

**Fiscal Impact Analysis of Permanent Rules  
10A NCAC 41B  
Breath Alcohol Test Regulations and Alcohol Screening Test Devices**

**Date:** October 28, 2019

**Agency:** NC Commission for Public Health  
Department of Health and Human Services, Division of Public Health  
Chronic Disease and Injury Control Section, Forensic Tests for Alcohol Branch

**Contacts:** Virginia Niehaus, Rulemaking Coordinator  
[virginia.niehaus@dhhs.nc.gov](mailto:virginia.niehaus@dhhs.nc.gov)  
919-707-5006

Fritz LaBarge, Forensic Tests for Alcohol Branch Head  
[fritz.labarge@dhhs.nc.gov](mailto:fritz.labarge@dhhs.nc.gov)  
919-707-5253

**Rule Citations:** 10A NCAC 41B .0322 Intoximeters: Model Intox EC/IR II  
10A NCAC 41B .0323 Preventive Maintenance: Intoximeters: Model Intox  
EC/IR II  
10A NCAC 41B .0503 Approved Alcohol Screening Test Devices: Calibration

**Relevant Statutes:** NCGS 20-16.3; NCGS 20-139.1

**Purpose of Proposed Rules:** To add one additional breath testing instrument and five additional alcohol screening test devices. For proposed rule text, see Appendix 1.

**State Government Impact:** Yes  
**Local Government Impact:** Yes  
**Private Sector Impact:** Yes  
**Substantial Economic Impact:** No

**1. Reason for Proposed Amendments to 41B .0322 and .0323**

The Intox EC/IR II is the only breath testing instrument currently approved for use by the Department for chemical analysis of a person's breath in any implied consent offense (driving while impaired). The Intox EC/IR II instrument is no longer manufactured and has been replaced in production by the manufacturer with the upgraded Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument. Both instruments are included on the National Highway Safety Transportation Administration (NHTSA) Conforming Products List: 49 CFR Part 40, as required by 10A NCAC 41B .0313. The upgrades to the Intox EC/IR II (Enhanced with serial number 10,000 or higher) are: updated processor, updated graphics display, larger memory capacity, and updated internal printer.

The Department approves breath testing instruments listed on the National Highway Traffic Safety Administration, Conforming Products List of Evidential Breath Measurement Devices. Instruments are approved on the basis of results of evaluations by the Forensic Tests for Alcohol (FTA) Branch. Evaluations are not limited in scope and may include any factors deemed appropriate to ensure the accuracy, reliability, stability, cost, and ease of operation and durability of the instrument being evaluated. Evaluations were conducted by the FTA Branch on the Intox EC/IR II (Enhanced with serial number 10,000 or higher) to ensure the accuracy, reliability,

stability, cost, and ease of operation and durability of the instrument. It was determined that all requirements were met. The testing protocol for the Intox EC/IR II instrument and for the Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument is identical.

The Intox EC/IR II currently approved for use in North Carolina was put into service in 2007. The analytical technology used in this instrument is identical to that used in the Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument. While the Intox EC/IR II (Enhanced with serial number 10,000 or higher) has additional features which improve the usability and functionality of the instrument, the largest benefit of including it as an approved instrument is it is currently available for purchase, having replaced the Intox EC/IR II.

#### Proposed Rule Changes

The proposed rules change the language in 10A NCAC 41B .0322 Intoximeters: Model Intox EC/IR II by adding the Model Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument as an instrument approved for use by the Department for chemical analysis of a person's breath in any implied consent offense.

The proposed rules change the language in 10A NCAC 41B .0323 Preventive Maintenance: Intoximeters: Model Intox EC/IR II by adding the Model Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument into the preventive maintenance procedures rule.

#### State Government Economic Impact

The addition of the Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument will have a positive economic impact on State government. The Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument is identical in appearance, construction, and operation, to the Intox EC/IR II. The FTA Branch provides training and support for all evidential instruments and the current training and support provided by the FTA Branch for the Intox EC/IR II instrument will also satisfy the requirements of the Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument.

As the instruments are identical in appearance, construction, and operation, the FTA Branch Electronics Technician would not need additional factory training on the maintenance and repair. Parts purchased to complete maintenance and repair of the Intox EC/IR II (Enhanced with serial number 10,000 or higher) instrument would be identical to parts purchased for the Intox EC/IR II instrument and would not result in additional cost. Training materials would be updated to reflect that the training provided is for the two instruments during the transition period, with minimal economic impact, as these materials are developed by the FTA Branch and ordered frequently.

#### Local Government Economic Impact

There will be no substantial economic impact. There is no discernable difference in the manner in which the two instruments appear or function, so no additional training is required for instrument operators trained as chemical analysts.

Users will benefit from additional features which improve the usability and functionality of the instrument, and the ability to purchase approved, new instruments when necessary since the older instrument is no longer manufactured.

#### Private Sector Economic Impact

There will be no economic impact in the short term. This will allow the FTA Branch to purchase the Intox EC/IR II (Enhanced with serial number 10,000 or higher) from the sole source vendor if necessary in the future. There are no planned purchases at this time.

## **2. Reason for Proposed Amendments to 41B .0503**

No screening test for alcohol concentration is a valid one unless the alcohol screening test device used is one approved by the Department and the screening test is conducted in accordance with the applicable rules as to the manner of its use. Additional alcohol screening test devices have been evaluated by the FTA Branch and have met the minimum requirements as set forth in the Department specifications for Alcohol Screening Test Devices for use by law enforcement officers in conducting on the scene tests of drivers for alcohol concentration.

Several alcohol screening test devices included on the current list are no longer available for purchase, but remain on the list as they are still being used by law enforcement agencies. Adding additional alcohol screening test devices to the approved list would be beneficial as it would offer additional choices for law enforcement agencies and create a competitive market environment, possibly resulting in lower prices.

### Proposed Rule Changes

Additional alcohol screening test devices have been evaluated by the FTA Branch and meet the minimum requirements set forth in the Department specifications for alcohol screening test devices for use by law enforcement officers in conducting on the scene tests of drivers for alcohol concentration. The proposed rules add the following alcohol screening test devices to the existing list of approved alcohol screening test devices:

- ALCO-SENSOR III (Enhanced with Serial Numbers above 1,200,000), manufactured by Intoximeters, Inc.
- ALCO-SENSOR FST (Enhanced with Serial Numbers 200,000 and higher), manufactured by Intoximeters, Inc.
- LIFELOC FC10, manufactured by Lifeloc Technologies, Inc.
- INTOXILYZER 500, manufactured by CMI, Inc.
- ALCOVISOR MERCURY, manufactured by PAS International.

### State Government Economic Impact

The inclusion of additional alcohol screening test devices will have moderate economic impact. The FTA Branch provides training and support for all approved alcohol screening test devices. Providing training and support would require the FTA Branch to purchase newly approved alcohol screening test devices for classroom training of law enforcement officers, the end users. Additionally, the FTA Branch Electronics Technician may need to be factory trained on the maintenance and repair of these new devices, and the FTA Branch would be required to purchase parts necessary to complete maintenance and repairs as this service is provided free of charge to law enforcement agencies for all approved devices. Train the trainer training would be conducted by those attending factory training to familiarize all FTA Branch training staff responsible for alcohol screening test device training. Travel for training is regularly assigned to staff as part of their job duties and would not incur additional labor cost. All expenses related to adding additional alcohol screening test devices would be funded with dollars provided by the North Carolina Governor's Highway Safety Program (GHSP). Estimated economic impact is limited to the following:

- \$13,730 - FTA Branch purchase of alcohol screening test devices for training purposes
- \$ 6,000 – Travel expenses for factory training for staff
- \$ 1,500 – Maintenance parts and tools

### Local Government Economic Impact

There will be little or no economic impact. There is no mandate to purchase newly approved devices. If purchased, alcohol screening test devices recommended for inclusion on the approved list share similar costs as existing approved alcohol screening test devices. Training is provided by the FTA Branch at no charge in the theory, operation, and maintenance of all approved alcohol screening test devices. This training is optional and is not required of law enforcement officers who operate the alcohol screening test

devices. Once approved, those alcohol screening test devices will be included in the ongoing training program provided by the FTA Branch.

The cost of any alcohol screening test device can be offset by credits earned by law enforcement agencies participating in the GHSP Statewide Traffic Enforcement Program (STEP), which encourages participation at GHSP sponsored events and highway safety initiatives with incentive credits. Credits earned by law enforcement agencies may be redeemed for alcohol screening test devices. If STEP credits are not used to acquire newly or otherwise approved devices, local agencies would have to fund the purchase. The proposed amendment will be positive in that it will offer more choices and flexibility when an agency acquires a device. All approved devices, existing and newly approved, provide the same functionality.

#### Private Sector Economic Impact

The proposed amendment will have an unknown impact on the private sector. It is estimated that the number of alcohol screening test devices acquired for use by local agencies will remain consistent with prior years' purchases. Adding these newly approved devices to the approved list will simply offer more choices to law enforcement agencies that choose to purchase. At this time, it is unknown what device individual law enforcement agencies may select for use. All approved devices, existing and newly approved, provide the same functionality.

#### **Summary**

In summary, the proposed rules will:

1. Add one additional breath testing instrument, the Intox EC/IR II (Enhanced with serial number 10,000 or higher); and
2. Add five additional alcohol screening test devices.

Local government and private sector entities will benefit from the inclusion of an additional breath testing instrument because the old model is no longer manufactured and the new model provides additional features which improve the usability and functionality of the instrument. State government will incur costs for purchasing, training, and maintaining new alcohol screening test devices, but local government entities will benefit from additional choice and flexibility. Local law enforcement agencies purchasing decisions – and thus the impact on manufacturers, is unknown.

## Appendix 1

10A NCAC 41B .0322 is proposed for amendment as follows:

**10A NCAC 41B .0322 INTOXIMETERS: MODEL INTOX EC/IR II AND MODEL INTOX EC/IR II  
(ENHANCED WITH SERIAL NUMBER 10,000 OR HIGHER)**

The operational procedures to be followed in using the Intoximeters, Model Intox EC/IR II and Model Intox EC/IR II (Enhanced with serial number 10,000 or higher) are:

- (1) ~~Insure~~ Ensure instrument displays time and date;
- (2) ~~Insure~~ Ensure observation period requirements have been met;
- (3) Initiate breath test sequence;
- (4) Enter information as prompted by the instrument; ~~prompted~~;
- (5) Verify instrument accuracy;
- (6) When "PLEASE BLOW" appears, collect breath sample;
- (7) When "PLEASE BLOW" appears, collect breath sample; and
- (8) Print test record.

If the alcohol concentrations differ by more than 0.02, a third or fourth breath sample shall be collected when "PLEASE BLOW" appears. Subsequent tests shall be administered as soon as feasible by repeating steps (1) through (8), as applicable.

*History Note: Authority G.S. 20-139.1(b);*

*Eff. November 1, 2007;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.*

## Appendix 1

10A NCAC 41B .0323 is proposed for amendment as follows:

**10A NCAC 41B .0323 PREVENTIVE MAINTENANCE: INTOXIMETERS: MODEL INTOX EC/IR II AND MODEL INTOX EC/IR II (ENHANCED WITH SERIAL NUMBER 10,000 OR HIGHER)**

The preventive maintenance procedures for the Intoximeters, Model Intox EC/IR II and Model Intox EC/IR II (Enhanced with serial number 10,000 or higher) to be followed at least once every four months are:

- (1) Verify the ethanol gas canister displays at least 51 pounds per square inch (psi) of pressure, or the alcoholic breath simulator thermometer shows 34 degrees, plus or minus .2 degree centigrade;
- (2) Verify instrument displays time and date;
- (3) Initiate breath test sequence;
- (4) Enter information as prompted;
- (5) Verify instrument accuracy;
- (6) When "PLEASE BLOW" appears, collect breath sample;
- (7) When "PLEASE BLOW" appears, collect breath sample;
- (8) Print test record;
- (9) Run diagnostic program and confirm preventive maintenance status of "Pass"; ~~Verify Diagnostic Program;~~  
and
- (10) Verify that the ethanol gas canister is being changed before expiration date, or the alcoholic breath simulator solution is being changed every four months or after 125 Alcoholic Breath Simulator tests, whichever occurs first.

A signed original of the preventive maintenance ~~record~~ record, or an electronic copy of the signed original of the preventive maintenance record, shall be kept on file at the North Carolina Department of Health and Human Services for at least three years.

*History Note: Authority G.S. 20-139.1(b2);*

*Eff. November 1, 2007;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.*

## Appendix 1

10A NCAC 41B .0503 is proposed for amendment as follows:

### **10A NCAC 41B .0503 APPROVED ALCOHOL SCREENING TEST DEVICES: CALIBRATION**

(a) The following breath alcohol screening test devices are approved as to type and make:

- (1) ALCO-SENSOR (with two-digit display), manufactured ~~made~~ by Intoximeters, Inc.
- (2) ALCO-SENSOR III (with three-digit display), manufactured ~~made~~ by Intoximeters, Inc.
- (3) ALCO-SENSOR IV, manufactured by Intoximeters, Inc.
- (4) ALCO-SENSOR FST, manufactured by Intoximeters, Inc.
- (5) S-D2, manufactured by CMI, Inc.
- (6) S-D5, manufactured by CMI, Inc.
- ~~(7) ALCO-SENSOR III (Enhanced with Serial Numbers above 1,200,000), manufactured by Intoximeters, Inc.~~
- ~~(8) ALCO-SENSOR FST (Enhanced with Serial Numbers 200,000 and higher), manufactured by Intoximeters, Inc.~~
- ~~(9) LIFELOC FC10, manufactured by Lifeloc Technologies, Inc.~~
- ~~(10) INTOXILYZER 500, manufactured by CMI, Inc.~~
- ~~(11) ALCOVISOR MERCURY, manufactured by PAS International.~~

(b) The agency or operator shall verify instrument calibration of each alcohol screening test device at least once during each 30 day period of use. The verification shall be performed using ~~by employment of~~ an alcoholic breath simulator with a ~~using~~ simulator solution in accordance with Paragraph (c) of this Rule ~~the rules in this Section~~ or an ethanol gas canister in accordance with Paragraph (d) of this Rule. ~~canister.~~

(c) Alcoholic breath simulators used exclusively to verify instrument calibration of alcohol screening test devices shall have the solution changed every 30 days or after 25 calibration tests, whichever occurs first.

(d) Ethanol gas canisters used exclusively to verify instrument calibration of alcohol screening test devices shall not be utilized beyond the expiration date on the canister.

(e) Requirements of Paragraphs (b), (c), and (d) of this Rule shall be recorded on an alcoholic breath simulator log or an ethanol gas canister log designed by the Forensic Tests for Alcohol Branch within the North Carolina Department of Health and Human Services and maintained by the user agency in accordance with the user agency's retention policy. ~~agency.~~

*History Note: Authority G.S. 20-16.3;*

*Eff. February 1, 1976;*

*Readopted Eff. December 5, 1977;*

*Amended Eff. July 1, 2007; November 1, 2005; April 1, 2001; January 1, 1995; January 4, 1994; April 1, 1993; January 4, 1993;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.*