Proposal No. 19-146

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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10. Proposal Subject	Micropipettor Verification
11. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas, .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists, NSSP Laboratory Evaluation Checklists, 6. Shellfish Laboratory Evaluation Checklist for PCR Microbiology
12. Text of Proposal/ Requested Action	The requested action is to adopt the new text for the NSSP PCR Microbiology checklist, section 1.4 Laboratory Equipment item 1.4.24.
13. Public Health Significance	Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. One QA component includes verifying the measurement accuracy of pipetting instruments including micropipettors. There are no recognized references that state micropipettors must receive third party certifications. There is no indication as to what "Level" calibration should exist. The reference for this item is only **#2, Good Laboratory Practice**. Accuracy measurement assurance should be based on workload and use, not calendar year. Pipette calibration values on certificates obtained in a calibration laboratory (known as a controlled laboratory) do not accurately transfer to the NSSP laboratory and therefore do not provide assurance and defensibility. A pipette's measurement accuracy is influenced by its *physical uncertainty*, *environmental uncertainty* (i.e., temperature, vibration and humidity) and *operator use uncertainty*. These uncertainties will differ between laboratories. Pipette performance in the NSSP (non-controlled laboratories) is impacted by the temperature and viscosity of the fluid, the skill of the operator and choice of tip. Conducting in-house verifications for each operator, using a verified balance provides a better assessment of the actual measurement accuracy of what the pipet is delivering. When the uncertainty of measurement exceeds the stated laboratory established threshold, adjustments are made. As a component of a Laboratory's Quality Management System, the individual laboratory can institute legally defensible and measurement assurance practices appropriate for the laboratory's workload, testing and ambient conditions. Savings: Calibration Cost Information from one Pipet Manufacturer: 1. Calibration and Maintenance - Offers three "levels" of examination, with an

	assorted number of readings at 3 volumes, across different channel pipettors. Cost Range $30 - $225 per unit. 2. Calibration only (center channel only) - $30 - $180 if unit passed on the initial attempt. Non-Operational pipette repair evaluation (no calibration and parts additional cost) starting at $28/unit.
14. Cost Information	N/A