

Single Laboratory Validation (SLV) Protocol

For Submission to the Interstate Shellfish Sanitation Conference (ISSC)

For Method Approval

Critical Information: Applicants shall attach all procedures, with materials, methods, calibrations and interpretations of data with the request for review and potential approval by the ISSC. The ISSC also recommends that submitters include peer-reviewed articles of the procedure (or similar procedures from which the submitting procedure has been derived) published in technical journals with their submittals. Methods submitted to the ISSC LMR committee for acceptance will require, at a minimum, 6 months for review from the date of submission.

Note: The applicant should provide all information and data identified above as well as the following material, if applicable:

Justification for New Method

- Name of the New Method.
- Specify the Type of Method (e.g., Chemical, Molecular, or Culture).
- Name of Method Developer.
- Developer Contact Information [e.g., Address and Phone Number(s)].
- Date of Submission.
- Purpose and Intended Use of the Method.
- Need for the New Method in the NSSP, Noting Any Relationships to Existing Methods.
- Method Limitations and Potential Indications of Cases Where the Method May Not Be Applicable to Specific Matrix Types.
- Other Comments.

Method Documentation

- Method Title.
- Method Scope.
- References.
- Principle.
- Analytes/Measurands.
- Proprietary Aspects.
- Equipment.
- Reagents.
- Media.
- Matrix or Matrices of Interest.
- Sample Collection, Preservation, Preparation, Storage, Cleanup, etc.
- Safety Requirements.
- Other Information (Cost of the Method, Special Technical Skills Required to Perform the Method, Special Equipment Required and Associated Cost, Abbreviations and Acronyms Defined and Details of Turn Around Times [Time Involved to Complete the Method]).
- Test Procedures, (Be Specific and Provide Easy-to-Follow Step-by-Step Procedures and indicate critical steps.).
- Quality Control (Provide Specific Steps.).

- Validation Criteria (Include Accuracy / Trueness, Measurement Uncertainty, Precision [Repeatability and Reproducibility], Recovery, Specificity, Working and Linear Ranges, Limit of Detection, Limit of Quantitation / Sensitivity, Ruggedness, Matrix Effects and Comparability (if intended as a substitute for an established method accepted by the NSSP).
- Data and Statistical Analyses Performed for Each Validation Criterion Tested (Be Specific and Provide Clear Easy-to-Follow Step-by-Step Procedures.).
- Calculations and Formulas Used for Each Validation Criterion Tested.
- Results for Each Validation Criterion Tested.
- Discussion of Each Validation Criterion Tested.
- Summary of Results.

Additional Requirement

If a laboratory method is found acceptable for use in the National Shellfish Sanitation Program and adopted by the Interstate Shellfish Sanitation Conference, the method submitter will draft a laboratory checklist that can be used to evaluate laboratories performing their procedure. The checklist will be submitted to the ISSC and reviewed by the Laboratory Quality Assurance Committee for Conference approval.

(For guidance: refer to the checklists in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2003, Guidance Documents, Chapter II - Growing Areas, .11 Evaluation of Laboratories by State Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.)