Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Monthly Laboratory Grade Water Testing
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter III. Laboratory
Text of Proposal/ Requested Action	@.02 Methods. A. Microbiological. Methods for the analyses of shellfish and shellfish growing or harvest waters shall be: (1) The Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. (2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used: (a) A validated AOAC, BAM, or EPA method; (b) An Emergency Use Method pursuant to .02 D. (1) and (2) below. B. Chemical and Physical. Methods for the analysis of shellfish and shellfish growing or harvest waters shall be: (1) The Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI. of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. (2) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings. (3) When there is an immediate or ongoing critical need for a Method and no Approved NSSP Method exists, the following may be used: (a) A validated AOAC, BAM, or EPA method; (b) An Emergency Use Method pursuant to .02 D. (1) and (2) below. C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be: (1) The Approved NSSP Methods validated for use in the

	National Shellfish Sanitation Program under Procedure XVI. Of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. (2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used: (a) A validated AOAC, BAM, or EPA method; (b) An Emergency Use Method pursuant to .02 D. (1) and (2) below. D. Emergency Use Methods. (1) When there is an immediate or critical need and no Approved NSSP Method exists, an unapproved or non-validated method may be used for a specific purpose provided that: (a) The appropriate FDA Regional Office is notified within a reasonable period of time regarding the method employed; and (b) The ISSC Executive Board is notified within a reasonable period of time regarding the method employed. (2) When it is necessary to continue the use of the emergency method employed under D. (1) beyond the initial critical need, then the following minimum criteria shall be provided to the ISSC Executive Board for interim approval: (a) Name of Method. (b) Date of Submission. (c) Specific purpose or intent of the method for use in the NSSP. (d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method. (e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable. (f) Any peer reviewed articles detailing the method. (g) Name of developer(s) or Shellfish Control Authority submitter. (h) Developer/submitter contact information. (3) Within two (2) years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Laboratory Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission. E. Laboratory Grade Water, AKA Reagent Water Microbiologically Suitable Water, Type 1 Water. For the required monthly testing of the laboratory's reagent grade water for microbiological contamination, the following may be used: (1) An AOAC, BAM, or EPA approved method; (2) Heterotrophic plate count equivalent methods as described in *Standard Methods for the Examination of Water and Wastewater or Compendium of Methods for the Microbiological Examination of Foods.*
Public Health Significance	Although this is a monthly requirement, there are currently no approved NSSP methods that specifically address reagent water. For labs that support multiple Federal programs with this requirement, adding this would provide clearer guidance while

	allowing each lab to choose the method that best conforms to the analysis they routinely perform. The savings of time and money allows resources to be used to protect public health more wisely.
Cost Information	Cost will be determined by each lab dependent on method used.