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 18	A .0301	DEFINITIONS	
6	The following of	lefinition	s shall apply throughout Sections .0300 to .0900 through .0800 of this Subchapter:	
7	(1)	"Adult	erated" means the following:means:	
8		(a)	Any any shellfish that have been harvested from prohibited areas; polluted areas as defined	
9			in 15A NCAC 03I .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-	
17			program-nssp, at no cost;	
18		<u>(c)</u>	any shellfish that may have been contaminated by flood waters in accordance with Rule .0405	
19			of this Subchapter;	
20		(c)(d)	Any any shellfish which that exceed the bacteriological standards in Rule .0430 of this	
21			Subchapter; and	
22		(d)(e)	Any any shellfish which are that have been deemed to be an imminent hazard; hazard.	
23	<del>(2)</del>	"Appro	oved area" means an area determined suitable for the harvest of shellfish for direct market	
24		purpos	es.	
25	<del>(3)</del>	"Bulk	shipment" means a shipment of loose shellstock.	
26	<del>(4)</del>	"Buy b	ooat or buy truck" means any boat which that complies with Rule .0419 of this Subchapter or	
27		truck v	which complies with Rule .0420 of this Subchapter that is used by a person permitted under these	
28		Rules t	o transport shellstock from one or more harvesters to a facility permitted under these Rules.	
29	<del>(5)</del> (2)	"Certif	ication 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		<del>letter s</del>	ymbol-two-letter abbreviation designating the type of operation certified.	
33	<u>(3)</u>	"Clean	" means free from dirt, debris, dust, marks, stains, waste materials, litter, or foreign material.	
34	<del>(6)</del> (4)	"Critic	al control point" means a point, step-step, or procedure in a food process at which control can	
35		be app	lied, and a food safety hazard can as a result be prevented, eliminated eliminated, or reduced to	
36		accepta	able levels.	

1	<del>(7)</del> (5)	"Critical limit" means the maximum or minimum value to which a physical, 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	<del>(8)</del> (6)	$\underline{\hbox{$"$Depurate" or $"$Depuration"$ $"$depuration"$ }} \\ \underline{\hbox{$mechanical purification or the removal of adulteration}}$
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	<del>(9)</del> (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	<del>(10)</del> (8)	"Division" means the Division of Environmental Health or its authorized agent. Marine Fisheries.
12	<u>(9)</u>	"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		<u>cost.</u>
16	<u>(10)</u>	"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, <u>chemical-chemical,</u> or physical property that may cause a
20		food to be unsafe for human consumption.
21	<u>(12)</u>	"Good repair" means maintained to function as designed and without defect.
22	<del>(12)</del> (13)	"HACCP plan" means a written document that delineates the procedures a shellfish dealer follows to
23		implement food safety controls.
24	<del>(13)</del> (14)	"Hazard analysis critical control point (HACCP)" means a system of inspection, control_control, and
25		monitoring measures initiated by a <u>shellfish</u> dealer to identify microbiological, <u>ehemical</u> <u>chemical</u> , or
26		physical food safety hazards which that are likely to occur in shellfish products produced by the dealer.
27	<del>(14)</del> (15)	"Heat shock process" means the practice of heating shellstock to facilitate removal of the shellfish
28		meat from the shell.
29	<del>(15)</del> (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		${\color{red} \textbf{effects, or a serious risk of irreparable damage to the environment if no immediate action is taken.} \underline{\textbf{has}}$
32		the same meaning as defined in G.S. 130A-2.
33	<del>(14)</del> (17)	"In-shell product" means non-living, processed shellfish with one or both shells present.
34	<del>(16)</del> (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

1		(b) Any shellfish which are not labeled as required by these Rules.
2	<u>(19)</u>	"National Shellfish Sanitation Program (NSSP)" means the federal/state cooperative [federal state
3		industry program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate
4		Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish [that is adequate to
5		ensure that the shellfish produced in accordance with the NSSP Guide For The Control Of
6		Molluscan Shellfish will be safe and sanitary. produced and sold for human consumption.
7	<del>(17)</del>	"Operating season" means the season of the year during which a shellfish product is processed.
8	<del>(18)</del>	"Person" means an individual, corporation, company, association, partnership, unit of government or
9		other legal entity.
10	<u>(20)</u>	"Pests" means animals or insects, including dogs, cats, birds, rodents, flies, and larvae.
11	<u>(21)</u>	"Plant" means the establishment or place where shellfish processing occurs by shellfish dealers.
12	<u>(22)</u>	"Processing" or "processed" means any activity associated with the handling, shucking, freezing,
13		packing, labeling, or storing of shellfish in preparation for distribution. This includes the activities of
14		a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
15	<del>(19)</del>	"Prohibited area" means an area unsuitable for the harvesting of shellfish for direct market purposes.
16	<del>(20)</del> (23)	"Recall procedure" means the detailed procedure the permitted-shellfish dealer will use to retrieve
17		product from the market when it is determined that the product may not be safe for human consumption
18		as determined by the State Health Director. is adulterated or misbranded.
19	<del>(21)</del>	"Relaying or transplanting" means the act of removing shellfish from one growing area or shellfish
20		grounds to another area or ground for any purpose.
21	<del>(22)</del> (24)	"Repacking plant" means a shipper, the establishment or place where a shellfish dealer, other than the
22		original shucker-packer, who-repacks shucked shellfish into other containers for delivery to the
23		consumer.containers.
24	<del>(23)</del> (25)	"Reshipper" means a shipper who ships shucked shellfish in original containers, or shellstock, from
25		permitted shellstock dealers to other dealers or to consumers.person that purchases shellfish from a
26		shellfish dealer and sells the product without repacking or relabeling to another shellfish dealer,
27		wholesaler, or retailer.
28	<u>(26)</u>	"Responsible individual" means the individual present at a shellfish dealer that is the supervisor or
29		the supervisor's designee at the time of the inspection. [ If no individual is the supervisor, then any
30		employee is the responsible individual.
31	<del>(24)</del>	"Sanitary survey" means the evaluation of factors having a bearing on the sanitary quality of a shellfish
32		growing area including sources of pollution, the effects of wind, tides and currents in the distribution
33		and dilution of polluting materials, and the bacteriological quality of water.
34	<del>(25)(27)</del>	"Sanitize" means the a bactericidal treatment by a process which meets the temperature and chemical
35		concentration levels in 15A NCAC 18A .2619.has the same meaning as defined in 21 CFR 110.3,
36		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-
2		110/subpart-A/section-110.3, at no cost.
3	<del>(26)</del> (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	<del>(27)</del> (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		$\underline{.0300 \; through \; .0800 \; of \; this \; Subchapter \; shall \; not \; \underline{include \; apply \; to \; scallops \; \underline{when \; \underline{if}} \; the \; final \; product \; is \; \underline{final \; product} \; fi$
8		the shucked adductor muscle only.
9	<u>(30)</u>	"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	<del>(28)</del> (31)	"Shellstock" means any <u>live molluscan</u> shellfish which that remain in their shells.
13	<del>(29)</del> (32)	"Shellstock conveyance" means all trucks, <u>vessels</u> , trailers, or other conveyances used to transport
14		shellstock.
15	<del>(30)</del>	"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	<del>(31)</del> (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	<del>(32)</del> (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	<u>(35)</u>	"Use" means employ, set, operate, or permit to be operated or employed.
22	<del>(33)</del> (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. <del>130.4-230;</del> 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, <del>1987.</del> <u>1987:</u>
32		Readopted Eff. April 1, 2024.

1	15A NCAC 18A	.0305 is repealed through readoption as published in 38:03 NCR 129 as follows:
2		
3	15A NCAC 18A	.0305 APPEALS PROCEDURE
4		
5	History Note:	Authority G.S. 130A-230;
6		Eff. February 1, 1987;
7		Amended Eff. September 1, <del>1990.</del> 1990;
8		Repealed 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 .04010431 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0401
6	.0431); has been transferred and recodified from Rules .09010931 of Title 10 Subchapter 10B of the North Carolin
7	Administrative Code (T10.10B .09010931), 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 th
11	Subchapter, including shellfish dealers, shellstock plants, reshippers, shucking and packing plants, repacking plant
12	depuration 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. <del>130.4-230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>
17	Eff. February 1, 1987;
18	Amended Eff. April 1, 1997; December 1, <del>1987.</del> 1987;
19	Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0402 is readopted as published in 38:03 NCR 129 as follows: 2 3 GENERAL REQUIREMENTS FOR OPERATION 15A NCAC 18A .0402 4 (a) During the operating season the plant shall be used for no purpose other than the handling of shellfish. All 5 unnecessary equipment and materials shall be removed from the plant and the floors kept clear for thorough cleaning. 6 (b) (a) All floors, walls, shucking benches and stools, shucking blocks, tables, skimmers, blowers, colanders, buckets, 7 or any other equipment or utensils used in the processing operation shall be cleaned and sanitized daily, or more 8 frequently as may be necessary during the day's operation to prevent the introduction of undesirable microbiological 9 organisms and filth into the shellfish product. Shellfish dealers shall provide mechanical refrigeration that is capable 10 of maintaining an ambient temperature of 45°F or less and be sized to handle one day's production. The mechanical 11 refrigeration shall include an automatic temperature regulating control and be equipped with an accurate, operating 12 thermometer in the refrigerated storage area. If the sole means of refrigeration is a portable unit, that unit shall be 13 capable of operating utilizing alternating current electrical power that will allow the unit to be plugged into a power 14 supply during transport and at the certified facility. 15 (c) (b) Ceilings and windows shall also be kept clean. Refrigerators, refrigeration rooms, and ice boxes shall be washed and sanitized. Food contact surfaces shall be easily cleanable, corrosion-resistant, constructed of non-toxic 16 17 and food-grade materials, and shall be kept in good repair. Shellfish dealers shall only use food contact surface 18 equipment that conforms to standards found in the guidance document within the National Shellfish Sanitation 19 Program (NSSP) Guide for the Control of Molluscan Shellfish, Section II: Model Ordinance titled "Shellfish Industry 20 Equipment Construction Guide", which is incorporated by reference, including subsequent amendments and editions. 21 A copy of the reference material can be found at https://www.fda.gov/food/federalstate-food-programs/national-22 shellfish-sanitation-program-nssp at no cost. 23 (c) Food contact surfaces of equipment, utensils, and containers shall be cleaned at the end of each day or operation and shall be sanitized prior to the start-up of each day's activities. Food contact surfaces shall also be cleaned and 24 25 sanitized following any interruption during which the surfaces have become contaminated. 26 (d) Non-food contact surfaces such as equipment, floors, walls, ceilings, and windows shall be kept clean and in good 27 repair. 28 (d) (e) Wheelbarrows, measures, baskets, shovels, and other implements used in the handling of shellstock shall not 29 be used for any other purpose and shall be cleaned and stored in the shellstock room when not in prior to use. 30 (f) Shellfish dealers shall provide a temperature measuring device accurate to +/- 2°F for use in monitoring product 31 temperatures. 32 33 Authority G.S. 130A 230; 113-134; 113-182; 113-221.2; 143B-289.52; History Note:

34

35

Eff. February 1, <del>1987.</del> <u>1987.</u> Readopted Eff. April 1, 2024.

1 15A NCAC 18A .0403 is readopted as published in 38:03 NCR 129-130 as follows: 2 3 15A NCAC 18A .0403 SUPERVISION AND TRAINING 4 (a) The owner shellfish dealer shall personally supervise or shall designate an a responsible individual whose principal 5 duty shall be to supervise and be responsible for compliance with the Rules rules of this Subchapter. No unauthorized 6 persons individuals shall be allowed in any processing area of the plant during periods of operation. For the purpose 7 of this Rule, "unauthorized individual" shall mean an individual that is not designated and trained by the shellfish 8 dealer or responsible individual to perform specific processing tasks in the facility. 9 (b) The shellfish dealer shall ensure that all employees that manufacture, process, pack, or hold food obtain training 10 in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, 11 in accordance with 21 CFR 117.4, which is incorporated by reference, including subsequent amendments and editions. 12 A copy of the reference material can be found at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-13 117/subpart-A/section-117.4 at no cost. Employees shall complete the training within 30 days following the initial 14 hire date. The shellfish dealer or responsible individual shall maintain a record of the completed training. 15 Authority G.S. 130A 230; 113-134; 113-182; 113-221.2; 143B-289.52; 16 History Note: 17 *Eff. February 1*, <del>1987.</del>1987; 18 Readopted Eff. April 1, 2024.

1	15A NCAC 18A	\text{\text{\text{.0404} is readopted as published in 38:03 NCR 130 as follows:}
2		
3	15A NCAC 18A	A .0404 CONSTRUCTION
4	Shellfish plants	shall be adequate in size and construction sized and constructed to permit compliance with the
5	operational prov	risions of Sections .0300 through .0800 of this Subchapter.
6		
7	History Note:	Authority G.S. <del>130.A 230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
8		Eff. February 1, <del>1987.</del> 1987:
0		Readonted Eff April 1 2024

1	15A NCAC 18A .0405 is readopted as published in 38:03 NCR 130 as follows:		
2			
3	15A NCAC 18A .0405 PLANT LOCATION FACILITY FLOODING		
4	(a) Shellfish plants shall be located so that they will not be subject to flooding by high tides.		
5	(b) If the facility floors are flooded, processing shall be discontinued until flood waters have receded and the facility		
6	and equipment are cleaned and sanitized.		
7	(c) Any shellfish that may have been contaminated by flood waters shall be deemed adulterated and shall be destroyed		
8			
9	History Note: Authority G.S. <del>130A 230;</del> <u>113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;</u>		
10	Eff. February 1, <del>1987.<u>1987;</u></del>		
11	Readopted Eff. April 1, 2024.		

1	15A NCAC 18A	A .0406 is readopted as published in 38:03 NCR 130 as follows:	
2			
3	15A NCAC 18A	A .0406 FLOORS	
4	Floors shall be	of-concrete or other equally impervious material, constructed so that they may be are easily and	
5	thoroughly cleaned-cleanable, and shall be sloped so that water drains completely and rapidly. For new construction,		
6	the joints between walls and floors shall be rounded to expedite cleaning. completely, and kept in good repair. The		
7	junction betwee	n floors and walls shall be sealed to render them impervious to water in areas where the floor gets wet	
8	and is used to st	ore shellfish, process food, or clean equipment and utensils.	
9			
10	History Note:	Authority G.S. <del>130.4-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>	
11		Eff. February 1, <del>1987.</del> 1987;	
12		Readopted Eff. April 1, 2024.	

1	15A NCAC 18A .0407 is readopted as published in 38:03 NCR 130 as follows:		
2			
3	15A NCAC 18A .0407 WALLS AND CEILINGS		
4	Walls to a height of at least two feet above the floor shall be constructed of smooth concrete or other equally		
5	impervious material. The remainder of the walls and ceilings shall be smooth concrete, cement plaster, or other		
6	material approved by the Division and shall be painted with a light color washable paint.		
7	(a) Walls and ceilings in areas where shellfish are stored, handled, processed, or packaged or where food handling		
8	equipment or packaging materials are stored shall be constructed of smooth, easily cleanable, non-corrosive		
9	impervious material. The walls and ceilings in these areas shall also be light-colored, such as white in color, so that		
10	unclean surfaces can be detected.		
11	(b) Doors and windows shall be tightly fitted and kept in good repair so as to keep pests and weather out of the facility.		
12			
13	History Note: Authority G.S. <del>130.4-230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>		
14	Eff. February 1, <del>1987.<u>1987;</u></del>		
15	Readopted Eff. April 1, 2024.		

1	15A NCAC 18A .0408 is readopted as published in 38:03 NCR 130 as follows:		
2			
3	15A NCAC 18A	A .0408 LIGHTING	
4	(a) Natural or a	rtificial lighting shall be provided in all parts of the plant. <del>Light bulbs, fixtures, or other glass suspended</del>	
5	within the plant	shall be safety type or otherwise protected to prevent contamination in case of breakage. Lighting	
6	intensities shall be a minimum of 25 foot candles foot-candles on working surfaces in packing and shucking rooms.		
7	rooms and a minimum of 10 foot-candles measured at a height of 30 inches above the floor throughout the rest of the		
8	processing portion of the facility.		
9	(b) Light bulbs, fixtures, or other glass within the plant shall be shatterproof or shielded to prevent food contamination		
10	in case of break	age.	
11			
12	History Note:	Authority G.S. <del>130A 230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>	
13		Eff. February 1, <del>1987.<u>1987.</u>1987;</del>	
14		Readopted Eff. April 1, 2024.	

1	15A NCAC 18A	A .0409 is	readopted as published in 38:03 NCR 130 as follows:
2			
3	15A NCAC 18A	A .0409	VENTILATION
4	Ventilation shal	ll be provid	led to eliminate prevent odors and condensation. condensation from contaminating shellfish,
5	food contact sur	rfaces, or f	ood packaging materials.
6			
7	History Note:	Authori	ty G.S. <del>130A-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
8		Eff. Feb	ruary 1, <del>1987.<u>1987:</u></del>
9		Readon	ted Eff. April 1, 2024.

1	15A NCAC 18A .0410 is readopted as published in 38:03 NCR 130 as follows:
2	
3	15A NCAC 18A .0410 FLY PEST CONTROL
4	(a) All outside exterior openings shall be screened, screened or provided with wind curtains curtains, or be provided
5	with other fly control methods approved by the Division. to prevent the entrance of pests. All screens shall be kept
6	good repair. All outside exterior doors shall open outward and shall be self-closing.
7	(b) The use and storage of pesticides and rodenticides shall comply with all applicable state state and feder
8	guidelines. laws and rules.
9	(c) No pets or other animals shall be allowed in those portions of the facility where shellfish, food handling equipmen
10	or packaging materials are stored, handled, processed, or packaged.
11	
12	History Note: Authority G.S. <del>130.A 230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
13	Eff. February 1, <del>1987.</del> 1987;
14	Readopted Eff. April 1, 2024.

1	15A NCAC 18A	.0411 is repealed through readoption as published in 38:03 NCR 130 as follows:
2		
3	15A NCAC 18A	.0411 RODENT AND ANIMAL CONTROL
4		
5	History Note:	Authority G.S. 130A-230;
6		<i>Eff. February 1, <del>1987.</del>1987;</i>
7		Repealed Eff. April 1, 2024

1	15A NCAC 18A .0412 is readopted as published in 38:03 NCR 130-131 as follows:	
2		
3	15A NCAC 18A .0412 PLUMBING AND HAND WASHING FACILITIES	
4	(a) All plumbing shall be in compliance with applicable plumbing codes.	
5	(b) Hand washing facilities shall be provided with running water at a minimum temperature of 100°F dispensed from	
6	a hot and cold combination faucet.	
7	(c) Hand washing facilities shall be provided in or adjacent to each bathroom and in shucking and packing rooms.	
8	Hand washing facilities in packing areas shall be located where supervisors can observe employee use.	
9	(d) Hand washing facilities shall be separate from three-compartment or other sinks used for cleaning equipment and	
10	utensils.	
11	(e) Soap, single service towels in protected dispensers, and an easily cleanable waste receptacle shall be available and	
12	used at hand washing facilities. Other hand drying devices may be used if approved by the Division of Marine Fisheries	
13	based upon being equally effective at drying hands without the potential for recontamination.	
14		
15	History Note: Authority G.S. <del>130.4-230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>	
16	Eff. February 1, <del>1987.</del> 1987;	

Readopted Eff. April 1, 2024.

17

1 15A NCAC 18A .0413 is readopted as published in 38:03 NCR 131 as follows: 2 3 15A NCAC 18A .0413 WATER SUPPLY 4 (a) The water supply shall be from a source approved by the Division. (b) The water supply used shall be located, constructed, maintained, and operated in accordance with the Commission 5 6 for Public Health's rules governing water supplies. Copies of 15A NCAC 18A .1700 and 15A NCAC 18C may be 7 obtained from the Division. 8 (a) The water supply used shall be in accordance with 15A NCAC 18A .1720 through .1728, 15A NCAC 18C, or 02 9 NCAC 09C .0703, which are incorporated by reference, including subsequent amendments. 10 (b) If the water supply is from a private source, samples for bacteriological analysis shall be collected by the Division 11 of Marine Fisheries prior to use and after the water supply has been repaired or disinfected, and submitted for analysis 12 to the State Laboratory of Public Health or other laboratory that is certified in accordance with 10A NCAC 42C .0102, 13 which is incorporated by reference, including subsequent amendments. 14 (c) Cross-connections with unapproved water supplies shall be prohibited. A backflow or back siphonage of a solid, 15 liquid, or gas containment into the water supply shall be precluded by use of an air gap or backflow prevention device in accordance with applicable plumbing codes. 16 17 (d) Hot and cold running water under pressure shall be provided to food preparation, utensil, and hand washing areas 18 and any other areas in which water is required for cleaning. Running water under pressure shall be provided in 19 sufficient quantity to carry out all food preparation, utensil washing, hand washing, cleaning, and other water-using 20 operations. 21 22 Authority G.S. 130A 230; 113-134; 113-182; 113-221.2; 143B-289.52; History Note: 23 *Eff. February 1, 1987;* 24 Amended Eff. September 1, 1990.1990;

18 1 of 1

Readopted Eff. April 1, 2024.

25

1	15A NCAC 18A .0414 is readopted as published in 38:03 NCR 131 as follows:	
2		
3	15A NCAC 18A .0414 TOILET FACILITIES	
4	Separate and convenient toilet facilities shall be provided for each sex employed and shall comply with the N.C. State	
5	Building Code, Volume 2, Plumbing. Floors, walls, and ceilings shall be smooth, easily cleanable and kept clean	
6	Fixtures shall be kept clean. All toilet wastes and other sewage shall be disposed of in a public sewer system or in the	
7	absence of a public sewer system, by an on site sewage disposal system approved by the Department in accordance	
8	with G.S. 130A-335.	
9	(a) Toilets shall be provided in the plant by the owner or responsible individual and shall be kept clean and in good	
10	repair.	
11	(b) Toilet tissue, in a holder, shall be provided by the owner or responsible individual.	
12	(c) Toilet room doors shall not open directly into a processing area and shall be tight-fitting and self-closing.	
13	(d) All toilet wastes and other sewage shall be disposed of in accordance with 15A NCAC 18A .1900 or 15A NCAC	
14	02H .0200, which are incorporated by reference, including subsequent amendments.	
15		
16	History Note: Authority G.S. <del>130.4-230;</del> <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>	
17	Eff. February 1, 1987;	
18	Amended Eff. September 1, <del>1990.</del> <u>1990;</u>	
19	Readopted Eff. April 1, 2024.	

1	15A NCAC 18A .0415 is readopted as published in 38:03 NCR 131 as follows:	
2		
3	15A NCAC 18A .0415 WASTE DISPOSAL PREMISES	
4	Shells, washings, and other wastes shall be disposed of in a sanitary landfill or in a sanitary manner approved	ed by the
5	Division.	
6	(a) The premises shall be maintained free from conditions that may constitute an attractant, breeding	place, or
7	harborage for pests such as unmowed weeds or grass, uncontained litter or waste, or unused equipment.	
8	(b) To prevent pests and odors, shells and other solid waste shall not be permitted to accumulate on the prer	nises.
9		
10	History Note: Authority G.S. <del>130.4-230;</del> <u>113-134;</u> <u>113-182;</u> <u>113-221.2;</u> <u>143B-289.52;</u>	
11	Eff. February 1, <del>1987.</del> 1987:	
12	Readopted Eff. April 1, 2024.	

1	15A NCAC 18A .0416 is readopted as published in 38:03 NCR 131-132 as follows:
2	
3	15A NCAC 18A .0416 PERSONAL HYGIENE
4	(a) All employees shall wash their hands thoroughly with soap and running water before beginning work and again
5	after each interruption. interruption or if their hands may have become soiled or contaminated. Signs to this effect
6	shall be posted in conspicuous places in the plant by the operator. Hand washing signs shall be posted by the owner or
7	responsible individual at each hand washing facility in a language understood by employees.
8	(b) All persons handling shucked shellfish shall sanitize their hands before beginning work and again after each
9	interruption.
10	(e)(b) All persons individuals employed or engaged in the handling, shucking, or packing packing, or repacking of
11	shellfish shall wear clean, washable outer clothing. Clean plastic or rubber aprons, overalls, and rubber gloves shall
12	be considered satisfactory.
13	(c) All individuals employed or engaged in the shucking, packing, or repacking of shellfish shall wear hair restraints
14	and have clean fingernails free from nail polish and that are short enough to not extend past the fingertips. Employees
15	shall not wear jewelry other than easily cleanable rings. The use of absorbent wraps or absorbent finger cots shall not
16	be permitted.
17	(d) Employees shall not eat, drink, use electronic cigarettes or vaping products, or use tobacco in any form in the
18	rooms where shellfish are stored, processed, or handled.
19	(e) All persons An individual known to be a carrier of any disease which that can be transmitted through the handling
20	of shellfish or who have has an infected wound or open lesion on any exposed portion of their bodies the body shall
21	be prohibited from handling shellfish.shellfish or coming into contact with food contact surfaces.
22	
23	History Note: Authority G.S. <del>130.4-230.</del> 113-134: 113-182: 113-221.2: 143B-289.52:

Eff. February 1, <del>1987.</del> <u>1987</u>;

Readopted Eff. April 1, 2024.

24

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I	15A NCAC 18A	1.0417 is readopted as published in 38:03 NCR 132 as follows:
2		
3	15A NCAC 18A	A .0417 LOCKERSEMPLOYEES' PERSONAL ARTICLES
4	A separate roor	n or locker shall be provided for storing employees' street clothing, aprons, gloves, and personal
5	articles. Employ	vees' street clothing, aprons, gloves, food, drink, and personal articles shall be stored in a room or
6	locker separate	From any area where shellfish are shucked or packed or any area that is used for the cleaning or storage
7	of utensils.	
8		
9	History Note:	Authority G.S. <del>130.4-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
10		Eff. February 1, <del>1987.</del> 1987;
11		Readopted Eff. April 1, 2024.

1	15A NCAC 18A	1.0418 is readopted with changes as published in 38:03 NCR 132 as follows:
2		
3	15A NCAC 18A	A .0418 SUPPLY STORAGE
4	(a) Storage roo	om 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, uten	sils, and single-service articles. Each of the following categories of toxic substances shall be stored
9	separate from o	ne [another:]another using spacing or partitioning such that one category of toxic substance is not
10	mistaken for and	other category:
11	<u>(1)</u>	pesticides and rodenticides;
12	<u>(2)</u>	detergents, sanitizers, and cleaning agents; and
13	<u>(3)</u>	caustic acids, polishes, and other chemicals.
14	(c) Cleaning co	ompounds, sanitizers, and other toxic substances shall be labeled and used in accordance with the
15	manufacturer's l	abel directions.
16		
17	History Note:	Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
18		Eff. February 1, <del>1987.</del> 1987;
19		Readopted Eff. April 1, 2024.

1	15A NCAC 18A .0419 1	s readopted as published in 38:03 NCR 132 as follows:	
2			
3	15A NCAC 18A .0419	HARVEST BOATS VESSELS AND VEHICLES	
4	All boats used in the har	rvesting and handling of shellstock shall be kept clean and repaired such that the shellstock	
5	thereon shall not be sub	ject to adulteration by bilge water, by leakage of water from prohibited areas, or by other	
6	means. Decks, holds, or l	oins used for shellstock on boats shall not be washed with water from prohibited areas. Human	
7	wastes shall not be disch	narged into shellfish waters.	
8	(a) It shall be unlawful	to use vessels or vehicles that are engaged in the commercial harvest, handling, or transport	
9	of shellstock in such a n	nanner that allows contact of shellstock with bilge water, standing water, or other sources of	
10	contamination in the ves	sel or vehicle.	
11	(b) It shall be unlawful to allow dogs or other animals on or inside vessels or vehicles that are engaged in the		
12	commercial harvest or tr	commercial harvest or transport of shellstock.	
13	(c) It shall be unlawfu	l to discharge human waste overboard from vessels or vehicles used in the harvesting of	
14	shellstock.		
15			
16	History Note: Author	rity G.S. <del>130.4-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>	
17	Eff. Fe	ebruary 1, <del>1987.<u>1</u>987;</del>	
18	<u>Reado</u>	pted Eff. (Pending legislative review pursuant to S.L. 2019-198).	

1	15A NCAC 18A	1.0420 is readopted with changes as published in 38:03 NCR 132 as follows:
2		
3	15A NCAC 18A	A .0420 TRANSPORTING SHELLSTOCKSHELLFISH
4	(a) All shellstoo	k-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 to eliminate the entrance of
6	<u>pests, painted w</u>	ith a light color washable paint, kept clean, and shall be subject to inspection by the Division. Division
7	of Marine Fishe	ries.
8	(b) Shellstock shall be shipped under temperature and sanitary conditions in accordance with these Rules which wil	
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 operatin	g thermometer. It shall be unlawful to transport shellstock and in-shell product unless shipped under
12	mechanical refri	geration and the shipping conveyance is pre-chilled and maintained at an ambient temperature of 45°F
13	or below. The st	orage area of the shipping conveyance shall be equipped with an accurate, operating thermometer.
14	(c) Buy boats as	nd buy trucks shall be kept clean with water from a source approved by the Division under Rule .0413
15	of this Subchapt	er. Buy boats and buy trucks shall provide storage space for clean shipping containers, identification
16	tags, and record	sIt 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. <del>130A-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
20		Eff. February 1, 1987;
21		Amended Eff. May 1, <del>1994.</del> <u>1994;</u>
22		Readopted Eff. (Pending legislative review pursuant to S.L. 2019-198).

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1
       15A NCAC 18A .0421 is readopted with changes as published in 38:03 NCR 132-133 as follows:
 2
 3
                                  DAILY RECORD RECORDS
       15A NCAC 18A .0421
 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
                         quantity and type of shellfish received;
                (4)
18
                         time shellfish were received; and
               (5)
19
                         time shellfish were mechanically refrigerated.
                (6)
20
       (c) Each shellfish shipment shipped by a shellfish dealer shall be accompanied by a shipping document that includes:
21
                         name, address, and certification number of shipping dealer;
                <u>(1)</u>
22
                <u>(2)</u>
                         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. <del>130A 230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>
36
                        Eff. February 1, 1987;
37
                         Amended Eff. August 1, 1998.1998;
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I	15A NCAC 18A	.0422 is readopted as published in 38:03 NCR 133 as follows:
2		
3	15A NCAC 18A	.0422 SHELLSTOCK CLEANING
4	No person shall o	offer for sale any shellstock which that have not been washed free of bottom harvest area sediments
5	and detritus. Wat	er used for shellstock washing shall be obtained from a water source in accordance with Rule .0413
6	of this Section or	from a growing area in the open status and classified as "approved" or "conditionally approved" as
7	defined in Rule .(	0901 of this Subchapter.
8		
9	History Note:	Authority G.S. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
10		Eff. February 1, <del>1987.</del> 1987;
11		Readopted Eff. April 1, 2024.

1	15A NCAC 18A	A .0423 is readopted as published in 38:03 NCR 133 as follows:
2		
3	15A NCAC 18A	A .0423 SALE OF LIVE SHELLSTOCK
4	Only live shells	tock shall be offered for sale.
5		
6	History Note:	Authority G.S. <del>130A 230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>
7		Eff. February 1, <del>1987.<u>1987;</u></del>
R		Readonted Eff April 1 2024

1	15A NCAC 18A	A .0424 is	readopt	ted as published in 38:03 NCR 133 as follows:
2				
3	15A NCAC 18	A .0424	SHEL	LFISH RECEIVING
4	No <del>person</del> -shell	fish deale	<u>r</u> shall r	eceive or <del>accept</del> <u>accept:</u>
5	<u>(1)</u>	any <del>she</del>	<del>llfish</del> <u>sh</u>	nellstock from:
6		<u>(a)</u>	a licen	nsed shellfish harvester unless unless:
7			<u>(i)</u>	the container or package bears the harvest tag or label required by these Rules.as
8				required in Rule 15A NCAC 03K .0109 and in accordance with the HACCP plan;
9				<u>and</u>
10			<u>(ii)</u>	the shellstock was harvested from a growing area in the open status and classified
11				as "approved" or "conditionally approved" as defined in Rule .0901 of this
12				Subchapter and as indicated on the harvest tag; or
13		<u>(b)</u>	anothe	er shellfish dealer unless the container or package bears the tag as required in Rule
14			.0425	of this Section or, in the case of a bulk shipment, Rule .0426 of this Section; and
15	<u>(2)</u>	any she	ellfish fr	om another shellfish dealer unless:
16		<u>(a)</u>	it is ac	ecompanied by the documentation required in Rule .0421(c) of this Section; and
17		<u>(b)</u>	the she	ellfish temperature and other critical limits are in compliance with the HACCP plan.
18				
19	History Note:	Author	ity G.S.	<del>130.4-230;-</del> 113-134; 113-182; 113-221.2; 143B-289.52;
20		Eff. Fe	bruary 1	, 1987;
21		Amend	ed Eff. A	lpril 1, <del>1997.<u></u>1997;</del>
22		Reador	nted Eff	April 1 2024

1	15A NCAC 18A .0426 is readopted as published in 38:03 NCR 133 as follows:			
2				
3	15A NCAC 18A .0426 BULK SHIPMENTS <u>BETWEEN SHELLFISH DEALERS</u>			
4	(a) For the purpose of this Rule:			
5	(1) "bulk shipment" shall mean a shipment of a shellstock lot between shellfish dealers.			
6	(2) "shellstock lot" shall mean a single type of bulk shellstock or containers of shellstock of no more			
7	than one day's harvest from a single growing area harvested by one or more harvesters.			
8	(b) Shipment in bulk Bulk shipments shall not be made except where if the shipment is from only one consignor to			
9	one consignee and accompanied by the uniform shipping tag.consignee, both of which shall be shellfish dealers.			
10	(c) When a shellstock lot is shipped, if multiple containers are used they shall be on a wrapped pallet, in a tote, in a			
11	net bailer, or other container and the unit shall be tagged with a single tag in accordance with Rule .0425 of this			
12	Section. The single tag shall also include a statement that "All shellstock containers in this lot have the same harvest			
13	date and area of harvest" and shall include the number of individual containers in the unit.			
14	(d) The shellfish dealer shall provide a transaction record that accompanies the bulk shipment that contains the same			
15	information required on a dealer's tag in Rule .0425 of this Section and additionally states the name of the consignee.			
16	which shall be a shellfish dealer.			
17	(e) Bulk shipments shall be kept above the floor using pallets to prevent the shellstock from becoming contaminated			
18	unless the shipping conveyance has a channeled floor.			
19				
20	History Note: Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;			
21	Eff. February 1, <del>1987.</del> 1987;			
22	Readopted Eff. April 1, 2024.			

1	15A NCAC 18A	A .0427 is readopted as published in 38:03 NCR 133-134 as follows:			
2					
3	15A NCAC 18A	A .0427 SHELLSTOCK SHELLFISH STORAGE			
4	Shellstock held	in wet or dry storage must be kept so that they will not become adulterated. All shellstock held in dry			
5	storage shall be kept under mechanical refrigeration at a temperature of 45°F (7.1°C) or below. All refrigerated				
6	shellstock storage areas shall be equipped with an operating thermometer.				
7	(a) It shall be unlawful to fail to keep shellstock and in-shell product under mechanical refrigeration at a temperatur				
8	of 45°F or below unless otherwise required by proclamation issued under the authority of 15A NCAC 03K .0110 of				
9	otherwise specified in the HACCP plan.				
10	(b) Refrigerated	d storage areas shall be equipped with an accurate, operating thermometer.			
11	(c) It shall be u	nlawful to fail to keep shucked shellfish under temperature control at a temperature of 45°F or below.			
12					
13	History Note:	Authority G.S. <del>130.A 230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>			
14		Eff. February 1, 1987;			
15		Amended Eff. May 1, 1994; December 1, <del>1987.</del> 1987;			
16		Readopted Eff. (Pending legislative review pursuant to S.L. 2019-198).			

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 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. <del>130A 230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>			
17	Eff. February 1, <del>1987.<u>1987:</u></del>			
18	Readopted Eff. April 1, 2024.			

1 15A NCAC 18A .0429 is readopted as published in 38:03 NCR 134 as follows: 2 3 15A NCAC 18A .0429 STOPSALE EMBARGO OR DISPOSAL OF SHELLFISH 4 (a) When it has been determined by the Division of Marine Fisheries that shellfish have not been grown, harvested, 5 stored, treated, transported, handled, shucked, packed packed, or offered for sale in compliance with 15A NCAC 18A 6 Sections .0300 through .0900 of this Subchapter, those shellfish shall-may be deemed adulterated adulterated in 7 accordance with Rule .0438 of this Section, except as required in Rules .0405 and .0430 of this Section. 8 (b) Shellfish or shellfish products processed or prepared for sale to the public determined to be adulterated or 9 misbranded shall be subject to stopsale or disposal by the Division. The Division may temporarily or permanently 10 issue an order to stop sale or condemn, destroy, or otherwise dispose of all shellfish or shellfish containers found to 11 be adulterated or misbranded embargo or disposal by the Division in accordance with G.S. 113-221.4. The authority 12 of marine fisheries inspectors to seize shellfish or shellfish products pursuant to G.S. 113-137 shall not be affected by 13 this Rule. 14 (c) All shellfish shall be disposed of in a manner prescribed by the Division or by a court of appropriate jurisdiction. 15 (c) If voluntary disposal of adulterated or misbranded shellfish or shellfish products is alternatively chosen by the shellfish dealer, responsible individual, or other person or facility specified in Rule .0401 of this Section, the product 16 17 disposal shall be observed by a Division employee. 18 19 History Note: Authority G.S. 130A 230; 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52; 20 Eff. February 1, 1987.1987; 21 Readopted Eff. April 1, 2024.

I	15A NCAC 18A	A .0430 is readopted with changes as published in 38:03 NCR 134 as follows:		
2				
3	15A NCAC 18A	A .0430 BACTERIOLOGICAL <u>AND CONTAMINATION</u> STANDARDS		
4	Shellfish shucke	ed 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 pathoge	enic 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 adul	terated by the Division.shall be deemed adulterated by the Division of Marine Fisheries if:		
9	<u>(1)</u>	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	<u>(2)</u>	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-		
15	<u>(3)</u>	be found at https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-		
15 16	(3)	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		
15 16 17	(3)	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 the shellfish contain any contaminant that renders it unsafe for human consumption in accordance		
15 16 17 18	<u>(3)</u>	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 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		
15 16 17 18 19	(3)	be found at <a href="https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf">https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf</a> , at no cost; or 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;		
15 16 17 18 19 20	(3)	be found at <a href="https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf">https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf</a> , at no cost; or 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		
15 16 17 18 19 20 21	(3)	be found at <a href="https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf">https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf</a> , at no cost; or 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		
15 16 17 18 19 20 21 22	(3)	be found at <a href="https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf">https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf</a> , at no cost; or 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 <a href="https://www.fda.gov/food/federalstate-food-procedures-1970-full-text.pdf">https://www.fda.gov/food/federalstate-food-procedures-1970-full-text.pdf</a> , at no cost; or		
15 16 17 18 19 20 21 22 23	(3)  History Note:	be found at <a href="https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf">https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf</a> , at no cost; or 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 <a href="https://www.fda.gov/food/federalstate-food-procedures-1970-full-text.pdf">https://www.fda.gov/food/federalstate-food-procedures-1970-full-text.pdf</a> , at no cost; or		
15 16 17 18 19 20 21 22 23 24		be found at <a href="https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf">https://www.issc.org/Data/Sites/1/media/-22-com-docs/apha-recommended-procedures-1970-full-text.pdf</a> , at no cost; or 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 <a href="https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp">https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp</a> , at no cost.		

1	15A NCAC 18A	.0432 is readopted as published in 38:03 NCR 134-135 as follows:
2		
3	15A NCAC 18A	A .0432 PUBLIC DISPLAY OF CONSUMER ADVISORY
4	All facilities and	persons shellfish dealers permitted in by Rule .0302 of this Subchapter and all other businesses and
5	persons that sell	or serve raw shellfish shall post one of the following consumer advisories or an equivalent statemen
6	in a conspicuous	s-place where it may be readily observed by the public the following consumer advisory: in the area
7	where raw shellf	ish is sold or served:
8	<u>(1)</u>	"Consumer Advisory
9		Eating raw or undercooked oysters, elams clams, whole scallops, or mussels
10		may cause severe illness. People with the following conditions are at
11		especially high risk: liver disease, alcoholism, diabetes, cancer, stomach or
12		blood disorder, or weakened immune system. Ask your doctor if you are
13		unsure of your risk. If you eat shellfish and become sick, see a doctor
14		immediately."immediately."; or
15	<u>(2)</u>	"Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs
16		may increase your risk of foodborne illness, especially if you have certain
17		medical conditions."
18	Nothing in this I	Rule is intended to supersede regulation of restaurants or other establishments subject to 15A
19	NCAC 18A .260	00 or the U.S. Food Code.
20		
21	History Note:	Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
22		Temporary Adoption Eff. October 12, 1998; February 1, 1998;
23		Eff. April 1, <del>1999.</del> <u>1999:</u>
24		Readopted Eff. April 1, 2024.

1	15A NCAC 18A .0433 is readopted as published in 38:03 NCR 135 as follows:
2	
3	15A NCAC 18A .0433 HAZARD ANALYSIS
4	Each shellfish dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely t
5	occur for each kind of shellfish product processed by that dealer and to identify the preventative measures that the
6	dealer can apply to control those hazards. For the purpose of this Rule, "reasonably likely to occur" shall mean a foo
7	safety hazard for which a processor would establish controls because experience, illness data, scientific reports, or
8	other information provide a basis to conclude that there is a reasonable possibility that it will occur in the absence of
9	those controls, as defined in 21 CFR 123.6, which is incorporated by reference, including subsequent amendment
10	and editions. A copy of the reference material can be found at https://www.ecfr.gov/current/title-21/chapter
11	I/subchapter-B/part-123, at no cost.
12	
13	History Note: Authority G.S. <del>130.4-230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>
14	Eff. August 1, <del>2000.</del> 2000;
15	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 HACCP PLAN 15A NCAC 18A .0434 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 List list the food safety hazards that are reasonably likely to occur; (1) 11 (2) List list the critical control points for each of the food safety hazards; 12 (3) <u>List list</u> 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; (5) 15 List list any corrective action plans to be followed in response to deviations from critical limits at 16 critical control points; 17 Provide provide a record keeping system that documents critical control point monitoring; and (6)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. (b) With the exception of a shellfish dealer that has not been permitted for interstate commerce, the following 24 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 <u>(1)</u> 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

37 safety hazards. Verification procedures shall include:

CFR 123.7, 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-B/part-123/subpart-

(d) At least annually, each shellfish dealer shall verify that the HACCP plan is being implemented to control food

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A/section-123.7#p-123.7(b), at no cost.

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36

1	<u>(1)</u>	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	<u>(2)</u>	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 r	equired 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	<u>(1)</u>	the name and location of the dealer;
11	<u>(2)</u>	the date and time of the activity that the record reflects;
12	<u>(3)</u>	the signature or initials of the individual performing the operation; and
13	<u>(4)</u>	the identity of the product and the production code, if any.
14		
15	History Note:	Authority G.S. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;
16		Eff. August 1, <del>2000.</del> 2000;
17		Readopted Eff. April 1, 2024.

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1	15A NCAC 18A	A .0435 is readopted as published in 38:03 NCR 136 as follows:
2		
3	15A NCAC 18.	A .0435 SANITATION MONITORING REQUIREMENTS
4	(a) Each shellfi	sh dealer shall monitor, at a minimum, monitor the following sanitation items: items when the plant is
5	operational:	
6	(1)	Safety safety of water;
7	(2)	Condition condition and cleanliness of food contact surfaces;
8	(3)	Prevention prevention of eross contamination; cross-contamination;
9	(4)	Maintenance maintenance of hand washing, hand sanitizing sanitizing, and toilet facilities;
10	(5)	Protection protection of shellfish, shellfish packaging materials materials, and food contact surfaces
11		from adulteration; becoming adulterated;
12	(6)	Proper-proper labeling, storage storage, and use of toxic compounds;
13	(7)	Control control of employees with adverse health conditions; and
14	(8)	Exclusion exclusion of pests from the facility.
15	(b) Monitoring records of these sanitation items shall be recorded at least daily and shall include the date and time of	
16	the activity that	the record reflects, and the signature or initials of the individual performing the operation. The records
17	shall be reviewe	ed and signed by the owner or designated individual within one week of recording.
18		
19	History Note:	Authority G.S. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
20		Eff. August 1, <del>2000.2000;</del>
2.1		Readonted Eff. April 1, 2024

1	15A NCAC 18A	.0436 is repealed through readoption as published in 38:03 NCR 136 as follows:
2		
3	15A NCAC 18A	.0436 MONITORING RECORDS
4		
5	History Note:	Authority G.S. 130A-230;
6		Eff. August 1, <del>2002.</del> 2002;
7		Renealed Eff. April 1 2024

1	15A NCAC 18A	A .0437 is adopted as published in 38:03 NCR 136-137 as follows:
2		
3	15A NCAC 18	A .0437 IN-SHELL PRODUCT
4	(a) In-shell pro	duct shall be kept under mechanical refrigeration at a temperature of 45°F or below.
5	(b) In-shell pro	oduct shall be tagged or labeled to contain the following indelible and legible information listed in
6	sequential orde	<u>r:</u>
7	<u>(1)</u>	the shellfish dealer's name, address, and certification number assigned by the shellfish control
8		agency in the state of the shellfish dealer's location;
9	<u>(2)</u>	the original shipper's certification number, except if the in-shell product is depurated, the original
10		shipper's certification number is not required;
11	<u>(3)</u>	a "SELL BY DATE" that indicates the shelf-life or the words "BEST IF USED BY" followed by a
12		date when the product would be expected to reach the end of its shelf-life. The date shall include
13		month, day, and year;
14	<u>(4)</u>	if the in-shell product is depurated, the depuration cycle number or lot number;
15	<u>(5)</u>	the most precise identification of the harvest location as is practicable, including the initials of the
16		state of harvest, and the state or local shellfish control authority's designation of the growing area
17		by indexing, administrative, or geographic designation. If the authority in another state has not
18		indexed growing areas, then a geographical or administrative designation shall be used (e.g., Long
19		Bay, shellfish lease or franchise number, or lot number);
20	<u>(6)</u>	the type and quantity of in-shell product; and
21	<u>(7)</u>	the following statement in bold type on each tag or label: "THIS TAG IS REQUIRED TO BE
22		ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT
23		ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN
24		LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT
25		DATE) OR "THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL
26		CONTAINER IS EMPTY OR IS RELABELED AND THEREAFTER KEPT ON FILE, IN
27		CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN LAST
28		SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE) ."
29	(c) In-shell pro	duct shall include one of the following consumer advisories, or equivalent statement:
30	<u>(1)</u>	"Consumer Advisory
31		Eating raw or undercooked oysters, clams, whole scallops, or mussels may cause severe illness.
32		People with the following conditions are at especially high risk: liver disease, alcoholism, diabetes,
33		cancer, stomach or blood disorder, or weakened immune system. Ask your doctor if you are unsure
34		of your risk. If you eat shellfish and become sick, see a doctor immediately."
35	<u>(2)</u>	"Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk
36		of foodborne illness, especially if you have certain medical conditions."
37	(d) The statem	ent "Keep Refrigerated" or an equivalent statement shall be included on the tag or label.

1	(e) If in-shell product for retail sale is packed in individual containers of five pounds or less and shipped in a master
2	container that includes a tag in compliance with Paragraph (b) of this Rule, the individual containers of five pounds
3	or less shall not require tags as specified in Paragraph (b) of this Rule if a lot code number is included on each container
4	that allows traceback of the in-shell product to the master container. A consumer advisory shall be included on each
5	retail package in accordance with Paragraph (c) of this Rule.
6	
7	History Note: Authority G.S. 113-134; 113-182; 113-221.2; 143B-289.52;

8

Eff. April 1, 2024.

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1	15A NCAC 18A	.0438 is adopted as published in 38:03 NCR 137 as follows:
2		
3	15A NCAC 18A	A .0438 INSPECTIONS AND COMPLIANCE SCHEDULE
4	(a) If a critical	deficiency is detected during an inspection of a shellfish dealer by a Division of Marine Fisheries
5	inspector:	
6	<u>(1)</u>	the deficiency shall be corrected by the shellfish dealer during that inspection; or
7	<u>(2)</u>	the shellfish dealer shall immediately cease production affected by the deficiency.
8	If the shellfish de	ealer fails to correct the deficiency during the inspection, the Division shall initiate the suspension or
9	revocation proce	ss for the Shellfish Dealer Permit and Certificate of Compliance as set forth in 15A NCAC 03O .0504.
10	For the purpose	of this Rule, "critical deficiency" shall mean a condition or practice that results in the production of a
11	shellfish product	that is adulterated or presents a threat to the health or safety of the consumer.
12	(b) Shellfish pro	ducts affected by a critical deficiency shall be controlled to prevent adulterated product from reaching
13	consumers. The	Division shall:
14	<u>(1)</u>	embargo or destroy adulterated shellfish in accordance with Rule .0429 of this Section;
15	<u>(2)</u>	initiate a recall of adulterated shellfish; and
16	<u>(3)</u>	notify enforcement officials for the United States Food and Drug Administration, as well as shellfish
17		control authorities in states that are known to have received adulterated shellfish.
18	(c) If a key or	other deficiency is detected during an inspection of a shellfish dealer by a Division inspector, a
19	compliance sche	dule shall be issued by the Division inspector that provides a time frame by which the deficiency shall
20	be corrected by the shellfish dealer. For the purpose of this Rule, "key or other deficiency" shall mean a deficiency	
21	other than a critical deficiency.	
22	(d) If a shellfish	dealer fails to meet the compliance schedule, the Division shall proceed with one of the following
23	options:	
24	<u>(1)</u>	revise the existing compliance schedule:
25	<u>(2)</u>	initiate the suspension or revocation process for the Shellfish Dealer Permit and Certificate of
26		Compliance as set forth in 15A NCAC 03O .0504; or
27	<u>(3)</u>	seek other administrative remedies.
28	(e) Nothing in the	his Rule shall be construed to limit or make null any option for remedy in accordance with Rule 15A
29	NCAC 03O .050	4 or other available administrative remedy.
30		
31	<u>History Note:</u>	Authority G.S. 113-134; 113-182; 113-221.2; 113-221.4; 143B-289.52;
32		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 or	
6	Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement [Policy, which is incorporated by	
7	reference, including subsequent amendments and editions. A copy of the reference material can be found a	
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 .05010504 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18
6	.05010504); has been transferred and recodified from Rules .10011004 of Title 10 Subchapter 10B of the Nor
7	Carolina Administrative Code (T10.10B .10011004), effective April 4, 1990.
8	
9	15A NCAC 18A .0501 GENERAL REQUIREMENTS FOR SHELLSTOCK PLANTS AND RESHIPPER
10	The rules in Section .0400 and the rules of this Section shall apply for the operation of shellstock plants and reshipper
11	
12	History Note: Authority G.S. <del>130.4-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
13	Eff. February 1, <del>1987.</del> 1987;
14	Readopted Eff. April 1, 2024.

1	15A NCAC 18A .0502 is readopted as published in 38:03 NCR 137 as follows:		
2			
3	15A NCAC 18A	.0502 GRADING SHELLSTOCK AND COMMINGLING	
4	(a) For the purpo	ose of this Rule:	
5	<u>(1)</u>	"commingling" shall mean the act of combining different lots of shellfish harvested on different	
6		days in the same growing area or combining different lots of shellstock harvested from different	
7		growing areas.	
8	<u>(2)</u>	"lot" shall mean clams from one day's harvest, from a single growing area, harvested by one or more	
9		harvesters.	
10	(a)(b) The gradi	ng of shellstock by a shellfish dealer shall be conducted only in a permitted shellstock plant.	
11	(b)(c) A separate grading room or area separate from other processing operations shall be required for the grading of		
12	shellstock.		
13	(d) The grader t	used to grade shellstock, and any other accessories or tables used in the grading operation, shall be	
14	constructed to be easily cleanable and shall be kept in good repair.		
15	(e) Shellfish dealers shall not commingle any shellfish, except for clams with prior approval of a commingling plan		
16	by the Division of Marine Fisheries. A commingling plan shall be approved by the Division based on limiting the		
17	dates of harvest and growing areas and maintaining lot identity so that each individual lot of shellfish can be traced		
18	back to its harvest source.		
19			
20	History Note:	Authority G.S. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;	
21		Eff. February 1, <del>1987.</del> 1987:	
22		Readopted Eff. April 1, 2024.	

1 of 1

1	15A NCAC 18A	.0503 is repealed through readoption as published in 38:03 NCR 137 as follows:
2		
3	15A NCAC 18A	.0503 GRADER
4		
5	History Note:	Authority G.S. 130A-230;
6		Eff. February 1, <del>1987.</del> 1987;
7		Repealed Eff April 1 2024

l	15A NCAC 18A .0504 is readopted as published in 38:03 NCR 137-138 as follows:	
2		
3	15A NCAC 18A .0504 RESHIPPERS	
4	(a) Reshippers shall meet all applicable requirements for shellstock plants. When shucked shellfish are reshipped	ed,
5	they shall be obtained from a permitted shipper. The shucked shellfish shall be received in approved shippi	ng
6	containers at a temperature of 40°F (4°C) or below. The temperature of the shellfish shall not exceed 40°F (4°C)	<del>C</del> )
7	during the holding and shipping periods.	
8	(b) Reshippers shall keep adequate and accurate records indicating the source from which shellfish were purchased,	
9	the date purchased, the name of the waters from which the shellfish were harvested, and the names and addresses	<del>-of</del>
10	persons to whom the shellfish were sold for a period of one year.	
11	Reshippers shall only purchase shellfish from other shellfish dealers and sell the product to other shellfish deale	rs.
12	wholesalers, or retailers without repacking or relabeling.	
13		
14	History Note: Authority G.S. <del>130A-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>	
15	Eff. February 1, 1987;	
16	Amended Eff. September 1, <del>1990.</del> 1990;	
17	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	
4	REPACKING PLANTS	
5		
6	Rules .06010619 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A	
7	.06010619); has been transferred and recodified from Rules .11011119 of Title 10 Subchapter 10B of the North	
8	Carolina Administrative Code (T10.10B .11011119), 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 plan	
13	and repacking plants.	
14		
15	History Note: Authority G.S. <del>130A 230;</del> <u>113-134;</u> 113-182; 113-221.2; 143B-289.52;	
16	Eff. February 1, <del>1987.</del> 1987;	
17	Readopted Eff. April 1, 2024.	

1	15A NCAC 18A	.0602 is readopted as published in 38:03 NCR 138 as follows:
2		
3	15A NCAC 18A	.0602 SEPARATION OF OPERATIONS
4	A shucking and	packing plant shall provide separate rooms-areas for shellstock storage, shucking, heat shock, and
5	general storage.	A separate packing area with delivery shelf that is separate from other processing areas and with a
6	delivery window	or shelf as set forth in Rule .0605 of this Section shall be required.
7		
8	History Note:	Authority G.S. <del>130.4-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
9		Eff. February 1, <del>1987.</del> 1987;
10		Readopted Eff. April 1, 2024.

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I	15A NCAC 18A	A .0603 is readopted as published in 38:03 NCR 138 as follows:
2		
3	15A NCAC 18	A .0603 HOT WATER SYSTEM
4	An automatical	y regulated hot water system shall be provided which that has sufficient capacity to furnish water at a
5	temperature of	at least 130°F <del>(54°C)</del> during all hours of shucking and packing plant operation.
6		
7	History Note:	Authority G.S. <del>130A-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
8		Eff. February 1, <del>1987.<u>1987</u>;</del>
9		Readopted Eff. April 1, 2024.

1	15A NCAC 18A	1.0604 is repealed through readoption as published in 38:03 NCR 138 as follows
2		
3	15A NCAC 18A	A .0604 HANDWASHING FACILITIES
4		
5	History Note:	Authority G.S. 130A-230;
6		Eff. February 1, <del>1987.</del> 1987;
7		Renealed Eff April 1 2024

1	15A NCAC 18A .06	05 is readopted as published in 38:03 NCR 138 as follows:
2		
3	15A NCAC 18A .06	05 DELIVERY WINDOW OR SHELF
4	(a) A delivery wind	ow or a non-corrosive shelf shall be installed in the partition between the shucking room area and
5	packing area. No shu	uckers or unauthorized personnel shall be allowed in the packing room or area. The <u>If a</u> delivery
6	window is used it s	hall be equipped with a shelf completely covered with smooth, non-corrosive metal or other
7	impervious material	approved by the Division for such purpose, and shall be sloped to drain towards the shucking
8	<del>room.</del> area.	
9	(b) No shuckers or	individuals that are not designated as packers by the owner or responsible individual shall be
10	allowed in the packing	ng area.
11		
12	History Note: Au	thority G.S. <del>130.4-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
13	Efs	f. February 1, <del>1987.<u>1</u>987.</del>
14	<u>Re</u>	adopted Eff. April 1, 2024.

1	15A NCAC 18A	A .0606 is readopted as published in 38:03 NCR 138 as follows:	
2			
3	15A NCAC 18	A .0606 NON-FOOD CONTACT SURFACES	
4	All non-food contact surfaces of equipment such as cabinets and shelving shall be non absorbent, impervious and		
5	constructed to b	e easily <del>cleaned.cleanable.</del>	
6			
7	History Note:	Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;	
8		Eff. February 1, <del>1987.<u>1987.</u></del>	
9		Readopted Eff. April 1, 2024.	

1	15A NCAC 18A	A .0607 is readopted as published in 38:03 NCR 138 as follows:
2		
3	15A NCAC 18A	A .0607 SHUCKING BENCHES
4	Shucking bench	es, tables, and contiguous walls to a height of at least two feet above the bench top, shall be of smooth
5	concrete, non-co	prrosive metal, or other durable <del>non-absorbent impervious material, free from cracks and pits, and so</del>
6	constructed so t	hat drainage is complete and rapid and is directed away from the stored shellfish. Shucking blocks
7	shall be solid, one-piece construction, removable, and easily cleanable. The stands, stalls stalls and stools shall be or	
8	smooth material	and shall be painted with a light colored light-colored washable paint paint, such as white in color,
9	so that unclean	surfaces can be detected.
10		
11	History Note:	Authority G.S. <del>130.A-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
12		Eff. February 1, <del>1987.</del> 1987;
13		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 eleanable; 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 Authority G.S. 130A 230; 113-134; 113-182; 113-221.2; 143B-289.52; 16 History Note:

Eff. February 1, 1987;

Readopted Eff. April 1, 2024.

Amended Eff. September 1, 1990.1990;

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1	15A NCAC 18	A .0609 is readopted as published in 38:03 NCR 138-139 as follows:
2		
3	15A NCAC 18	A .0609 SANITIZING EQUIPMENT
4	Washing and s	anitizing facilities, including a three-compartment wash sink of adequate size to wash the largest
5	utensils used in	the plant shucking and packing plant, shall be provided in a section of the plant convenient to so that
6	it can service th	ne work areas. The sink shall be kept in good repair. Permanent hot and cold water connections, with
7	combination su	pply faucets, shall be installed so that all vats may receive hot and cold water. Either steam, hot water,
8	or a sanitizing s	solution shall be used to sanitize utensils and equipment.
9		
10	History Note:	Authority G.S. <del>130A-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
11		Eff. February 1, 1987;
12		Amended Eff. December 1, <del>1987.<u>1987</u>.</del>
13		Readopted Eff. April 1, 2024.

1	15A NCAC 18A	A .0610 is readopted as published in 38:03 NCR 139 as follows:
2		
3	15A NCAC 18	A .0610 EQUIPMENT SANITATION
4	All utensils and	tools, such as opening knives, shucking pails, measures, skimmers, colanders, tanks, tubs, paddles,
5	and containers	which that come in contact with the shellfish shall be thoroughly cleaned and then sanitized:sanitized
6	<u>by:</u>	
7	(1)	by steam in a steam chamber or box equipped with an indicating thermometer located in the coldest
8		zone, by exposure to a temperature of 170°F (76°C)-for at least 15 minutes, or to a temperature of
9		200°F (93°C) for at least five minutes;
10	(2)	by-immersion in hot water at a temperature of 170°F (76°C) for at least two minutes (a thermometer
11		is required);minutes;
12	(3)	by-immersion for at least one minute in, or exposure for at least one minute to, to a constant flow of
13		of, a solution containing not less than 100 parts per million chlorine residual. Utensils and equipment
14		which have to that must be washed in place will-shall require washing, rinsing, and sanitizing; or
15	(4)	by a bactericidal treatment method which will provide equivalent sanitization to that provided by
16		the methods authorized in (1), (2), or (3), as determined by the Division. If the bactericidal
17		immersion or spray treatment is employed, testing kits shall be used to ensure that minimum solution
18		strengths are maintained throughout the cleaning process.other equivalent products and procedures
19		approved in 21 CFR 178.1010, which is incorporated by reference, including subsequent
20		amendments and editions. A copy of the reference material can be found at
21		https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-178/subpart-B/section-
22		<u>178.1010</u> , at no cost.
23	A testing method	od or equipment shall be available and used to test chemical sanitizers to ensure minimum prescribed
24	strengths.	
25		
26	History Note:	Authority G.S. <del>130A-230;</del> <u>113-134; 113-182; 113-221.2; 143B-289.52;</u>
27		Eff. February 1, <del>1987.</del> 1987:
28		Readopted Eff. April 1, 2024.

1	15A NCAC 18A	A .0611 is readopted as published in 38:03 NCR 139 as follows:
2		
3	15A NCAC 18.	A .0611 EQUIPMENT STORAGE
4	Equipment and	utensils which that have been cleaned and given bactericidal treatment sanitized shall be stored in a
5	manner to prote	et against prevent contamination.
6		
7	History Note:	Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
8		Eff. February 1, <del>1987.</del> 1987:
9		Readopted Eff. April 1, 2024.

I	ISA NCAC ISA	1.0612 is readopted as published in 38:03 NCR 139 as follows:		
2				
3	15A NCAC 18A	A .0612 ICE		
4	(a) Ice shall be	obtained from a water supply approved by the Division of Marine Fisheries pursuant to Rule .0413 of		
5	this Subchapter	this Subchapter and shall be stored and handled in a sanitary manner to prevent contamination and keep the		
6	ice clean.			
7	(b) All equipment used in the handling of ice shall be used for no other purpose and shall be cleaned and sanitized at			
8	least once each	day the facility is in operation.		
9				
10	History Note:	Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;		
11		Eff. February 1, <del>1987.</del> 1987;		
12		Readopted Eff. April 1, 2024.		

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15A NCAC 18A .0613 is readopted as published in 38:03 NCR 139 as follows:

1 2 3

## 15A NCAC 18A .0613 SHELLFISH SHUCKING

- 4 (a) Shellfish shall be shucked in a manner that they are not subject to adulteration to prevent contamination. Shellstock
- 5 shall be reasonably free of mud when excessive sediment prior to being shucked. Only live shellstock shall be shucked.
- 6 (b) Shucking of shellstock shall only be permitted on approved-shucking tables or benches. benches in accordance
- 7 with Rules .0402 and .0607 of this Subchapter. Floors used by shuckers shall not be used for the storage of shellfish
- 8 or the retention of shucking pails or other food contact containers.
- 9 (c) When shellstock are stored in the shucking room, protection shall be provided for the storage space to prevent
- 10 possible adulteration the shellstock from becoming adulterated from wash water wastes and from the feet of the
- 11 employees.
- 12 (d) Shucking pails shall be placed so as to exclude the drippings from shells and from the hands of shuckers. The
- pails shall be rinsed with running tap water before each filling.
- 14 (e) Shucked shellfish, when washed, shellfish shall be thoroughly washed on a skimmer or a container approved by
- the Division of Marine Fisheries with cold running water from a source approved by the Division under in accordance
- with Rule .0413 of this Subchapter.
- 17 (f) The return of excess shucked shellfish from the packing room shall not be allowed. All shucked shellfish shall be
- packed before leaving it leaves the packing room.
- 19 (g) If blowers are used for cleansing, the total time that shellfish are in contact with water after leaving the shucker,
- 20 including the time of washing, rinsing, and any other contact with water water, shall not be more than 30 minutes. In
- computing the time of contact with water, the length of time that shellfish are in contact with water that is agitated,
- 22 agitated shall be calculated at twice its-the actual length. length of time that the shellfish are in contact with the water.
- 23 Before packing into containers for shipment or delivery for consumption, the shellfish shall be drained and packed
- 24 <u>drained. Shellfish shall be packed</u> without any added substance.
- 25 (h) Pre-cooling of shucked shellfish shall be done in equipment which meets National Sanitation Foundation standards
- 26 or the equivalent.

27

- 28 History Note: Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
- 29 *Eff. February 1, 1987;*
- 30 Amended Eff. September 1, <del>1990.</del> <u>1990</u>;
- 31 <u>Readopted Eff. April 1, 2024.</u>

1 15A NCAC 18A .0614 is readopted as published in 38:03 NCR 139-140 as follows: 2 3 15A NCAC 18A .0614 **CONTAINERS** 4 (a) Containers used for transporting shucked shellfish shall be made from food safe materials approved by the United 5 States Food and Drug Administration-food-safe materials. These containers shall not be reused for packing shellfish. 6 (b) Shucked shellfish shall be packed and shipped in containers, sealed so that tampering can be detected. Each 7 individual container shall have permanently recorded container, so as to be conspicuous, the shuckerpacker's, repacker's, or distributor's name and address, and the shuckerpacker's or repacker's certification number. The shucker-8 9 packer's or repacker's name and address and certification number shall be permanently and visibly recorded on the 10 label of each container used for shucked shellfish. 11 (c) Any container of shucked shellfish which that has a capacity of 64 fluid ounces or more shall be dated as of the 12 date shucked include the words "DATE SHUCKED" followed by the date shucked permanently recorded on both-the 13 lid and sidewall or bottom of the container. The date shall consist of either the abbreviation for the month and 14 number of the day of the month or the Julian format (YDDD), the last digit of the four-digit year and the three-digit 15 number corresponding to the day of the year. 16 (d) Any container of shucked shellfish which that has a capacity of less than 64 fluid ounces shall indicate a SELL BY date include the words "SELL BY" or "BEST IF USED BY" followed by a date when the product will reach the 17 18 end of its projected shelf life. The date shall consist of the abbreviation for the month and number of the day of the 19 month. 20 (e) For fresh frozen shellfish, the year shall be added to the date for non-Julian format. If fresh frozen, the container 21 shall be labeled as frozen in equal size type immediately adjacent to the type of shellfish. If a frozen container of 22 shucked shellfish is thawed and repacked, the container shall be labeled as previously frozen. 23 (f) Each container of shucked shellfish shall include a consumer advisory. The following statement, or an equivalent 24 statement, shall be included on all containers: "Consuming raw or undercooked meats, poultry, seafood, shellfish, or 25 eggs may increase your risk of foodborne illness, especially if you have certain medical conditions." (d)(g) No person shall use containers bearing a certification number other than the number assigned to him.him or 26

29 *History Note:* Authority G.S. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 143B-289.52; 30 *Eff. February 1, 1987*;

31 Amended Eff. August 1, 1998; February 1, 1997; December 1, <del>1987.</del> <u>1987.</u> 1987;

32 Readopted Eff. April 1, 2024.

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1 15A NCAC 18A .0615 is readopted as published in 38:03 NCR 140 as follows: 2 3 15A NCAC 18A .0615 SHELLFISH COOLING 4 Shucked shellfish shall be cooled to an internal temperature of 45°F (7°C) or less within two hours after delivery to the packing room. Storage temperatures shall be 40° F (4° C) or below. No ice or other foreign substance shall be 5 allowed to come into contact with the shellfish after processing has been completed. 6 7 (a) For shellstock that has not been refrigerated prior to processing, shucked meats and in-shell product shall be chilled 8 to an internal temperature of 45°F or less within three hours of shucking or processing. 9 (b) For shellstock that has been refrigerated prior to processing, shucked meats and in-shell product shall be chilled to an internal temperature of 45°F or less within four hours after removal from refrigeration. 10 11 (c) If heat shock is used, once shellstock is shucked, the shucked shellfish meats shall be cooled to an internal temperature of 45°F or less within two hours from the time of heat shock. 12 (d) Shucked and packed shellfish shall be stored in covered containers at an ambient temperature of 45°F or less or 13 14 covered in ice. 15 16 History Note: Authority G.S. <del>130A 230; 113-134; 113-182; 113-221.2; 143B-289.52;</del> 17 *Eff. February 1, 1987;* 18 Amended Eff. April 1, 1997.1997;

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Readopted Eff. April 1, 2024.

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1	15A NCAC 18A	A .0616 is readopted as published in 38:03 NCR 140 as follows:	
2			
3	15A NCAC 18	A .0616 SHELLFISH FREEZING	
4	(a) If shellfish	are to be frozen, they shall be frozen within three days of shucking and packing and the shucked date	
5	shall be preceded by the letter (F).packing. Containers of frozen shellfish shall be labeled in accordance with Rule		
6	.0614 of this Se	ection.	
7	(b) A temperature of $0^{\circ}$ F ( $18^{\circ}$ C) $0^{\circ}$ F or less shall be maintained in the frozen storage rooms.		
8			
9	History Note:	Authority G.S. <del>130A-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;	
10		Eff. February 1, 1987;	
11		Amended Eff. April 1, 1997; December 1, <del>1987.</del> <u>1987;</u>	
12		Readonted Eff April 1 2024	

1	15A NCAC 18A	A .0617 is repealed through readoption as published in 38:03 NCR 140 as follows:
2		
3	15A NCAC 18A	A .0617 SHIPPING
4		
5	History Note:	Authority G.S. 130A-230;
6		Eff. February 1, 1987;
7		Amended Eff. April 1, <del>1997.<u>1997;</u></del>
8		Renealed Eff April 1 2024

1 15A NCAC 18A .0618 is readopted as published in 38:03 NCR 140-141 as follows:

2

## 15A NCAC 18A .0618 HEAT SHOCK METHOD OF PREPARATION OF SHELLFISH

- 4 (a) Facilities. If a shucking and packing plant uses the heat shock process, it shall be done in a separate room adjacent
- 5 to the shellstock storage room and the shucking room.
- 6 (b) Tank construction. The heat shock tank shall be constructed of smooth, non-corrosive metal, designed to drain
- 7 quickly and completely and to be easily and thoroughly cleaned.cleanable.
- 8 (c) Booster heaters. All heat shock tanks shall be equipped with booster heaters that are thermostatically controlled.
- 9 (d) Shellstock washing. All shellstock subjected to the heat shock process shall be thoroughly-washed with flowing
- 10 potable water immediately prior to the heat shock operation.
- 11 (e) Water temperature. During the heat shock process the water shall be maintained at not less than  $140^{\circ}F$  ( $60^{\circ}C$ ) or
- more than 150°F (65°C).150°F. An accurate thermometer shall be available and used to determine the temperature
- during the heat shock process. The heat shock tanks shall be drained and cleaned at the end of each day's operation.
- 14 (f) Alternatives to heat shock method.—Nothing in these Rules this Rule shall be construed to prohibit any other
- process which that has been found by the Division of Marine Fisheries to be equally effective.
- 16 (g) Water requirements. At least eight gallons of heat shock water shall be maintained in the tank for each one half
- 17 <u>one-half</u> bushel of shellstock being treated. All water used in the heat shock process shall be from a source approved
- by the Division under in accordance with Rule .0413 of this Subchapter.
- 19 (h) Cooling. Immediately after the heat shock process, all treated shellstock shall be subjected to a cool-down with
- 20 <u>flowing potable tap-water</u>. All <u>heat shocked heat-shocked shellstock</u> shall be handled in a manner to prevent
- 21 adulteration of the product the product from becoming adulterated. Shellfish which that have been subjected to the
- heat shock process shall be cooled to an internal temperature of  $45^{\circ}$ F  $(7^{\circ}$ C) or below within two hours after this process
- 23 and shall be placed in storage at 40°F (4°C) 45°F or below.
- 24 (i) Cleaning. At the close of each day's operation, the heat shock tank shall be completely emptied of all water, mud,
- 25 <u>and detritus, and thoroughly cleaned and then rinsed with flowing potable water.</u>
- 26 (j) Sanitizing.—All heat shock tanks shall be sanitized immediately before starting each day's operation.
- 27 (k) The procedure for the heat shock process shall be posted in a location that can be viewed by employees to help
- 28 ensure the correct procedure can be followed.

29

- 30 History Note: Authority G.S. <del>130.4-230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;
- 31 *Eff. February 1, 1987;*
- 32 Amended Eff. August 1, 2002; August 1, 1998; February 1, 1997; September 1, <del>1990.</del> <u>1990</u>:
- 33 <u>Readopted Eff. April 1, 2024.</u>

1 15A NCAC 18A .0619 is readopted as published in 38:03 NCR 141 as follows:

2

## 15A NCAC 18A .0619 REPACKING OF SHELLFISH

- 4 (a) If repacking is practiced, it shall be done strictly conducted in accordance with all the requirements stipulated for
- 5 shucking and packing plants in the rules of this Section except those for requirements related to shucking.
- 6 (b) The shucked shellfish to be repacked shall be received at the repacking plant in approved shipping containers at a
- 7 temperature of  $32^{\circ} 40^{\circ}F$  ( $0^{\circ} 4^{\circ}C$ )  $45^{\circ}F$  or less.
- 8 (c) Shellfish shall not be repacked more than one time.
- 9 (d) The temperature of the shellfish shall not exceed <u>an internal temperature of 45°F (7°C) for more than two hours</u>
- during the repacking process.
- 11 (e) Containers with a capacity of 64 fluid ounces or less in which shucked shellfish are repacked shall indicate a SELL
- 12 BY date preceded by the letter R. Containers with a capacity above 64 fluid ounces in which shucked shellfish are
- 13 repacked shall be dated to show the original shucking date and repacking date, which will be preceded by the letter
- 14 (R). Containers of repacked shellfish shall be repacked and labeled in accordance with Rule .0614 of this Section,
- 15 except that the original date of shucking shall be added to the new repacked container or the original date of shucking
- shall be used in establishing the "SELL BY" or "BEST IF USED BY" date.
- 17 (f) Repackers shall keep accurate records indicating the source from which shellfish were purchased, the date packed,
- 18 the date of purchase, the area within the state or territory from which the shellfish were harvested, and the names and
- addresses of persons shellfish dealers to whom the shellfish were sold.

20

- 21 History Note: Authority G.S. <del>130A 230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>
- 22 *Eff. February 1, 1987;*
- 23 Amended Eff. December 1, <del>1987.</del>1987;
- 24 <u>Readopted Eff. April 1, 2024.</u>

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. <del>130A 230; 113-134; 113-182; 113-221.2; 143B-289.52;</del>

Eff. April 1, <del>1997.</del> 1997;

Readopted Eff. April 1, 2024.

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1	15A NCAC 18A	.0621 is repealed through readoption as published in 38:03 NCR 141 as follows:
2		
3	15A NCAC 18A	A .0621 RECALL PROCEDURE
4		
5	History Note:	Authority G.S. 130A-230;
6		Eff. August 1, <del>1998.</del> <u>1998;</u>
7		Renegled Fift 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 .07010713 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A			
6	.07010713); has been transferred and recodified from Rules .12011213 of Title 10 Subchapter 10B of the Nort			
7	Carolina Administrative Code (T10.10B .12011213), effective April 4, 1990.			
8				
9	15A NCAC 18	A .0701 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, requirement			
12	for depuration shall be in accordance with the 2019 Revision of the National Shellfish Sanitation Program (NSSF			
13	Guide for the Control of Molluscan Shellfish chapter titled "Depuration", which is incorporated by reference, no			
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			
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 requirement			
19	established und	er 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 1	NSSP exists, the following may be used:		
23	<u>(1)</u>	a validated Association of Analytical Communities, Bacteriological Analysis Manual, or		
24		Environmental Protection Agency method; or		
25	<u>(2)</u>	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. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;		
29		Eff. February 1, <del>1987.<u>1987</u>.</del>		
30		Readopted Eff. April 1, 2024.		

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1	15A NCAC 18A	.0702	0703 are repealed through readoption as published in 38:03 141 as follows:
2			
3	15A NCAC 18A	.0702	FACILITY SUPERVISION
4	15A NCAC 18A	.0703	FACILITY DESIGN AND SANITATION
5			
6	History Note:	Authori	ty G.S. 130A-230;
7		Eff. Feb	oruary 1, <del>1987.<u>1987;</u></del>
8		<u>Repeale</u>	ed Eff. April 1, 2024.

1	15A NCAC 18A	.0704 is r	epealed as published in 38:03 NCR 141 as follows:
2			
3	15A NCAC 18A	.0704	LABORATORY PROCEDURES
4			
5	History Note:	Authority	y G.S. 113-134; 113-182; 113-221.2; 143B-289.52;
6		Eff. Febr	uary 1, 1987;
7		Amendea	l Eff. September 1, 1991; September 1, 1990;
8		Readopte	ed Eff. May 1, <del>2021.</del> 2021 <u>:</u>
9		Renealed	l Eff April 1, 2024

1	15A NCAC 18A	4 .0705 -	.0713 are repealed through readoption as published in 38:03 NCR 142 as follows:
2			
3	15A NCAC 18	A .0705	FACILITY OPERATIONS
4	15A NCAC 18	A .0706	SHELLFISH SAMPLING PROCEDURES
5	15A NCAC 18	A .0707	DEPURATION PROCESS WATER CONTROL - SAMPLING PROCEDURES
6	15A NCAC 18	A .0708	DEPURATION TREATMENT PROCESS WATER - STANDARDS
7	15A NCAC 18	A .0709	DEPURATION - SHELLFISH MEAT STANDARDS
8	15A NCAC 18	A .0710	ULTRAVIOLET UNIT
9	15A NCAC 18	A .0711	SHELLSTOCK STORAGE
10	15A NCAC 18	A .0712	DEPURATION - TAGGING AND RELEASE OF SHELLFISH
11	15A NCAC 18	A .0713	DEPURATION - RECORDS
12			
13	History Note:	Author	ity G.S. 130A-230;
14		Eff. Fe	bruary 1, 1987;
15		Amend	ed Eff. September 1, 1990; December 1, <del>1987.<u>1</u>987;</del>
16		<u>Repeal</u>	<u>ed Eff. April 1, 2024.</u>

1	15A NCAC 18A	A .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	.08010806);	has been transferred and recodified from Rules .13011306 of Title 10 Subchapter 10B of the North		
7	Carolina Administrative Code (T10.10B .13011306), effective April 4, 1990.			
8				
9	15A NCAC 18	A .0801 GENERAL REQUIREMENTS FOR WET STORAGE OF SHELLSTOCK		
10	The rules in Sec	etion .0400 shall apply for wet storage of shellstock.(a) In addition to and to the extent not inconsistent		
11	with other appli	cable 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 Grov	ving Areas" incorporated by reference include:		
19	<u>(1)</u>	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	<u>(2)</u>	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. <del>130A 230;</del> 113-134; 113-182; 113-221.2; 143B-289.52;		
27		Eff. February 1, <del>1987.<u>1987.</u></del>		
28		Readopted Eff. April 1, 2024.		

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1
     15A NCAC 18A .0802 - .0806 are repealed through readoption as published in 38:03 NCR 142 as follows:
2
3
                            PLANT DESIGN: SANITATION: AND WET STORAGE
     15A NCAC 18A .0802
4
     15A NCAC 18A .0803
                            WET STORAGE WATER
5
     15A NCAC 18A .0804
                            SHELLSTOCK CLEANING
6
     15A NCAC 18A .0805
                            WET STORAGE TANKS
7
     15A NCAC 18A .0806
                            SHELLSTOCK CONTAINERS
8
9
     History Note:
                    Authority G.S. 130A-230;
10
                    Eff. February 1, <del>1987.</del> <u>1987.</u>
11
                    Repealed Eff. April 1, 2024.
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