

Proposal Subject	Laboratory Method Acceptance into NSSP
Specific NSSP Guide Reference	Constitution By-Laws and Procedures of the ISSC
Text of Proposal/ Requested Action	<p>The Laboratory Methods Review Committee must review laboratory methods that are to be accepted into the ISSC program. The Laboratory Methods Review Committee must follow Procedure XVI found in the Constitution By-Laws and Procedures of the Interstate Shellfish Sanitation Conference. If a public health emergency should arise, the Executive Committee shall approve new laboratory procedures. Such emergency action shall involve consultation with a quorum of the Laboratory Methods Review Committee. The Laboratory Methods Review Committee at the next ISSC Meeting will review new methods, accompanied by their validation and collaborative studies data, which were allowed by the emergency action. Such review can result in the method being accepted as a particular type method or denied acceptance. During this time period, the committee will evaluate and review a laboratory checklist for the method submitted by the method's author(s). Since not all methods listed in the <i>Bacteriological Analytical Manual</i> (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.</p> <p>At the time of method submission, the submitter(s) must also include a draft laboratory checklist that is to be used during laboratory evaluation by Laboratory Evaluation Officers.</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 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 05-303 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.