

Proposal Subject:	Definitions for Types I, II, III and IV Methods
Specific NSSP Guide Reference:	2009 NSSP Section II - Model Ordinance - Purpose and Definitions
Text of Proposal/ Requested Action	<p>Add the following definitions:</p> <p>(115) <u>Type I Methods mean the core methods of analysis used to support established Program requirements within the NSSP. Type I methods have been evaluated and the performance characteristics for specific applications in the NSSP have been determined and found fit for purpose.</u></p> <p>(116) <u>Type II Methods mean permanent methods of analysis used widely within the NSSP as alternative methods to improve turnaround time, cost effectiveness or to develop analytical capacity beyond what is achieved by the core methods. Type II methods are NSSP validated and the performance characteristics for specific applications within the NSSP have been determined and found fit for purpose.</u></p> <p>(117) <u>Type III Methods mean interim methods of analysis used to fill an ongoing NSSP Program need. Type III methods are NSSP validated and the performance characteristics for specific applications within the NSSP have been determined and found fit for purpose. Type III methods are designated for periodic review and assessment by the Laboratory Methods Review Committee for continued use, redesignation or deletion.</u></p> <p>(118) <u>Type IV Methods mean provisional methods of analysis developed to fill an ongoing NSSP Program need. Type IV methods are newly accepted for use in the NSSP and/or not yet used for Program support outside the laboratory in which the method was developed and/or validated. Type IV methods are NSSP validated and the performance characteristics for specific applications within the NSSP have been determined and found fit for purpose. Type IV methods are designated for periodic review and assessment by the Laboratory Methods Review Committee for continued use, redesignation or deletion.</u></p> <p>(119) Wet storage means</p>
Public Health Significance:	These definitions help clarify the various categories of analytical methods accepted for use in the NSSP.
Cost Information (if available):	None
Action by 2011 Laboratory Methods Review Committee	Recommended no action on Proposal 11-106. Rationale – Proposal 11-106 is addressed by action on Proposal 11-104 and Proposal 11-307.
Action by 2011 Task Force III	Recommended no action on Proposal 11-106. Rationale-Proposal 11-106 was resolved by Task Force action on Proposal 11-104 and Proposal 11-307.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-106.
Action by FDA February 26, 2012	<p>Concurred with Conference action on Proposal 11-106 with the following comments.</p> <p>FDA concurs with the “No Action” taken on Proposal 11-106. However, the Summary of</p>

Actions incorrectly states that the reason for “No Action” was that Proposal 11-106 was addressed by action taken on Proposal 11-104. The Summary of Actions should be edited to correctly reflect that Proposal 11-106 was addressed by action taken on Proposal 11-104 and Proposal 11-307.