



Department of
Environmental
Conservation



New York State Report

Bureau of Shellfisheries

Debra Barnes, Chief, Shellfisheries

Northeast Shellfish Sanitation Association Meeting
Plymouth, MA
April 9-10, 2019



Shellfisheries Bureau (23 permanent staff; 4 seasonal)

Four Units:
Growing Area Classification
Shellfish Inspection
Shellfish Management
Shellfish Laboratory

2018 Growing Area Classification Changes

Upgrades in 5 SGAs:

Seasonally uncertified to certified	+ 28 acres
Uncertified to seasonally uncertified	+ 886 acres
Extend seasonal periods, 2 areas	<u>+ 254 acres</u>
Total:	+1168 acres

Downgrades in 7 SGAs :

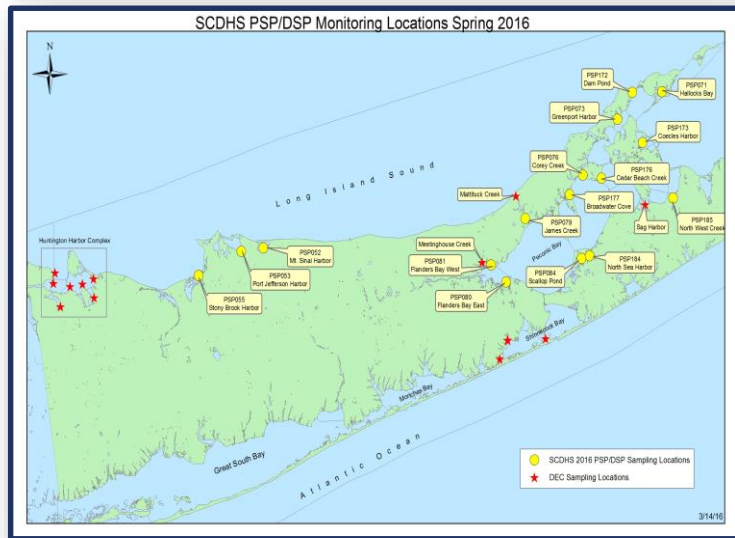
Certified to seasonally uncertified	- 1135 acres
Seasonally uncertified to uncertified	- 99 acres
Certified to uncertified year-round	<u>- 32 acres</u>
Total:	- 1266 acres

Net change: - 98 acres



Department of
Environmental
Conservation

***Prohibited Areas – Closed to Shellfish Harvest**



2018-19 Rainfall / STP Conditional Programs

Shelter Island Town: Dering Harbor

11/21/18 – 4/26/19; 118 acres

STP function normal



Oyster Bay Town: Oyster Bay Harbor

12/12/18 – 4/26/19; 168 acres

Rain $\leq 0.40''$ & STP normal

Huntington Town: Centerport Harbor

12/13/18 – 4/5/19; 53 acres

Rain $\leq 0.20''$ & 2 Pump Stations



Southampton Town: North Sea Harbor/

Fish Cove; 12/12/18 – 4/12/19; 73 acres

Rain $\leq 0.30''$

Hempstead Town: Middle Bay

12/5/18 – 4/26/19; 715 acres; Rain $\leq 0.25''$



Department of Environmental Conservation


For the most up to date temporary closure information, please call our hotline at (631)444-0480.


[Conditional Shellfish Harvesting Programs](#) are running in the towns of Shelter Island, Hempstead, Huntington, Southampton, and Oyster Bay.

These maps are provided for reference only. Official written descriptions of all closures may [be found here](#).

Instructions:
Use +/- buttons or scroll to zoom in and out of the map.

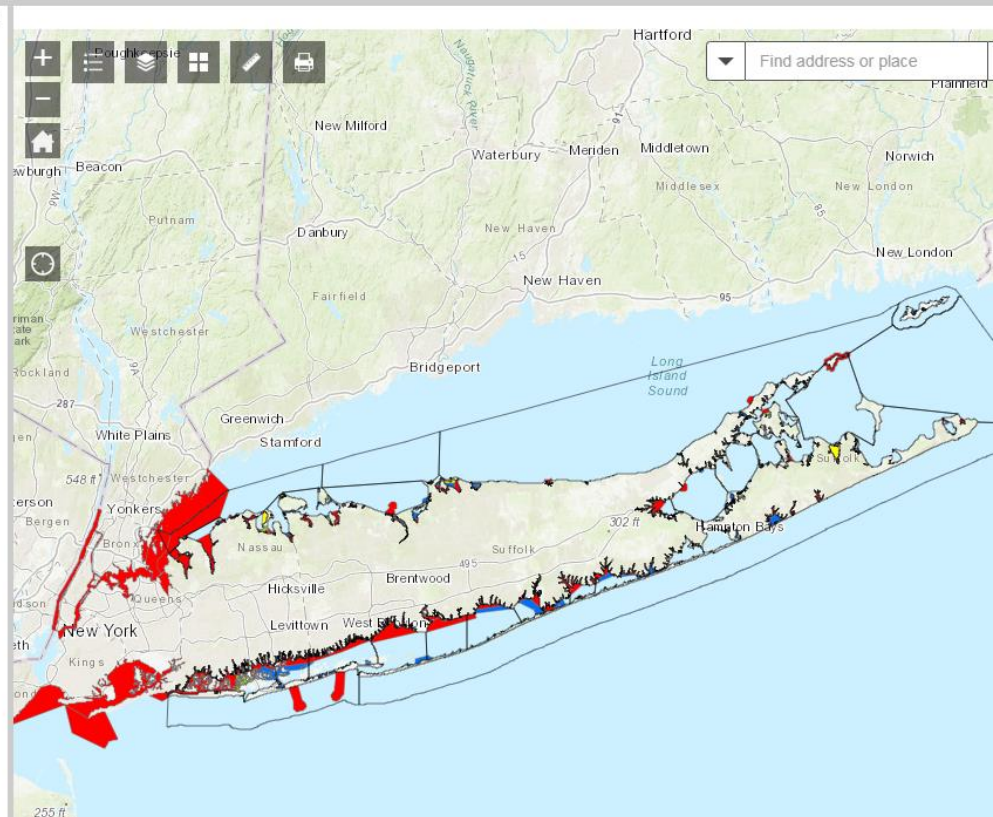
Click on  to view the legend.

Click on  to turn layers on and off.

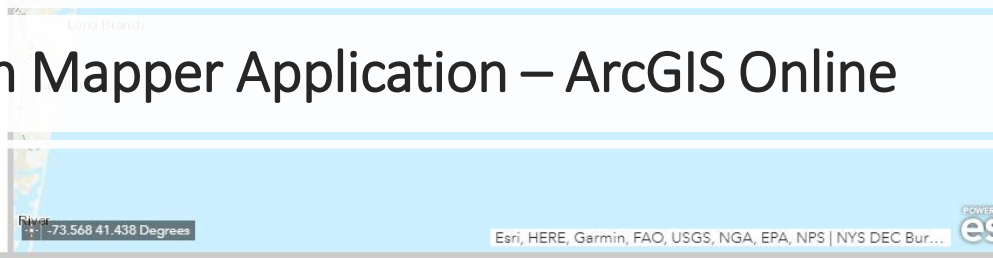
Click on  to change the basemap.

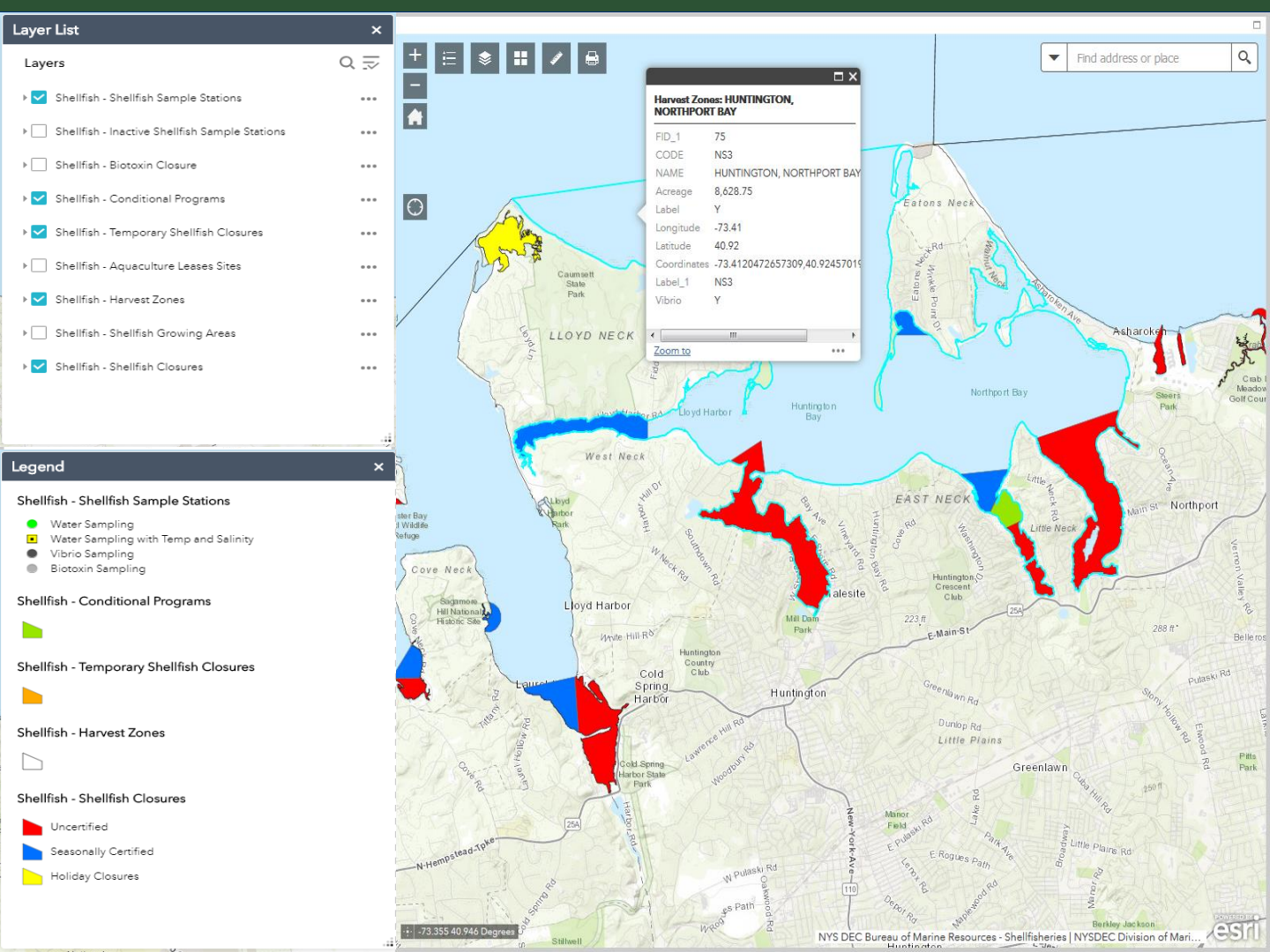
[NYS DEC Homepage](#)

Last updated on January 4, 2019.



Public Shellfish Mapper Application – ArcGIS Online





Laboratory Quality Management Systems (QS)

Coordinated activities to establish and control work processes in an organization to ensure consistent quality results;
International Organization for Standardization (ISO)

- All aspects of the laboratory operation need to be addressed in the QS to assure quality elements are met
- **International Standard - ISO 17025** specifies the general requirements for the competence of testing and calibration laboratories – third party reviewed process



Proposal 17-114: NSSP Quality System-Laboratory Evaluation Checklist Submitted by the FDA (ISSC 2017 Biennial Meeting)

- Added a new Quality System - Laboratory Evaluation Checklist to the NSSP for laboratories
- *Public Health Significance:* A Quality System is critical to the successful defense of laboratory data. Whether the data is challenged in a court of law or during an audit for customer or quality, a Quality System provides a level of assurance upon which data can be relied ...
- If the lab **fails** to maintain a Quality System, an onsite evaluation will not be scheduled until such time as the nonconformities are rectified
- *Cost Information:* **There will not be an additional immediate cost** as this would be the first step in the routine triennial evaluation cycle



Defensible
Data

Shellfish Laboratory Evaluation Checklists (NSSP Guide 10/17/18)

- Lab evaluations are based on a series of six procedure-based checklists and now the new Quality System (QS) checklist
- The QS checklist was intended to assist labs in organizing their records to determine if the lab was ready for an on-site evaluation by a Laboratory Evaluation Officer (LEO) or desk audit
- Since initial implementation of the QS in 2018, States are finding out that past FDA recognized lab practices are no longer accepted by the LEOs
- The Quality Checklist: Part III - Quality Control: 3.5 Temperature Measuring Devices (TMDs): FDA's "new" interpretation of the term "calibration" of thermometers has forced state labs to send out all of their "working" thermometers for certification testing by a 3rd party to *acquire temperature calibration certificates*
- Historically, states have calibrated all their "working" thermometers against a Standards thermometer traceable to an NIST thermometer
- Labs are being placed in a **non-conforming status and "corrective action" is costing thousands of dollars to move their program evaluation forward**

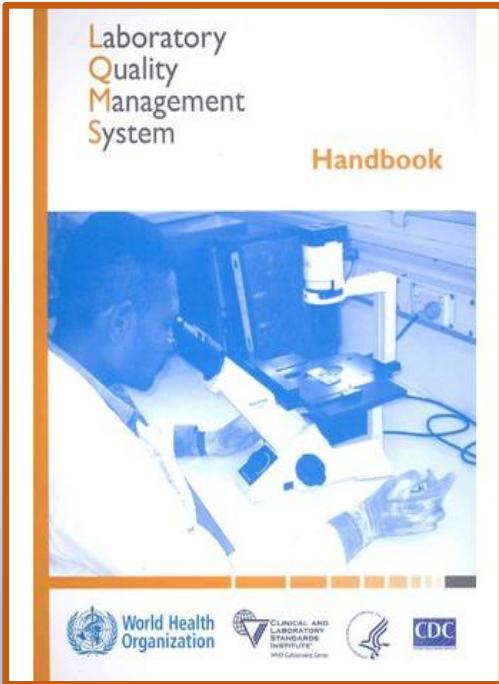


Recommendations for “Standardization” to Assist States with Quality Systems for Labs

ISO/IEC 17025

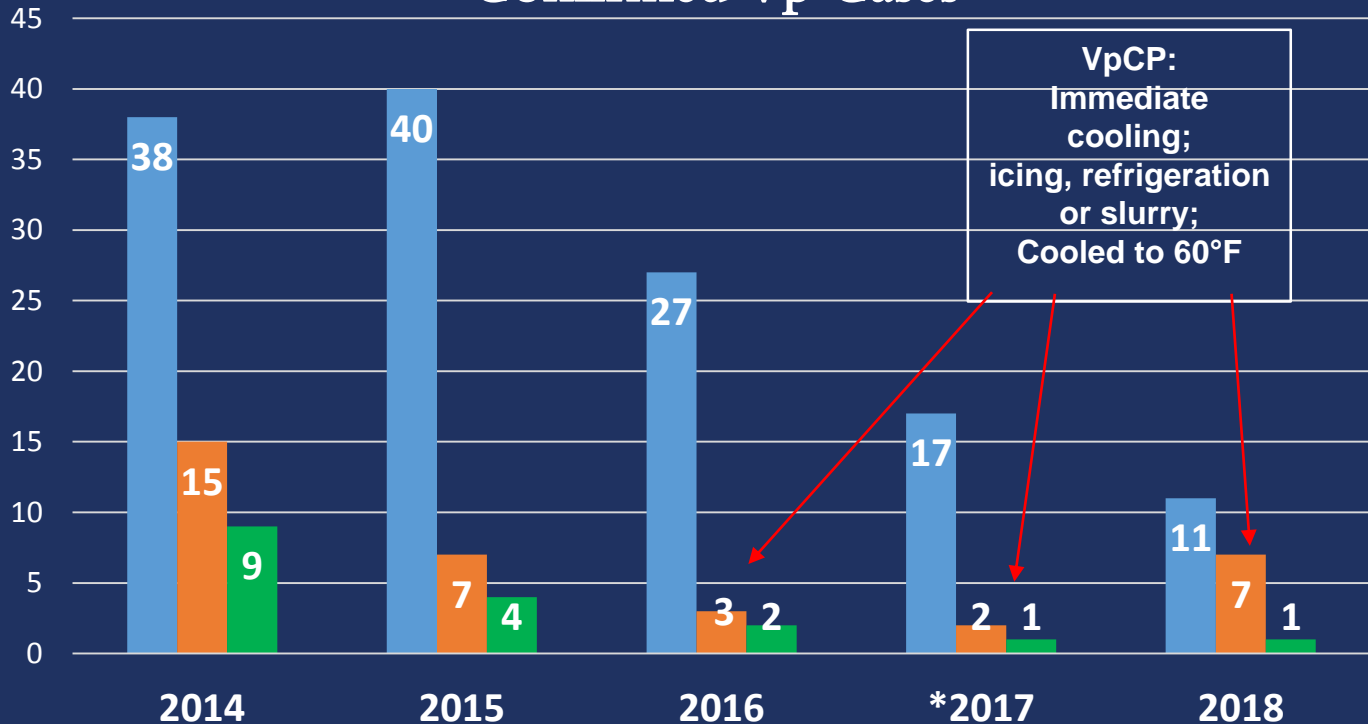
“Standardization on Steroids”

1. Need for a reasonable phase-in period with input from the states;
2. Provide training resources (boiler plate forms, reference wordage per checklist item, documents & presentations); and
3. Provide **a realistic estimate of costs** to initiate new required activities



© 2011 Pages: 248

Confirmed Vp Cases



- TOTAL Vp CASES REPORTED IN NY OR TO NY
- LINKED TO NY HARVEST AREAS (MULTI-SOURCE)
- LINKED TO SINGLE NY HARVEST AREAS

*Not all confirmed

Floating Aquaculture – Bird Issues

- Effective 2018, Bird Mitigation Plans required for shellfish aquaculture permits with floating gear; applies to existing and new permits
- Closures of two culture sites due to excessive fecal coliform contamination in oyster meats; fourth year
- Bird Mitigation compliance or submergence of gear before retesting of shellfish and reopening of culture sites
- Closures approximately one month in duration at sites



NEW YORK STATE PLANT & SHIPPING ELEMENT

FDA Evaluations 2015 – 2018

New York meets the first 6 of the 7 Criteria (not evaluated in 2016)

7 – In-Field Plant Criteria

- **2015** – 8 of 13 firms evaluated had *Critical deficiencies*, but were corrected on site during inspection
- 2 of the 13 firms evaluated had more than the allowable amount of *Key* deficiencies for checklist items 8 – 27

Overall rating in “Conformance with Deficiencies”



Department of
Environmental
Conservation

NEW YORK STATE PLANT & SHIPPING ELEMENT

- 2017 – 6 of 14 firms evaluated had **Critical deficiencies*, but were corrected on site during inspection
- 2018 – 5 of 14 firms evaluated had **Critical deficiencies*, but were corrected on site during inspection
- *Even though all deficiencies were corrected, it is now considered an automatic failure

Also some plants exceeded the number of *Key* deficiencies allowed in both years (some *Keys* were also corrected during inspection)

Overall rating in “Major Non Conformance”



New York Shellfish Restoration Initiative

\$10.4M Restoration Plan announced by
Governor Cuomo Sept 2017 - Two Year Project (2018/19)

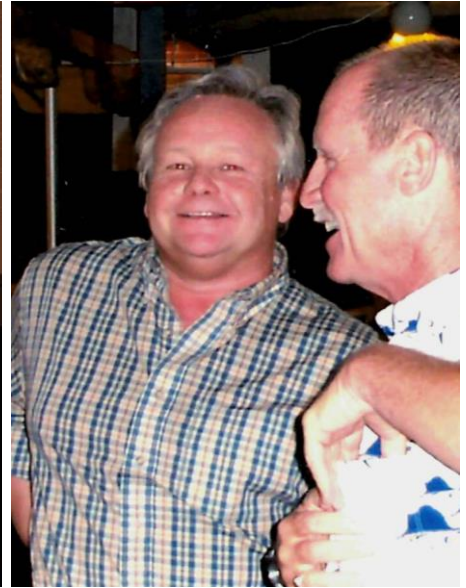
- Largest restoration project in NYS
- Establish 5 shellfish sanctuary sites across Long Island to improve water quality and restore shellfish populations
- 3 sanctuaries authorized in town waters and shellfish stocking commenced at one site (Bellport Bay)



Public Hatchery Grants & Adult Clam Stocking

- \$7.25M in public hatchery grants awarded to towns & Suffolk County Cooperative Extension to increase shellfish seed production; Target **150M shellfish** (115M seed clams & 35M spat-on-shell oysters); **production delays due to new hatchery construction**
- Target of 28M adult clams from dealers and by restarting transplant program in Raritan Bay; **382K clams from dealers planted in one sanctuary**
- Anticipate extension of project timeline and decrease in adult clam targets to complete project by 2021; **numerous contractual and legal challenges with implementation**





*In Dedication to Memory
of Bill Hastback
42 years of State Service with NYSDEC*
