Rabies Vaccine Process Deviations

1. All deviations from the filed/approved Outline of Production for Rabies vaccine products must be reviewed by the Inspection Section Leader (SL) or their Acting, with concurrence from the PEL Virology Section Leader.

2. The Specialist will review the request, discuss with appropriate personnel within the program and make a recommendation to the Inspection SL in the form of an email, see suggested format below. The background documentation will be submitted to the Inspection SL for informational purposes.

Subject: Est. XXX - Request for exception to OP Code XXXX.XX, Serial YYYYYY

Body of the email:
We received a request from (firm), Est. XXX, dated (Month DD, YYYY), concerning a deviation from Section (list section of OP, Code XXXX.XX for Serial YYYYYY), (True Name of the Product).

The deviation occurred (Explain deviation)

(Paragraph explaining why this is/isn't an issue)

(If recommending approval) Based on this information, it is my recommendation that CVB would not require the firm to supply host animal efficacy data in each species intended for this serial and related subserials and they could be considered eligible for release.

3. The Inspection SL will review the recommendation and send the forward the information and her assessment in an email to Donna Gatewood, Virology Section Leader (or if she is absent, email her Acting) with a cc: to the responsible Specialist. If the Acting Inspection Section Leader prepares this email, they will cc: the Inspection SL. The Inspection Section Leader will add the following statement to the email being sent to Donna Gatewood:

Please respond with history to this email with "I agree", "Need more information", or "I disagree". This will become a part of the record regarding this request.

4. After Donna (or her Acting) has responded, the Specialist will print the email and include it with the deviation letter.

5. The Specialist will draft a process deviation letter and enter information into database.

Note: No process deviation letter will be signed without the information from Donna. Section Leaders initialing yellows need to ensure documentation is in the file.

6. The email will be filed with the background information and the process deviation letter in the CVB file room.