropriate for the product(s) prepared? Line clearance procedures performed in between production runs may be the primary focus for firms that manufacture diagnostic tests, where as many safeguards against cross contamination of licensed product should be established for injectable vaccines.
3. In areas **where product is exposed** to the surroundings, is it clear whether manipulations occur inside or outside of a compartment? For example, this should be obvious in a fill suite but what about other areas, such as blending?

The documents should state where product is exposed to the surroundings and therefore, there should be a higher degree of scrutiny in our review of these areas regarding the firm's description of how cross contamination is mitigated.

4. Look at any potential negative impact R&D activities may have on licensed/permitted product. For example, sharing of equipment, positioning of R&D to product preparation areas, and so forth. Is the listing of Exemptions to 9 CFR 109.1 and 109.2 adequate to address concerns here?
5. Is the air handling system adequate in areas where product is exposed to the surroundings for the functions performed? Assess **directional airflow** (e.g., air flowing into or out of a fill suite) and air **filtration** (HEPA filters) for the air supplying production rooms and compartments to make this determination. Some questions to consider are: Is air re-circulated within a room, and what is the turn-over rate per unit time? Do some rooms have a dedicated air supply? Is backflow prevention necessary and if so, is it in-place?
6. In assessing traffic patterns, determine how **personnel** and **materials** enter into and exit out of production rooms.
7. Ensure **room function(s) are spelled out** clearly in the blueprint legend or in an addendum to this legend (e.g., methods to mitigate cross-contamination – airlock function, clothes change). Often times, the room function supplied by the firm is more like a room name. Providing an adequate description of the room function(s) is key in determining if methods to mitigate cross contamination are appropriate.
8. We have explained in the most recent VSM 800.78 what the firm should list as equipment; however, if a document comes in with toilets shown, for example, do not consider this as an issue in determining to accept or reject the documents. If there are blatant errors regarding stationary equipment identified on the blueprint or corresponding legend, inform the firm. The documents may be sent back unfiled or result in a request for revisions.
9. If a floor drain or sink is located in a production room, do the documents describe any backflow prevention in the drain lines to prevent the possibility of effluent draining into the room?

This is by no means an all-inclusive list of items to consider in reviewing facility document submissions. If you have a question regarding the review that cannot be found or is not clear in 9 CFR 108 or VSM 800.78, then don't hesitate to discuss the issue with the Facilities Manager or Inspection and Compliance (IC) Section Leader.

### III. REVIEW PROCESS

1. Process facility documents in order in which they are received in your queue. Exceptions may arise based on program priorities.
2. The Biologic Compliance Assistants (BCAs) will perform the preliminary review of the submitted documents using **CVB-WI-0109**, *Preliminary Review of Facility Documents (BCA)*. Summary of changes will no longer be required for electronically submitted legends and addenda (once they have been filed electronically). Summary of changes will still be needed for those facility documents submitted as hard copies. The BCA preliminary review includes ensuring the documents submitted are identified correctly, the documents are complete in accordance with 9 CFR 108 and performing a document compare between the filed document and the submitted document for electronic submissions. The compare document will be identified as the type “Compare Document” and attached to the Mail Log (ML). The BCA may also attach a document titled “Facility Document Discrepancy” that informs the Specialist of any discrepancies identified in their preliminary review.
3. Determine if the BCA had previously audited the documents back unprocessed and if so, were the proper correction made? Depending on the BCA’s concern(s) noted on the Facility Document Discrepancy document, the Specialist may need to identify those concerns on **CVB-TEM-0042**, *Facility Document Correspondence* (hard copy), or **CVB-TEM-0044**, *Facility Document Correspondence* (for electronic submissions). If a portal submission, the previous ML should be informationally linked, if revisions were requested or if documents were unprocessed. This should be done by the submitter, if not done the BCA or Specialist can informationally link them.
4. Review the Specialist’s response to the facility documents submitted immediately prior to the submission currently under review to see if the firm has addressed all of the concerns previously raised. If it is determined through your review that the overall quality of the submission is poor and/or the firm has not addressed issues needing correction as stated in the previous facility document correspondence, then the submitted documents may be returned unfiled along with the completed **CVB-TEM-0042/CVB-TEM-0044** form. In addition, communicate to the firm that a regulatory action may be taken if the next facility document submission does not provide complete and accurate information.
5. If there is to be a regulatory action based on the facility document submission, reference the date of the previous facility document letter(s) sent to the firm. The firm may be in violation of 9 CFR 114.1 if they have not addressed previous CVB requests to make revisions to one or more of the facility documents.

6. Facility documents filed with CVB as electronic are no longer eligible for page changes. Each submission needs to be a complete revision. The supersedes date does not need to be applied to or assessed for correctness for each document page. If the supersedes dates are provided, you do not need to check these against the filed facility documents. Hard copy submissions may still utilize page changes.
7. For legends and addenda, evaluate the document compare report for electronic submissions or summary of changes for hard copy submissions to determine if the changes made are acceptable. For plot plans and blueprints, compare the summary of changes to the documents submitted. The two should be in agreement. If not, then contact the firm for clarification and/or return the documents unprocessed.
8. We will no longer be making pen-and-ink changes to the documents. Instead, make note of items needing revision in your response back to the firm. This is for both hard copy and electronic submissions.
  - a. **Rule of thumb**, if it was acceptable for a pen and ink change, most likely it is appropriate to request a revision rather than send back unfiled.
  - b. Hard copy – questions can be asked to clarify submissions. Document the conversation in a phone log and attach to the Mail Log (ML).
  - c. Electronic submissions – the Specialist can initiate a child loop, “Request info from Submitter” with specific questions. The firm can reattach or change documents to clarify. It is the Specialist’s responsibility to ensure the changed documents meet the specification in 9 CFR 108 as they will not be reviewed by the BCA.
  - d. Examples for clarifying questions are:
    - i. Information that PEL has approved the movement of organisms into a specific area.
    - ii. Disinfectants used (trade names vs. active agents)
9. The Facility Document Submission form (FDS) is used for hard copy submissions but is not used for electronic submissions.
10. Document all revisions or reasons for returning a document on the **CVB-TEM-0042/CVB-TEM-0044**. Only one template per ML should be used.
  - a. Upload **CVB-TEM-0042** to ML as “Internally Routed” (Hard Copy).
  - b. Upload **CVB-TEM-0044** to ML as “Outgoing General Correspondence” (Electronic)

**DOCUMENTATION OF REVIEW OF HARD COPY DOCUMENTS**

1. Center for Veterinary Biologics Inspection and Compliance Facility Document Submission Worksheet. This form is currently under review by OMB and will be referred to as Facility Document Submission form or FDS.

- a. Complete the bottom portion of the FDS form by checking one or more of the three boxes in Block 9, CVB Action.  
 Box 9.A - Documents Filed  
 Box 9.B - Documents Filed, Revisions Requested  
 Box 9.C - Documents Returned
- b. Sign the form in Block 10.A. Leave Block 10.B blank as this is the date the documents are stamped/sent back to the firm. This date will be filled in by the BCA performing the final processing of the submission.

**IV. PROCESSING OF THE FACILITY DOCUMENTS (SPECIALIST)**

There will only be three possible outcomes for each facility document:

	<b>Hard Copy – FDS Marked</b>	<b>Electronic Stamp</b>	<b>Electronic Nomenclature</b>
Filed, No revisions or comments	Document Filed	Filed with the USDA-APHIS Biologics Program Blueprint/Legend	CVB
Filed with Revisions requested	Documents Filed, Revisions Requested	Filed with the USDA-APHIS Biologics Program with Revisions Requested Blueprint/Legend	REV
Returned, not filed	Documents Returned	No stamp	Not returned electronically

After review, the Specialist will apply the appropriate stamp and date to each electronic document, see Section VII.

**V. NOMENCLATURE FOR ELECTRONIC FACILITY DOCUMENTS**

Specialist will be responsible for naming each electronic facility document attachment using a standard convention.

Example:

**Est## Primary Site Ancillary Site Document Type Designation**

**██████████\_BPL\_Bld2**

Definitions:

- a. EST## – self explanatory



- b. Primary Site – designated name, usually city location where the primary inspection site is located for the document being reviewed. LSRTIS classification as manufacturing, testing, quarantine.
- c. Ancillary Site – designated name of the site that is associated with the primary site. LSRTIS classification of Ancillary site. – Ancillary sites could be full address, street name, or city. - **may not be needed**
- d. Document Type

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	BPLA	In Comments
Blueprint Addendum	BPA	In Name of Document

- e. Since addendums serve a specific purpose there is a need to further identify each addendum with the type of addendum it is below are standard abbreviations that should be used.

Addendum Type	Abbreviation
Fraction List	Fraction
Decontamination Procedures	Decon
Bio containment & 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	CC
Most BPA and PPA are related to mitigating	

cross contamination	
Other	Other

Designation – this includes building number or addendum designation.

EXAMPLES:

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

██████████\_BPL\_Bld2

B) If the document is addendum A, Fraction List for building 2, the designation would be “Bld2\_A”.

██████████\_BPLA\_Bld2\_A\_Fraction

C) If the document is an addendum A, Fraction List that covers multiple building, the designation would not include the building number in the name but would in the comment field.

██████████\_BPLA\_A\_Fraction

## Create Attachment

MailLog #	Establishment	Product Code	Brief Description	Type	Date Submitted
213912	██████████		Facility Documents for ██████████ site. Single copy provided.	Facility Document	July 15, 2019

Select File Location  Uploaded File  Hard Copy

Select File to Upload ██████████ Documents\181026.pdf

Type \*

Version #

Tags

Comments

- f. Version – This will be a consecutive number for every submission of a revision to the facility document. This first electronic submission will be designated as Version 1. If the firm has not designated a version, the Center of Veterinary Biologics (CVB) will designate the version of CVB’s internal purposes. **Only filed documents will receive a version number. Documents sent back unfiled will not have a version number.**

**General Naming Rules –**

**For Version 2 and above – ALWAYS LOOK AT SHAREPOINT FOR THE MOST CURRENT NAMING CONVENTION**

1. **No Building Numbers – use address for Plot Plan, Plot Plan Legend, and Plot Plan Addendum**
2. **Use Building Numbers for Blueprint, Blueprint Legend, and Blueprint Addendum**
3. **No Building Reference in Name – but listed in the comments – Addendums (other than blueprint or plot plan drawings listed as addendum)**
4. **Use the firm’s nomenclature for naming**  
**If the blueprint is labeled as [REDACTED], Building 1, first floor the document name should be [REDACTED]\_BP\_Bld1\_firstfloor**  
**IF the blueprint is labeled 1<sup>st</sup> floor the document name should be [REDACTED]\_BP\_Bld1\_1stfloor**

**Communication with Records Management**

1. Comments to be added to sharepoint are the responsibility of the Specialist. The Comments should only be for unique issues. You can tell by the name the document is a blueprint (BP) so you should not add the comment blueprint. But if the blueprint is of the entire facility (some buildings are submitted in sections) the comment should be “Entire Facility”
2. The comments field to be used shows up when you click on “+ Create New Document Record”. See Create Attachment above. The type of document must be Outgoing Enclosure.
3. If you change a document name after the submission has been sent, use the Mail Log “Make Request”. Add establishment and include the ML and changes to the document name in brief description.

# Make Request

Type \*

Records Management Help

Establishment

Product

## Sharepoint Site – Examples

Name	ML Number	Version #	CVB or REV	Comments	Created
BP_Admin_Bld1	...	1	CVB		January 30
BP_Bld1_LevelsA_B	...	2	CVB		August 17, 2018
BP_Bld1_LevelsC_D	...	2	CVB		August 17, 2018
BP_Bld2_LevelA	...	1	CVB		October 16, 2018
BP_Bld2_LevelB	...	1	CVB		October 16, 2018
BP_Bld2_LevelC	...	1	CVB		October 16, 2018
BP_Bld7	...	1	CVB		January 30
BP_Bld8_Necropsy1	...	1	CVB		January 30
BP_LrgAnimalBlds2_3_4	...	1	CVB	1, Large Animal Blds 2,3,4	January 30
BP_	...	1	CVB		January 30
BP_	...	1	CVB		January 30
BP_	...	1	CVB		January 30

	[REDACTED]	Industrial_BPLA_A_Other	...	[REDACTED]	1	CVB	coded equipment; Blds [REDACTED]
	[REDACTED]	Industrial_BPLA_B_Decon	...	[REDACTED]	1	CVB	Blds [REDACTED]
	[REDACTED]	Industrial_BPLA_C_Decon	...	[REDACTED]	1	CVB	Blds [REDACTED]
	[REDACTED]	Industrial_BPLA_D_CC	...	[REDACTED]	1	CVB	Blds [REDACTED]
	[REDACTED]	Industrial_BPLA_E_109	...	[REDACTED]	1	CVB	Blds [REDACTED]
	[REDACTED]	Industrial_PP	...	[REDACTED]	1	CVB	

**VI. UNPROCESSED DOCUMENTS (SPECIALIST)**

**NOTE: Documents returned unprocessed will not have a Stamp, Date, or Signature applied to the document.**

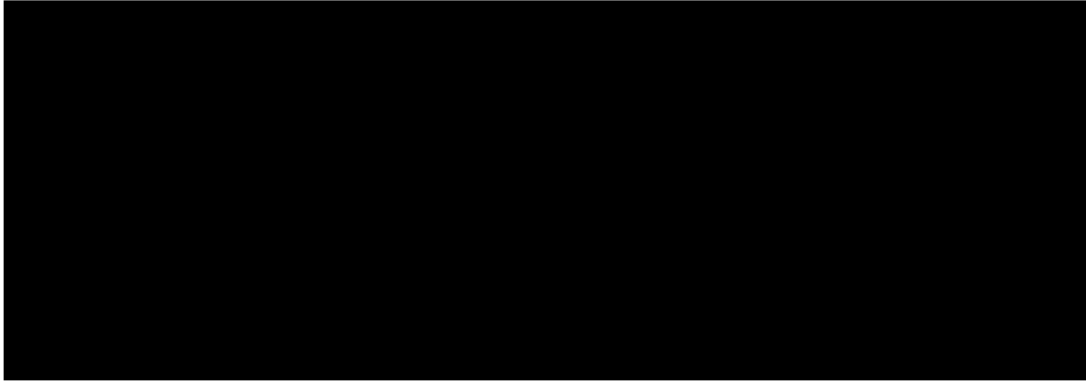
A. Complete the correspondence with comments as to why the document is being returned unprocessed.

1. Hard copy
  - a. Comments returned on **CVB-TEM-0042**. Attach document as “Internally Routed”.
  - b. On FDS (hard copy), check “Documents Returned” and sign in Block 10.A. (do not date).
2. Electronic Submission
  - a. Comments returned on **CVB-TEM-0044**. Attach document as “Internally Routed”.
  - b. Unprocessed documents will not be uploaded as “IC Clean Copy”
  - c. Add a follow-up date that corresponds to the timeframe specified on the **CVB-TEM-0044** in the ML. Recommend 30 to 60 days.
  - d. Add tag “Returned Unprocessed” if the entire submission is returned.

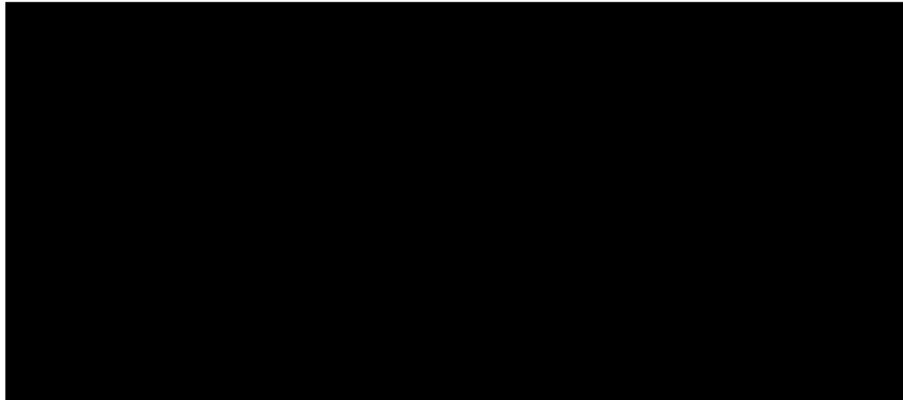
**VII. DOCUMENTS PROCESSED – STAMPING/DATING (SPECIALIST)**


Documents Filed with no revisions requested or Documents Filed with revisions requested.

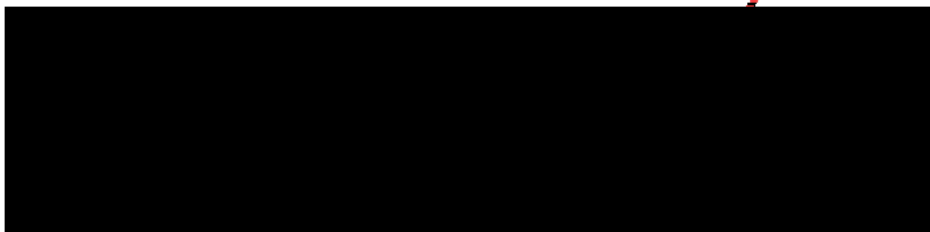
A. Apply STAMP



2. Select 

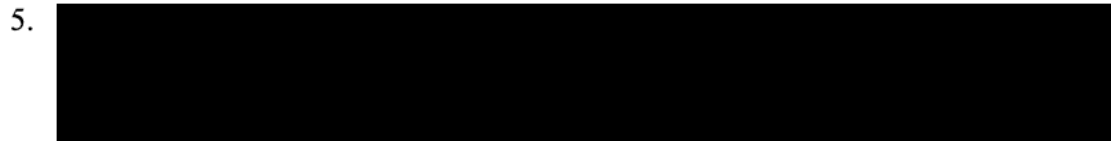



3. On 

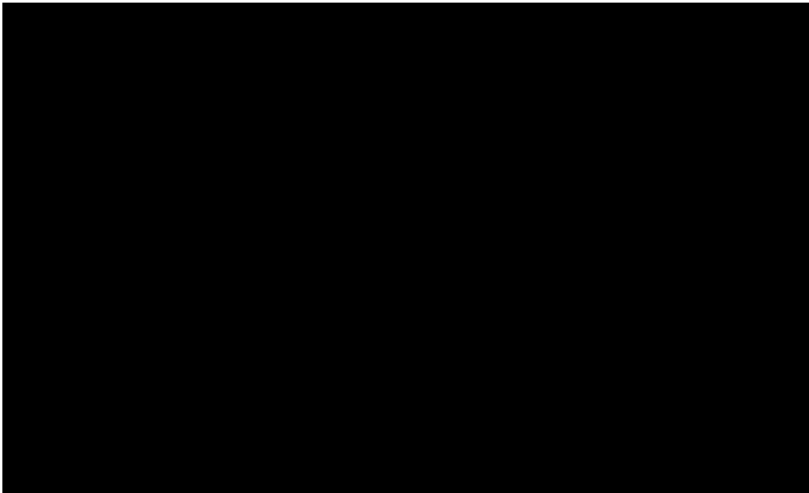


Building 1 

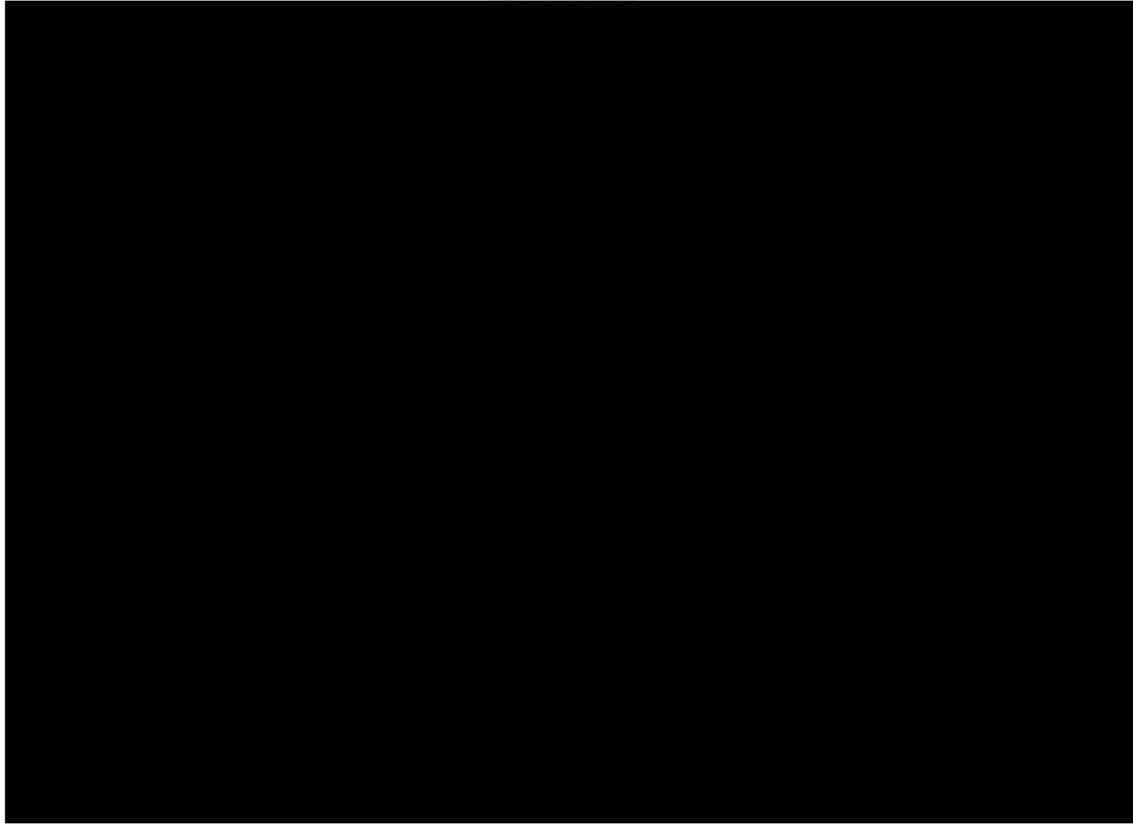
4. Select 



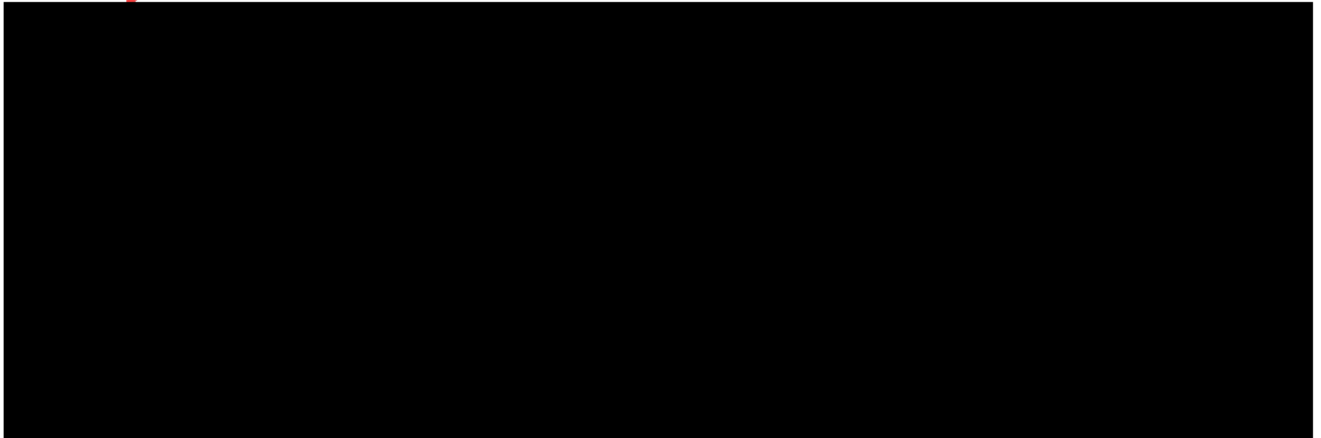
7. Select File and browse to find the appropriate saved stamp that should be saved on each Specialist's 



8. 
9. 

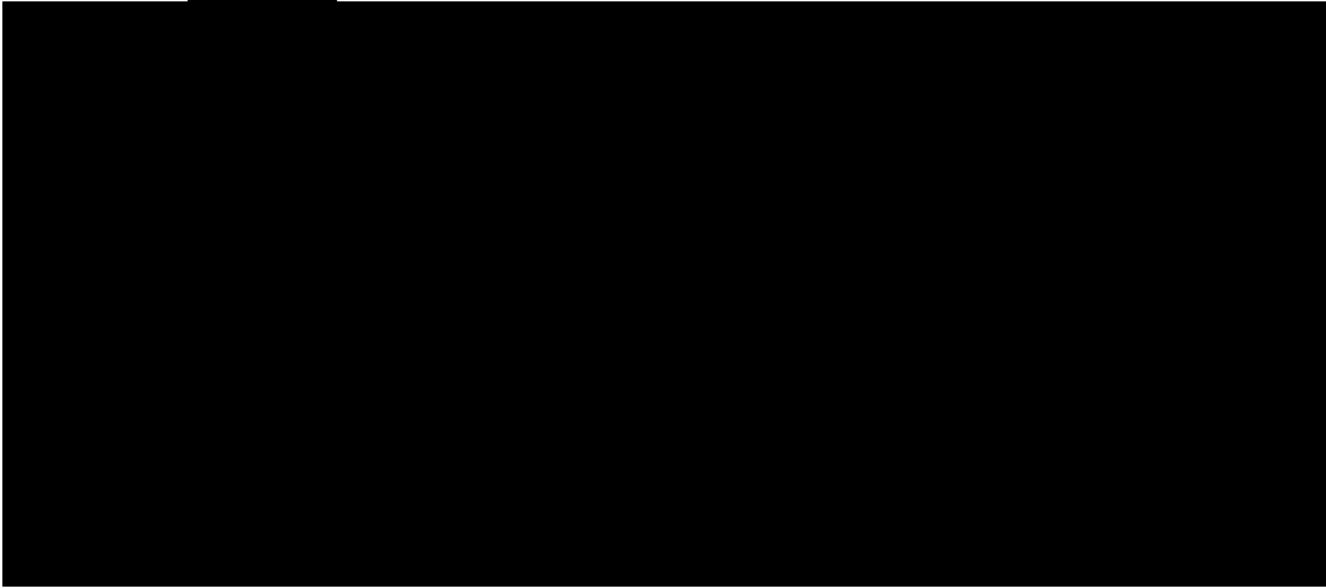


B.

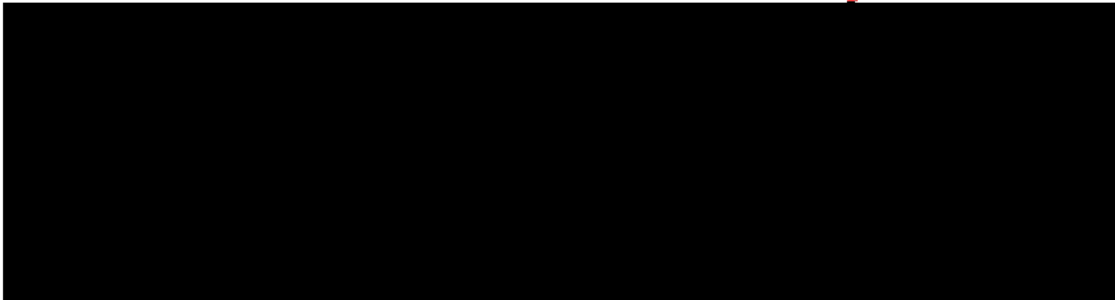




2. Select [REDACTED]



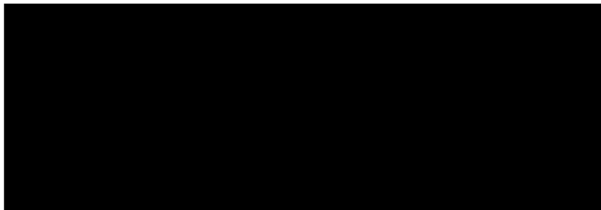
3. On [REDACTED]



Building 1

4. Select [REDACTED]

[REDACTED]

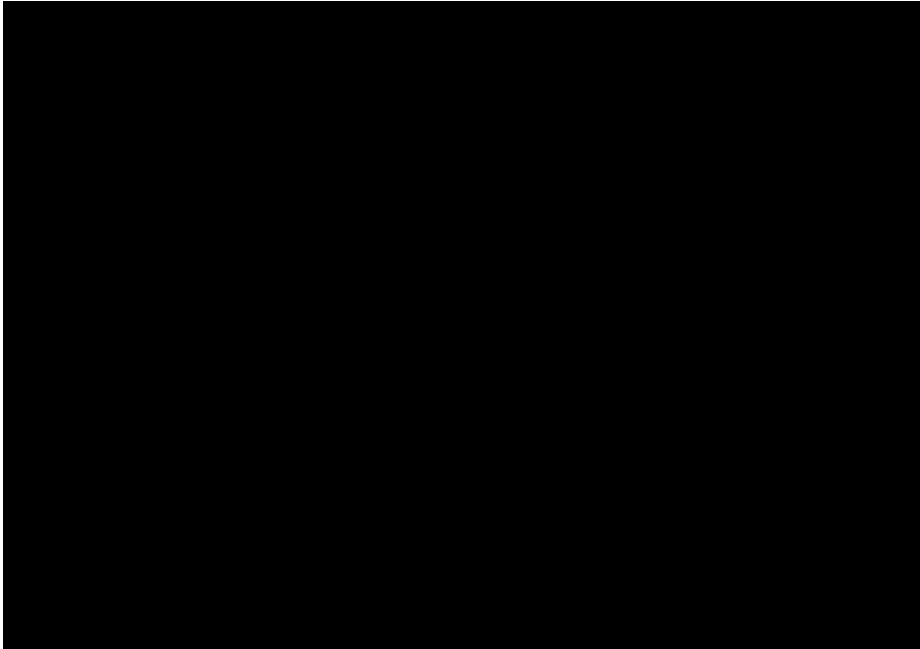


5. Select [REDACTED]

6. Enter [REDACTED]

7. Change [REDACTED]

8. Adjust [REDACTED]
9. Adjust [REDACTED]
10. Select [REDACTED]



C. Name document, see Section VII.

FILED (example) Example: [REDACTED]\_BPL\_Bld2\_CVB

REVISIONS (example) Example: [REDACTED]\_BPL\_Bld2\_REV

D. Upload the stamped/dated facility document(s) to the mail log item as “**IC Clean Copy**”

**Most documents will move directly to Section IX Finalization at this point except those that are unique or have policy issues/questions that the specialist determines management review is required, if this is the case then proceed to Section VIII.**

### **VIII. DOCUMENT REVIEW (SECTION LEADER)**

Once all of the documents have been reviewed, processed, and uploaded to the ML, the ML item will be sent to the specialist unit Section Leader (SL) for policy review.

1. The Specialist will send the ML item using “Section Leader Review(IC)”. Assign the specialists supervisor (or designate).


2. The SL assigned will review the documents for consistent policy. This is also an opportunity to review the **CVB-TEM-0042/CVB-TEM-0044** document, assure the appropriate stamp has been applied to the document, and assure the file is named in accordance with naming convention described in See Section V and Section VII.C above.
3. After SL review there are two options.
  - a. If the SL has determined all the documents in the ML item conform to the process and policy, the SL will forward the ML item to the appropriate BCA for finalization.
  - b. If the SL has determined that items need clarified by the Specialist prior to moving forward, the SL will make comments on the **CVB-TEM-0042/CVB-TEM-0044** and attached a revised copy to the ML item.
    - 1) If the SL determines that a further SL review of the documents is required after the Specialist has made corrections, the SL leader would not approve the documents when sending back to the Specialist by selecting “Cancel” in the pop up. If a Specialist applied the wrong stamp, the Specialist will need to redo the stamp. Go to edit PDF watermark. Remove. This will remove both the stamp and date that was previously applied.
    - 2) If the SL determines that they do not need to review the documents again after the Specialist has made corrections, the SL would approve the documents when sending back to the Specialist. Once the Specialist makes appropriate corrections, they send to the appropriate BCA for finalization.

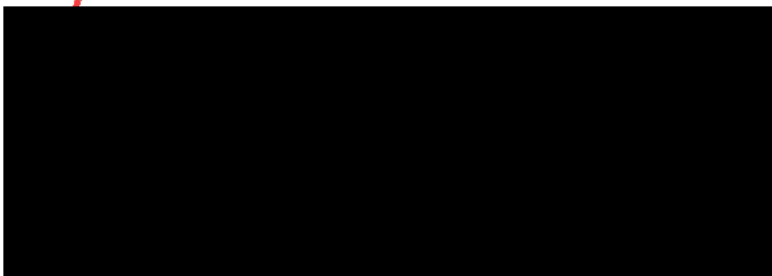
## **IX. FINALIZATION – BCA role, CVB-WI-0113**


## **X. SIGN CORRESPONDENCE (IC) - SPECIALIST**

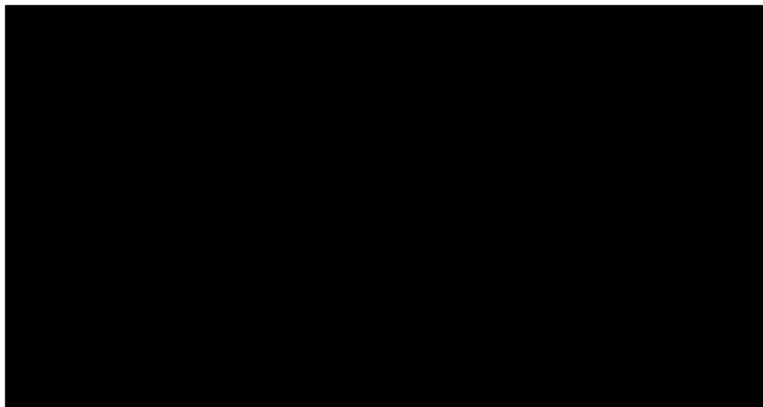
- A. Hard copy
  1. Ensure the **CVB-TEM-0042** has been dated.
    - a. The FDS form should be “Outgoing General Correspondence
    - b. The **CVB-TEM-0044** should be “Outgoing Enclosure”
    - c. The ML should be tagged “SUPPRESS Response from Portal”
  2. Click on Sign Correspondence
  3. Move to “Section Leader – Final Authorization”
- B. Electronic Submission
  1. If needed, digitally sign **CVB-TEM-0044**  
Attach to Document Tab as “Outgoing General Correspondence”

2. If documents are to be filed with or without revisions requested, sign each facility document – use invisible digital signature.
3. For documents that are not going to be filed, do not sign them and add a follow-up date in the Follow-Up section of the ML. Go to 4 below

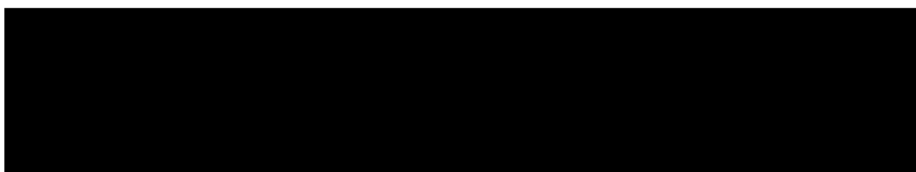
a. Select 



b. Select 



c. On 



Building 4

Function: Preparation of bacterial veterinary biological products, QC testing, and R&D. Construction Materials: Steel frame with exterior walls composed of concrete panels with a metal roof. Interior wall are epoxy-painted concrete block or drywall or fiberglass reinforced paneling. Ceilings are epoxy-paint

d. Select [redacted]



e. Make sure the [redacted] allowed.



f. Sign and save. See Section V and VII.C for nomenclature – should not have to change.

g. Upload the signed document to the ML as “Outgoing Enclosures.”

h. Add the “Version #” to the Version Field on the Create Attachment screen.

### Create Attachment

Mail Log #	Establishment	Product Code	Brief Description	Type	Date Submitted
177943	999		Test on adding documents	Facility Document	February 09, 2018

Attachment 177943.3 created

Select File Location  Uploaded File  Hard Copy

Select File to Upload [redacted] 999 Ames BP Bld2-CVB.pdf

Type \*

Version #

Tags

Comments

- i. Once all documents have been dated, signed, and uploaded, move the ML item to “Section Leader-Final Authorization.”
4. If a document is not being filed, ensure the Tag “Returned Unprocessed” is added to the document and add the comment “returned unprocessed.” This can be done by editing the attachment as follows:

A. Click on Doc ID

Doc ID	Type	File Name	Create Date	Comments	Hard Copy
	Blueprint	2018_0614_Sub to CVB_BP_Building A_2nd floor.pdf	07/05/2018		
	Summary of Changes (Required)	2018_0614_Sub to CVB_BP_Building A_2nd floor_SOC.pdf	07/05/2018		
	IC Clean Copy	196. [redacted] BP_2018_0614_Sub to CVB_BP_Building A_2nd floor-CVB.pdf	07/12/2018		

Showing 1 to 3 of 3 entries

B. Click on Edit

## Show Attachment

MailLog #	Establishment	Product Code	Brief Description
[redacted]	[redacted]	NA0000	Revision to Blueprint, Building A, 2nd floor with corresponding summary of change

<b>Attachment ID</b>	[redacted]
<b>File</b>	Show 2018_0614_Sub to CVB_BP_Building A_2nd floor.pdf
<b>Type</b>	Blueprint
<b>Create Date</b>	2018-07-05 11:47:23 CDT
<b>Create User</b>	NCAH-Portal, NCAH-Portal
<b>Last Modified Date</b>	
<b>Last Modified User</b>	
<b>Comments</b>	
<b>Tags</b>	

**Edit** **Cancel**

C. Choose the tag “Returned Unprocessed – Document” and click Add.

**Edit Attachment**

MailLog #	Establishment	Product Code	Brief Description
[REDACTED]	[REDACTED]	NA0000	Revision to Blueprint, Building A, 2nd floor with corresponding summary of change

Attachment ID: [REDACTED]

Current File: 2018\_0614\_Sub to CVB\_BP\_Building A\_2nd floor.pdf

Type: Blueprint

Tags: Returned Unprocessed - Doc **+ Add**

Comments: [REDACTED]

[Update] [Cancel]

Not certain which “Tag” is the correct?

C. States Returned Unprocessed but the screen shot above shows Returned Unprocessed – Document.

	no Outgoing Correspondence	mail item	true	IC	true
Returned Unprocessed		Mail Item	True	IC	False
Email Verification		Mail Item	True	IC	False
Bench Records		Mail Item	True	IC	False
Regulatory Correspondence		Mail Item	True	IC	False
All wholesalers and distributors		Mail Item	True	IC	False
All known persons		Mail Item	True	IC	False
Licensed premises		Mail Item	True	IC	False
Regulatory Action		Mail Item	True	IC	False
Pilot Project		Mail Item	True	IC	True
Product Distributed		Mail Item	True	IC	False
Select Agent		Mail Item	False	IC	False
Firm Priority		Mail Item	True	IC	False
Return Action Required by the Firm		Mail Item	True	IC	False
Voluntary Stop Sale - Lift		Mail Item	True	IC	False
Partial Voluntary Stop Sale		Mail Item	True	IC	False
Returned Unprocessed - Document		Document	True	IC	True

D. Add returned unprocessed to comments and click update.

## Edit Attachment

Mail Log #	Establishment	Product Code	Brief Description	Type
[REDACTED]		NAD000	Revision to Blueprint, Building A, 2nd floor with corresponding summary of changes	Facility Do

Attachment ID	[REDACTED]
Current File	2018_0614_Sub to CVB_BP_Building A_2nd floor.pdf
Type	Blueprint
Tags	<input type="checkbox"/> + Add Returned Unprocessed - Document ✖
Comments	returned unprocessed

E. Once completed, send to “Section Leader Final Authorization”.

## XI. SECTION LEADER FINAL AUTHORIZATION

### A. Hard copy

1. Review attachments to ensure they are complete – make sure the signed FDS form has been scanned and uploaded. If needed, make sure the **CVB-TEM-0042** is complete.
2. Move Forward to “Certified Receipt” to the responsible BCA.
3. If being returned unprocessed, ensure the Tag “Returned Unprocessed” is added.

### B. Electronic Submission - This is the final IC step prior to the ML item being returned to the firm via the NCAH Portal.

1. Each document should be opened and reviewed to assure:
  - a. The proper stamp and date are shown on each page of the document.
  - b. There is a statement in a blue box stating “Certified by (Specialist).
  - c. The **CVB-TEM-0044** is digitally signed by the Specialist.
  - d. The file name has the appropriate status (“CVB” or “REV”).
2. If all the documents in the ML are not being filed, then ensure the Tag “Returned Unprocessed” is added to the ML.
3. If all is satisfactory, then the SL approves the ML.
4. This moves the document to records management. (See work instruction)



### Electronic Document Flow Chart

