

## Burgos, Alexander N

---

**Subject:** FW: Marine Fisheries Commission RFC  
**Attachments:** 15A NCAC 18A .0301.docx; 15A NCAC 18A .0401.docx; 15A NCAC 18A .0418.docx; 15A NCAC 18A .0420.docx; 15A NCAC 18A .0421.docx; 15A NCAC 18A .0428.docx; 15A NCAC 18A .0430.docx; 15A NCAC 18A .0434.docx; 15A NCAC 18A .0439.docx; 15A NCAC 18A .0501.docx; 15A NCAC 18A .0601.docx; 15A NCAC 18A .0608.docx; 15A NCAC 18A .0620.docx; 15A NCAC 18A .0701.docx; 15A NCAC 18A .0801.docx; RRC Marine Fisheries Commission\_Responses.docx

---

**From:** Everett, Jennifer <jennifer.everett@deq.nc.gov>  
**Sent:** Thursday, January 25, 2024 4:11 PM  
**To:** Ascher, Seth M <seth.ascher@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Blum, Catherine <catherine.blum@deq.nc.gov>; Reynolds, Phillip T <preynolds@ncdoj.gov>; Maier, Shawn <shawn.maier@deq.nc.gov>; Nelson, Shawn <shawn.nelson@deq.nc.gov>; Jenkins, Shannon <shannon.jenkins@deq.nc.gov>  
**Subject:** RE: Marine Fisheries Commission RFC

Hi Seth,

Attached are the re-written rules and responses to your technical change requests from the MFC.

**Alex** – please send an evite to all cc'd on this email for next week's meeting.

Thanks!

Jennifer Everett  
DEQ Rulemaking Coordinator  
N.C. Depart. Of Environmental Quality  
Office of General Counsel  
1601 Mail Service Center  
Raleigh, NC 27699-1601  
Tele: (919)-707-8595  
<https://deq.nc.gov/permits-rules/rules-regulations/deq-proposed-rules>

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties.

**Request for Changes Pursuant to  
N.C. Gen. Stat. § 150B-21.10**

Staff reviewed these Rules to ensure that each Rule is within the agency’s statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

If the request includes questions, please contact the reviewing attorney to discuss.

In order to properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

**Note the following general instructions:**

1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
  - Wrong: “~~a~~Association”
  - Right: “~~association~~ Association”
6. Treat punctuation as part of a word. For example:
  - Wrong: “day;; and”
  - Right: “~~day;~~ day; and”
7. Formatting instructions and examples may be found at:  
<https://www.oah.nc.gov/rule-format-examples>

**If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.**

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0301

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*I found the definition in item 19 confusing (p. 3 lines 2-4). If it is what you mean, consider if the something like the definition on the NSSP website would work, <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>. I.e. bracketing the existing definition and replacing with “means the federal/state cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption.”*

Please see the proposed change to the rule (as shown just below) to address the concern.

"National Shellfish Sanitation Program (NSSP)" means the federal/state cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption."

*On p. 3, line 27, do you mean “each” or “every” employee? As opposed to any employee.*

The intent is not for all (or multiple) employees to be the responsible individual, but only the employee that is designated by the shellfish dealer as the responsible individual in accordance with Rule 18A .0403. Please see the proposed change to the rule (as shown just below) to address the concern.

(26) "Responsible individual" means the individual present at a shellfish dealer that is the supervisor or the supervisor's designee at the time of the inspection. ~~If no individual is the supervisor, then any employee is the responsible individual.~~

*On p. 4, line 1, is “SELL BY” intentionally all caps?*

Yes, “SELL BY” in all caps is intentional to bring attention to it for consumers. The use of caps for this is a requirement of the National Shellfish Sanitation Program.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0401

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The material on lines 5 through 7 is a codifier note and is not up to the agency to delete. These notes are necessary to accommodate rule references in previously created documents. If you think the note is incorrect or no longer necessary, let the codifier know.*

[The text has been restored.](#)

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0402

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 10, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 30 for similar reasons, consider “accurate to [~~+/-~~°2F] within two degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0412

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 5, we recommend not using abbreviations in non-technical sections of rules. I.e. “[~~100°F~~] 100 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0418

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The word "separate" in item b, lines 6 and 7, is potentially vague. Is it meant to mean a separate room, area, or just separated from one another. The first sentence suggests that it is sufficient for the listed items to be stored anywhere other than processing areas or food contact surfaces. Is this correct?*

It is meant to mean a separate room or area. Please see the proposed change to the rule (as shown just below) to address the concern.

*Regrading the list in the second sentence, is the intent that these items be stored in separate rooms? Would separate shelves be sufficient? Or if they were on the same shelf but not intermingled?*

The intent is for these items to be stored away from each other, so they are not mistaken in their use. Please see the proposed change to the rule (as shown just below) to address the concern.

**15A NCAC 18A .0418 SUPPLY STORAGE**

~~(a) Storage room shall be provided for storing shipping containers, tags, and other supplies. Shipping containers, boxes, and other supplies shall be stored in a storage room or area. The storage room or area shall be kept clean.~~

~~(b) Pesticides, rodenticides, chemical agents, sanitizers, and other toxic substances shall be stored separate from processing areas or food contact surfaces using spacing or partitioning so that they cannot contaminate food, equipment, utensils, and single-service articles. Each of the following categories of toxic substances shall be stored separate from one another using spacing or partitioning such that one category of toxic substance is not mistaken for another category:~~

- ~~(1) pesticides and rodenticides;~~
- ~~(2) detergents, sanitizers, and cleaning agents; and~~
- ~~(3) caustic acids, polishes, and other chemicals.~~

~~(c) Cleaning compounds, sanitizers, and other toxic substances shall be labeled and used in accordance with the manufacturer's label directions.~~

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024



REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0420

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 5, what does “tightly constructed” mean?*

“Tightly constructed” is intended to mean constructed in such a way that it does not allow the entrance of pests, such as flies, insects, etc. into the food storage area. Please see the proposed change to the rule (as shown just below) to address the concern.

**15A NCAC 18A .0420 TRANSPORTING SHELLSTOCKSHELLFISH**

(a) All ~~shellstock-shellfish~~ storage areas in trucks, ~~boats, trucks, vessels,~~ trailers, and other conveyances used for transporting ~~shellstock-shellfish~~ shall be enclosed, tightly constructed **to eliminate the entrance of pests**, ~~with a light color washable paint,~~ kept clean, and shall be subject to inspection by the ~~Division.~~ Division of Marine Fisheries.

*On line 11, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 16, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0421

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 7 and 8, what is the definition for “retail sales”?*

A "retail sale" means the sale of shellfish directly to end consumers. Please see the proposed change to the rule (as shown just below) to address the concern.

*As a concrete example, would sales from a dealer to a restaurant count as a retail sale?*

Sales from a dealer to a restaurant would not count as a retail sale as it is not direct to the consumer. Please see the proposed change to the rule (as shown just below) to address the concern.

**15A NCAC 18A .0421 DAILY RECORD RECORDS**

(a) ~~All permitted persons-shellfish dealers~~ who conduct any business of buying, selling, or shipping shellfish shall keep an accurate, daily record ~~which that~~ shall show the names ~~and addresses~~ of all persons from whom shellfish are received, the address of any shellfish dealer from whom shellfish are received, the location of the source of shellfish, and the names and addresses of all persons to whom shellfish are sold or ~~shipped~~-shipped with the exception of retail sales. For the purpose of this Rule, “retail sale” shall be defined as the sale of shellfish directly to end consumers. These records ~~shall be recorded and~~ shall be kept on file for a minimum of one year-year for fresh shellfish, and a minimum of two years for frozen shellfish. All records shall be open to inspection by the Division of Marine Fisheries at the dealer facility at any time during business hours.

*On line 24, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0427

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 8, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 11, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0428

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 4, what is the definition of a "public health reason"? What are the limits of this term?*

Please see the proposed change to the rule (as shown just below) to address the concern, including the deletion of "for any public health reason" and language that has been added.

**15A NCAC 18A .0428 SAMPLING AND TESTING**

Samples of shellfish may be taken and bacteriologically examined ~~for any public health reason under the authority of the Marine Fisheries Commission~~ by agents of the Division of Marine Fisheries at any time or place ~~for routine quality control checks or to evaluate for threats of physical injury or adverse health effects to consumers.~~ This may include bacteriological examination or analysis for poisonous or deleterious substances as listed in the latest approved edition of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section IV: Guidance Documents, Chapter II: Growing Areas; Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood, which is incorporated by reference, including subsequent amendments and editions. A copy of the reference material can be found at <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost. Samples of shellfish shall be furnished, upon ~~request,~~ request of the Division, by operators of plants, trucks, carriers, stores, restaurants, and other places where shellfish are sold.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0430

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 11, what is a "standard plate count"?*

A "standard plate count" is a microbiological test used to estimate the density of bacteria in a given sample. We are required to use a specific method for this test. Please see the proposed change to the rule (as shown just below) to capture that requirement.

**15A NCAC 18A .0430 BACTERIOLOGICAL AND CONTAMINATION STANDARDS**

~~Shellfish shucked or in the shell and intended or offered for sale in North Carolina that exceed an Escherichia coli Most Probable Number of 230 per 100 grams of sample or a total bacteria count of more than 500,000 per gram or contain pathogenic organisms in sufficient numbers to be hazardous to the public health shall be deemed adulterated by the Division. Shellfish contaminated by any other substance which renders it unsafe for human consumption shall be deemed adulterated by the Division.~~ shall be deemed adulterated by the Division of Marine Fisheries if:

- (1) the concentration of Escherichia coli exceeds a Most Probable Number (MPN), as defined in Rule .0901 of this Subchapter, of 230 per 100 grams of sample;
- (2) the total bacteria count, as determined by a standard plate count, exceeds 500,000 colony-forming units, as defined in Rule .0901 of this Subchapter. **The standard plate count method, as detailed in Recommended Procedures for the Examination of Sea Water and Shellfish 4<sup>th</sup> Edition, is incorporated by reference, not including subsequent amendments and editions. The method can be found at <https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf> at no cost; or**
- (3) the shellfish contain any contaminant that renders it unsafe for human consumption in accordance with the latest approved edition of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, Section IV: Guidance Documents, Chapter II: Growing Areas; Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood, which is incorporated by reference, including subsequent amendments and editions. A copy of the reference material can be found at <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024



REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0434

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*Regarding item (b), on p 1 lines 24-29, what is “training in the application of HACCP principles”?*

Training in the application of HACCP principles prepares shellfish dealers to know the principles of HACCP, the seafood HACCP FDA regulation, how to conduct a hazard analysis, and how to develop a HACCP plan for a seafood business.

*How would someone know if training counted for the purposes of this rule?*

Please see the proposed change to the rule (as shown just below) to address the ambiguity.

(b) With the exception of a shellfish dealer that has not been permitted for interstate commerce, the following functions shall be performed by an individual who has successfully completed ~~training in the application of HACCP principles to shellfish processing~~ Segment one and Segment two of a seafood HACCP training course approved by the Seafood HACCP Alliance or an equivalent training course where the curriculum covers the principles of HACCP, ~~conducting a hazard analysis, and developing a HACCP plan for a seafood business~~:

- (1) developing a HACCP plan;
- (2) reassessing and modifying the HACCP plan; and
- (3) performing the record review specified in Paragraph (d) of this Rule.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0437

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 4, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0439

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*Is the FDA Enforcement Policy on Recalls incorporated already? Where? If not, it appears that it needs to be.*

Please see the proposed change to the rule (as shown just below) that incorporates the FDA enforcement policy.

**15A NCAC 18A .0439 RECALL PROCEDURE**

Each shellfish dealer shall adopt and adhere to a written procedure for conducting recalls of adulterated or misbranded shellfish products. This written procedure shall be based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy, which is incorporated by reference including, subsequent amendments and editions. A copy of the reference material can be found at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7>, at no cost. This procedure shall include shellfish dealers notifying the Division of Marine Fisheries and any consignee receiving affected product when a recall begins, as well as removal or correction of the affected product.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0501

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The material on lines 5 through 7 is a codifier note and is not up to the agency to delete. These notes are necessary to accommodate rule references in previously created documents. If you think the note is incorrect or no longer necessary, let the codifier know.*

[The text has been restored.](#)

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0502

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*What are the standards for shellfish grading? I didn't see an explanation in these rules and was unable to quickly locate them in the incorporated material.*

Shellfish grading is an optional process used by some dealers to cull and sort shellstock according to size. For example, a bag of clams in the shell may be run through a grader to separate them into different sizes in order to fulfill a customer's order for a certain size only. The requirements of this rule are focused on keeping the grading equipment clean and providing a sanitary environment if the dealer chooses to engage in sorting shellstock using this equipment.

*Related to the previous question, on line 13, what is a grader?*

A grader is a piece of equipment, usually mechanical, that separates different sizes of shellstock. "Grading" and "grader" are terms understood by the stakeholders of these rules.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0601

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The material on lines 6 through 8 is a codifier note and is not up to the agency to delete. These notes are necessary to accommodate rule references in previously created documents. If you think the note is incorrect or no longer necessary, let the codifier know.*

[The text has been restored.](#)

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0603

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 5, we recommend not using abbreviations in non-technical sections of rules. I.e. "~~130°F~~ 130 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0608

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 9, what is a "V-type thread"?*

A "V-type thread" is the threads on a screw that are at an angle (60-degree angle) that makes it difficult to effectively clean the screw should the screw be present in the food contact surface area. Rule 18A .0402 requires that all equipment is constructed in accordance with the "Shellfish Industry Equipment Guide" so as to be easily cleanable. Please see the proposed change to the rule (as shown just below) to address the concern.

(b) All equipment, including external and internal blower lines and hoses below a point two inches above the overflow level of the tank and blower drain valves, shall be constructed as to be easily ~~cleanable;~~ cleanable ~~and there shall be no V-type threads in the food product zone of the blower.~~ in accordance with the "Shellfish Industry Equipment Guide" referenced in Rule 18A .0402.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024



REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0610

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 8, we recommend not using abbreviations in non-technical sections of rules. I.e. ~~"170°F~~ 170 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 9, we recommend not using abbreviations in non-technical sections of rules. I.e. ~~"45°F~~ 200 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 10, we recommend not using abbreviations in non-technical sections of rules. I.e. ~~"170°F~~ 170 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public

Seth Ascher

Commission Counsel

Date submitted to agency: January 12, 2024

health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0615

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 8, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 10, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 12, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public

Seth Ascher

Commission Counsel

Date submitted to agency: January 12, 2024

health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 13, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0616

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 7, we recommend not using abbreviations in non-technical sections of rules. I.e. “[0°F] 0 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0618

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 11, we recommend not using abbreviations in non-technical sections of rules. I.e. "~~140°F~~ 140 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 12, we recommend not using abbreviations in non-technical sections of rules. I.e. "~~150°F~~ 150 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 22, we recommend not using abbreviations in non-technical sections of rules. I.e. "~~45°F~~ 45 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public

Seth Ascher

Commission Counsel

Date submitted to agency: January 12, 2024

health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 23, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0619

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 7, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

*On line 9, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024



REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0620

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*Is item (a) on line 4 meant to apply only to shellfish being thawed for repacking? If so, consider "Frozen shellfish that are being thawed for repacking shall be thawed".*

Item (a) on line 4 is meant to apply to shellfish being thawed, but not necessarily for repacking. The intent is not that all shellfish have to be thawed, but instead if the dealer chooses to thaw shellfish, it shall be thawed at a temperature that will not create a food safety issue. Please see the proposed change to the rule (as shown just below) to address the concern.

**15A NCAC 18A .0620 SHELLFISH THAWING AND REPACKING**

- (a) ~~Frozen shellfish~~ If frozen shellfish are thawed, they shall be thawed ~~under temperatures not to exceed 45° F (7° C)~~ at a temperature of 45°F or less.
- (b) Shellfish held for thawing shall be separated from other shellfish.
- (c) Thawed shellfish shall not exceed ~~45° F (7° C)~~ 45°F for more than two hours during the repacking process.
- (d) Containers of repacked, thawed shellfish shall be labeled as required in Rule .0619 of this Section and shall also be labeled as "PREVIOUSLY FROZEN", or equivalent.
- (e) ~~Thawed shellfish, which shellfish that remain in original containers,~~ containers shall be labeled as required in Rule .0614 of this Section and shall also be labeled as "PREVIOUSLY FROZEN", or equivalent.

*On line 4, we recommend not using abbreviations in non-technical sections of rules. I.e. "[~~45°F~~] 45 degrees Fahrenheit".*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the "sister" crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

*On line 6, we recommend not using abbreviations in non-technical sections of rules. I.e. “[45°F] 45 degrees Fahrenheit”.*

We request to continue use of the degrees symbol and abbreviation (Ex: 45°F) for temperature references in these rules. This would be consistent with the “sister” crustacea rules (15A NCAC 18A .0100) that also apply to some of the permitted facilities affected by these rules. Additionally, it is common practice for other public health rule sets involving foods such as the FDA Food Code, and the National Shellfish Sanitation Program Model Ordinance to use these abbreviations. The stakeholders using these rules are accustomed to seeing temperatures in this format so it will be clearer to them.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 12, 2024

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0701

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The material on lines 5 through 7 is a codifier note and is not up to the agency to delete. These notes are necessary to accommodate rule references in previously created documents. If you think the note is incorrect or no longer necessary, let the codifier know.*

The text has been restored.

*On line 20, what constitutes a "critical need" for the purposes of this rule? And who decides? I see that the term "critical need" appears in the NSSP Guide, but I'm not clear on the meaning.*

Please see the proposed change to the rule (as shown just below) to address the concern.

(c) ~~If there is an immediate or ongoing critical need for a method~~ If a method is needed for the analysis of depuration process water and shellfish that are used to evaluate the effectiveness of the depuration process and no method approved for use within the NSSP exists, the following may be used:

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Marine Fisheries Commission

RULE CITATION: 15A NCAC 18A .0801

**DEADLINE FOR RECEIPT: January 26, 2024**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The material on lines 5 through 7 is a codifier note and is not up to the agency to delete. These notes are necessary to accommodate rule references in previously created documents. If you think the note is incorrect or no longer necessary, let the codifier know.*

[The text has been restored.](#)

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel

Date submitted to agency: January 12, 2024

1 15A NCAC 18A .0301 is readopted with changes as published in 38:03 NCR 126-128 as follows:

2  
3 **SECTION .0300 – SANITATION OF SHELLFISH - GENERAL**

4  
5 **15A NCAC 18A .0301 DEFINITIONS**

6 The following definitions shall apply throughout Sections .0300 ~~to .0900~~ through .0800 of this Subchapter:

- 7 (1) "Adulterated" ~~means the following:~~ means:
- 8 (a) ~~Any any~~ shellfish that have been harvested from ~~prohibited areas;~~ polluted areas as defined  
9 in 15A NCAC 03L.0101;
- 10 (b) ~~Any any~~ shellfish that have been shucked, packed, or otherwise processed in a plant ~~which~~  
11 that has not been permitted by the Division of Marine Fisheries in accordance with these rules  
12 or by another state shellfish control "authority" as defined in the National Shellfish Sanitation  
13 Program (NSSP) Guide for the Control of Molluscan Shellfish, Section I: Purposes and  
14 Definitions, in accordance with these Rules; This definition is incorporated by reference,  
15 including subsequent amendments and editions. A copy of the reference material can be  
16 found at [https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-](https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp)  
17 program-nssp, at no cost;
- 18 (c) any shellfish that may have been contaminated by flood waters in accordance with Rule .0405  
19 of this Subchapter;
- 20 ~~(e)(d)~~ ~~Any any~~ shellfish ~~which that~~ exceed the ~~bacteriological~~ standards in Rule .0430 of this  
21 Subchapter; and
- 22 ~~(d)(c)~~ ~~Any any~~ shellfish ~~which are that~~ have been deemed to be an imminent ~~hazard;~~ hazard.
- 23 (2) ~~"Approved area" means an area determined suitable for the harvest of shellfish for direct market~~  
24 ~~purposes.~~
- 25 (3) ~~"Bulk shipment" means a shipment of loose shellstock.~~
- 26 (4) ~~"Buy boat or buy truck" means any boat which that~~ complies with Rule .0419 of this Subchapter or  
27 truck which complies with Rule .0420 of this Subchapter that is used by a person permitted under these  
28 Rules to transport shellstock from one or more harvesters to a facility permitted under these Rules.
- 29 ~~(5)(2)~~ "Certification number" means the unique identification number assigned by the state shellfish control  
30 agency to each certified shellfish ~~dealer.~~ dealer for each location. It consists of a ~~one to five digit one-~~  
31 ~~to-five-digit~~ number preceded by the ~~two letter~~ two-letter state abbreviation and followed by the ~~two~~  
32 ~~letter symbol~~ two-letter abbreviation designating the type of operation certified.
- 33 (3) "Clean" means free from dirt, debris, dust, marks, stains, waste materials, litter, or foreign material.
- 34 ~~(6)(4)~~ "Critical control point" means a point, ~~step~~ step, or procedure in a food process at which control can  
35 be applied, and a food safety hazard can as a result be prevented, ~~eliminated~~ eliminated, or reduced to  
36 acceptable levels.

- 1 ~~(7)~~(5) "Critical limit" means the maximum or minimum value to which a physical, ~~biological~~ ~~biological~~, or  
2 chemical parameter must be controlled at a critical control point to prevent, ~~eliminate~~ ~~eliminate~~, or  
3 reduce to an acceptable level the occurrence of the identified food safety hazard.
- 4 ~~(8)~~(6) "Depurate" or "Depuration" "deputation" means ~~mechanical purification or the removal of adulteration~~  
5 ~~from live shellstock by any artificially controlled means~~ the process of reducing the pathogenic  
6 organisms that may be present in shellstock by using a controlled aquatic environment as the treatment  
7 process.
- 8 ~~(9)~~(7) "Depuration facility" means ~~the physical structure wherein depuration is accomplished, including all~~  
9 ~~the appurtenances necessary to the effective operation thereof~~ any establishment or place where the  
10 depuration of shellfish occurs by a shellfish dealer.
- 11 ~~(10)~~(8) "Division" means the Division of ~~Environmental Health or its authorized agent~~ Marine Fisheries.
- 12 (9) "Easily cleanable" has the same meaning as defined in the 2017 U.S. Food Code. This definition is  
13 incorporated by reference, not including subsequent amendments and editions. A copy of the  
14 reference material can be found at <https://www.fda.gov/food/fda-food-code/food-code-2017>, at no  
15 cost.
- 16 (10) "Food contact surface" means the parts of equipment, including auxiliary equipment, that may be in  
17 contact with the food being processed, or that may drain into the portion of equipment with which  
18 food is in contact.
- 19 (11) "Food safety hazard" means any biological, ~~chemical~~ ~~chemical~~, or physical property that may cause a  
20 food to be unsafe for human consumption.
- 21 (12) "Good repair" means maintained to function as designed and without defect.
- 22 ~~(12)~~(13) "HACCP plan" means a written document that delineates the procedures a shellfish dealer follows to  
23 implement food safety controls.
- 24 ~~(13)~~(14) "Hazard analysis critical control point (HACCP)" means a system of inspection, ~~control~~ ~~control~~, and  
25 monitoring measures initiated by a shellfish dealer to identify microbiological, ~~chemical~~ ~~chemical~~, or  
26 physical food safety hazards ~~which that~~ are likely to occur in shellfish products produced by the dealer.
- 27 ~~(14)~~(15) "Heat shock process" means the practice of heating shellstock to facilitate removal of the shellfish  
28 meat from the shell.
- 29 ~~(15)~~(16) "Imminent hazard" means ~~a situation which is likely to cause an immediate threat to human life, and~~  
30 ~~immediate threat of serious physical injury, an immediate threat of serious physical adverse health~~  
31 ~~effects, or a serious risk of irreparable damage to the environment if no immediate action is taken~~ has  
32 the same meaning as defined in G.S. 130A-2.
- 33 ~~(14)~~(17) "In-shell product" means non-living, processed shellfish with one or both shells present.
- 34 ~~(16)~~(18) "Misbranded" means ~~the following:~~ as defined in G.S. 106-30 shall include any shellfish that are not  
35 labeled in compliance with these rules.
- 36 (a) — Any shellfish which are not labeled with a valid identification number awarded by regulatory  
37 authority of the state or territory of origin of the shellfish; or

(b) — Any shellfish which are not labeled as required by these Rules.

- (19) "National Shellfish Sanitation Program (NSSP)" means the federal/state cooperative [federal state industry] program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish [that is adequate to ensure that the shellfish produced in accordance with the NSSP Guide For The Control Of Molluscan Shellfish will be safe and sanitary.] produced and sold for human consumption.
- (17) "Operating season" means the season of the year during which a shellfish product is processed.
- (18) "Person" means an individual, corporation, company, association, partnership, unit of government or other legal entity.
- (20) "Pests" means animals or insects, including dogs, cats, birds, rodents, flies, and larvae.
- (21) "Plant" means the establishment or place where shellfish processing occurs by shellfish dealers.
- (22) "Processing" or "processed" means any activity associated with the handling, shucking, freezing, packing, labeling, or storing of shellfish in preparation for distribution. This includes the activities of a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
- (19) "Prohibited area" means an area unsuitable for the harvesting of shellfish for direct market purposes.
- ~~(20)~~(23) "Recall procedure" means the detailed procedure the permitted-shellfish dealer will use to retrieve product from the market when it is determined that the product may not be safe for human consumption as determined by the State Health Director is adulterated or misbranded.
- (21) "Relaying or transplanting" means the act of removing shellfish from one growing area or shellfish grounds to another area or ground for any purpose.
- ~~(22)~~(24) "Repacking plant" means a shipper, the establishment or place where a shellfish dealer, other than the original shucker-packer, who repacks shucked shellfish into other containers for delivery to the consumer containers.
- ~~(23)~~(25) "Reshipper" means a shipper who ships shucked shellfish in original containers, or shellstock, from permitted shellstock dealers to other dealers or to consumers person that purchases shellfish from a shellfish dealer and sells the product without repacking or relabeling to another shellfish dealer, wholesaler, or retailer.
- (26) "Responsible individual" means the individual present at a shellfish dealer that is the supervisor or the supervisor's designee at the time of the inspection. [If no individual is the supervisor, then any employee is the responsible individual.]
- (24) "Sanitary survey" means the evaluation of factors having a bearing on the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides and currents in the distribution and dilution of polluting materials, and the bacteriological quality of water.
- ~~(25)~~(27) "Sanitize" means the a bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619 has the same meaning as defined in 21 CFR 110.3, which is incorporated by reference including subsequent amendments and editions. A copy of the

1 reference material can be found at [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-110/subpart-A/section-110.3)  
2 110/subpart-A/section-110.3, at no cost.

3 ~~(26)~~(28) "SELL BY date" means a date ~~conspicuously~~ placed on a container or tag by which a consumer is  
4 informed of the latest date the product will remain suitable for sale.

5 ~~(27)~~(29) "Shellfish" means oysters, mussels, ~~scallops~~ scallops, and all varieties of ~~clams~~. ~~However, clams,~~  
6 whether shucked or in the shell, fresh, frozen, whole, or in part. ~~the term~~ The requirements of Sections  
7 .0300 through .0800 of this Subchapter shall not ~~include~~ apply to scallops ~~when~~ if the final product is  
8 the shucked adductor muscle only.

9 (30) "Shellfish dealer" means a plant to which a Shellfish Dealer Permit and Certificate of Compliance is  
10 issued by the Division for the activities of shellstock shipping, shucking or packing, repacking,  
11 reshipping, or depuration.

12 ~~(28)~~(31) "Shellstock" means any live molluscan shellfish ~~which~~ that remain in their shells.

13 ~~(29)~~(32) "Shellstock conveyance" means all trucks, vessels, trailers, or other conveyances used to transport  
14 shellstock.

15 (30) "Shellstock dealer" means a person who buys, sells, stores, or transports or causes to be transported  
16 shellstock which was not obtained from a person permitted under these Rules.

17 ~~(31)~~(33) "Shellstock plant" means any establishment or place where shellstock are washed, packed, or  
18 otherwise prepared for ~~sale~~ sale by a shellfish dealer.

19 ~~(32)~~(34) "Shucking and packing plant" means any establishment or place where shellfish are shucked and  
20 packed for ~~sale~~ sale by a shellfish dealer.

21 (35) "Use" means employ, set, operate, or permit to be operated or employed.

22 ~~(33)~~(36) "Wet storage" means the ~~temporary placement~~ storage by a shellfish dealer of shellstock from  
23 ~~approved areas, a growing area in the open status and classified as "approved" or "conditionally~~  
24 approved" as defined in Rule .0901 of this Subchapter, in containers or floats in natural bodies of ~~water~~  
25 water, or in tanks containing natural or synthetic sea ~~water~~ water at any permitted land-based activity  
26 or facility.

27  
28 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

29 *Eff. February 1, 1987;*

30 *Amended Eff. August 1, 2000; August 1, 1998; February 1, 1997; January 4, 1994; September 1,*  
31 *1990; December 1, ~~1987-1987;~~*

32 *Readopted Eff. April 1, 2024.*



1 15A NCAC 18A .0401 is readopted with changes as published in 38:03 NCR 129 as follows:

2  
3 **SECTION .0400 - SANITATION OF SHELLFISH - GENERAL OPERATION STANDARDS**

4  
5 Rules .0401 - .0431 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0401 -  
6 .0431); has been transferred and recodified from Rules .0901 - .0931 of Title 10 Subchapter 10B of the North Carolina  
7 Administrative Code (T10.10B .0901 - .0931), effective April 4, 1990.

8  
9 **15A NCAC 18A .0401 APPLICABILITY OF RULES**

10 The rules in this Section shall apply to the operation of all facilities and persons permitted in Rule .0302 of this  
11 Subchapter, including shellfish dealers, shellstock plants, reshippers, shucking and packing plants, repacking plants,  
12 deputation facilities, permittees with facilities approved for wet storage, and all other businesses and persons that buy,  
13 sell, transport, or ship shellfish. These ~~Rules do~~ rules shall not apply to ~~persons~~ individuals possessing shellfish for  
14 personal use.

15  
16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*  
17 *Eff. February 1, 1987;*  
18 *Amended Eff. April 1, 1997; December 1, ~~1987-1987;~~*  
19 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0418 is readopted with changes as published in 38:03 NCR 132 as follows:

2

3 **15A NCAC 18A .0418 SUPPLY STORAGE**

4 (a) ~~Storage room shall be provided for storing shipping containers, tags, and other supplies.~~ Shipping containers,  
5 boxes, and other supplies shall be stored in a storage room or area. The storage room or area shall be kept clean.

6 (b) Pesticides, rodenticides, chemical agents, sanitizers, and other toxic substances shall be stored separate from  
7 processing areas or food contact [surfaces.]surfaces using spacing or partitioning so that they cannot contaminate food,  
8 equipment, utensils, and single-service articles. Each of the following categories of toxic substances shall be stored  
9 separate from one [another:]another using spacing or partitioning such that one category of toxic substance is not  
10 mistaken for another category:

11 (1) pesticides and rodenticides;

12 (2) detergents, sanitizers, and cleaning agents; and

13 (3) caustic acids, polishes, and other chemicals.

14 (c) Cleaning compounds, sanitizers, and other toxic substances shall be labeled and used in accordance with the  
15 manufacturer's label directions.

16

17 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;

18 Eff. February 1, 1987-1987;

19 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0420 is readopted with changes as published in 38:03 NCR 132 as follows:

2  
3 **15A NCAC 18A .0420 TRANSPORTING SHELLSTOCKSHELLFISH**

4 (a) All ~~shellstock-shellfish~~ storage areas in trucks, ~~buy boats, buy trucks, vessels,~~ trailers, and other conveyances used  
5 for transporting ~~shellstock-shellfish~~ shall be enclosed, tightly ~~constructed,~~ **constructed to eliminate the entrance of**  
6 **pests,**  ~~painted with a light color washable paint,~~ kept clean, and shall be subject to inspection by the ~~Division.~~ Division  
7 of Marine Fisheries.

8 (b) ~~Shellstock shall be shipped under temperature and sanitary conditions in accordance with these Rules which will~~  
9 ~~keep them alive and clean and will prevent adulteration or deterioration. All shellstock shall be kept under mechanical~~  
10 ~~refrigeration at a temperature of 45°F (7.1°C) or below. All conveyances used to transport shellstock shall be equipped~~  
11 ~~with an operating thermometer. It shall be unlawful to transport shellstock and in-shell product unless shipped under~~  
12 mechanical refrigeration and the shipping conveyance is pre-chilled and maintained at an ambient temperature of 45°F  
13 or below. The storage area of the shipping conveyance shall be equipped with an accurate, operating thermometer.

14 (c) ~~Buy boats and buy trucks shall be kept clean with water from a source approved by the Division under Rule .0413~~  
15 ~~of this Subchapter. Buy boats and buy trucks shall provide storage space for clean shipping containers, identification~~  
16 ~~tags, and records. It shall be unlawful to transport shucked shellfish unless maintained under temperature control of~~  
17 45°F or below.

18  
19 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*  
20 *Eff. February 1, 1987;*  
21 *Amended Eff. May 1, ~~1994.~~1994;*  
22 *Readopted Eff. (Pending legislative review pursuant to S.L. 2019-198).*

1 15A NCAC 18A .0421 is readopted with changes as published in 38:03 NCR 132-133 as follows:

2  
3 **15A NCAC 18A .0421 ~~DAILY RECORD~~RECORDS**

4 (a) ~~All permitted persons shellfish dealers~~ who conduct any business of buying, selling, or shipping shellfish shall  
5 keep an accurate, daily record ~~which that~~ shall show the names ~~and addresses~~ of all persons from whom shellfish are  
6 received, the address of any shellfish dealer from whom shellfish are received, the location of the source of shellfish,  
7 and the names and addresses of all persons to whom shellfish are sold or ~~shipped,~~ shipped with the exception of retail  
8 sales. For the purpose of this Rule, "retail sale" shall be defined as the sale of shellfish directly to end consumers.  
9 These records ~~shall be recorded and~~ shall be kept on file for a minimum of one year-year for fresh shellfish, and a  
10 minimum of two years for frozen shellfish. All records shall be open to inspection by the Division of Marine Fisheries  
11 at the dealer facility at any time during business hours.

12 (b) All shellfish dealers who receive shellstock from licensed harvesters shall record the following information at the  
13 time of receipt:

- 14 (1) harvester name;  
15 (2) harvest area;  
16 (3) time of the start of harvest;  
17 (4) quantity and type of shellfish received;  
18 (5) time shellfish were received; and  
19 (6) time shellfish were mechanically refrigerated.

20 (c) Each shellfish shipment shipped by a shellfish dealer shall be accompanied by a shipping document that includes:

- 21 (1) name, address, and certification number of shipping dealer;  
22 (2) name and address of major consignee;  
23 (3) type and quantity of shellfish product;  
24 (4) date and time of shipment;  
25 (5) documentation that shipping conveyance is pre-chilled at 45°F or below prior to shipment; and  
26 (6) temperature of shellstock recorded by shipping dealer at time of shipment.

27 (d) A dealer receiving a shellfish shipment from another shellfish dealer shall record the temperature of the shipping  
28 conveyance and the temperature of the shellfish product received. These records shall be kept on file for a minimum  
29 of one year for fresh shellfish, and a minimum of two years for frozen shellfish. All records shall be open to inspection  
30 by the Division at the dealer facility at any time during business hours.

31 (e) Within 72 hours of any purchase or sale of shellfish, each purchase or sale shall be entered into a permanently  
32 bound ledger book, computer record, or any other method that permanently records the information and is organized  
33 so that it can be reviewed by the Division.

34  
35 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*  
36 *Eff. February 1, 1987;*  
37 *Amended Eff. August 1, ~~1998~~1998;*



1 15A NCAC 18A .0428 is readopted with changes as published in 38:03 NCR 134 as follows:

2

3 **15A NCAC 18A .0428 SAMPLING AND TESTING**

4 Samples of shellfish may be taken and bacteriologically examined for any public health reason under the authority  
5 of the Marine Fisheries Commission by agents of the Division of Marine Fisheries at any time or place place for  
6 routine quality control checks or to evaluate for threats of physical injury or adverse health effects to consumers. This  
7 may include bacteriological examination or analysis for poisonous or deleterious substances as listed in the latest  
8 approved edition of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish,  
9 Section IV: Guidance Documents, Chapter II: Growing Areas; Action Levels, Tolerances and Guidance Levels for  
10 Poisonous or Deleterious Substances in Seafood, which is incorporated by reference, including subsequent  
11 amendments and editions. A copy of the reference material can be found at <https://www.fda.gov/food/federalstate->  
12 food-programs/national-shellfish-sanitation-program-nssp, at no cost. Samples of shellfish shall be furnished, upon  
13 ~~request,~~ request of the Division, by operators of plants, trucks, carriers, stores, restaurants, and other places where  
14 shellfish are sold.

15

16 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

17 *Eff. February 1, ~~1987-1987;~~*

18 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0430 is readopted with changes as published in 38:03 NCR 134 as follows:

2  
3 **15A NCAC 18A .0430 BACTERIOLOGICAL AND CONTAMINATION STANDARDS**

4 Shellfish shucked or in the shell and intended or offered for sale ~~in North Carolina that exceed an Escherichia coli~~  
5 ~~Most Probable Number of 230 per 100 grams of sample or a total bacteria count of more than 500,000 per gram or~~  
6 ~~contain pathogenic organisms in sufficient numbers to be hazardous to the public health shall be deemed adulterated~~  
7 ~~by the Division. Shellfish contaminated by any other substance which renders it unsafe for human consumption shall~~  
8 ~~be deemed adulterated by the Division.~~ shall be deemed adulterated by the Division of Marine Fisheries if:

- 9 (1) the concentration of Escherichia coli exceeds a Most Probable Number (MPN), as defined in Rule  
10 .0901 of this Subchapter, of 230 per 100 grams of sample;  
11 (2) the total bacteria count, as determined by a standard plate count, exceeds 500,000 colony-forming  
12 units, as defined in Rule .0901 of this [Subchapter,] Subchapter. The standard plate count method,  
13 as detailed in Recommended Procedures for the Examination of Sea Water and Shellfish 4th Edition,  
14 is incorporated by reference, not including subsequent amendments and editions. The method can  
15 be found at [https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-](https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf)  
16 [procedures-1970-full-text.pdf](https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf), at no cost; or  
17 (3) the shellfish contain any contaminant that renders it unsafe for human consumption in accordance  
18 with the latest approved edition of the National Shellfish Sanitation Program (NSSP) Guide for the  
19 Control of Molluscan Shellfish, Section IV: Guidance Documents, Chapter II: Growing Areas;  
20 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in  
21 Seafood, which is incorporated by reference, including subsequent amendments and editions. A  
22 copy of the reference material can be found at [https://www.fda.gov/food/federalstate-food-](https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp)  
23 [programs/national-shellfish-sanitation-program-nssp](https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp), at no cost.

24  
25 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;  
26 Eff. February 1, 1987-1987;  
27 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0434 is readopted with changes as published in 38:03 NCR 135-136 as follows:

2  
3 **15A NCAC 18A .0434 HACCP PLAN**

4 (a) Each shellfish dealer shall have and implement a written HACCP Plan—plan specific to each kind of shellfish  
5 product processed. The owner or authorized designee individual shall sign the plan when implemented and after any  
6 modification—implemented, which shall signify that the plan has been accepted for implementation by the dealer. The  
7 HACCP plan shall also be signed by the owner or authorized individual after any modification or verification of the  
8 plan as required by this Rule. The plan shall be reviewed and updated, if necessary, at least annually.—The plan shall,  
9 at a minimum:

- 10 (1) ~~List~~ list the food safety hazards that are reasonably likely to occur;
- 11 (2) ~~List~~ list the critical control points for each of the food safety hazards;
- 12 (3) ~~List~~ list the critical limits that must be met for each of the critical control points;
- 13 (4) ~~List~~ list the procedures, and frequency thereof, that will be used to monitor each of the critical  
14 control points to ensure compliance with the critical limits;
- 15 (5) ~~List~~ list any corrective action plans to be followed in response to deviations from critical limits at  
16 critical control points;
- 17 (6) ~~Provide~~ provide a record keeping system that documents critical control point monitoring; and
- 18 (7) ~~List~~ list the verification procedures, and frequency thereof, that the dealer will use.

19 For the purpose of this Rule, "reasonably likely to occur" shall mean a food safety hazard for which a processor would  
20 establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude  
21 that there is a reasonable possibility that it will occur in the absence of those controls, as defined in 21 CFR 123.6,  
22 which is incorporated by reference, including subsequent amendments and editions. A copy of the reference material  
23 can be found at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123>, at no cost.

24 (b) With the exception of a shellfish dealer that has not been permitted for interstate commerce, the following  
25 functions shall be performed by an individual who has successfully completed [training in the application of HACCP  
26 principles to shellfish processing; Segment one and Segment two of a seafood HACCP training course approved by  
27 the Seafood HACCP Alliance or an equivalent training course where the curriculum covers the principles of HACCP,  
28 conducting a hazard analysis, and developing a HACCP plan for a seafood business;

- 29 (1) developing a HACCP plan;
- 30 (2) reassessing and modifying the HACCP plan; and
- 31 (3) performing the record review specified in Paragraph (d) of this Rule.

32 (c) If a deviation from a critical limit occurs, the shellfish dealer shall take corrective action in accordance with 21  
33 CFR 123.7, which is incorporated by reference, including subsequent amendments and editions. A copy of the  
34 reference material can be found at [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123/subpart-](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123/subpart-A/section-123.7#p-123.7(b))  
35 A/section-123.7#p-123.7(b), at no cost.

36 (d) At least annually, each shellfish dealer shall verify that the HACCP plan is being implemented to control food  
37 safety hazards. Verification procedures shall include:



1           (1)     a reassessment of the plan when a change occurs that could affect the hazard analysis, and a review  
2                   of any consumer complaints that have been received; and

3           (2)     a review, including signing and dating by the trained individual or responsible individual, of the  
4                   records that document the monitoring of critical control points, the taking of corrective actions, and  
5                   the calibrating of any process-monitoring instruments. This review shall occur within one week of  
6                   the day that the records are made.

7     (e) All records required by this Rule shall be retained at the dealer facility for at least one year after the date they were  
8     prepared in the case of refrigerated products, and at least two years after the date they were prepared in the case of  
9     frozen products and shall include:

10           (1)     the name and location of the dealer;

11           (2)     the date and time of the activity that the record reflects;

12           (3)     the signature or initials of the individual performing the operation; and

13           (4)     the identity of the product and the production code, if any.

14  
15     *History Note:     Authority G.S. ~~130A-230~~; 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;*  
16                    *Eff. August 1, ~~2000~~; 2000;*  
17                    *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0439 is adopted with changes as published in 38:03 NCR 137 as follows:

2

3 **15A NCAC 18A .0439 RECALL PROCEDURE**

4 Each shellfish dealer shall adopt and adhere to a written procedure for conducting recalls of adulterated or misbranded  
5 shellfish products. This written procedure shall be based on, and complementary to, the FDA Enforcement Policy on  
6 Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement ~~Policy-~~Policy, which is incorporated by  
7 reference, including subsequent amendments and editions. A copy of the reference material can be found at  
8 <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7>, at no cost. This procedure shall include shellfish  
9 dealers notifying the Division of Marine Fisheries and any consignee receiving affected product when a recall begins,  
10 as well as removal or correction of the affected product.

11

12 *History Note: Authority G.S. 113-134; 113-182; 113-221.2; 143B-289.52;*

13 *Eff. April 1, 2024.*

1 15A NCAC 18A .0501 is readopted with changes as published in 38:03 NCR 137 as follows:

2

3

**SECTION .0500 - OPERATION OF SHELLSTOCK PLANTS AND RESHIPPERS**

4

5 Rules .0501 - .0504 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A  
6 .0501 - .0504); has been transferred and recodified from Rules .1001 - .1004 of Title 10 Subchapter 10B of the North  
7 Carolina Administrative Code (T10.10B .1001 - .1004), effective April 4, 1990.

8

9 **15A NCAC 18A .0501 ~~GENERAL REQUIREMENTS~~ FOR SHELLSTOCK PLANTS AND RESHIPPERS**

10 The rules in Section .0400 and the rules of this Section shall apply for the operation of shellstock plants and reshippers.

11

12 *History Note: Authority G.S. ~~130A-230~~; 113-134; 113-182; 113-221.2; 143B-289.52;*

13 *Eff. February 1, ~~1987~~ 1987;*

14 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0601 is readopted with changes as published in 38:03 NCR 138 as follows:

2

3

**SECTION .0600 - OPERATION OF SHELLFISH SHUCKING AND PACKING PLANTS AND  
REPACKING PLANTS**

4

5

6 Rules .0601 - .0619 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A  
7 .0601 - .0619); has been transferred and recodified from Rules .1101 - .1119 of Title 10 Subchapter 10B of the North  
8 Carolina Administrative Code (T10.10B .1101 - .1119), effective April 4, 1990.

9

10 **15A NCAC 18A .0601 ~~GENERAL REQUIREMENTS~~ FOR SHUCKING AND PACKING PLANTS AND  
11 REPACKING PLANTS**

12 The rules in Section .0400 and the rules of this Section shall apply for the operation of shucking and packing plants  
13 and repacking plants.

14

15 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*  
16 *Eff. February 1, ~~1987-1987;~~*  
17 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0608 is readopted with changes as published in 38:03 NCR 138 as follows:

2

3 **15A NCAC 18A .0608 EQUIPMENT CONSTRUCTION**

4 (a) All pails, skimmers, measures, tanks, tubs, blowers, paddles, and other equipment, ~~which that~~ come into contact  
5 with shucked shellfish or with ice used for direct cooling of shellfish, shall be made of smooth, non-corrosive,  
6 impervious materials and constructed so as to be easily cleanable and shall be kept clean and in good repair.

7 (b) All equipment, including external and internal blower lines and hoses below a point two inches above the overflow  
8 level of the tank and blower drain valves, shall be constructed as to be easily ~~cleanable;~~ cleanable and there shall be  
9 no V-type threads in the food-product zone of the blower in accordance with the "Shellfish Industry Equipment Guide"  
10 referenced in Rule 18A .0402.

11 (c) The blower and skimmer drain shall not be directly connected with the sewer. There shall be an air ~~gap,~~ approved  
12 by the Division, ~~gap~~ between the blower and skimmer outlets. A floor drain shall be provided.

13 (d) Air-pump intakes shall be located in a place protected from dirt and other contamination, and shall be equipped  
14 with filters.

15

16 *History Note:* Authority ~~G.S. 130A-230;~~ 113-134; 113-182; 113-221.2; 143B-289.52;

17 Eff. February 1, 1987;

18 Amended Eff. September 1, ~~1990;~~ 1990;

19 Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0620 is readopted with changes as published in 38:03 NCR 141 as follows:

2

3 **15A NCAC 18A .0620 SHELLFISH THAWING AND REPACKING**

4 (a) ~~Frozen shellfish. If frozen shellfish are thawed, they shall be thawed under temperatures not to exceed 45° F (7°~~  
5 ~~C)-~~at a temperature of 45°F or less.

6 (b) Shellfish held for thawing shall be separated from other shellfish.

7 (c) Thawed shellfish shall not exceed 45° F (7° C) ~~45°F for more than two hours~~ during the repacking process.

8 (d) Containers of repacked, thawed shellfish shall be labeled as required in Rule .0619 of this Section and shall also  
9 be labeled as "PREVIOUSLY FROZEN", or equivalent.

10 (e) Thawed ~~shellfish, which~~ shellfish that remain in original containers, containers shall be labeled as required in Rule  
11 .0614 of this Section and shall also be labeled as "PREVIOUSLY FROZEN", or equivalent.

12

13 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*

14 *Eff. April 1, ~~1997.~~1997;*

15 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0701 is readopted with changes as published in 38:03 NCR 141 as follows:

2  
3 **SECTION .0700 - OPERATION OF DEPURATION (MECHANICAL PURIFICATION) FACILITIES**

4  
5 Rules .0701 - .0713 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A  
6 .0701 - .0713); has been transferred and recodified from Rules .1201 - .1213 of Title 10 Subchapter 10B of the North  
7 Carolina Administrative Code (T10.10B .1201 - .1213), effective April 4, 1990.

8  
9 **15A NCAC 18A .0701 ~~GENERAL REQUIREMENTS~~ GENERAL REQUIREMENTS FOR DEPURATION**

10 (a) The Rules in Section .0400 shall apply for the operation of depuration facilities. In addition to and to the extent  
11 not inconsistent with other applicable provisions of North Carolina Marine Fisheries Commission rules, requirements  
12 for depuration shall be in accordance with the 2019 Revision of the National Shellfish Sanitation Program (NSSP)  
13 Guide for the Control of Molluscan Shellfish chapter titled "Depuration", which is incorporated by reference, not  
14 including subsequent amendments and editions. A copy of the reference material is available online at:  
15 <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost.

16 (b) All laboratory analyses used to evaluate the effectiveness of the depuration process shall be performed by a  
17 laboratory found by a Food and Drug Administration (FDA) Shellfish Laboratory Evaluation Officer or by an FDA-  
18 certified State Shellfish Laboratory Evaluation Officer to conform or provisionally conform to the requirements  
19 established under the National Shellfish Sanitation Program (NSSP).

20 (c) If ~~there is an immediate or ongoing critical need for~~ a method ~~is needed~~ for the analysis of depuration process  
21 water and shellfish that are used to evaluate the effectiveness of the depuration process and no method approved for  
22 use within the NSSP exists, the following may be used:

- 23 (1) a validated Association of Analytical Communities, Bacteriological Analysis Manual, or  
24 Environmental Protection Agency method; or  
25 (2) an Emergency Use Method as set forth in the latest approved edition of the NSSP Guide for the  
26 Control of Molluscan Shellfish.

27  
28 *History Note: Authority G.S. ~~130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;~~*  
29 *Eff. February 1, ~~1987~~1987;*  
30 *Readopted Eff. April 1, 2024.*

1 15A NCAC 18A .0801 is readopted with changes as published in 38:03 NCR 142 as follows:

2  
3 **SECTION .0800 - WET STORAGE OF SHELLSTOCK**  
4

5 Rules .0801 - .0806 of Title 15A Subchapter 10B of the North Carolina Administrative Code (T15A.10B  
6 .0801 - .0806); has been transferred and recodified from Rules .1301 - .1306 of Title 10 Subchapter 10B of the North  
7 Carolina Administrative Code (T10.10B .1301 -.1306), effective April 4, 1990.  
8

9 **15A NCAC 18A .0801 ~~GENERAL REQUIREMENTS~~ GENERAL REQUIREMENTS FOR WET STORAGE OF SHELLSTOCK**

10 ~~The rules in Section .0400 shall apply for wet storage of shellstock.~~ (a) In addition to and to the extent not inconsistent  
11 with other applicable provisions of North Carolina Marine Fisheries Commission Rules, requirements for wet storage  
12 shall be in accordance with the 2019 Revision of the National Shellfish Sanitation Program (NSSP) Guide for the  
13 Control of Molluscan Shellfish (hereinafter referred to as "Model Ordinance") chapter titled "Wet Storage in Approved  
14 and Conditionally Approved Growing Areas", which is incorporated by reference except as provided in Paragraph (b)  
15 of this Rule, not including subsequent amendments and editions. A copy of the reference material is available online  
16 at: <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>, at no cost.

17 (b) Amendments and exceptions to the Model Ordinance chapter titled "Wet Storage in Approved and Conditionally  
18 Approved Growing Areas" incorporated by reference include:

19 (1) Section @.01, .04, C(1)(a) is amended to read: "Except for a water source in accordance with Rule  
20 .0413 of this Subchapter, the quality of the surface source water prior to treatment shall meet, at a  
21 minimum, the bacteriological standards for the conditionally approved classification in the open  
22 status. Water classified as prohibited or restricted shall not be used as source water."

23 (2) the following sections are not incorporated by reference and shall not apply: Sections @.01, .04,  
24 C(2)(a)(ii), @.01, .04, C(2)(b), @.01, .04, C(2)(c), and @.01, .04, C(2)(d).

25  
26 *History Note:* Authority G.S. 130A-230; 113-134; 113-182; 113-221.2; 143B-289.52;  
27 Eff. February 1, 1987-1987;  
28 Readopted Eff. April 1, 2024.



## Burgos, Alexander N

---

**From:** Everett, Jennifer  
**Sent:** Thursday, January 18, 2024 1:15 PM  
**To:** Ascher, Seth M; Blum, Catherine  
**Cc:** Burgos, Alexander N  
**Subject:** RE: Marine Fisheries Commission RFC

Thanks Seth,  
We'll be in touch!

Jennifer Everett  
DEQ Rulemaking Coordinator  
N.C. Depart. Of Environmental Quality  
Office of General Counsel  
1601 Mail Service Center  
Raleigh, NC 27699-1601  
Tele: (919)-707-8595  
<https://deq.nc.gov/permits-rules/rules-regulations/deq-proposed-rules>

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties.

---

**From:** Ascher, Seth M <seth.ascher@oah.nc.gov>  
**Sent:** Friday, January 12, 2024 12:13 PM  
**To:** Everett, Jennifer <jennifer.everett@deq.nc.gov>; Blum, Catherine <catherine.blum@deq.nc.gov>  
**Cc:** Burgos, Alexander N <alexander.burgos@oah.nc.gov>  
**Subject:** Marine Fisheries Commission RFC

Good afternoon,

I'm the attorney who reviewed the Rules submitted by the North Carolina Marine Fisheries Commission for the January 2024 RRC meeting. The RRC will formally review these Rules at its meeting on Wednesday, January 31, 2024, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get close to the meeting. If there are any other representatives from your agency who want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Attached is the Request for Changes Pursuant to G.S. 150B-21.10. Please submit the revised Rules and forms to me via email, no later than 5 p.m. on January 26, 2024.

**Seth Ascher**  
Counsel to the North Carolina Rules Review Commission  
Office of Administrative Hearings  
(984) 236-1934

Email correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized state official.