

Validation/Verification Work Group Report
August 13, 1007

The Validation/Verification Work Group met to complete discussions on revisions to Proposal 07-209. The following changes were made to the original proposal:

- The following bullet was inadvertently left out of section A (Process Validation) of the original proposal:
 - o Microbiological testing for initial levels will be by a 3 tube MPN using appropriate dilutions (10^{-1} - 10^{-6})
- This was in the guidance document that was adopted by the Board on an interim basis, but was left off of the proposal as submitted.
- In Section B (Equipment Validation): The first bullet was deleted and the following bullet was added “The process needs to be verified according to section D before labeling claims can be made.”
- Section C (Re-validation) The two options listed in this section were deleted because it was no longer needed since validation is now based upon a 3.52 log reduction with initial loads between 10,000 and 100,000/g. If the process fails verification, the validation in section A is required.
- The Verification section was replaced with the recommended verification protocol developed by the work group.
- The Verification Sampling Protocol Decision Tree was added to the proposal and a note was added to the bottom.

Additional Recommendations from the Validation-Verification Work Group

1. Recommend Task Force II discuss Proposal 07-209 as modified by the work group prior to Proposals 03-212 and 05-204. If Proposal 07-209 is adopted, recommend no action on 03-212 and 05-204.
2. Request that the validation – verification work group be re-appointed to complete documentation of historical background based upon the statistical probabilities of the development of the validation and verification procedures.