

Requirements for Electronic Outline of Production and Special Outline Templates

Where were changes made in the 9/4/2018 version?

1. [Page 3](#) - Name change in the "Direct Submission To" instruction: Nancy Clough was changed to Matthew Erdman

Where were changes made in the 7/11/2017 version?

1. [Page 2](#) - A link to User Guide B - Outline of Production Templates was added to section "CVB Templates Available" and individual links to each template were removed to facilitate updating of documents.
2. [Page 2](#) - Autologous products was added to the list of templates available

Requirements for Electronic Outline of Production and Special Outline Templates

Templates Require CVB Approval Prior to Use

All electronic Outlines of Production and Special Outlines must be submitted on a CVB-approved template containing the necessary elements to facilitate review and processing. All templates must conform to [Title 9, Code of Federal Regulations \(CFR\), Part 114.8-114.9](#) and Veterinary Services Memorandum [\(VSM\) 800.206](#).

CVB Templates Available

Establishments may utilize the Outline of Production (OP) templates provided by the CVB. Complete OP templates are available from the CVB in [User Guide B - Outline of Production Templates](#) for the following:

- Vaccines, Bacterins, Antigens, and Toxoids including Immunomodulators
- Diagnostic Test Kits
- Antiserum, Antitoxin and Normal Serum Products including Antibody Products
- Allergenic Extracts
- Autologous Products
- Special Outlines

Creating Your Own Templates

Alternatively, establishments may create their own OP templates for use.



If an establishment-specific OP template is created, it must be approved by the CVB prior to use.

The following features are required for firm-specific OPs and Special Outlines:

1. Create the template in Microsoft (MS) Word. MS Word 2010 or later is recommended (.docx format).
2. Incorporate all of the elements of the CVB-supplied cover page, headers, and footers. Click on the following hyperlinks for skeleton documents with the requisite elements for [OPs](#) and [Special Outlines](#) are available.
3. Number and name the headings in Outlines of Production in compliance with CVB's complete templates, both in content and order of appearance. The CVB relies on consistent placement of information. Do not omit any headings on your template. See [User Guide 19](#) regarding headings that may not apply to certain products.

Because of the variable nature of Special Outlines, no *standardized* heading names/numbers are required on these documents. Customized headings, however, should comply with the formatting requirements discussed in the next section (4) of this document.

4. Use MS Word style formatting to create headings that can be viewed in a navigation pane.
 - [Text instruction to create and customize MS Headings](#) for Word 2010 (but similar instructions also apply to later versions)
 - [Text instruction on using the navigation pane](#)
 - [Video instruction on MS headings and navigation pane](#) (please note that the video in this tutorial does not start at the same time as the audio)
 - Optional advanced feature: [Instructions to create a multi-level list in MS Word](#)

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Creating Your Own Templates (continued)

5. At a minimum, configure list headings down to level 2 (Heading 2), which corresponds to the lettered subheadings immediately subordinate to major Roman numeral headings (e.g., V.A) in 9CFR 114.9 and the complete CVB OP templates. It is permissible to configure further subheadings, if desired.
6. Any widely used font, such as Times New Roman, Arial, or Courier, may be used.
7. Contrary to the requirement in the 9CFR, we no longer require a top margin of 1.5" on the first page after the cover page. Configure the first page margins to agree with the rest of the pages.
8. The cover page will now be considered page 1 of the document, contrary to historical practice of starting page numbering on the page after the cover page. This is being changed so that the page number on the header agrees with the page number indicated by the MS Word software.
9. Electronically submitted Outlines will not be signed by the submitter. Do not configure a signature line for the firm in your template.

Submit Proposed Custom Template



Submit proposed establishment-specific OP templates via the NCAH Portal for CVB review, prior to use.

(It is not necessary to pre-approve Special Outlines as long as the starting point for customization is the CVB's Special Outline template and all headings appear in the navigation bar.)

For OP template approval requests, configure the submission's APHIS 2049 record in the NCAH Portal with the following values:

- Submission type: Correspondence
- Submission subtype: Administration
- Brief Description: Request approval of establishment-specific OP template
- Direct Submission To: Matthew Erdman OR Amy Gill (*do not select your regular reviewer*)