AGENCY: DHHS and Commission for Public Health

RULE CITATION: All Rules

**DEADLINE FOR RECEIPT: March 12, 2020** 

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

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

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

Where is CPH's statutory authority for these rules? Did you intend to reference G.S. 20-138.7(d)?

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

AGENCY: DHHS and Commission for Public Health

RULE CITATION: 10A NCAC 41B .0322

**DEADLINE FOR RECEIPT: March 12, 2020** 

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

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

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

At line 4, please consider beginning with: "The following operational procedures shall be followed when using the . . ."

In (2), what are the "observation period requirements?" If they are set in the manufacturer's requirements, please make that clear.

In (5), how is the instrument's accuracy verified? Is this done based upon the manufacturer's instructions?

Why does (7) repeat (6)? If your intent is to collect two samples, please consider amending (7) to say "collect the second breath sample" instead of "collect breath sample" to make that clear.

At line 15, are you capping the number of breath samples at 4?

At line 16, please define "as soon as feasible."

At lines 15 and 16, is an additional "sample" different from a subsequent "test?" Does a subsequent test fall under G.S. 20-139.1(b5)?

At line 17, who makes this determination and how is it determined which steps are applicable?

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

Ashley Snyder
Commission Counsel
Date submitted to agency: February 27, 2020

1	10A NCAC 411	B .0322 is amended as published in 34:11 NCR 908-909 as follows:	
2			
3	10A NCAC 41	B .0322 INTOXIMETERS: MODEL INTOX EC/IR II AND MODEL INTOX EC/IR II	
4		(ENHANCED WITH SERIAL NUMBER 10,000 OR HIGHER)	
5	The operational	procedures to be followed in using the Intoximeters, Model Intox EC/IR II and Model Intox EC/IR II	
6	(Enhanced with serial number 10,000 or higher) are:		
7	(1)	Insure Ensure instrument displays time and date;	
8	(2)	Insure Ensure observation period requirements have been met;	
9	(3)	Initiate breath test sequence;	
10	(4)	Enter information as prompted by the instrument; prompted;	
11	(5)	Verify instrument accuracy;	
12	(6)	When "PLEASE BLOW" appears, collect breath sample;	
13	(7)	When "PLEASE BLOW" appears, collect breath sample; and	
14	(8)	Print test record.	
15	If the alcohol concentrations differ by more than 0.02, a third or fourth breath sample shall be collected whe		
16	"PLEASE BLOW" appears. Subsequent tests shall be administered as soon as feasible by repeating steps (1) through		
17	(8), as applicable.		
18			
19	History Note:	Authority G.S. 20-139.1(b);	
20		Eff. November 1, 2007;	
21		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,	
22		<u>2018;</u> <del>2018.</del>	
23		Amended Eff. April 1, 2020.	
24			

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AGENCY: DHHS and Commission for Public Health

RULE CITATION: 10A NCAC 41B .0323

**DEADLINE FOR RECEIPT: March 12, 2020** 

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

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

At lines 6-7, who performs the preventative maintenance procedures? Please consider revising this sentence to say who shall do what.

At lines 6-7, if the maintenance is performed by DHHS as suggested by G.S. 20-139.1(b2), does this language meet the definition of a rule or is this internal agency management? See G.S. 150B-2(8a)(a).

At line 7, do you need to say "at least?" Rules always set minimum requirements.

Are the steps in (1)-(10) completed in accordance with the manufacturer's instructions? If so, please make that clear. If not, how do you verify the instrument's accuracy in (5)?

Why does (7) repeat (6)? If your intent is to collect two samples, please consider amending (7) to say "collect the second breath sample" instead of "collect breath sample" to make that clear.

At line 24, do you need to say "at least?" Rules always set minimum requirements.

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

1	10A NCAC 41B	.0323 is amended as published in 34:11 NCR 908-909 as follows:		
2				
3	10A NCAC 41B	.0323 PREVENTIVE MAINTENANCE: INTOXIMETERS: MODEL INTOX EC/IR II		
4		AND MODEL INTOX EC/IR II (ENHANCED WITH SERIAL NUMBER 10,000 OR		
5		HIGHER)		
6	The preventive i	maintenance procedures for the Intoximeters, Model Intox EC/IR II and Model Intox EC/IR II		
7	(Enhanced with serial number 10,000 or higher) to be followed at least once every four months are:			
8	(1)	Verify the ethanol gas canister displays at least 51 pounds per square inch (psi) of pressure, or the		
9		alcoholic breath simulator thermometer shows 34 degrees, plus or minus .2 degree centigrade;		
10	(2)	Verify instrument displays time and date;		
11	(3)	Initiate breath test sequence;		
12	(4)	Enter information as prompted;		
13	(5)	Verify instrument accuracy;		
14	(6)	When "PLEASE BLOW" appears, collect breath sample;		
15	(7)	When "PLEASE BLOW" appears, collect breath sample;		
16	(8)	Print test record;		
17	(9)	Run diagnostic program and confirm preventive maintenance status of "Pass"; Verify Diagnostic		
18		Program; and		
19	(10)	Verify that the ethanol gas canister is being changed before expiration date, or the alcoholic breath		
20		simulator solution is being changed every four months or after 125 Alcoholic Breath Simulator tests,		
21		whichever occurs first.		
22	A signed original of the preventive maintenance record record, or an electronic copy of the signed original of the			
23	preventive maintenance record, shall be kept on file at the North Carolina Department of Health and Human Services			
24	for at least three	years.		
25				
26	History Note:	Authority G.S. 20-139.1(b2);		
27		Eff. November 1, 2007;		
28		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,		
29		<u>2018;</u> <del>2018.</del>		
30		Amended Eff. April 1, 2020.		
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AGENCY: DHHS and Commission for Public Health

RULE CITATION: 10A NCAC 41B .0503

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

In (b), line 18, is it necessary to say "at least?" Rules always set minimum requirements.

At lines 21 and 24, does your regulated public understand the meaning of "exclusively" as used in this Rule?

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

1	10A NCAC 41B	.0503 is amended as published in 34:11 NCR 908-909 as follows:
2		
3	10A NCAC 41B	
4	• •	g breath alcohol screening test devices are approved as to type and make:
5	(1)	ALCO-SENSOR (with two-digit display), manufactured made by Intoximeters, Inc.
6	(2)	ALCO-SENSOR III (with three-digit display), <u>manufactured</u> made by Intoximeters, Inc.
7	(3)	ALCO-SENSOR IV, manufactured by Intoximeters, Inc.
8	(4)	ALCO-SENSOR FST, manufactured by Intoximeters, Inc.
9	(5)	S-D2, manufactured by CMI, Inc.
10	(6)	S-D5, manufactured by CMI, Inc.
11	<u>(7)</u>	ALCO-SENSOR III (Enhanced with Serial Numbers above 1,200,000), manufactured by
12		Intoximeters, Inc.
13	<u>(8)</u>	ALCO-SENSOR FST (Enhanced with Serial Numbers 200,000 and higher), manufactured by
14		Intoximeters, Inc.
15	(9)	LIFELOC FC10, manufactured by Lifeloc Technologies, Inc.
16	(10)	INTOXILYZER 500, manufactured by CMI, Inc.
17	(11)	ALCOVISOR MERCURY, manufactured by PAS International.
18	(b) The agency o	r operator shall verify instrument calibration of each alcohol screening test device at least once during
19	each 30 day perio	od of use. The verification shall be performed using by employment of an alcoholic breath simulator
20	with a using sim	ulator solution in accordance with Paragraph (c) of this Rule the rules in this Section or an ethanol
21	gas canister in ac	cordance with Paragraph (d) of this Rule. canister.
22	(c) Alcoholic br	eath simulators used exclusively to verify instrument calibration of alcohol screening test devices
23	shall have the sol	ution changed every 30 days or after 25 calibration tests, whichever occurs first.
24	(d) Ethanol gas	canisters used exclusively to verify instrument calibration of alcohol screening test devices shall not
25	be utilized beyon	d the expiration date on the canister.
26	(e) Requirement	s of Paragraphs (b), (c), and (d) of this Rule shall be recorded on an alcoholic breath simulator log or
27	an ethanol gas ca	nister log designed by the Forensic Tests for Alcohol Branch within the North Carolina Department
28	of Health and H	uman Services and maintained by the user agency in accordance with the user agency's retention
29	policy. agency.	
30		
31	History Note:	Authority G.S. 20-16.3;
32		Eff. February 1, 1976;
33		Readopted Eff. December 5, 1977;
34		Amended Eff. July 1, 2007; November 1, 2005; April 1, 2001; January 1, 1995; January 4, 1994;
35		April 1, 1993; January 4, 1993;
36		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,
37		2018; <del>2018.</del>

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