

Proposal Subject	Initial Load PHP Validation
Specific NSSP Guide Reference:	Guidance Documents, Chapter IV.04 Validation/Verification Interim Guidance
Text of Proposal/ Requested Action	<p>Add a new bullet to specify the use of a 3-tube MPN for initial load testing.</p> <p>Process Validation</p> <ul style="list-style-type: none">• Data....• All ...• Samples...• The...• Analytical...• <u>Microbiological testing for initial levels will be by a 3-tube MPN using appropriate dilutions (10^{-1} to 10^{-6})</u>• Microbiological.... <p>NOTE: This does not represent a significant change, but reflects the original intent of the validation/verification workgroup in developing guidance for process validation.</p>
Public Health Significance:	The initial load testing and validation/verification protocols were established based upon an initial level as determined by a 3-tube MPN. The current MO guidance specifies a single 5-tube MPN for processed samples but fails to indicate that the initial level is determined using a 3-tube MPN. The addition of the above bullet merely clarifies the intent of the validation/verification workgroup.
Cost Information (if available):	None
Action by 2005 Task Force II	Recommended adoption of Proposal 05-203 as submitted.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force II.
Action by USFDA	Concurred with Conference action.