Where were changes made in the March 31, 2025, version?

1. Updated links throughout the document and corrected formatting issues.

Where were changes made in the 1/7/2025 version?

1. Formatting Tips & Tricks section added to clarify on needs when workings with outline templates.

Where were changes made in the 6/18/2020 version?

1. All references to templates created by firms were removed as this practice is no longer accepted.

Where were changes made in the 9/27/2017 version?

1. Page 2, in the Baseline Version: Initial Electronic Submission for Documents Previously Submitted on Paper section, clarifying language was added (see red text below):

"To expedite processing of the baseline version, please submit baseline documents with text exactly as it appears in your currently approved Outline, including any pen-and-ink changes previously made by the CVB. Please do not submit new revisions with the baseline version, except for:"

Where were changes made in the 7/28/2017 version?

 Page 2, in the Baseline Version: Initial Electronic Submission for Documents Previously Submitted on Paper section, the bullet below was added: If you have an additional subheading to put in a section, add it at the end of the codified subheadings. Do not

If you have an additional subheading to put in a section, add it at the end of the codified subheadings. Do not renumber the codified subheadings to place it elsewhere in the section.

Where were changes made in the 5/9/2017 version?

1. Page 2, in the Baseline Version: Initial Electronic Submission for Documents Previously Submitted on Paper section, the text in bold below was added:

If a document has previously been submitted on paper, it is necessary to establish an electronic "baseline" from which to compare future revisions electronically. **A Baseline is considered to be a Complete Revision, not a New document.** To expedite processing of the baseline version, please submit baseline documents with text exactly as it appears in your currently approved Outline.

Specific Template Required

All electronic Outlines of Production and Special Outlines (herein collectively called Outlines) must be submitted on a MS Word template approved by the CVB. The CVB provided generic templates can be accessed in NCAH Portal User Guide B - Outline Templates.



🚹 Documents submitted in other formats will be returned unprocessed. 🕂

Repeated Revision of Same Document

The template is intended for use as an editable MS Word document throughout preparation, submittal, and processing. <u>Please do **not**</u> convert it to PDF or other read-only format to send to the CVB. The same document will be transferred repeatedly between the CVB and firm as updates are made. <u>Do not start a new document for each revision</u>. This allows us to leverage computerized track changes, commenting, and document comparisons for the greatest efficiency of review.



Therefore, **once electronic, stay electronic**. Do not intermix electronic and paper versions for a single document.

Complete Revisions Only

The CVB will accept only complete revisions of electronic documents. Individual page amendments will be returned unprocessed.

Completing the Form Fields

The cover page and subsequent page headers on the template have several "form fields" that appear with light gray instructions. Click directly over the instruction for the field to enter data or select a value from the dropdown picklist.

- Complete every field on the cover page.
- Once completed on the cover page, recurrent values will auto-populate on subsequent page headers. (Exception: You will need to designate the document as New or Complete Revision on both the cover page and the subsequent page header.)

Adding Outline Text

The CVB templates include codified section headings, do not edit the headings. You can insert any amount of text between the headings. Add additional sub-headings, when needed, at the *end* of a section.

Baseline Version: Initial Electronic Submission for Documents Previously Submitted on Paper

If a document has previously been submitted on paper, it is necessary to establish an electronic "baseline" from which to compare future revisions electronically. A Baseline is considered to be a Complete Revision, not a New document. To expedite processing of the baseline version, please submit baseline documents with text exactly as it appears in your currently approved Outline, including any pen-and-ink changes previously made by the CVB. **Please do <u>not</u> submit new revisions with the baseline version, except for:**

- Number the document with the cover page as page 1. (This is a change from the historical practice of leaving the cover page unnumbered and using the first page of the document body as page 1.)
- It is permissible to move text to an appropriate heading if your current paper template is not configured in accordance with the 9CFR headings.
- If you have an additional subheading to put in a section, add it at the end of the codified subheadings. Do not renumber the codified subheadings to place it elsewhere in the section.
- Do not remove major headings (I through VI) that may be unused for a given product. Instead mark them as Not Applicable.
- Do not remove *individual* subheadings that may not be applicable under an applicable major heading for a given product. Mark the unused subheadings as Not Applicable.
- If, however, a major heading is Not Applicable in its entirety, or merely cites another document, it is permissible to remove all of the unused subheadings under the unused major heading for a cleaner appearance.

Revising an Electronic Document

Once an <u>electronic</u> Outline has been filed with the CVB, make the next round of revisions directly on the *last filed version received from the CVB*. Don't use a different document onto which you have transcribed changes.

Preparing the last filed version for more revisions:

- 1. Open the most current CVB-approved Outline. Elect to "Save As" and save with a different file name. This clones a copy of the document currently on file with the CVB. As soon as you rename or begin to edit the cloned copy, the CVB digital signature associated with the last approval will disappear on the cloned copy. This is expected and appropriate.
- 2. Ensure that the document is set to display All Mark Up (see Review tab on MS Word ribbon) so that you can view any tracked inline insertions/deletions (commonly called pen-and-ink changes) the CVB may have made. If you cannot see these edits or can only see red lines in the left margin where the edits should be, then you are not in the correct Mark Up view.
- 3. <u>Accept (remove the markings from) any tracked changes</u> made by the CVB in the last review. Follow the hyperlink in the previous sentence to see detailed instructions on accepting tracked changes.
- 4. Remove the CVB mail log number of the last version from the lower left corner of the footer.

You will now have a clean copy, identical to the document approved by the CVB, but minus the CVB signature, CVB editing marks, and prior mail log number to use as a starting point for your next round of revisions.

- 5. With the Track Changes feature OFF, update the <u>version number</u>, superseded version number, date submitted, and supersedes date on the cover page. Do <u>not</u> use copy and paste to update fields, as this will copy the entire form field and not the text within it. The fields will not display correctly when there is one form field lying on top of (i.e., obscuring) another.
- 6. Turn on the <u>Tracked Changes feature in MS Word</u> prior to making any edits beyond the cover page. Follow the hyperlink in the previous sentence to see detailed instructions on tracking changes.

Making the next round of revisions for submission to the CVB:

- 1. Leave Tracked Changes on while you are editing the document.
- 2. For every text insertion/deletion/move, add a comment (using the <u>MS Word Commenting feature</u>) explaining the specific reason why the change was made. Insert the comment as close as possible to the point of the text change.
 - When inserting your cursor or highlighting text to serve as an insertion point or "anchor" for a comment, avoid clicking on/highlighting codified headings that are part of locked text in the CVB Outline template. Also avoid anchoring to space characters (which gives the appearance of linking to a blank area on the page). Both of these scenarios can cause issues with comments transcribing correctly into an electronic document comparison or an automated summary of changes.
 - Avoid adding a comment directly to any deletion. Instead add the comment to nearby text that has not been modified that as close to the deletion.

Summary of Changes

Since all of the edits and comments are shown in context within the body of the document, no separate Summary of Changes is required by the CVB. Firms are free to generate a Summary of Changes in addition to, *but not in lieu of*, tracked changes in context. Add-in software that auto-generates a summary based on tracked changes and comments is available commercially.

One such add-in is DocTools ExtractChanges Pro, available at <u>www.wordaddins.com</u>.¹

If a Summary of Changes is generated, keep it as a separate document; do *not* append it to the Outline.

¹*Mention of a proprietary product does not constitute a guarantee or warranty of the product by the USDA and does not imply its approval to the exclusion of other products that may be suitable.*

CVB Processing

When an electronic Outline is received, CVB will:

- 1. Perform an electronic document comparison to the last filed document to ensure that all changes in the new submission were tracked by the submitter.
- 2. Ensure formatting meets CVB requirements and text conforms to 9CFR 114.9 and VS Memorandum 800.206.
- 3. Remove (i.e., accept) all tracked changes and comments added by the submitter in this latest submission. This generates a clean copy to use as the basis for the CVB-stamped copy.
- 4. Make any necessary insertions/deletions initiated by the CVB as tracked changes. This mimics the historical practice of pen-and- ink changes made in red ink on paper copies.
- 5. Provide comments in a written summary (maintaining the current practice for paper submissions). Outgoing comments are not added in context so that the approved document has a cleaner appearance.
- 6. Update the version number of the approved document by adding "-CVB" to the end of the version number. If the document is returned unprocessed, "-UP" will be added to the version number.
- 7. Add the CVB mail log # associated with the submission in the footer.
- 8. Digitally sign the document in the footer if the document is being approved/filed. Documents returned unprocessed will not be digitally signed.

No Submitter Signatures



Do <u>not</u> sign the electronic Outline in any manner. The submitter's authenticated status as a Portal user is proof of identity. The review process is unnecessarily complicated by having a submitter signature on the document.

Using Left hand Navigation Bar

One of the benefits of the Outline template is that it is configured so you have a left-hand navigation bar for moving from one specific place to another in the document. By default, MS Word does not display the left-hand navigation. To show it, go to the View menu, and check the box next to Navigation Pane.

FILE	HOME	INSERT	DESIGN	PAGE LAYOUT	REFERENCES	MAILINGS	REVIEW 🔇	VIEW	DEVELOPER ACROBAT	ŕ	
Read Mode	Print Web Layout Layout Views	🖅 Outline 📃 Draft 🄇	 ☐ Ruler ☐ Gridlines ☑ Navigation Show 	zoon	Diamon D	age ble Pages Ne Width Wind	w Arrange dow All	Split	C View Side by Side Synchronous Scrolling Reset Window Position Window	Switch Windows •	Macros Macros

The Navigation Bar, as shown below, allows you to click on a particular heading and instantly go to that point in the Outline.

Search document 🔎 👻									
HEADINGS PAGES RESULTS									
	T I I I I I I I I I I I I I I I I I I I								
4	I. Composition of the Product								
	A. Microoganisms Used, Including Isolation and								
	B. Source and Date of Accession of Each Microorg								
	C. Strains								
	D. Proportion of Each Strain								
	II. Cultures								
	III. Harvest								
4	IV. Preparation of the Product								
	A. Method of Inactivation, Attenuation, or Detoxif								
	 B. Composition of Preservative, Adjuvant, or Stabi 								
	1. Adjuvant								
	2. Preservative								
	3. Stabilizer								
	C. Method and Degree of Concentration								
	D. Standardization of Product								
	 E. Assembly of Units to Make a Serial 								
	1. Example(s) of Serial Assembly								
	Volume of Average Carin								
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Formatting Tips & Tricks

If you are having issues with formatting when creating and revising an Outline:

1. Do not create a new Style. Use "Normal" Style when adding text to the CVB approved templates.



2. If you must copy and paste, use "Keep Text Only (T)" when pasting to not bring formatting into the current document.

3. When adding to lists, do not use autonumbering. Select "None" from the Bullet Library, Numbering Library, or List Library. *Note: when adding lists the style may change (autoformat) – correct this so "Normal" style is used.*



4. It may be helpful to adjust Auto Formatting. MS Word > File > Options > Proofing > AutoCorrect Options... > select the appropriate tab at the top depending on your need.



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5. As a last resort, you may have to start with a fresh template. The CVB provided generic templates can be accessed in <u>NCAH Portal User Guide B - Outline Templates</u>.