

Proposal Subject:	Laboratory Methods
Specific NSSP Guide Reference:	Section III Public Health Reasons and Explanation, Chapter III Laboratory @ .02 Methods
Text of Proposal/ Requested Action	<p>American Public Health Association (APHA) Recommended Procedures for the Examination of Seawater and Shellfish shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters. The official references of the NSSP for the examination of shellfish for <i>Vibrio cholerae</i>, <i>V. vulnificus</i>, and <i>V. parahaemolyticus</i> is the FDA Bacteriological Analytical Manual (BAM) <u>are the methods approved by the Laboratory Methods Review Committee and listed in Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory tests: Microbiological and Biotxin Analytical Methods.</u></p> <p>Since not all methods listed in the Bacteriological Analytical Manual (BAM) are collaboratively tested and approved, methods that appear in the BAM cannot be accepted into the program based solely on the method's inclusion in the BAM. The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program.</p>
Public Health Significance:	Laboratory methods detecting the direct or indirect presence of human pathogens must be proven to consistently work at various laboratories throughout the country and in participating MOU countries. Detailed review of scientific data (preferably from collaborative studies) by the Laboratory Methods Review Committee must be done.
Cost Information (if available):	None
Action by 2005 Task Force III	Recommended referral of Proposal 05-306 to the Executive Board to investigate ISSC approaches to adopting laboratory methods for use in the NSSP.
Action by 2005 General Assembly	Adopted recommendation of 2005 Task Force III.
Action by ISSC Executive Board August 19, 2005	Recommended appointment of a workgroup to determine what the role of the ISSC should be in adoption of laboratory methods. The workgroup is also directed to look at similar conferences' procedures regarding laboratory methods approval. The workgroup will report their findings to the Executive Board at the March 2006 meeting.
Action by USFDA	Concurred with Conference action.
Action by 2007 Laboratory Methods Review Committee	Recommended referral of Proposal 05-306 to an appropriate committee as determined by the Conference Chairman.
Action by 2007 Task Force III	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-306.
Action by 2007 General Assembly	Adopted recommendation of 2007 Task Force III.

Action by USFDA	December 20, 2007 Concurred with Conference action.
Action by 2009 Laboratory Methods Review Committee	Recommended adoption as amended. American Public Health Association (APHA) Recommended Procedures for the Examination of Seawater and Shellfish shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters. The official references of the NSSP for the examination of shellfish for <i>Vibrio cholerae</i> , <i>V. vulnificus</i> , and <i>V. parahaemolyticus</i> are the methods approved by the Laboratory Methods Review Committee approved for use in the NSSP and listed in Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory tests: Microbiological and Biotxin Analytical Methods.
Action by 2009 Task Force III	NOTE: The action taken by Task Force III was only to delete “approved for use in the NSSP and”. The remaining proposed language of Proposal 05-306 was addressed by Task Force I. Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 05-306.
Action by 2009 Task Force I	Recommended no action on the remaining proposed language of Proposal 05-306. Rationale: Proposal 05-306 is more appropriately addressed by Task Force I and II action on Proposals 07-103 and 09-229.
Action by 2009 General Assembly	Adopted recommendations of Task Force III and Task Force I on Proposal 05-306.
Action by USFDA 02/16/2010	Concurred with Conference action on Proposal 05-306.