

## Center for Veterinary Biologics

### Using the Pending Special Outline Worksheet

#### 1. Purpose

The Pending Special Outline Worksheet was developed to flag Special Outlines that have been stamped but are not yet approved for official use. They may be used for testing procedures that have yet to be fully validated or other reasons, as specified by the reviewer. This document provides guidance for uniform use of the worksheet.

#### 2. Procedure

**2.1** When a new SO for a test method is submitted, the LIE attaches the cover sheet to the SO. The reviewer is responsible for filling it out (and for putting it on the SO if the LIE misses doing it). If the SO describes a test method to be used for serial release, the SO should be stamped with a #5 stamp until the test method is approved for use in serial release testing.

**2.2** Certain SOs for procedures other than test methods may need a pending cover sheet. It is the responsibility of the reviewer to attach a cover sheet to such SOs.

**2.3** If a revised SO is submitted and the previous version has a pending cover sheet, the LIE moves the cover sheet to the new version and updates the "SO date" field. The reviewer updates the approvals, as necessary.

**2.4** Whenever applicable data are approved, the reviewer is responsible for adding dates and initials to the cover sheet. When all of the necessary data have been approved, the reviewer detaches the cover sheet.

**2.5** Completed cover sheets may be discarded. All approvals should be accessible in the electronic mail log.