Proposal Subject: Update Microbiology Laboratory Evaluation Checklist

Specific NSSP Guide Reference: NSSP Section IV. Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories By State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists Laboratory Evaluation Checklist – Microbiology

Text of Proposal/ Requested Action Update Microbiology Laboratory Evaluation Checklist. Please find the updated Microbiology Laboratory Checklist attached - word document titled "Revised Microbiology Checklist 11-08-2010.doc".

A summary of the changes is:

- Renumbered checklist items to accommodate proposed additions and deletions and to better identify each checklist item.
- Added, deleted or changed language for checklist items to be consistent with the PSP laboratory evaluation checklist.
- Deleted the requirement for metals testing on reagent water and the inhibitory residue test for washed lab ware and increased the requirements for the bromothymol blue test.
- Clarified and defined requirements for laboratory equipment, reagents including the bacterial quality control requirements for media productivity and method process control testing.
- Update thermometer requirements to accommodate state bans on the use of mercury thermometers.
- Updated the sterility check requirements for both in lab sterilized items and purchased pre-sterilized items.

Public Health Significance: The current microbiology laboratory checklist was last revised in 2009 when the male specific coliphage method was approved and added to the checklist. Deficiencies have been identified while using the microbiology checklist in evaluation of laboratories and the microbiology checklist is inconsistent with some requirements in the PSP checklist. It is important that the checklist items and quality assurance requirements are clear and understandable. It is important that quality assurance requirements among the different laboratory evaluation checklists remain as consistent as possible since many monitoring laboratories perform multiple types of tests and are evaluated using multiple NSSP checklists; inconsistencies among the checklist cause confusion, extra expense and work for the laboratories.

Cost Information (if available): None

Action by 2011 LMRC Recommended Proposal 11-108 be referred to the appropriate committee as determined by the Conference Chairman.

Action by 2011 Task Force I Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 11-108.

Action by 2011 General Assembly Adopted recommendation of 2011 Task Force I on Proposal 11-108.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-108.

Action by 2013 Laboratory Methods Review and Quality Assurance Recommended Proposal 11-108 be adopted with substitute updated document attached. Available upon request (20 page document)

Committee

Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 11-108.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-108.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-108.