

Summary of Changes

National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2019 Revision

Currently WAC 246-282-005, Minimum performance standards, references the U.S. Food and Drug Administration’s (FDA) 2017 National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish (guide), which all commercial shellfish-producing states are required to follow in order to place molluscan shellfish into interstate commerce. FDA has adopted a 2019 version of the NSSP guide, leaving the current rules out of date. This proposed rule will update the reference to the current standard.

The Department of Health has created this summary of changes table outlining the changes from the 2017 NSSP guide to the 2019 NSSP guide.

NSSP guide	
Chapter and title	Summary of changes
Section I. Purpose & Definitions	
Definitions	<p>Technical change to clarify definitions:</p> <ul style="list-style-type: none">• (74) Marina• (97) Raw• (107) Restricted Shellstock <p>Technical change to add definitions:</p> <ul style="list-style-type: none">• (66) Laboratory Evaluation Officer• (79) Mooring Area• (111) Sanitary Survey Officer• (117) Shellfish Standardization Inspector• (118) Shellfish Standardization Officer <p>Technical change to remove definitions:</p> <ul style="list-style-type: none">• (120) State Shellfish Standardization Inspector• (121) State Shellfish Standardization Officer
Section II. Model Ordinance	

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Chapter I. Shellfish Sanitation Program Requirements for the Authority

Technical change to add requirement of memorandum of understanding or equivalency agreement when shipping shellfish into the United States:

- @.01A(2) Administration

Technical change to add federal regulatory responsibility:

- @.01A(3) Administration: FDA and NOAA have regulatory responsibility in federal waters.
- @.01B State Laws and Regulations: Federal Agency requirements to have laws and regulations for the safety and sanitary control of growing areas and harvest control.
- @.01D Shared Responsibilities
- @.01E Administrative Procedures

Technical change to add personnel training requirements:

- @.01H Personnel Training requirements for implanting the NSSP

Technical change to add plant inspection requirement

- @.02F(3) Inspections

Technical change to previous language of criteria for laboratory evaluations and how conformance is to be determined

- @.03B1bii Technical Evaluation

Technical change to previous language of criteria for requirements for evaluation of the shellfish plant inspection program conformance designations

- @.03B4f Conformance Designations

<p>Chapter II. Risk Assessment and Risk Management</p>	<p>Technical clarification that the state or local epidemiologist in the state where an outbreak occurs will determine an epidemiological association during illness outbreaks related to shellfish:</p> <ul style="list-style-type: none"> • @.01A Outbreaks of Shellfish-Related Illness <p>Editorial change to reference the appropriate procedure to investigate food borne illnesses:</p> <ul style="list-style-type: none"> • @.01A Outbreaks of Shellfish-Related Illness <p>Technical clarification related to follow up required by the shellfish authorities after an epidemiological association has been made:</p> <ul style="list-style-type: none"> • @.01B-C Outbreaks of Shellfish-Related Illness <p>Technical change requiring actions by the shellfish authorities during multiple source outbreaks and implementing precautionary closures in shellfish growing areas:</p> <ul style="list-style-type: none"> • @.01C(2-3) Outbreaks of Shellfish-Related Illness <p>Technical clarification identifying the state authority responsibility related to post-harvest contamination or mishandling:</p> <ul style="list-style-type: none"> • @.01D Outbreaks of Shellfish-Related Illness <p>Technical clarification outlining the closure, reopening, and recall requirements related to not completing an investigation within 24 hours:</p> <ul style="list-style-type: none"> • @.01E Outbreaks of Shellfish-Related Illness <p>Technical clarification related to the closure of a growing area and the review of the potential pollution conditions within that growing area:</p> <ul style="list-style-type: none"> • @.01G Outbreaks of Shellfish-Related Illness <p>Technical change allowing shellfish product that is recalled as a result of an illness outbreak due to Norovirus to be reconditions and defining the time that product must be placed back in the growing area:</p> <ul style="list-style-type: none"> • @.01I Outbreaks of Shellfish-Related Illness <p>Technical change not requiring growing area closures related to Vibrio parahaemolyticus cases that are reported more than 60 days after harvest or when environmental parameters have changed:</p> <ul style="list-style-type: none"> • @.02A Shellfish Related Illnesses Associated with Vibrio parahaemolyticus (V.p.) <p>Technical change requiring the Authority to complete an investigation of the illnesses within 72 hours, closing implicated portions of growing areas if the investigation is not completed, notification to ISSC and FDA, recalls, and growing area evaluations related to multiple source illnesses:</p>
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- @.02A(4-8) Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus* (V.p.)

Technical change adding “for approved post-harvest processing to control the *Vibrio vulnificus* hazard” to the control measures to reduce the risk of V.v. illnesses:

- @.06E(1)(b)(i) *Vibrio vulnificus* Control Plan

Technical change amending options for *Vibrio vulnificus* control plans:

- @.06E(1)(c-d) *Vibrio vulnificus* Control Plan

Technical change requiring annual evaluations of *Vibrio vulnificus* control plans:

- @.06(2)(a) *Vibrio vulnificus* Control Plan

Technical clarification of *Vibrio parahaemolyticus* control plans allowing for oysters in compliance with cooling requirements labeled as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio parahaemolyticus* hazard:

- @.06B(4)(c) *Vibrio parahaemolyticus* Control Plan

Chapter IV. Shellstock Growing Areas

Technical change requiring the sanitary survey report to be reviewed and signed by the Sanitary Survey Officer and removing this recommendation to provide information to other agencies that have the regulatory responsibility to respond to pollution sources:

- @.01A(3)(a) and (4) Sanitary Survey

Technical change defining what an assessment of pollution sources during a shoreline survey may include:

- @.01D(f) Sanitary Survey

Technical change providing an exemption to the water quality standards for offshore state waters greater than three miles from shore where there are not pollution sources that will impact water quality:

- @.02C(3) Microbiological Standards

Technical change allowing water quality statistics and sampling techniques (SRS or APC) to be used in growing areas based on the reason the station is placed (point or nonpoint sources) not the reason for the existing classification of the area:

- @.02E-H Microbiological Standards

Editorial changes to clarify the classification of a growing area. Technical change to allow more than one classification to be used in a single growing area:

- @.03A(2) Growing Area Classification

Technical change to create a “controlled access” status in the case of biotoxins:

- @.03A(5) Growing Area Classification

Technical change establishing the use of marine water to determine reopening status when pathogens are of concern and FDA action levels for poisonous and deleterious substances:

- @.03A(5)(d) Growing Area Classification

Editorial changes to clarify the criteria used to determine Conditionally Approved classifications:

- @.03C(1)(a-d) Growing Area Classification

Technical change allowing the use of marine water quality to determine when a Conditional area can be reopened.

- @.03C(2)(c)(iii) Growing Area Classification

Technical change reducing the required samples in a Conditional area impacted by a wastewater treatment plant, combined sewer overflow, or

other point source from monthly to bimonthly when specific conditions are met:

- @.03C(3)(b)(a-b) Growing Area Classification

Technical change requiring FDA to classify harvest areas with known biotoxin hazards in a manner equivalent to the requirements of Chapter IV.

- @.03F Growing Area Classification

Technical change to add requirement for marine biotoxin sampling to include a combination of management strategies listed in the NSSP Model Ordinance and list those strategies in the Marine Biotoxin Plan:

- @.04B Marine Biotoxin Management Plan

Editorial change to change phytoplankton that “are known” to occur to phytoplankton that “have been documented” to occur:

- @.04B Marine Biotoxin Management Plan
- @.04B(1) Marine Biotoxin Management Plan

Technical change to add administrative procedure requirements to Biotoxin Management Plan and reference the guidance documents for specific criteria:

- @.04B(2)(a) Marine Biotoxin Management Plan: Maintain a toxin-producing phytoplankton and/or shellfish sampling program

Technical change to require shellfish harvested from growing areas place in the controlled access meets all conditions of harvest restrictions prior to sale:

- @.04B(2)(h) Marine Biotoxin Management Plan

Technical change to list marine biotoxin management strategies and remove previous language. Added management strategies listed:

- @.04B(4) Marine biotoxin management strategies
- @.04B(4)(a) Phytoplankton monitoring
- @.04B(4)(b) Routine shellfish toxicity monitoring
- @.04B(4)(c) Pre-harvest shellfish toxicity testing
- @.04B(4)(d) Shellfish lot testing
- @.04B(4)(e) Pre-harvest shellfish toxicity screening and lot testing

Technical change to require the marine biotoxin management plan to include memoranda of understanding between the Authority and individual growers to allow harvesting in growing areas place in controlled access:

- @.04B(5) marine biotoxin management plan- memoranda of understanding

Technical change to remove language describing the Authority’s requirement for establishing requirements for harvesting in closed waters:

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	<ul style="list-style-type: none"> • @.04B(5) marine biotoxin management plan- agreements or memoranda of understanding • @.04B(6) Federal Waters <p>Technical change to add “Controlled Access” as a term:</p> <ul style="list-style-type: none"> • @.04C Closed or Controlled Access Status of Growing Areas <p>Technical change to remove 5,000 cells/L for closure requirement for NSP:</p> <ul style="list-style-type: none"> • @.04C(1)(b): NSP <p>Technical change to add when the Authority can place a growing area in the controlled access status:</p> <ul style="list-style-type: none"> • @.04C(7) Controlled access status <p>Technical change requiring a pollution assessment of any marina area classified as Conditionally Approved or Conditionally Restricted:</p> <ul style="list-style-type: none"> • @.05A(1-2) Marinas <p>Technical change requiring the incorporation of Federal No Discharge Zones, local no discharge and occupancy by-laws, and use of pump out facilities into the dilution analysis used to create the classification around a marina:</p> <ul style="list-style-type: none"> • @.05B(f-g) Marinas <p>Technical change adding moorage areas to the evaluation requirements. This separates moorage areas from marinas and requires the Authority to complete an evaluation.</p> <ul style="list-style-type: none"> • @.06 Mooring Areas
Chapter VI. Shellfish Aquaculture	<p>Technical change to add a description of the mitigation measures to minimize the potential pollution of birds/mammals to the operational plan:</p> <ul style="list-style-type: none"> • .04A (6) Aquaculture That Attracts Birds or Mammals
Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas	<p>Technical change to clarify wet storage tanks shall have no detectable levels of coliform group as measured by an approved NSSP method appropriate for UV process water:</p> <ul style="list-style-type: none"> • .04C(1)(f) Wet Storage Source Water <p>Technical change to decrease the number of water samples required when testing for coliform group:</p> <ul style="list-style-type: none"> • .04C(2)b(i) Continuous Flow-through System

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Chapter VIII. Control of Shellfish Harvesting

Editorial change to clarify appropriate identification of growing areas where shellstock harvest is not allowed:

- @.01A(2)(d) Control of Shellstock Growing Areas
- @.01A(3)(b) Control of Shellstock Growing Areas
- @.01B (2) Patrol of Growing Areas

Technical change to remove requirement for officer training:

- @.01B(6) Patrol of Growing Areas

Technical change to remove Standardized Evaluation Criteria:

- @.01B(8) Patrol of Growing Areas

Technical change to clarify the Authority's requirements to establish water temperature and air temperature:

- @.02C Shellstock Time to Temperature Controls

Editorial change to clarify the disposal of human sewage and bodily fluids:

- .02D(1) Disposal of Human Sewage and Bodily Fluids

Technical change to add the requirement for a disposal system to be available for vehicle operator:

- .02D(2) Disposal of Human Sewage and Bodily Fluids

Technical change to add "IN CHRONOLOGICAL ORDER" to 90 day statement for harvesters:

- .02F(5)(e) Shellstock Identification

Technical change to add ice production requirements for harvesters:

- .02H Ice Production

Technical change to add shellstock harvesting requirements in Federal Waters:

- .03 Shellstock Harvesting in Federal Waters

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Chapter IX. Transportation	<p>Technical change to add requirement for disposal of human sewage and bodily fluids:</p> <ul style="list-style-type: none"> • .01G Conveyances Used to Transport Shellstock to the Original Dealer • .02C Conveyances Used to Transport Shellstock from Dealer to Dealer <p>Technical change to add the requirement for the temperature of shellstock to be recorded by the shipping dealer at the time of shipment:</p> <ul style="list-style-type: none"> • .05A(2) Transportation Records
Chapter X. General Requirements for Dealers	<p>Technical change to remove hand sanitizing as a requirement:</p> <ul style="list-style-type: none"> • .02(4) General Sanitation Requirements <p>Technical change to recognize depuration processor as a type of certification:</p> <ul style="list-style-type: none"> • .04B(5) Types of Certification <p>Editorial change to clarify dual-purpose tag use:</p> <ul style="list-style-type: none"> • .05B(3) Shellstock Identification, Tags • .05B(4) Shellstock Identification, Tags <p>Technical change to alter language used on a restricted use shellstock tag:</p> <ul style="list-style-type: none"> • .05E Shellstock Identification <p>Technical change to add restricted shellfish from federal waters:</p> <ul style="list-style-type: none"> • .09A Restricted Shellfish from Federal Waters
Chapter XI. Shucking and Packing	<p>Technical change to add a Critical Limit under the receiving Critical Control Point for restricted shellstock:</p> <ul style="list-style-type: none"> • .01A(1) Receiving Critical Control Point- Critical Limit <p>Technical change to remove requirement of maintaining conveyance temperature in Receiving Critical Limit:</p> <ul style="list-style-type: none"> • .01A(2) Receiving Critical Control Point- Critical Limit <p>Technical change to remove hand sanitizing requirement:</p> <ul style="list-style-type: none"> • .02C(3)(b) Employee practices • .02D Maintenance of Hand Washing and Toilet Facilities <p>Technical change to remove requirement for toilet paper to be in a suitable holder:</p> <ul style="list-style-type: none"> • .02D(6) Maintenance of Hand Washing and Toilet Facilities

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Chapter XII. Repacking of Shucked Shellfish	<p>Technical change to remove hand sanitizing requirement:</p> <ul style="list-style-type: none"> • .02C(2)(b) Prevention of Cross Contamination • .02D Maintenance of Hand Washing and Toilet Facilities <p>Technical change to remove requirement for toilet paper to be in a suitable holder:</p> <ul style="list-style-type: none"> • .02D(3)(c) Maintenance of Hand Washing and Toilet Facilities
Chapter XIII. Shellstock Shipping	<p>Technical change to remove requirement of maintaining conveyance temperature in Receiving Critical Limit:</p> <ul style="list-style-type: none"> • .01A(2)(d) Receiving Critical Control Point- Critical Limit <p>Technical change to remove hand sanitizing requirement:</p> <ul style="list-style-type: none"> • .02C(2)(a) Employee practices • .02D Maintenance of Hand Washing and Toilet Facilities <p>Technical change to remove requirement for toilet paper to be in a suitable holder:</p> <ul style="list-style-type: none"> • .02D(3)(c) Maintenance of Hand Washing and Toilet Facilities
Chapter XIV. Reshipping	<p>Technical change to remove requirement of maintaining conveyance temperature in Receiving Critical Limit:</p> <ul style="list-style-type: none"> • .01A(1)(d) Receiving Critical Control Point- Critical Limit <p>Technical change to remove hand sanitizing requirement:</p> <ul style="list-style-type: none"> • .02C(2)(a) Employee practices • .02D Maintenance of Hand Washing and Toilet Facilities <p>Technical change to remove requirement for toilet paper to be in a suitable holder:</p> <ul style="list-style-type: none"> • .02D(3)(c) Maintenance of Hand Washing and Toilet Facilities

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Chapter XV. Depuration	<p>Technical change to remove requirement of maintaining conveyance temperature in Receiving Critical Limit:</p> <ul style="list-style-type: none"> • .01A(2)(d) Receiving Critical Control Point- Critical Limit <p>Technical change to remove hand sanitizing requirement:</p> <ul style="list-style-type: none"> • .02C(3)(a) Prevention of Cross Contamination • .02D Maintenance of Hand Washing and Toilet Facilities <p>Technical change to remove requirement for toilet paper to be in a suitable holder:</p> <ul style="list-style-type: none"> • .02D(5)(c) Maintenance of Hand Washing and Toilet Facilities <p>Technical change to add requirements for depuration using MSC Viral controls for shellstock harvested from Conditionally Restricted Growing Areas:</p> <ul style="list-style-type: none"> • .03K Supplemental Requirements for Depuration
Section IV. Guidance Documents	
	Has not yet been updated