

Submitting Facility Documents to Inspection and Compliance (IC)

Where were changes made in the 8/1/2018 version?

1. [Page 2](#): Additional information was added to the descriptions of 'Primary Site' and 'Additional Sites'
2. [Page 3](#): Additional information was added to the description of 'Related Submissions'
3. [Page 4](#): New section was added called 'Document Formatting'
4. [Page 5](#): New screen shot was added showing the 'Add Facility Document' button in attachments section
5. [Page 6](#): New information on 'Version #' field was added

Submitting Facility Documents to Inspection and Compliance (IC)

This guide is intended for use by firms using the NCAH Portal for submitting facility documents to Inspection and Compliance (IC). It is expected that procedures described [9 CFR 108](#) and [VS Memo 800.78](#) will still be followed.

Facility documents are electronically submitted to IC using the APHIS 2048 submission section in the NCAH Portal. This detailed guide for submitting facility documents is intended for use in conjunction with the instructions in the [General Guide for CVB Inspection & Compliance E-Submission Correspondence \(2048\) \(User Guide 9\)](#).

CREATING A FACILITY DOCUMENT SUBMISSION

Information

Establishment* 999 - Your Firm, Inc. ▼

Primary Site 123 1st Street, Ames, IA 50010 ▼

Additional Sites ▼ 

- 125 1st Street, Ames, IA 50010 

Product Code(s)* 

- Code: NA0000 


VBI #

Note: Format must be ##-###

You must click on the plus sign buttons after you make your selection from the list.

Primary Site - Click on the down arrow in the field to see a list of sites for your establishment. Select the address of the main location where facilities are located. There should only be one primary site selected. Primary site is defined by CVB-IC as an "Inspection Area"; areas on an establishment license that are normally inspected during a single in-depth inspection. [Manufacturing, Quarantine, Testing, or Foreign Manufacturing sites].


Additional Sites - Click on the down arrow in the field to see a list of additional sites for your establishment. Select the address of the building (if different from the primary address), click on the plus sign button. You may enter additional address by selecting from the drop down menu and clicking on the plus sign button again. To remove a site, click on the minus sign button next to that site. Additional Sites are other sites at a given site that are also on an establishment license, but considered Ancillary. There should be one plot plan (site plan) per submission.

 **NOTE:** If the site is not listed in this drop down, leave the field blank and add a comment in the Brief Description field that this is a New Site.

Product Code(s) - This is a required field. Enter "NA0000" and click on the plus sign button. A window will pop up asking if there is a serial number tied to the product code, click on the "NO Serial #" button.

Is there a Serial Number tied to Product Code NA0000?

Serial Number


VBI # - Leave blank

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The screenshot shows a web form for submitting facility documents. The fields are as follows:

- Submission Type***: A dropdown menu with "Facility Document" selected.
- Subtypes**: A dropdown menu with a blue "+" button to its right.
- Tags**: A dropdown menu with a blue "+" button to its right.
- Brief Description***: A text input field containing the placeholder text "Enter any necessary information here."
- Direct Submission To**: A dropdown menu with "Murle, Douglas" selected.
- Also Notify (cc)**: A dropdown menu with a blue "+" button to its right. To the right of the field, the name "Peterson, Amber" is listed with a red "-" button to its right.
- Related Submissions**: A text input field with a blue "+" button to its right. To the right of the field, the text "ML #10011" is listed with a red "-" button to its right.
- Verification**: A checked checkbox followed by the text "I agree that I've looked over this information and everything entered is true to my knowledge."
- Save**: A green button with a checkmark and the text "Save".

Submission Type - Click on the down arrow in the field to see a list of options. Select "Facility Document".

 **NOTE:** You will enter a more detailed explanation of the type (i.e. Plot Plan, Plot Plan Legend, Blueprint, etc.) when you add the attachment later in the process.

Submission Subtypes - Leave blank

Tags - This field may be left blank. Click on the down arrow in the field to see a list of options.

 Use the tag "Firm Priority" with discretion. Using this tag will delay other submissions for the firm. Use this only if the submission is a high priority for the firm for processing.


Brief Description - This is a required field with a maximum character limit of 200. If you are submitting for a New Site/Building indicate that here and enter the address. If you are submitting addenda that cover multiple buildings, list those buildings in this field.

Direct Submission To - This is a required field. Click on the down arrow in the field to see a list of options. This lists any Biologics Specialist within the CVB-IC unit. This will not route the submission directly to the recipient; it's used as a tool to help determine who the submission can be manually routed to. Select one name from the list.

Also Notify (cc) - This optional field provides the firms the ability to "carbon copy" any individual(s) within the CVB. Select a name from the list and then click the plus sign button to add that person. Your selection will show to the right of the field. Repeat to add additional CVB Employees. Use the red minus sign button to remove people.

Related Submissions - This optional field can be used to enter the Mail Log numbers of any related submissions. Enter the number only and click on the blue plus sign button. Your selection will show to the right of the field. Repeat to add additional. Use the red minus sign button to remove entries. Add related submissions for any mail log that was returned unprocessed on the previous submission, or returned with requested revisions.

- Review your submission and then click in the checkbox by the verification statement.
- Click the "Save" button.

 At this point the submission is not yet complete. You must add attachments prior to submitting to the CVB.

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Document Formatting:

- Only new or complete revisions are accepted. The CVB will not process individual page changes.
- Plot Plan and Blueprint Legends and Addendums should not be scans; these need to have the capability of word comparison to previous versions.
- There should be at least a 1 inch margin at the bottom of all the documents for CVB Stamps.
- A Facility Document Submission (FDS) Form is not required for electronic submission.
- To ensure efficiency and quality review, the CVB suggests the following:
 - A mail log submission should be for one site only. A site is defined as an area depicted on a plot plan.
 - Submit 5 or less facility document attachments per mail log submission
 - This could be for one building
 - Must include the summary of changes
 - Legends and Addenda only need summary of changes for the first electronic submission.
 - Drawings need a summary of changes on every submission.
 - One summary of changes per submission; ensuring the different document types are clearly identified within the document.



Submitting Facility Documents to Inspection and Compliance (IC)

ADDING ATTACHMENTS

➤ Click on the "Add Attachments" button.

2048 Submission Info

Status	Submission Entered
Establishment	999 - Your Firm, Inc.
Site	123 1st Street, Ames, IA 50010 - Manufacturing Site
Additional Sites	• 125 1st Street, Ames, IA 50010 - Mailing Address
Products/Serials	• NA0000
VBI #	
Submission Type	Facility Document
Submission Subtype(s)	None Entered
Tag(s)	None Entered
Brief Description	Enter any necessary information here.
Direct Submission To	Murte, Douglas
Also Notify (cc)	None Entered
Related Submissions	None Entered

Submission History

Action	Timestamp	User	Info
Submission Entered	May-29-2018 10:31 AM CDT	Peterson, Amber	

[✎ Edit](#)
[✎ Add Attachments](#)
[🔒 Submit To CVB](#)
[📄 Save as PDF](#)
[🗑 Delete Submission](#)
[🏠 Return to Dashboard](#)

➤ Click on the "Add Facility Document" button to open the attachment section.

Add Attachments - CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

[CVB Home](#) / Add Attachments Submission Form (APHIS 2048)

Current Attachments NA

New Attachments

[+ Add Document](#)
[+ Add Facility Document](#)

I agree that I've looked over this information and everything entered is true to my knowledge.

[✔ Save to Submission](#)
[✖ Cancel](#)

Submitting Facility Documents to Inspection and Compliance (IC)

ADDING ATTACHMENTS (continued)

New Attachments

Facility Document Attachment
REMOVE

File

PDF
PDF for testing purposes.pdf

Remove
Browse ...

Comments

Building 1

Type*

Blueprint
▼

Version #

1

Note: May not have multiple attachments with the same name.

+ Add Document
+ Add Facility Document

I agree that I've looked over this information and everything entered is true to my knowledge.

✔ Save to Submission
✖ Cancel

File - Click on the "Browse" button to choose the file you want to upload (the "Remove" button will appear after you've uploaded a file). **Facility documents need to be uploaded as .pdf files.** *Note: Each file should only be for one item – for example each building's blueprint must be downloaded as a separate file.* Each blueprint legend for a specific building can be submitted as a separate file; be consistent for entire establishment. Addenda that cover more than one building may be submitted as a single file as Addenda.

Type - This is a required field. Click on the down arrow to see a list of options. Select the one the best describes the file you are attaching. For facility documents choose Plot Plan, Plot Plan Legend, Blueprint, Blueprint Legend, Fraction List, Decontamination Procedures, Biocontainment & Biosafety Practices, Exemptions to 9 CFR 109, Movement of Materials between Licensed Premises, Storage of Master Seed off Licensed Premises, Alternative Location of Storage of Records, Summary of Changes (Plot Plan, Blueprints, Addendum Blueprint (Specialized Blueprint) only.)

Comments - This optional field is limited to 150 characters. Comments pertaining specifically to the individual document may be entered here.

Version # - Each submission from the firm should be numeric, the first electronic submission starts at "1". When the CVB processes the submission, a suffix of "-CVB" or "-REV" is added to the file name. The second submission by the firm would be "2".

When submitting again after an unprocessed facility document is returned, the latest version would be the next sequential number of a filed/signed facility document. For example Version 2 is returned unprocessed by the CVB, the firm's electronic submission should be resubmitted as Version 2 again.

- When the CVB processes the submission, a suffix is added to the file name.
 - "-CVB" is added for filed/signed documents and an invisible CVB digital signature is added
 - "-REV" is added to filed/signed documents that need revisions at the next annual review
 - There is no stamp or digital signature added to documents that are unprocessed. These documents will not be filed or returned; however an Outgoing Correspondence document will be returned to the firm specifying the deficiencies.

Submitting Facility Documents to Inspection and Compliance (IC)

ADDING ATTACHMENTS (continued)

- You may use the "Add Document" button to add additional files to this submission.
- When you are ready to move forward, click in the checkbox by the verification statement.
- Click on the "Save to Submission" button.
- The facility document submission has now been created and is ready to be submitted to the CVB. Refer to [User Guide 9 - General Guide for CVB Inspection & Compliance E-Submission Correspondence \(2048\)](#) for instructions on how to submit to the CVB. Remember that the ability to submit to CVB is based on a user's role so not all users will see this option.

 **NOTE: Preliminary facility documents should be submitted as General Correspondence (See 9 CFR 108.6)**