Introduction.

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish Guidance Documents provide the public health principles supporting major components of the NSSP, its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most States apply the requirements intrastate. All requirements of the Program can be found in the current edition of the NSSP Model Ordinance.

A goal of the NSSP is to control the safety of molluscan shellfish for human consumption by preventing unnecessary growth of bacterial pathogens resulting from improper or ineffective cooling or from time to temperature abuse.

Chapter II. Risk Assessment and Risk Management.

Authorities must conduct Risk Assessments to determine the appropriateness of developing *Vibrio vulnificus (Vv)* or *Vibrio parahaemolyticus (Vp)* Control Plans.

The Authority in conjunction with the FDA will determine whether the State will implement a *Vv* plan, a *Vp* plan, or the control option for all other harvested shellstock (see Table 1). In developing *Vv* and *Vp* Control Plans the Authority must conduct *Vv* and *Vp* risk evaluations. The specific requirements of these evaluations are detailed in Chapter II. @ .04 and Chapter II. @ .05.

Chapter VIII. Harvesters Time to Temperature Control.

There are several pathogens that can cause illness from consumption of molluscan shellfish. Not all known pathogens associated with shellfish reproduce in the shellfish. However there are several pathogens that multiply in shellfish and present a health concern. Most *Vibrios* grow in shellfish and the rate of growth is dependent upon temperature. To minimize illness, the NSSP includes controls to limit exposure to warm temperatures. The controls begin at harvest and are applied at every level of processing and handling. This guidance document provides an explanation of those controls.

A. Authority Responsibilities.

Authorities must establish time to temperature controls for harvesters. The Authority in conjunction with the FDA will determine whether the State will implement a *Vv* Plan (Chapter II. @.04), a *Vp* Plan (Chapter II. @.05), or the control option of Chapter VIII. @.02 A. (3). In developing *Vv* and *Vp* Control Plans the Authority must conduct *Vv* and *Vp* risk evaluations. The specific requirements of these evaluations are detailed in Chapter II. @.04 and Chapter II. @.05. The Authority will advise the industry of the applicable harvest controls. The water and air temperatures used to establish these controls shall be representative of the temperatures of growing areas of the state from which harvesting is occurring.

B. Harvesters.

Harvesters must be aware of the applicable time to temperature requirements. Harvesters can obtain this information by contacting the Shellfish Control Authority responsible for regulating shellfish harvesting. Harvesters must adhere to the time to temperature requirements of the individual State *Vibrio* Plans or follow the matrix below.

Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Exposure to Receipt at the Dealers Facility
Level 1	<50°F (10°C)	36 hours
Level 2	50°F - 60 °F (10°C - 15 °C)	24 hours
Level 3	>60 °F - 80 °F (15 °C - 27 °C)	18 hours
Level 4	>80 °F (>27 °C)	12 hours

Table 1

The harvest controls and *Vv* and *Vp* State Control Plans and the matrix above apply only to the harvester or harvester/dealer of shellstock for the purposes of handling and delivery of shellstock to the original dealer.

The harvester must provide harvest records to the original shellfish dealer demonstrating compliance with the applicable time and temperature requirements. This record may be in the form of a harvester tag, trip record, or other record deemed appropriate by the Authority. The record must include the date and time harvest begins for each lot of shellfish harvested. For States that establish and limit harvest times the recording of the time harvest begins may not be necessary. The time harvest begins is the time when the first shellstock in a lot is taken from the water or, in the case of intertidal harvest, the time of first exposure. Should the harvesting technique used involve re-submerging, the Authority must approve the harvesting technique to assure that the harvest method does not promote post harvest growth of pathogens associated with shellfish. The Authority shall not allow re-submerging techniques that promote *Vibrio* growth. It is expected that some harvest vessels will be equipped with refrigeration capabilities to accommodate large volume harvesting. Where cooling occurs on a harvest vessel, or prior to delivery to the original dealer, the harvester must provide documentation to the original dealer that the time and temperature requirements established by the Authority have been met.

To comply with the time to temperature requirements for harvested shellstock (Chapter VIII. @.02 A (1), (2), and (3)), the type of cooling must be capable of achieving the required internal temperature within the time frames required in the State *Vibrio* Control Plans or 50°F (10°C) prior to shipment (see shellstock storage critical control point Chapter XIII. .01 B. (3) and (4)). The use of temporary or inadequate cooling is not acceptable. Cooling that occurs prior to receipt by the original dealer does not alleviate the dealer requirement to document the time to internal temperature requirements.

To comply with the time to temperature requirements for shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP), or "For Shucking Only by a Certified Dealer", the dealer must comply with one of the options below:

Option 1
The dealer must shuck or introduce into Wet Storage or Depuration, within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03; or

Option 2
The dealer must place the shellstock in temperature control within the applicable time to temperature controls of Chapter VIII. @.02 A (3) and Chapter XIII .03.

Ocean Quahogs (*Arctica islandia*) and Surf Clams (*Spisula solidissima*) are excluded from the time to temperature controls of State *Vibrio* Control Plans or the matrix outlined in Chapter VIII. @.02 A. (1) (2) and (3). This exclusion applies only when these products are intended for thermal processing. Authorities may exclude other species when intended for thermal processing.

In harvesting situations which expose shellstock to direct sunlight that increases product temperature, the Authority must consider the appropriateness of shading in the development of *Vv* and *Vp* Control Plans and may require shading when implementing controls for all other shellstock harvesting.

Chapter IX.

Conveyances Used to Transport Shellstock to the Original Dealer.

Conveyances used to transport shellstock from the harvest area to the original dealer shall be constructed to prevent contamination, deterioration, or decomposition of the shellstock during transport.

For shellstock being delivered within the time to temperature controls of Chapter VIII. @.02 A. (1) (2) and (3), refrigeration of the conveyance is not required. However, shellstock transport must comply with Chapter IX .01 C. and may not be shipped in a manner which would cause the temperature of the shellstock to increase. Persons responsible for transporting shellstock must take reasonable steps to assure that the shellstock temperature is not increased unnecessarily as a result of the method of transport. An example would be a closed-in truck with a high internal temperature caused by very warm ambient temperature or exposed to direct sunlight for a long period of time while closed. The Authority shall monitor this activity to assure compliance. When temperature control is necessary during transport to the original dealer to comply with the Authority established time to temperature controls, the shellstock must be cooled with ice or mechanical refrigeration. This cooling must be capable of achieving the required internal temperature of 55°F (12.7°C) for shellstock harvested under State *Vv* Plans or 50°F (10°C) for all other shellstock.

Should compliance with internal temperatures involve refrigeration on board the vehicle or in the transportation conveyance prior to reaching the original dealer, shellstock must be cooled as necessary to comply with the internal temperature of 55°F (12.7°C) for shellstock harvested under State *Vv* Plans or 50°F (10°C) for all other shellstock. Refrigeration units must be pre-chilled to 45°F (7.2°C) and the refrigeration unit must be maintained at a temperature to ensure that the shellstock temperature is not allowed to increase. Ice can also be used to cool shellstock. Any ice on-site at a certified dealer shall be from potable water in a commercial ice machine or come from a source certified by the Authority or the appropriate regulatory Authority. Once cooling of the shellstock begins, that cooling must be continued using an acceptable cooling method.

Conveyances Used to Transport Shellstock from Dealer to Dealer.

Shellstock being transported from dealer to dealer must be shipped in containers which can be easily cleaned and maintained to prevent contamination. Shellstock must be shipped on pallets when shipped in bulk. Pallets are not necessary if the conveyance has channeled flooring.

If shellstock is shipped with other cargo, the shellstock must be protected from contamination by the other cargo. Shellstock must be refrigerated or cooled at all times when shipping from dealer to dealer. Conveyances must be pre-chilled to 45°F (7.2°C) or below prior to loading. It is acceptable to use ice as a means of cooling. The dealer shall keep a record of compliance with the pre-chilling requirement; this record is not intended to be a HACCP record for the shipping dealer.

All shipments of shellstock shall be accompanied with a documentation record indicating the time of shipment and that all shipping containers were pre-chilled. The documentation required in Chapter IX. .05 must include the time of shipment, the means of cooling, and indicate the temperature to which the conveyance was pre-chilled if mechanical refrigeration was the means of cooling (This documentation is not intended to be a HACCP record for the shipping dealer). In situations when the dealer chooses to ship product not harvested under a State *Vibrio* Plan that has not achieved the internal temperature of 50°F (10°C), the shipping documentation must provide notice to the receiving dealer that the product was shipped prior to achieving an internal temperature of 50°F (10°C). Additionally, the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. The documentation stating the time of shipment will accompany the bill of lading and will be used by the receiving dealer to determine the length of shipment.

This control will allow product to be shipped while cooling is occurring. Should the receiving dealer choose not to further ship the shellstock with a time/temperature recording device, the dealer must cool and document that the product has reached an internal temperature of 50°F (10°C) prior to reshipping.

Chapter XI. Shucking and Packing Dealer Requirements.

Shellstock Received from Harvesters

Dealers receiving shellstock from a harvester must only accept shellstock that is accompanied by documentation from the harvester indicating the time of harvest. The original dealer must document and maintain a record that cooling of the shellstock began at a time that wascompliant with the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), or (3). Shellstock intended for shucking must include the same harvester documentation as shellstock intended for raw consumption. The documentation may be in the form of a harvester tag which includes date and time of harvest or a trip record, or other form that meets the requirements of the Authority.

Although a record is not required of the shipment temperature from the harvester, dealers should make sure that the means of transport to the dealer does not allow unreasonable temperature increases.

The dealer must document and maintain a HACCP record that the shellstock received from harvesters are either shucked or placed in a refrigeration unit at or below 45°F (7.2°C) within the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3) and Chapter XIII .03.

Storage Requirements

All shellstock obtained from a licensed harvester shall be placed in a storage area maintained at 45°F (7.2°C) or less within two (2) hours of receipt. This two (2) hour requirement does not allow the dealer to exceed the time to temperature requirements of Chapter VIII. @.02 A. (1) or (2)as outlined in State *Vibrio* Control Plans.

In cases when shellstock that is harvested in compliance with State *Vv* or *Vp* Plans does not reach the dealer within the time periods outlined in the State *Vibrio* Plans, the dealer may elect as a corrective action to convert the shellstock to a restricted use such as PHP or “For Shucking Only by a Certified Dealer”. Should the dealer choose this option the dealer must adhere to the time to temperature requirements of Chapter VIII. @ .02 A. (3).

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for shucking and packing must document and maintain a record that the shellstock was received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

When a dealer receives shellstock that was harvested in compliance with Chapter VIII @ .02 A (3) not cooled to an internal temperature of 50°F (10°C) prior to shipment the receiving dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05 (Indicate in a record the presence of a time/temperature recording device). For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation. Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary. If the shipment is less than four (4) hours, a time temperature recording device is not required.

Storage Requirements

Shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B. (1) or B. (2) for more than two (2) hours at points of processing or transfer such as loading docks.

Once shellstock has been shucked by the dealer, the dealer shall comply with the processing and storage Critical Control Points of Chapter XI. .01 D. and E.

All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Chapter XIII. Shellstock Shipping Dealer Requirements.

Shellstock Received from Harvesters

Dealers receiving shellstock from a harvester must only accept shellstock that is accompanied by documentation from the harvester indicating the time of harvest. The original dealer must document and maintain a record that cooling of the shellstock began at a time compliant with the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3). Shellstock intended for further processing must include the same harvester documentation as shellstock intended for raw consumption. The documentation may be in the form of a harvester tag which includes date and time of harvest or a trip record or other form that meets the requirements of the Authority.

Although a record is not required of the shipment temperature from the harvester, dealers should make sure that the means of transport to the dealer does not allow unreasonable temperature increases.

The dealer must document and maintain a HACCP record that the shellstock was shucked, iced, or placed in a refrigeration unit at or below 45°F (7.2°C) within the time to temperature requirements of Chapter VIII. @.02 A. (1), (2), and (3).

Storage Requirements

All shellstock obtained from a licensed harvester shall be placed in a storage area maintained at 45°F (7.2°C) or less within two (2) hours of receipt. This two (2) hour requirement does not allow the dealer to exceed the time to temperature requirements of Chapter VIII. @.02 A. (1)or (2)as outlined in State *Vibrio* Control Plans.

Shellstock received from harvesters that harvested shellstock in compliance with the State *Vibrio vulnificus* Control Plan as outlined in Chapter VIII. @.02 A. (1) must be placed in refrigeration within the times outlined in the State *Vv* Control Plan and cooled by the original shipper to 55°F (12.7°C) within the time period outlined in the State *Vv* Control Plan (see Chapter XIII. .01 B. (3)), unless the shellstock is labeled for a restricted use. The original dealer must document that the internal temperatures listed above were achieved within the time frame outlined in the State *Vv* Control Plan.

Shellstock received from harvesters that harvested shellstock in compliance with the State *Vp* Control Plan as outlined in Chapter VIII. @.02 A. (2) must be cooled by the original shipper to 50°F (10°C) (see Chapter XIII. .01 B. (3)), unless the shellstock is labeled for a restricted use. The original dealer must document that the internal temperatures listed above were achieved within the time frame outlined in the State *Vv* Control Plan. Shellstock cooled to an internal temperature of 55°F (12.7°C) to comply with a *Vv* Control Plan is considered in compliance with this requirement. It is assumed that refrigeration capable of achieving an internal temperature of 55°F (12.7°C) within six (6) hours would also achieve an internal temperature of 50°F (10°C) within ten (10) hours.

Shellstock received from harvesters that harvested shellstock in compliance with the time to temperature control matrix outlined in Chapter VIII. @.02 A. (3) and restricted use shellstock must be cooled to an internal temperature of 50°F (10°C) prior to shipment (see Chapter XIII. .01 B. (4)). (Product intended for relay, wet storage, depuration, or *Mercenaria sp* which is being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed in Chapter XIII. .01 B. (4).) The original dealer must document that the internal temperatures listed above have been achieved prior to shipment.

In cases when shellstock that is harvested in compliance with State *Vv* or *Vp* Plans does not reach the dealer within the time periods outlined in the State *Vibrio* Plans, the dealer may elect as a corrective action to convert the shellstock to a restricted use such as PHP or “For Shucking Only by a Certified Dealer”. Should the dealer choose this option the dealer must adhere to internal temperature requirements of Chapter XIII .01 B. (4).

Where cooling occurs on a harvest vessel, or prior to delivery to the original dealer, the harvester must provide documentation to the original dealer that the time and temperature requirements the Authority and outlined in the State *Vibrio* Control Plan have been met. The information must be included in the dealer’s HACCP records.

Shipping Requirements

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature recording device indicating that continuing cooling has occurred.

Prior to shipping shellstock received from harvesters the dealer must comply with the internal temperature requirements of Chapter XIII. .01 B. (3) and (4).

Should the original dealer choose to ship shellstock which was harvested in compliance with the time to temperature control matrix outlined in Chapter VIII. @.02 A. (3) but has not been cooled to an internal temperature of 50°F (10°C), the dealer shall include a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary.

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for shipping and repacking must document and maintain a record that the shellstock was received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

When a dealer receives shellstock that was not cooled to an internal temperature of 50°F (10°C) prior to shipment the receiving dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. Additionally the dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation. Note that allowances for routine refrigeration defrost cycles and other short duration temperature fluctuations may be necessary. If the shipment is less than four (4) hours, a time temperature recording device is not required.

Shellstock acceptability (receiving Critical Control Points) can be determined as follows:

1. The presence of enough ice on the shellfish to provide cooling to achieve required internal temperatures; or
2. An ambient temperature of 45°F (7.2°C) or less in the conveyance as measured by a thermometer; or
3. An internal temperature of 50°F (10°C) which can be measured by opening the shellstock and measuring the meat or using a temperature indicating gun which measures product temperature; or
4. The shipment of shellfish is accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of any shellstock that was shipped prior to meeting internal temperature required and notice of the presence of a time/temperature device indicating that continuous cooling has occurred.
5. For shellstock which was shipped prior to achieving an internal temperature of 50°F (10°C) the dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. The dealer must indicate in a record the presence of a time/temperature recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation.

Storage Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration, or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B. (1) or B. (2) for more than two (2) hours at points of processing or transfer such as loading docks. All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Shipping Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

Should the original dealer choose to ship shellstock which was received with documentation indicating that the product was not cooled to an internal temperature of 50°F (10°C) prior to shipment, the dealer must adhere to one of the following:

1. Include documentation indicating that the shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuing cooling has occurred. The shipment must be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have

a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**

2. Should a dealer receive shellstock from a dealer who has elected to ship the shellstock prior to achieving required internal temperatures the dealer may choose to cool the product to an internal temperature of 50°F (10°C) or less prior to shipment. In this case a time temperature device will not be required. The dealer must document in a HACCP record that the internal temperature of 50°F (10°C) was met prior to shipment.

Chapter XIV. Reshipping

Shellstock Received from Another Certified Dealer

Dealers receiving shellstock from another certified dealer for reshipping must document and maintain a record that the shellstock was received iced; in a conveyance at or below 45°F (7.2°C); or at an internal temperature of 50°F (10°C) or less. Dealers receiving shellstock from another certified dealer must also document and maintain a record that the shipment was accompanied by documentation indicating (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.

Should the shipping dealer have chosen to ship product harvested under the time temperature requirements of Chapter VIII @.02 A. (3) or restricted use shellstock prior to achieving required internal temperatures, the shellstock must be accompanied by a time/temperature recording device which indicates that continuing cooling has occurred. The shipment must also be accompanied by a shipping document indicating the time of shipment and that all shipping containers were prechilled.

Shellstock acceptability (receiving Critical Control Points) can be determined as follows:

1. The presence of enough ice to contact the shellfish and provide cooling to achieve required internal temperatures; or
2. An ambient temperature of 45°F (7.2°C) or less in the conveyance as measured by a thermometer; or
3. An internal temperature of 50°F (10°C) which can be measured by opening the shellstock and measuring the meat or using a temperature indicating gun which measures product temperature; or
4. The shipment of shellfish is accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting internal temperature required and notice of the presence of a time/temperature device indicating that continuous cooling has occurred.
5. For shellstock which was shipped prior to achieving an internal temperature of 50°F (10°C) the dealer must review the data of the time/temperature recording device and document in a record that continuing cooling has occurred since the time of shipment, as required in Chapter XI. .05. The dealer must indicate in a record the presence of a time/temperature

recording device. For shipments that have multiple deliveries, it is acceptable for each delivery to have an individual time/temperature recording device or be shipped with a single time/temperature recording device that each receiving dealer can use for documentation.

Storage Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shellstock that has been refrigerated must not be allowed to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in Model Ordinance Chapter XI. .01 B (1) or B (2) for more than two (2) hours at points of processing or transfer such as loading docks. All shucked shellfish shall be maintained and shipped at or below 45°F (7.2°C).

Shipping Requirements for Dealers Receiving Shellstock from another Certified Dealer

All shipments of shellstock must be accompanied by documentation that indicates (1) time of shipment; (2) that conveyance was pre-chilled; and (3) notice of shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuous cooling has occurred.
Should the original dealer choose to ship shellstock which was received with documentation indicating that the product was not cooled to an internal temperature of 50°F (10°C) prior to shipment, the dealer must adhere to one of the following:

1. Include documentation indicating that the shellstock that was shipped prior to meeting required internal temperature and notice of a time/temperature device indicating that continuing cooling has occurred. The shipment must be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). **[C]**
2. Should a dealer receive shellstock from a dealer who has elected to ship the shellstock prior to achieving required internal temperatures the dealer may choose to cool the product to an internal temperature of 50°F (10°C) or less prior to shipment. In this case a time temperature device will not be required. The dealer must document in a HACCP record that the internal temperature of 50°F (10°C) was met prior to shipment.

Internal Temperature Measurements.

When monitoring the internal temperature of shellstock, it is acceptable to open the shellstock and measure the temperature of the shellfish directly using a thermometer or use a temperature detector device which provides the external temperature of the product. Where possible, but especially in cases in which product appears to be packaged for final sale, methods for determining the internal temperature of the shellstock should not compromise the integrity of the container. Should circumstances dictate that the measurement of the internal temperature of individual shellfish is necessary then particular care should be taken so as to avoid transferring heat from the equipment used by, and from the hands of the inspector to the shellfish. Individual oysters are typically no more than 0.2 kg in mass and can be warmed relatively quickly through handling by bare hands

and when exposed to equipment or environments which are at a higher temperature than the original internal temperature of the animal.

Prying open the shells of shellfish is a time consuming and inherently destructive process (those animals measured must be discarded). The internal temperature of shellstock is, under most circumstances, reflected by the external temperature of the space surrounding the shellfish, or the external temperature of the shell of the animal, at the center of a packaged mass of shellstock (box, sack, bag, etc.). This temperature may be measured by inserting a standard analog or digital thermometer probe into the package to an appropriate depth or by exposing the shellfish at the center of the package for rapid measurement of the external shell temperature such as is made possible with laser guided infrared temperature measurement devices.

Time/Temperature Recording Devices – The time/temperature recording device must allow the receiving dealer to document that continuing cooling has occurred during transport.

Cooler Process Study Guidance

An alternative to monitoring product temperatures would be properly designed cooling process studies that demonstrate that cooling critical limits will be met. The cooling process studies must evaluate cooling times under worst case conditions found in the facility.

Factors including ambient air temperatures, product temperatures at arrival, amount of product to be cooled, arrangement of product in the cooler, and opening of the cooler door must be considered in the study. In conducting the studies, confirmatory product temperatures should be taken at the area of the cooler that is likely to have the least cooling ability. For instance, product temperature should be taken in the middle of a pallet in the most difficult cooling portion of the cooler.

Once a study is completed, the study should detail requirements needed to achieve compliance with the critical limits. Requirements could include such items as cooler capacity or arrangement of product in the cooler. Once identified, the monitoring of the critical limits would include records to document that the requirements identified in the study to meet the critical limit are in place. The written study remains with the HACCP records.

This guidance can be utilized as a guide by the Authority when a certified dealer chooses not to physically monitor the initial temperature storage Critical Control Point (CCP) for each incoming lot of shellstock under the NSSP Model Ordinance as required by State *Vibrio vulnificus (Vv)* or *Vibrio parahaemolyticus (Vp)* Control Plans. The dealer can demonstrate the ability of the cooler to achieve required internal shellstock temperatures through a study that demonstrates that their mechanical refrigeration unit is able to cool shellstock to 50°F for *Vp* or 55°F for *Vv* within the required maximum time frame. This would enable the firm to monitor the ambient temperature of the refrigeration unit without requiring the firm to take the internal shellstock temperatures at the exact time of ten (10) hours (*Vp*) or six (6) hours (*Vv*) for each lot of shellfish on each day of the *Vv* or *Vp* Control Plan season. This guidance assumes that the refrigeration unit has a continuous

temperature recording device (TRD) or the dealer manually monitors the cooler ambient temperature each day.

1. Determine the parameters of the cooler process study based on expected maximum load during implementation of a *Vv* or *Vp* Control Plan. This study can be used to satisfy internal temperature requirements for A. (3) shellstock.

2. Over three (3) days of refrigerated storage, starting with the first day of the *Vv* or *Vp* season, record the "internal" shellstock temperature at the time of loading into the cooler.

3. Record the days' maximum air and water temperature in the vicinity of the harvest area.

4. Record the internal shellstock temperatures after six (6) hours of refrigerated storage for *Vv* and at ten (10) hours of refrigerated storage for *Vp* and record the results.

5. If the internal shellstock temperatures meet the Model Ordinance requirements for cooling, continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

6. When the air or water temperatures in the vicinity of the harvest area have increased by 10°F since the initial process study date repeat process study as described in No. 1 through No. 4 above.

7. If results meet the Model Ordinance requirements for cooling continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

8. When the air or water temperatures in the vicinity of the harvest area have increased by another 10°F since the initial process study date repeat process study as described in No.1 through No. 4 above.

9. If results meet the Model Ordinance requirements for cooling continue to only monitor the cooler ambient temperatures as you normally would under your HACCP Plan.

10. If following the process studies the cooler has been shown to achieve the required internal shellstock temperature, including at least one (1) three (3)-day period of maximum loading under elevated air and water temperatures, then the study is considered successful and the certified dealer needs only to continue to monitor the routine cooler ambient temps as per their HACCP Plan.

Note: Changes to maximum shellfish loading or cooler capacity or changes to cooler compressor would require additional Re-Validation Process Studies.