

**Proposal Subject:** V.v. Illness Review Subcommittee Procedures  
Procedure XVII.

**Specific NSSP  
Guide Reference:** Constitution, Bylaws, and Procedures

**Text of Proposal/  
Requested Action** Procedure XVII. ~~Reciprocity~~ Procedure for *Vibrio vulnificus* (V.v.) Illness Review  
Committee Procedures

Section 1. Charge.

The V.v. Illness Review Committee will annually review all V.v. cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) V.v. case as outlined in Model Ordinance Section II Chapter II @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:

- Subdivision a. Conducting annual V.v. Risk Evaluations;
- Subdivision b. Risk per serving determinations;
- Subdivision c. V.v. Control Plan Evaluations;
- Subdivision d. V.v. Contingency Plan Evaluations; and
- Subdivision e. Reviewing illness trends.

Section 2. Procedures.

- Subdivision a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means.
- Subdivision b. FDA (currently Shellfish Specialist Mark Glatzer) will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee.
- Subdivision c. The information from the COVIS forms will be shared with the V.v. Illness Review Committee for review.
- Subdivision d. The V.v. Illness Review Committee will review the cases and incorporate the appropriate information into a chart (see attachment A) which will serve as the Committee report.
- Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.
- Subdivision f. The availability of the report will be announced to the ISSC membership.

Section 3. A copy of the report will be posted on the ISSC website. Criteria and Guidelines. The Committee will use the following

criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In this context “etiologically confirmed “shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory other than a State laboratory.”

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean “associated with” the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

Subdivision d. Were the shellfish raw or undercooked? If the victim developed V.v. septicemia after consumption the shellfish are considered to have been raw or undercooked.

Subdivision e. From what State was the shellfish harvested?

Subdivision f. Did the case involve septicemia from consumption: The following guidance will be used in determining if the case is a septicemia or a gastroenteritis case. Clinical signs and symptoms V.v. septicemia include:

Subdivision i. V.v. bacteria isolated from blood.

Subdivision ii. Fever measured as above 100 degree Fahrenheit.

Subdivision iii. Death as outcome (septicemia has a mortality rate of over 50% - 70%).

Subdivision iv. Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.

Subdivision v. Shock because of the sepsis (again this can happen also because of a wound infection).

Subdivision g. Indications case may not be V.v. septicemia from consumption:

Subdivision i. Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia

Subdivision ii. Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering bodies through the skin, there might be a visible wound or just a small scratch),

therefore more likely a wound infection.

Subdivision iii. History of pre-existing and sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.)

Subdivision iv. Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data. V.v. septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods.

Section 4. Challenges to Committee Findings

Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

*Vibrio Vulnificus* Illness Review Criteria Table on next page.

Procedure XVIII. Reciprocity

**Public Health  
Significance:**

**Cost Information  
(if available):**

**Action by 2013  
Task Force III** Recommended adoption of proposal 13-310 as submitted.

**Action by 2013  
General Assembly** Adopted recommendation of 2013 Task Force III on Proposal 13-310.

**Action by FDA  
May 5, 2014** Concurred with Conference action on Proposal 13-310.

*Vibrio vulnificus* Illness Review Criteria Table

Review Date: \_\_\_\_\_

Case Identifier/Number:			Criteria Status Determination		
Criteria			Yes	No	Unknown
<b>1. Etiologically Confirmed</b> <b>Blood</b> <b>Stool</b>					
<b>2. Epidemiologically Linked?</b>					
<b>3. Septicemia Illness?</b>					
<b>4. Reporting State?</b>					
<b>5. Commercial Harvest?</b>					
<b>6. Were shellfish consumed?</b>					
a. Specify shellfish consumed:			<b>Oysters</b>	<b>Clams</b>	<b>Specify Other</b>
b. Date of consumption: _____					
c. Is onset consistent with consumption of shellfish? Date of onset _____					
<b>7. Trace-back Information</b>					
a. Were shipping tags available? If other trace-back information reported, list:					
b. State of harvest, harvest area (s), and harvest date (list all reported).					
Harvest Area	Harvest State	Harvest Date	Species		Comment