

**ISSC 2023
Committee Report**

Committee Name: Cleansing Study Committee

Committee Chair: Andy Haines for Bob Schuster

Meeting Dates: Multiple Calls

Committee Members:

Andy Haines (Substitute Chair)

Nyle Taylor

Debra Barnes

Bob Schuster

Ned Gaine

Alissa Dragan

Kathy Brohawn

Miranda Ries

Scott Berbells

Jeff Kennedy

Vanessa Zoubkosky-White

Jill Fleiger

Quentin Forrest (FDA Delegate)

Jessica Jones (FDA Advisor)

Bill Kramer (for Joel Hansel) (EPA)

John Jacobs (NOAA)

Chris Schillaci (NOAA Advisor)

Charges

Charge 1: Proposal 19-145: Guidance on Cleansing Studies

Findings/Conclusions: The committee met several times to work on the development of a guidance document relating to cleansing studies for reopening. During discussion, the committee focused on several primary questions: 1) When is a cleansing study required within the Model Ordinance, 2) How should cleansing studies be designed and conducted, and 3) How frequently do cleansing studies need to be updated. The committee has developed a guidance document answering the first question, but continues to work on the second and third, particular with regards to sample size determination and statistical significance.

Recommendation:

- 1) The committee recommends adoption of the Guidance Document text included in Attachment 1.
- 2) The committee recommends that this proposal be referred back to an appropriate committee as determined by the conference chair to allow for further development of additional sections of the Guidance Document.

- 3) The committee recommends expanding the charge of the committee to include reviewing Model Ordinance language relating to cleansing studies for reopening.

Guidance on Studies Used in the Reopening of an Area Temporarily Placed in the Closed Status Due to an Emergency Condition, a Discharge of Raw Sewage, or when Conditional Area Management Plan (CAMP) Performance Standards are not Met

Note: Similar contaminant reduction studies associated with shellstock relaying and validation studies associated with the depuration process are not covered in this guidance document. Instead, each has their own specific requirements which are covered in Chapter V. and Chapter XV., as well as Guidance Documents Chapter II .10 and .19, respectively.

A. When Are Studies Required?

Per Chapter IV. @.03 A.(5)(d) and C.(2)(c), studies are required for reopening a closed area to establish the environmental conditions and time required for pathogens (as measured by microbiological indicators) in shellstock and water to return to acceptable levels following the impact from an emergency condition, discharge of raw sewage, or when conditional area management plan (CAMP) performance standards are not met. Listed below is a summary of scenarios for reopening options:

1) Scenarios where studies are required to reopen once the emergency situation or condition has returned to normal, or CAMP performance standards are fully met, and sufficient time has elapsed to allow the shellstock to reduce pathogens and for the growing area water quality to return to acceptable levels:

(a) Chapter IV. @.03A.(5)(d):

- Reopening due to closures resulting from an emergency condition or situation when pathogens are of concern (other than raw untreated sewage discharged from a sewage collection system or WWSD), studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water.
- Reopening due to emergency closures caused by the occurrence of raw untreated sewage discharged from a sewage collection system or WWSD, when the closure duration is less than 21 days or when analytical shellstock samples are utilized for comparison to the levels established in the Chapter IV. @.02 E. (4). The authority may use studies to establish pre-determined male-specific coliphage (MSC) levels in shellfish samples that are conducted no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted.

(b) Chapter IV. @.03 C.(2)(c)(iii):

For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status.

- Reopening due to closures impacted by pathogens (other than raw untreated sewage discharged from a sewage collection system or WWSD) from a failure to comply with its conditional management plan, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. These studies may establish criteria for reopening based on coliform levels in the water.
- Reopening due to temporary closures impacted by sewage from a failure to comply with the conditional management plan based on the WWSD performance standards, studies may be conducted to establish sufficient elapsed time and shall document the interval necessary for reduction of viral levels in the shellstock. These studies may establish pre-determined levels based on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in shellfish meats.

2) *Scenarios where sampling is required to reopen when a study is not conducted, include:*

(a) Chapter IV. @.03A.(5)(d):

- Reopening due to emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a sewage collection system or WWSD, when the closure duration is intended to be less than 21 days, the analytical sample results shall not exceed the levels established in Chapter IV. @.02 E. (4).
- Reopening due to emergency closures of harvest areas when poisonous or deleterious substances are the concern, sampling shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances, guidance levels, and levels that are deemed unsafe through risk evaluation.

(b) Chapter IV. @.03C.(2)(c)(iii):

- Reopening due to temporary closures impacted by sewage from a failure to comply with the conditional management plan based on the WWSD performance standards, analytical sample results shall not exceed the MSC level established in Chapter IV. @.02 E. (4).
- Water quality sampling can be used to reopen an area following temporary closures resulting from a failure to comply with conditional management plan performance standards based on the effects of non-point sources of pollution such as rain events and/or stormwater runoff.

3) *Scenarios where no studies or sampling are required to reopen, include:*

(a) Chapter IV. @.03A.(5)(d)(ii) and C.(2)(c)(iii):

- Reopening due to the temporary closure from a discharge of raw untreated sewage or exceedance of management plan performance standards relating to WWTP function. If no studies or analytical samples are collected and compared to the levels

established in Chapter IV. @.02 E. (4), the area must be in the closed status until the event is over and twenty-one (21) days have passed.