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

1. Updated links and screenshots throughout document.

This is a detail guide to be used in conjunction with the <u>2049 General User Guide (User Guide 10)</u> and <u>Creating/Revising</u> <u>Electronic Outlines (User Guide 18)</u>. It is not intended for stand-alone use.

This guide pertains to submitting Outlines of Production and Special Outlines for licensed or prelicense product. ***Do NOT use this guide for Outlines for unlicensed product exported under the Food and Administration's Export Reform and Enhancement Act of 1996. ***

Creating an Outline Submission

Use the 2049 portal interface to submit Outlines to Policy, Evaluation, and Licensing, per the instructions in the <u>General User</u> <u>Guide</u>. Use the following values.

- Submission type
 - If this is the 1st <u>electronic</u> submission for a particular Outline or Special Outline, then select either "Outline (Baseline Version Only)" OR "Special Outline (Baseline Version Only)" respectively
 - For all document revisions subsequent to receiving a filed Baseline (version Baseline-CVB) from the CVB select "Outline" OR "Special Outline"
- Submission subtype leave this field blank

When adding attachments, portal users are given the option to upload an Incoming Outline or other kind of document.

Add Attachments - VETERINARY BIOLOGICS REGULA	ATORY E-SUBMISSION FC	RM - POLICY, EVALUATION, AI	ND LICENSING (APHIS 2049)			
CVD Users / Add Attachments Colonization From	(4.0) (0.0 40)			-5		
CVB Home / Add Attachments Submission Form	(APHIS 2049)					
Current Attachments	NΔ			- 3		
New Attachments	Add Document	Add Incoming Outline		- 7		
New Attachments	• Add Document			- 7		
I agree that I've looked over this information and everything entered is true to my knowledge.						
	Save to Submission	on Cancel		- 5		
A generate generation	and an all a set	the second from	- Andrewski - Andr	A.		

Attaching Outline documents

- Attach only one Outline or Special Outline per submission. Only new documents or complete revisions are accepted. The CVB will not process individual page changes.
- Use the attachment type "Incoming Outline" for the actual Outline/Special Outline submitted for approval. ***Do not use this attachment type for anything other than the Outline. ***
- Use the <u>CVB-supplied template</u> and <u>formatting instructions</u> for the Outline.

Entering Outline Specific Information

After electing to add an incoming outline, the following information is requested:

Outline Document		REMOVE
File		
Select file	Browse	
<u>Type*</u>		
Incoming Outline		
Comments		
2		
Outline Version #*		
3		
Note: May not have multiple attachments with the same name.		

File: Identify the file to be uploaded.

Comments: Enter any comments specific to the *individual Outline* being uploaded.

Version #: Enter the version number assigned to the Outline being uploaded. See <u>User Guide 19</u> for details on versioning.

Attaching Other Supporting Documents

- Documents other than the actual Outlines may be added with the attachment type "Incoming (Core) Document".
- Such supporting documents may include, but are not limited to, additional instructions/requests for your reviewer.
- Do NOT attach APHIS Form 2015, as this is not necessary for portal submissions.
- It is not necessary to submit a compiled Summary of Changes (as all changes are tracked in-line). If, however, you wish to submit a Summary of Changes *in addition to* in-line tracking, submit the Summary as a separate document. Do not insert it to the Outline.

Appearance In Portal Once Processed:

There will be an Outline file returned with an updated version number. If the Outline was approved (digitally signed), the outgoing version will be designated as the incoming version + "-CVB". If the Outline was returned unprocessed, it will not be digitally signed, and the outgoing version number will be the incoming version + "-UP".

There also may be a comments document; if there are no comments, there will be a "No Return Form Comments" statement in the CVB Response section.

Submitted Files	File	Туре	Submitter's Study ID	Outline Version #	Comments	Date Added
	test.docx	Incoming Outline		3		12/08/2016
CVB Response Files	File		 Outline Version # 	Туре		
	Tested2.docx		3-CVB	Outgoin	g Outline	
CVB Response	No Return Form Com	ments				